

international  
GUIDELINES

# **PRESSURE ULCER PREVENTION**

prevalence and incidence in context



**a consensus document**

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##### Box 3 page 11:

- pressure ulcer – image courtesy of Professor Hiromi Sanada
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## FOREWORD

Pressure ulcers present a major health challenge worldwide: they affect large numbers of people and result in considerable health system expenditure. Studies that examine pressure ulcer occurrence have become of increasing interest in the drive to reduce the number of patients affected. However, quantifying pressure ulceration is complex. Additionally, variations in the type of data collected and methods used during collection make valid study comparisons difficult.

The principles presented in this document represent the consensus opinion of an international group of experts in pressure ulcer prevention and treatment. Many of these experts met in February 2008 to examine the role of epidemiological studies in the development and evaluation of pressure ulcer prevention programmes. The statements developed provide guidance on performing prevalence and incidence studies and how to use data collected to improve standards of care.

This document is of interest to all those involved in the field of pressure ulcers, including those who deliver healthcare, conduct research and develop policy. It is hoped that the document will contribute to accurate, standardised data collection and valid interpretation, and will ultimately reduce rates of pressure ulceration worldwide.

**Professor Keith Harding**



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# pressure ulcer prevention

1. Whitfield MD, Kaltenthaler EC, Akehurst RL, et al. How effective are prevention strategies in reducing the prevalence of pressure ulcers? *J Wound Care* 2000; 9(6): 261-66.
2. Kaltenthaler E, Whitfield MD, Walters SJ, et al. UK, USA and Canada: how do their pressure ulcer prevalence and incidence data compare? *J Wound Care* 2001; 10(1): 530-35.
3. Whittington KT, Briones R. National prevalence and incidence study: 6-year sequential acute care data. *Adv Skin Wound Care* 2004; 17(9): 490-94.
4. Clark M. Pressure ulcers. In: *Skin Breakdown. The silent epidemic*. Hull: Smith and Nephew Foundation, 2007.
5. Torra i Bou J, García-Fernández FP, Pancorbo-Hidalgo PL, Furtado K. Risk assessment scales for predicting the risk of developing pressure ulcers. In: Romanelli M, Clark M, Cherry G, et al (eds). *Science and Practice of Pressure Ulcer Management*. London: Springer-Verlag, 2006.
6. Woodbury MG, Houghton PE. Prevalence of pressure ulcers in Canadian healthcare settings. *Ost Wound Manage* 2004; 50(10): 22-38.
7. Orsted HL, Rosenthal S. Pressure ulcer awareness program pilot. Overview of pilot project. *Wound Care Canada* 2007; 5(1): 40-46.
8. Sanada H, Miyachi Y, Ohura T, et al. The Japanese Pressure Ulcer Surveillance Study: a retrospective cohort study to determine prevalence of pressure ulcers in Japanese hospitals. *Wounds* 2008; 20(6): 176-82.
9. 5 Million Lives Campaign. *Getting Started Kit: Prevent Pressure Ulcers How-to Guide*. Cambridge, MA: Institute for Healthcare Improvement, 2008. Available from: [www.ihl.org](http://www.ihl.org). Accessed October 2008.

It has long been recognised that pressure ulcers (PUs) are a major cause of morbidity, mortality and healthcare burden globally<sup>1-4</sup> and that many PUs are avoidable<sup>5</sup>.

Efforts to reduce the occurrence of PUs therefore need to focus on prevention rather than on treatment. This has led to the development of programmes and protocols to prevent PUs. In addition, some national organisations have created major campaigns and government interest in setting targets to reduce the number of patients who have PUs.

As a result, the occurrence of PUs is increasingly being used to assess the quality of care delivered by a health system or facility and the effectiveness of the PU prevention initiatives in place. Best practice requires evaluation of the effectiveness of these initiatives.

Evaluation includes epidemiological studies that collect data to count individuals with PUs and to assess how numbers change over time. For example, data can be used to estimate the total number of patients with PUs within a particular population (ie **prevalence**) and the rate at which new PUs are occurring (ie **incidence**). Box 1 provides some examples of the use of prevalence and incidence to assess PU awareness and prevention programmes.

## BOX 1 | Using prevalence and incidence to assess PU prevention strategies

### Canada

A PU awareness and prevention programme was developed and implemented by the Canadian Association of Wound Care ([www.preventpressureulcers.ca](http://www.preventpressureulcers.ca)). This followed an estimate by a 2003 study that across all Canadian healthcare settings one in four individuals (26%) suffered from a PU<sup>6</sup>. The programme was based in part on guidelines produced by the Registered Nurses Association of Ontario for the prevention and management of PUs ([www.rnao.org](http://www.rnao.org)). In a six-month pilot of the programme in an acute care setting, PU prevalence decreased from 23.4% to 15.2%<sup>7</sup>. The programme is now being implemented across Canada

### Japan

In 2002, the Japanese government introduced a scheme of financial penalties for hospitals that failed to implement a series of specified PU prevention strategies. Overall prevalence of PUs of all stages before the scheme was 4.3%; it fell to 3.6% after one year. The proportion of Stage III and IV PUs decreased from 23.9% to 18.8% and from 10.9% to 8.1% respectively after one year<sup>8</sup>

### USA

Since 2003, Owensboro Medical Health System (OMHS) in Kentucky has instituted a number of processes and strategies for reducing facility-acquired PUs including education, changes in documentation processes and use of pressure redistribution. In a period of just over two years, the incidence of facility-acquired PUs in acute care dropped by 93% (from 20.6% to 1.4%)<sup>9</sup>

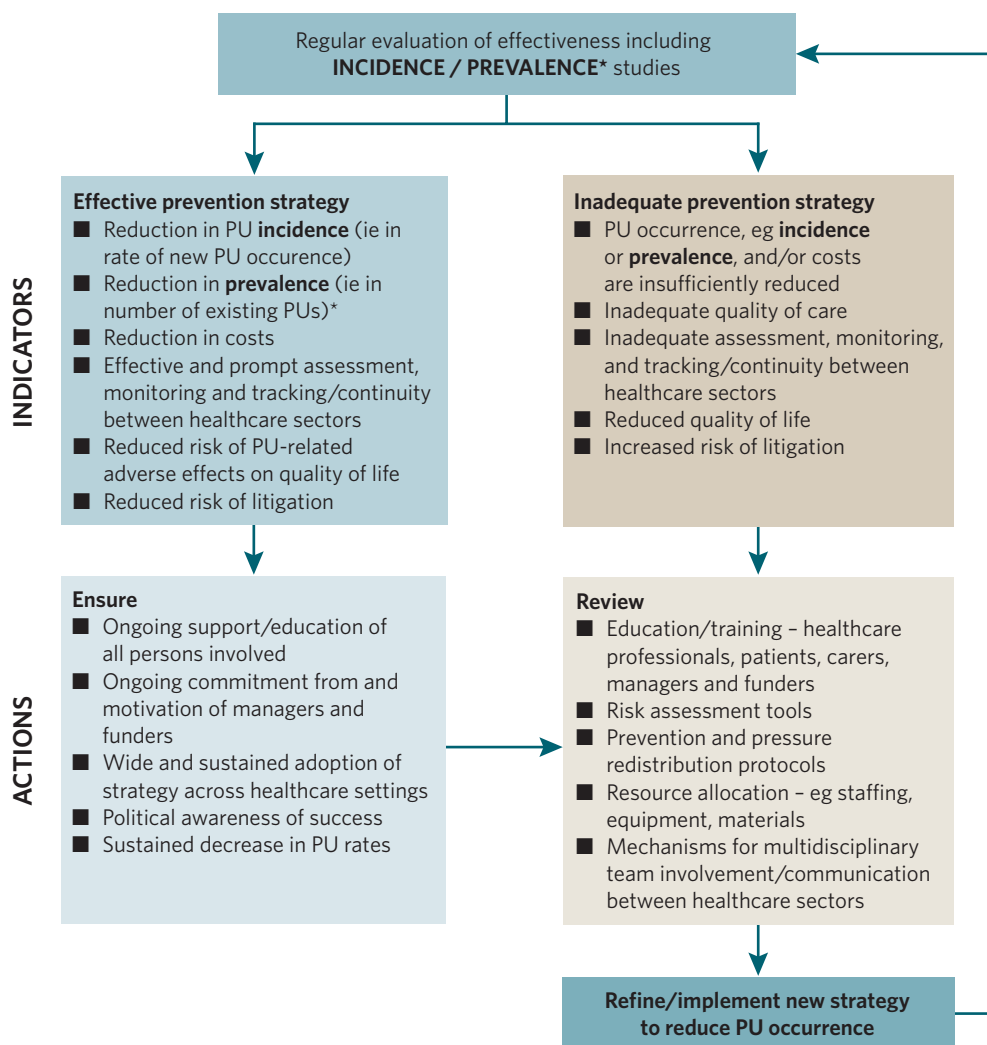
In addition to providing information on the effectiveness of prevention strategies, good quality prevalence and incidence studies have the potential to contribute to:

- refinement of PU prevention strategies and risk assessment tools (Figure 1, page 2)
- public policy by helping to determine resource requirements (eg in Italy, PU prevalence figures were used to lobby the government, resulting in funding for the public health service (Servizio Sanitario Nazionale) to provide reimbursement for support surfaces).



**The results of PU prevalence and incidence studies can be used to raise awareness, to reduce PU occurrence, and to improve clinical practice**

**Figure 1 |** Role of prevalence and incidence studies in monitoring and developing strategies to reduce PU occurrence



\* NB Prevalence provides a less direct measure of prevention strategy effectiveness than does incidence (see page 5)

The implementation of effective PU prevention strategies requires buy-in from all stakeholders. Buy-in relies on good communication between healthcare professionals, managers, funders and payers, with direct targeting of politicians to ensure availability of funding, and appropriate allocation and reimbursement of resources.

**Educational resources**

Many of the educational resources on the prevention, identification and treatment of PUs, and on performing prevalence and incidence studies that have been produced by national and international organisations can be accessed via the Internet

# defining prevalence and incidence

## PREVALENCE

**Point prevalence** is the method used most commonly to indicate prevalence. It measures the proportion of a defined set of people who have a PU at a particular moment in time (Box 2). It therefore includes those admitted to the healthcare facility with a PU and those who have developed one between admission and the time of the study.

## INCIDENCE

Incidence provides information on the rate of occurrence of cases of **new** PUs over time. The calculation of incidence can be complex because strictly speaking, the time element is the sum of the time, eg days or months, that each patient involved in the study was at risk of a PU but was PU-free. Since this may be difficult or impossible to calculate precisely, alternative less complex incidence analyses may be used.

A commonly used, simplified form of incidence analysis is **cumulative incidence**, which may also be referred to as **incidence estimate** or simply as **incidence**. Cumulative incidence indicates the proportion of the population studied that develops a new PU over a specified time period, ie it expresses the rate of occurrence of new PUs (Box 2). In PU incidence studies, the time period is usually in weeks or months, rather than years. Figure 2 (page 4) provides a graphical representation of point prevalence and cumulative incidence.

### BOX 2 | Basic definitions

#### Point prevalence (%)

$$= \frac{\text{no. of patients with a PU at the particular point in time}}{\text{total no. of patients in the population studied at a particular point in time}} \times 100$$

#### Cumulative incidence (%) per time period specified

$$= \frac{\text{no. of patients developing a PU during the specified time period}}{\text{total no. of patients in the population studied over a specified time period}} \times 100$$

NB These formulae describe how percentage (%) is calculated, ie prevalence and incidence per 100 patients. Sometimes prevalence and incidence are reported as rates for larger numbers of patients, eg per 1000 patients or 10,000 patients. In these situations the 'x 100' factor of the formulae is replaced by 'x 1000' or 'x 10,000' respectively. Prevalence would then be reported per number of patients and cumulative incidence per time period per number of patients



The terms 'prevalence' and 'incidence' are often used quite loosely and may be applied incorrectly. However, these terms have different definitions and implications; they should not be used interchangeably, and should be clearly defined in study reports

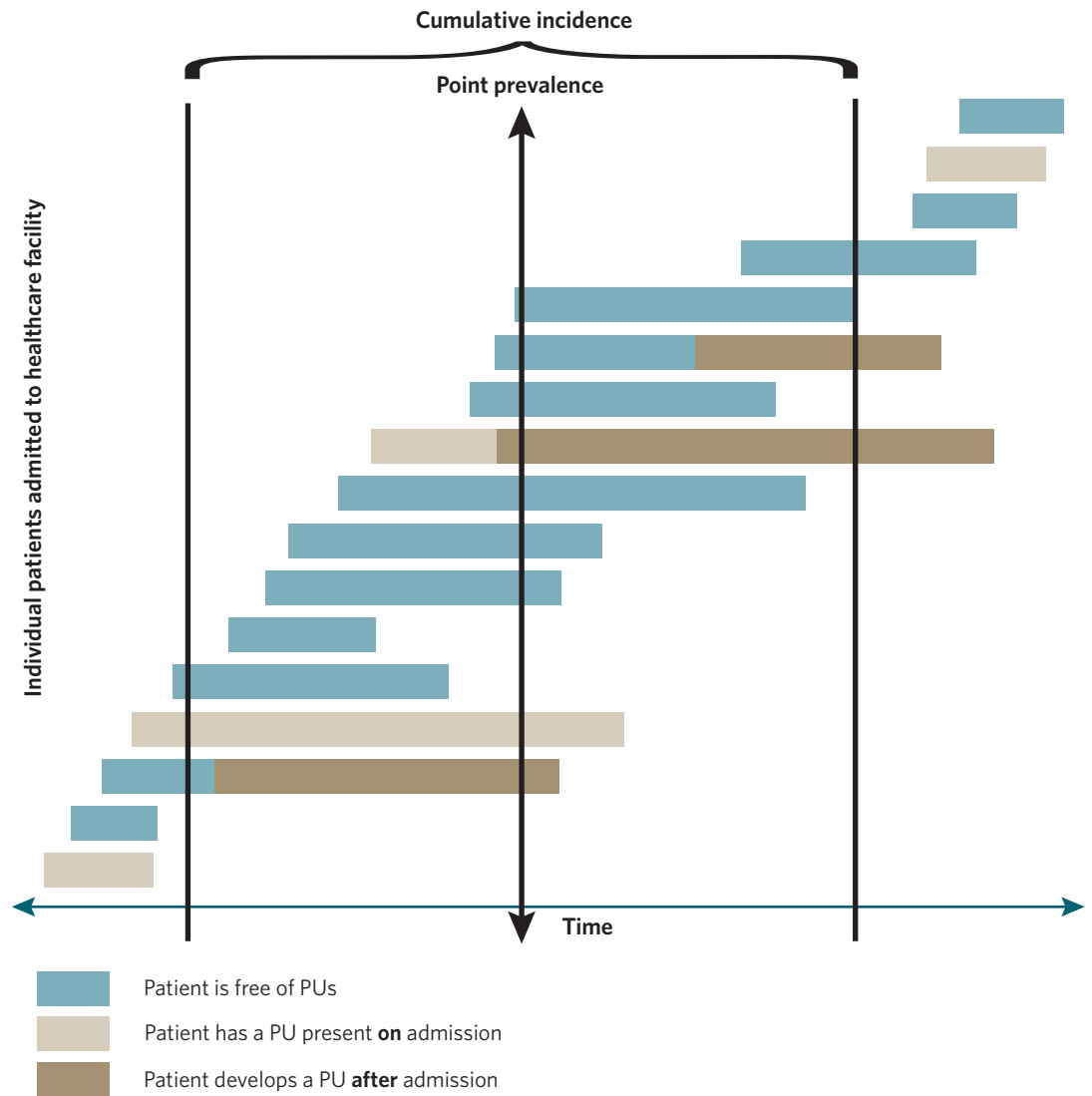
## FURTHER DEFINITIONS

### Period prevalence

For practical reasons, eg the timeframe required for data collection, studies may sometimes measure period prevalence. It is calculated from the number of patients who have a PU at any time during a specified period of time (rather than at one point in time). Therefore, it is in effect a combination of incidence and prevalence.

**Figure 2 | Point prevalence and cumulative incidence: an example**

NB This diagram and the resulting prevalence/incidence rates are provided as an aid to understanding only.



$$\text{Point prevalence} = \frac{3 \text{ patients with one or more PUs}}{9 \text{ patients assessed}} \times 100 = 33\%$$

$$\text{Cumulative incidence (counting only patients with a new PU who were initially PU-free)*} = \frac{2 \text{ patients developing a new PU}}{12 \text{ patients assessed}} \times 100 = 17\% \text{ per time period assessed}$$

\*Incidence studies usually define the patient population as those who are free of PUs at the beginning of the time period. Occasionally, studies include patients who had one or more existing PU at the beginning of the time period and then develop a further PU (see reworked example below). In general this method is not recommended. However, it is important to recognise that using different patient inclusion criteria will produce different results that may have different implications

$$\text{Cumulative incidence (counting all patients with a new PU)*} = \frac{3 \text{ patients developing a new PU}}{12 \text{ patients assessed}} \times 100 = 25\% \text{ per time period assessed}$$

10. Ayello EA, Frantz R, Cuddigan J, Jordan R. Methods for determining pressure ulcer prevalence and incidence. In: Cuddigan J, Ayello EA, Sussman C (eds). *Pressure Ulcers in America: Prevalence, incidence, and implications for the future*. Reston, VA: NPUAP, 2001.

### **Incidence density**

Incidence density indicates the number of new cases that occur per unit of population-time at risk. For example, it may indicate the number of patients developing a PU per 1000 hospital inpatient days or per 100 admissions to hospital.

### **Hospital (or facility)-acquired PU rate**

This is a type of 'snapshot' study intended to differentiate hospital (or facility)-acquired PUs from those acquired in the community. The records of any patient with at least one PU are examined for evidence of a PU on admission. The results are usually expressed as the percentage of patients who did not have a PU on admission who acquire one after admission.

The reliability of facility-acquired PU rates is dependent on the accuracy and completeness of admission skin assessments and documentation. When reliable data are available, this method provides a more accurate measure of the effectiveness of prevention programmes than does prevalence data alone.

## **PREVALENCE AND INCIDENCE STUDIES**

Many studies have examined PU prevalence and incidence, and have produced very varied results<sup>2</sup>. In addition to differences in the quality of care provided and level of adherence to prevention protocols, the differences may be related to variations in:

- definitions of prevalence and incidence, the differences between them and the interpretations that can be placed on them
- how the outcomes were derived: how the study was conducted, the assumptions it made, which data were collected and how they were collected, the care setting/patient population studied.

An appreciation of the importance of these factors and their impact on study results will aid meaningful interpretation and will assist the design and implementation of future studies.

## **USING PREVALENCE AND INCIDENCE**

The information produced by prevalence studies and incidence studies is different and has different implications (Table 1, page 6)<sup>10</sup>. There is an increasing tendency for healthcare providers, funders and payers to use incidence as an indicator of quality of care; they may link performance targets, funding, and incentive or penalty schemes to the results of such epidemiological studies. Although epidemiological studies can be used to track the effectiveness of PU prevention strategies over time, they do not measure the effectiveness of PU treatment.

Studies of PU incidence are generally considered to provide the clearest indication of the effectiveness of a PU prevention protocol. Even though an effective prevention protocol may produce a reduction in prevalence as well as in incidence, the effect on prevalence is likely to be less obvious.

Appropriate interpretations and comparisons of prevalence and incidence studies are made challenging by the wide range and potential variability of the factors involved, eg the **criteria used for the definition of the patient population studied** (see pages 9-10) and **PU identification and classification** (see pages 11-15). For incidence studies, results will also vary according to the time period studied.

11. Defloor T, Clark M, Witherow A, et al. EPUAP statement on prevalence and incidence monitoring of pressure ulcer occurrence 2005. European Pressure Ulcer Advisory Panel (EPUAP), 2005. Available at: [www.epuap.com/review6\\_3/page5.html](http://www.epuap.com/review6_3/page5.html). Accessed September 2008.
12. Bonita R, Beaglehole R, Kjellström T. *Basic Epidemiology, 2nd edition*. World Health Organization, 2006.

The table below compares prevalence and incidence, and highlights the importance of understanding the differences between them when interpreting the information they provide.

**Table 1 | Comparison of prevalence and incidence (adapted from<sup>11,12</sup>)**

	Prevalence	Incidence
<b>Description</b>	<ul style="list-style-type: none"> <li>Measures number of people with <b>existing</b> PUs at a given point in time in a specified population</li> </ul>	<ul style="list-style-type: none"> <li>Measures number of people with a <b>new</b> PU over specified study period in a specified population</li> </ul>
<b>Information provided</b>	<ul style="list-style-type: none"> <li>Indicates what proportion of the study population had a PU at a given time</li> </ul>	<ul style="list-style-type: none"> <li>Indicates the rate of PU development over a particular time period in a given population</li> </ul>
<b>Uses</b>	<ul style="list-style-type: none"> <li>Indicates burden of PUs</li> <li>Aids assessment of resource requirements and planning of health services</li> <li>May collect additional data to aid assessment of compliance with prevention and treatment protocols</li> <li>Can aid differentiation of community versus facility-acquired PUs (with accurate documentation of admission skin assessment)</li> </ul>	<ul style="list-style-type: none"> <li>Increasingly used as an indicator of quality of care</li> <li>Study may produce data that prompts a review of factors that contribute to the development of PUs and may therefore suggest prevention strategies</li> <li>Tracking of comparable incidence rates over time may indicate the effectiveness of preventive measures</li> <li>May collect additional data to aid prevention and compliance with prevention and treatment protocols</li> </ul>
<b>Limitations</b>	<ul style="list-style-type: none"> <li>Does not provide as direct a measure of quality of care or efficacy of prevention protocols as does incidence</li> </ul>	<ul style="list-style-type: none"> <li>May be more time-consuming and therefore more expensive than prevalence studies</li> </ul>



**A clear understanding of the implications and pitfalls of PU prevalence and incidence studies is essential for all healthcare practitioners, managers, payers and funders involved in the development, implementation and assessment of PU prevention protocols**



#### **APPLICATION TO PRACTICE**

**The definitions of the epidemiological terms used in a study should always be examined - definitions may vary and terms are sometimes applied incorrectly**

**Comprehension of the definitions is essential for appropriate study interpretation and comparison**

**Because prevalence and incidence are expressed in terms of patients, it is important that studies of PU occurrence count patients with PUs, not individual PUs themselves**

**When patients have more than one PU apparently eligible for inclusion in a prevalence or incidence study, data are usually reported for the most severe ulcer**



# data collection and recording

The quality of data collected in PU prevalence and incidence studies has the potential to greatly affect the value of the studies' results. Table 2 summarises potential sources of data and how these might influence the quality of the data collected.

**Table 2 | Data sources for PU incidence and prevalence studies**

Data source	Comments
Medical/nursing/care records: paper-based	<ul style="list-style-type: none"> <li>Data extraction is difficult and time-consuming</li> <li>More likely to be incomplete than computer-based records</li> <li>Lower grade/stage PUs may be under-represented</li> <li>Data are likely to be of lower quality than from an assessor's study-specific examination of each patient</li> </ul>
Medical/nursing/care records: computer-based	<ul style="list-style-type: none"> <li>Data extraction is generally easier than from paper-based records</li> <li>Set up may ensure that incomplete records are less likely</li> <li>Reliability of data is likely to be lower than that from an assessor's study-specific examination of each patient</li> </ul>
Adverse incident reports/registers	<ul style="list-style-type: none"> <li>Even where PU reporting is mandatory, under-reporting is likely</li> <li>Lower grade/stage PUs may be under-represented</li> </ul>
Internal assessors examining each patient	<ul style="list-style-type: none"> <li>Consistency of reporting is improved</li> <li>Costly and time-consuming</li> <li>Patients may be more likely to provide informed consent to a known healthcare professional than to an external assessor</li> </ul>
External assessors examining each patient	<ul style="list-style-type: none"> <li>Consistency of reporting is improved</li> <li>Costly and time-consuming</li> <li>May be associated with a higher rate of patients declining to provide informed consent</li> <li>Logistics of arranging an external assessor may result in a time delay in reviewing patients</li> </ul>
External assessors interviewing staff	<ul style="list-style-type: none"> <li>Under-reporting is likely</li> <li>Costly and time-consuming</li> </ul>

The quality of the data is also affected by the:

- assessors' level of training and skill in performing clinical assessments such as PU risk assessment, skin inspection and PU classification
- data recorders' level of training and skill in completing documentation
- type and content of the data recording system
- ease of extraction of data from the recording system
- length of time over which data are collected.



**Accurate, consistent data recording is essential to ensure reliable results from PU prevalence and incidence studies**

## RETROSPECTIVE AND PROSPECTIVE STUDIES

**Retrospective studies**, ie studies that look back and use data recorded previously for other purposes, may face limitations as a result of the scope of the data recording and collection systems that were in place. Although it may be possible to include large numbers of patients, it is probable that a high number of individuals were involved in obtaining and recording data. This raises questions about the degree of inter-rater reliability<sup>13</sup>. In addition, it has been shown that a high proportion of PUs are not documented<sup>3</sup>, and so prevalence and incidence figures based on retrospective analysis of medical records are likely to be underestimates.

13. Fletcher J. How can we improve prevalence and incidence monitoring? *J Wound Care* 2001; 10(8): 311-14.

**Prospective studies**, ie those planned to collect data in the future, have the opportunity to set up systems that collect precisely the data required in a format that is appropriate for analysis. The data collection systems can be designed to be incorporated into daily clinical practice so that they prompt assessments as required and guide appropriate intervention where necessary.

### Tips for planning prevalence and incidence studies

Involvement of a medical statistician in the planning phase of a study will help to ensure the data collected are suitable for analysis to assess the intended outcome.

#### Consider and determine:

- The purpose of the study, eg:
  - assessment of burden of PUs
  - evaluation of effectiveness of current PU prevention strategies
- The most appropriate study outcome to achieve this purpose, eg prevalence or incidence analysis, taking into account resource and funding availability\*
- Whether the study will be prospective or retrospective
- Data source – will medical records be used or will patients’ skin be examined?
- Where data will be collected, eg in acute or chronic services, medical or surgical departments
- Who will be included, eg patients in community or hospital settings, patients with neurological problems
- When data collection will occur, over what time period and how frequently
- The data required – eg PU classification, risk factor assessment, cause, PU characteristics (eg site/dimensions), patient age/sex, comorbidities, current prevention protocol/strategy, patient population specific categories of data (eg for paediatric and neonatal populations)
- Who will conduct the data collection
- Education, training and inter-rater reliability testing requirements for observers/data recorders
- Whether to involve external assessors to monitor quality of assessment and data recording
- Education and training requirements for observers/data recorders
- For prospective studies, the prevention protocol to be used for patients identified as being at risk of a PU and associated resource and training requirements
- When data collection will start and stop, when data will be analysed, and when results will be available
- Approval processes required, eg trial registration, ethics committees
- Who will perform the statistical analysis
- Additional resources required, eg staff, clinical/administrative equipment
- How the results will be disseminated and applied

\*In practice, funding and resource availability may be major factors in determining the type and scope of study performed



The ultimate goal of PU management is prevention: good quality prevalence and incidence studies provide essential information that can be used to aid improvements in risk assessment and prevention strategies



#### APPLICATION TO PRACTICE

**When programmes to reduce PU occurrence are introduced they should ideally integrate data collection systems that can provide information for clinical audit and prevalence/incidence studies**  
**Appropriate training and testing are required for all assessors and data recorders**

# defining the study population

14. Pancorbo-Hidalgo PL, Garcia-Fernandez FP, Lopez-Medina IM, Alvarez-Nieto C. Risk assessment scales for pressure ulcer prevention: a systematic review. *J Adv Nurs* 2006; 54(1): 94-110.
15. Waterlow J. The Waterlow score card. Available at: [www.judy-waterlow.co.uk/the-waterlow-score-card.htm](http://www.judy-waterlow.co.uk/the-waterlow-score-card.htm). Accessed September 2008.
16. Bergstrom N, Braden BJ, Laguzza A, Holman V. The Braden scale for predicting pressure sore risk. *Nurs Res* 1987; 36(4): 205-10.
17. Norton D. Calculating the risk: reflections on the Norton Scale. *Decubitus* 1989; 2(3): 24-31. Erratum in: *Decubitus* 1989; 2(4): 10.
18. VanGilder C, MacFarlane GD, Meyer S. Results of nine international pressure ulcer prevalence surveys: 1989 to 2005. *Ost Wound Manage* 2008; 54(2): 40-54.
19. Schoonhoven L, Haalboom JRE, Bousema MT, et al. Prospective cohort study of routine use of risk assessment scales for prediction of pressure ulcers. *BMJ* 2002; 325(7368): 797.
20. Defloor T, Grypdonck MF. Validation of pressure ulcer risk assessment scales: a critique. *J Adv Nurs* 2004; 48(6): 613-21.

Defining the population to be surveyed is a fundamental step in planning a prevalence or incidence study. The nature of this population will have a profound effect on the findings. This largely relates to **case mix**, ie the types of patient within the study and their risk of pressure ulceration. For example, it would be expected that the prevalence and incidence of PUs would be higher in a geriatric unit than in a maternity unit. Similarly, studies that include a wide range of care settings and patients are likely to produce lower prevalence/incidence rates than studies that focus on one (or more) 'high risk' settings or populations.

Defining the study population allows prevalence and incidence studies to be placed in the correct context and involves specifying the:

- **care setting(s)** – eg community or hospital, acute or chronic services, one particular or a range of services/settings, inpatient or outpatient departments
- **inclusion and exclusion criteria** – eg scores on a given risk assessment scale, comorbidities, patient characteristics, and, for incidence studies, how data from patients with a pre-study PU is handled.

Although care settings may form a useful basis for determining a patient population, study populations may also be selected (across or within care settings) on the basis of level of risk (eg only patients that pass a predetermined threshold for risk of a PU are entered into the study) or the presence of a comorbidity, eg a hip fracture.

## DETERMINING RISK

Whilst it is clear that pressure, shear, friction, moisture and temperature play an important role in producing the tissue damage that results in PUs, it is unknown exactly what makes one patient more susceptible than another. Numerous potential risk factors have been identified and it has been postulated that these contribute to risk by affecting the tolerance of the patient's tissues to pressure, shear, friction, moisture and temperature.

It has been recognised that experienced clinical evaluation may not identify all patients at risk of developing a PU<sup>14</sup>. To aid recognition of risk, many PU risk assessment scales have been produced<sup>15-17</sup>. Even so, these scales may define some patients who subsequently develop a PU as being 'not at risk'<sup>18</sup>.



**Experienced clinical evaluation and the use of PU risk assessment scales can play complementary roles in identifying patients at risk: one should not replace the other**

The use of risk assessment scales provides a means of stratifying patients by score itself, or into groups such as 'low' or 'high' risk. This is potentially useful in defining populations in PU prevalence and incidence studies. However, comparisons between studies may be complicated by the way risk assessment scales have been used, eg by each study using:

- different cut-off points for the same scale
- different risk assessment scales.

Although some scales are widely used, they have variable validity<sup>19</sup>. An important issue affecting risk assessment scale validity is that some studies of validity have not taken into account that a proportion of patients (for ethical reasons) received PU preventive measures<sup>20</sup>. This would be expected to affect validity study outcome because the chance of those patients who received preventive measures developing a PU will have been altered.

Risk assessment scales also vary in the criteria tested, and some do not assess widely recognised risk factors, such as poor nutritional status, advanced age and use of medical devices. Further confusion may occur when studies use different risk assessment scale cut-off points from those used to aid clinical decision-making.



**Use of a PU risk assessment scale must be combined with a suitable PU prevention protocol**

21. Lahmann N, Halfens RJ, Dassen T. Effect of non-response bias in pressure ulcer prevalence studies. *J Adv Nurs* 2006; 55(2): 230-36.

### **INFORMED CONSENT**

Ethical considerations are more frequently requiring that persons surveyed for epidemiological studies provide informed consent. When such consent is required, some will understandably decline study participation and others will be unable to give consent. Variances in the proportion of the study population that does not participate for these reasons has the potential to significantly affect the comparability of the results of epidemiological studies<sup>21</sup>.

Non-participation has numerous causes. By ensuring that potential participants and their families/carers fully understand the aim of the study and what is involved, healthcare practitioners may be able to maximise participation rates.

### **Tips for assessing PU risk**

- On admission to any healthcare setting, everyone should be assessed for risk of PUs:
  - In some settings where risk of PUs is inherently low (eg maternity services), risk assessment may be informal and based on experienced clinical judgment. Use of a formal risk assessment tool should be prompted by the presence of a major PU risk factor, eg immobility, increased age, reduced sensation, poor nutrition/skin condition/tissue perfusion
  - In settings where risk of PUs is higher (eg intensive care units, geriatric services), formal risk assessment using an appropriate tool should be routine
- In any setting participating in a PU prevalence/incidence study, use of a formal risk assessment tool is likely to be routine for all patients
- PU risk assessment should be documented and identification of risk should be linked to implementation of an appropriate prevention protocol
- Risk assessment should be repeated at appropriate intervals and when an individual's general condition changes
- Those undertaking risk assessment need to understand why they are doing it, how to do it, and what to do with the results, eg how and when to use formal risk assessment tools and the criteria for entry into a PU prevention protocol



### **APPLICATION TO PRACTICE**

**PU prevalence and incidence studies need to state inclusion and exclusion criteria, method of risk assessment, and cut-off points for defining levels of risk**

# identifying pressure ulcers

22. NPUAP. *Pressure ulcer stages revised by NPUAP*. National Pressure Ulcer Advisory Panel (NPUAP), 2007. Available at: [www.npuap.org/pr2.htm](http://www.npuap.org/pr2.htm). Accessed September 2008.
23. EPUAP. *Pressure ulcer treatment guidelines*. European Pressure Ulcer Advisory Panel (EPUAP), 1998. Available at: [www.epuap.org/gltreatment.html](http://www.epuap.org/gltreatment.html). Accessed September 2008.
24. Defloor T, Schoonhoven L, Fletcher J, et al. Pressure ulcer classification. Differentiation between pressure ulcers and moisture lesions. *EPUAP Review* 2005; 6(3). Available at: [www.epuap.org/review6\\_3/page6.html](http://www.epuap.org/review6_3/page6.html). Accessed September 2008.
25. Evans J, Stephen-Haynes J. Identification of superficial pressure ulcers. *J Wound Care* 2007; 16(2): 54-56.

Correct identification of PUs underpins meaningful prevalence and incidence studies. **Definitions** of PUs include those from the:

- **National Pressure Ulcer Advisory Panel (NPUAP):** 'localised injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction. A number of contributing or confounding factors are also associated with PUs; the significance of these factors is yet to be elucidated'<sup>22</sup>
- **European Pressure Ulcer Advisory Panel (EPUAP):** 'an area of localised damage to the skin and underlying tissue caused by pressure, shear, friction and or a combination of these'<sup>23</sup>.

Accurate diagnosis of a PU will involve differentiation from other wound types. Particular difficulty lies in distinguishing superficial PUs from other forms of skin damage, eg moisture lesions (such as incontinence-associated dermatitis (IAD) and those caused by sweat), and dressing or tape damage (Box 3). (NB Sometimes the term 'incontinence-associated dermatitis' is used synonymously with the broad term 'moisture lesion'. However this does not accurately reflect the wide range of causes of moisture lesions.)

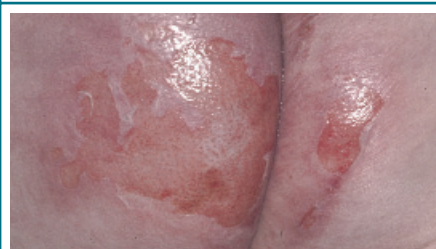
Regular, thorough **skin inspection** is the key to detecting pressure damage. Particular attention should be paid to vulnerable areas, especially over bony prominences or any body part subjected to prolonged pressure. As a minimum, documented skin inspection should form part of admission procedures. The frequency of repeat inspections will be determined by the initial findings, the individual's level of risk for PU development and the type of healthcare setting.



**Although it is essential to differentiate PUs from other types of skin damage, PUs may co-exist with other types of wound and each will require intervention as appropriate**

## BOX 3 | Distinguishing PUs, moisture lesions/IAD and dressing or tape damage (adapted from<sup>24,25</sup>)

PU's	Moisture lesions/IAD	Dressing or tape damage
<ul style="list-style-type: none"> <li>■ Pressure and/or shear present</li> <li>■ Generally located over a bony prominence or body area subjected to pressure</li> <li>■ Regularly shaped wounds are more likely to be PUs than moisture lesions/IAD (NB PUs may also be irregular in shape)</li> <li>■ Distinct edges</li> <li>■ Skin erythema is non-blanchable</li> </ul>	<ul style="list-style-type: none"> <li>■ Often intragluteal, may occur over a bony prominence</li> <li>■ Pressure and shear should be excluded</li> <li>■ Moisture is present - eg shining wet skin caused by urinary incontinence or diarrhoea</li> <li>■ May be diffuse in shape with several closely located areas involved</li> <li>■ Edges are often diffuse or irregular</li> <li>■ Superficial unless become infected</li> <li>■ No necrosis present</li> <li>■ If redness is not uniformly distributed, IAD or a moisture lesion is more likely than a PU</li> <li>■ Maceration of surrounding skin may be present</li> <li>■ Often symmetrical ('copy lesions')</li> </ul>	<ul style="list-style-type: none"> <li>■ Occurs where dressings or tape have been used</li> <li>■ May present as skin discolouration, contact dermatitis, or broken, stripped skin</li> <li>■ Tends to represent the shape of the tape or dressing</li> </ul>



# classification

26. NPUAP. *NPUAP Deep Tissue Injury consensus, 2005*. National Pressure Ulcer Advisory Panel (NPUAP), 2005. Available at: [www.npuap.org/DOCS/DTI.doc](http://www.npuap.org/DOCS/DTI.doc). Accessed September 2008.

PU classification schemes provide a means of stratifying and quantifying wound severity, and may aid consistency of assessment and reporting. Many classification systems are in existence; generally, they are based on the extent of tissue damage. Although most use four (or sometimes five) numbered stages or grades, systems vary in:

- criteria used for each stage/grade
- complexity
- level of training required for accurate use.

Box 4 summarises two of the most widely used systems. The systems are subtly different, illustrating that the use of different classification systems in different PU prevalence or incidence studies may contribute to difficulties in making and interpreting study comparisons.

## Note

The EPUAP and NPUAP are working on an integrated definition and classification of PUs that was not available at the time of printing. Please see [www.epuap.org](http://www.epuap.org) and [www.npuap.org](http://www.npuap.org) for updates

## BOX 4 | Summary of NPUAP and EPUAP PU classification systems

NPUAP <sup>22,26</sup>	EPUAP <sup>23</sup>
<p><b>Stage I</b></p> <ul style="list-style-type: none"> <li>■ Non-blanchable erythema of intact skin usually over a bony prominence</li> <li>■ Darkly pigmented skin may not have visible blanching; its colour may differ from the surrounding area</li> <li>■ The area may be painful, firm, soft, warmer or cooler compared to surrounding tissue</li> </ul>	<p><b>Grade 1</b></p> <ul style="list-style-type: none"> <li>■ Non-blanchable erythema of intact skin</li> <li>■ Discolouration of the skin, warmth, oedema, induration or hardness may also be used as indicators, particularly in individuals with darker skin</li> </ul>
<p><b>Stage II</b></p> <ul style="list-style-type: none"> <li>■ Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed</li> <li>■ Presents as a shiny or dry shallow ulcer without slough or bruising</li> <li>■ May also present as an intact or open/ruptured serum-filled blister</li> </ul>	<p><b>Grade 2</b></p> <ul style="list-style-type: none"> <li>■ Partial thickness skin loss involving epidermis, dermis or both</li> <li>■ The ulcer is superficial and presents as an abrasion or blister</li> </ul>
<p><b>Stage III</b></p> <ul style="list-style-type: none"> <li>■ Full thickness skin loss</li> <li>■ Subcutaneous fat may be visible, but not bone, muscle or tendon</li> </ul>	<p><b>Grade 3</b></p> <ul style="list-style-type: none"> <li>■ Full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to but not through underlying fascia</li> </ul>
<p><b>Stage IV</b></p> <ul style="list-style-type: none"> <li>■ Full thickness skin loss with exposed bone, tendon or muscle</li> </ul>	<p><b>Grade 4</b></p> <ul style="list-style-type: none"> <li>■ Extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures, with or without full thickness skin loss</li> </ul>
<p><b>Unstageable</b></p> <p>Full thickness tissue loss in which the base of the ulcer is covered with slough and/or eschar</p>	
<p><b>Deep tissue injury</b></p> <p>Purple or maroon localised area of discoloured intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The effect may be preceded by tissue that is painful, firm, mushy, boggy, and warmer or cooler than adjacent tissue. Evolution may be rapid exposing additional layers of tissue even with optimal treatment</p>	

For all classification systems, inter-rater reliability is an issue. For some, inter-rater reliability has been shown to be greater in the reporting of severe stages/grades of PUs when compared to that of less severe PUs<sup>27</sup>. This indicates a particular need for training in the identification of lower stage/grade PUs (see non-blanchable erythema below).



**Data collectors should receive training in the use of whichever PU classification system is employed in a prevalence/incidence study**

27. Healey F. The reliability and utility of pressure sore grading scales. *J Tissue Viability* 1995; 5(4): 111-14.
28. Vanderwee K, Grypdonck MH, De Bacquer D, Defloor T. The reliability of two observation methods of nonblanchable erythema, Grade 1 pressure ulcer. *Appl Nurs Res* 2006; 19(3): 156-62.

### **NON-BLANCHABLE ERYTHEMA**

The NPUAP and EPUAP classification systems use non-blanchable erythema as a defining feature of Stage I/Grade 1 PUs. This is differentiated from blanchable erythema, which often precedes non-blanchable erythema. Blanchable erythema is reddening of the skin that blanches (pales) under light pressure; non-blanchable erythema remains reddened when pressure is applied. Use of a transparent interface to apply pressure may aid assessment of whether erythema is blanchable or non-blanchable (Figure 3)<sup>28</sup>.

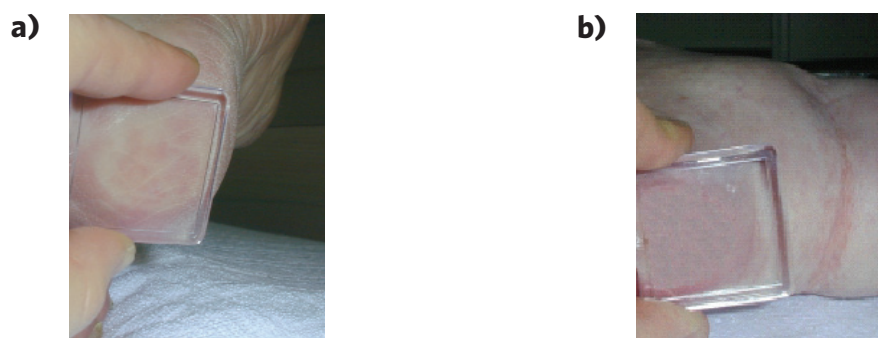
Difficulties exist with determining the best way to apply and determine 'light pressure', and also in observing blanching in darkly pigmented skin. As a result of these difficulties, the EPUAP and NPUAP have devised additional criteria for Stage I/Grade 1 PUs that may aid identification (Box 4, page 12)<sup>22,23</sup>.

The difficulties of identifying and classifying Stage I/Grade 1 PUs have resulted in the omission of these from some epidemiological studies<sup>2</sup>. The prevalence and incidence rates produced by these studies would be expected to be lower than if PUs of all stages/grades were included.



**International consensus on a PU classification scheme would be a major step forward in improving consistency and aiding PU prevalence/incidence study comparisons**

**Figure 3 |** Blanching (a) and non-blanching (b) erythema using a transparent interface



### **UNSTAGEABLE**

The NPUAP classification system defines an unstageable PU as one in which there is full thickness tissue loss, but the base of the ulcer is covered with slough and/or eschar obscuring its true depth<sup>22</sup> (Box 4, page 12). In prevalence and incidence studies using the NPUAP system, unstageable PUs should be categorised and analysed separately.

29. Ohura T, Ohura N, Oka H. Incidence and clinical symptoms of hourglass and sandwich-shaped tissue necrosis in Stage IV pressure ulcers. *Wounds* 2007; 19(11): 310-19.
30. NPUAP. *The facts about reverse staging in 2000*. The NPUAP Position Statement. National Pressure Ulcer Advisory Panel (NPUAP), 2000. Available from: [www.npuap.org/archive/positn5.htm](http://www.npuap.org/archive/positn5.htm). Accessed September 2008.
31. Dealey C, Lindholm C. Pressure ulcer classification. In: Romanelli M, Clark M, Cherry G, et al (eds). *Science and Practice of Pressure Ulcer Management*. London: Springer-Verlag, 2006.
32. Baharestani MM, Ratliff CR. Pressure ulcers in neonates and children: an NPUAP white paper. *Adv Skin Wound Care* 2007; 20(4): 208-20.

## DEEP TISSUE INJURY

In recent years, there has been much debate surrounding whether there is a need for a separate definition and classification system for deep tissue injuries (DTIs) within the NPUAP PU classification system.

The debate has been prompted by recognition that **DTIs can progress quickly and inevitably to full skin thickness ulceration**<sup>29</sup>. Therefore, classifying DTIs as NPUAP Stage I or II PUs (because there is no skin loss) could be seen to wrongly imply that the injury is relatively minor and may heal relatively quickly with appropriate intervention<sup>26</sup>. As a result, the NPUAP has recently produced a definition of suspected DTI (Box 4, page 12). The implications of the use of a separate definition have yet to be fully determined. (NB When using the EPUAP classification system (Box 4), DTIs are usually classified as Grade 4.)

Inclusion of DTI within the numbered NPUAP or EPUAP classification systems has raised concerns about the validity of using prevalence and incidence studies as an indicator of quality of care: many DTIs may arise prior to admission to a hospital or other healthcare facility. Penalties applied by funders to healthcare institutions as the result of DTI occurrence may therefore be unmerited.



**Evaluation of prevalence and incidence studies should determine whether Stage I/ Grade 1 PUs have been included, and how DTIs have been considered**

## REVERSE STAGING

Unfortunately, PU classification systems have been seen to imply that healing or improvement in a PU results in lower staging/grading. However, these systems are based on anatomy and type of tissue damaged. Stage IV/Grade 4 PUs heal by granulation, contraction and re-epithelialisation. Therefore, re-classifying a Stage IV/Grade 4 PU to Stage III/Grade 3 or lower is not strictly correct, and for the purposes of prevalence and incidence studies a Stage IV/Grade 4 PU should always be classified as such<sup>30,31</sup>. Use of reverse staging to document improvement in PUs is inappropriate and may mislead assessments of quality of care. Specific tools designed to monitor healing of PUs are available<sup>30,31</sup>.



**Reverse staging is not recommended for assessing healing of PUs**

## PU'S RELATED TO MEDICAL DEVICES

PUs can sometimes occur as a result of medical devices, eg nasal cannulae, tracheostomy plates, casts or clip-on devices for monitoring oxygen saturation. In children, about half of PUs are device-related<sup>32</sup>. Prevalence and incidence studies may consider performing a separate analysis of these events.

## UNDER-REPORTING

Under-reporting, particularly of lower grade/stage PUs, may be due to lack of recognition of the early signs of pressure damage. Paradoxically, increasing awareness of PUs and providing risk assessment training (alongside implementation of related risk-based prevention protocols) may result in increased reporting of PUs as understanding improves. This is likely to be particularly true of Stage I/Grade 1 PUs, where improved understanding empowers healthcare practitioners to take positive action to encourage resolution.



33. Vanderwee K, Clark M, Dealey C, et al. Pressure ulcer prevalence in Europe: a pilot study. *J Eval Clin Pract* 2007; 13(2): 227-35.

The use of PU prevalence and incidence studies to measure quality of care can result in under-reporting by healthcare practitioners because of guilt or fear of personal recrimination and financial penalties for the healthcare institution.

Under-reporting of PUs in patients transferred from one healthcare sector or institution to another can be a particular problem. This emphasises that PU assessment should be conducted and documented very early after admission so that the receiving institution can accurately identify PUs and DTIs already in existence.



**Education about the value and interpretation of epidemiological studies is vital to ensure accurate reporting of PUs by practitioners and appropriate and fair use by healthcare funding bodies of incidence and prevalence data**

#### Tips for identifying PUs

- Practitioners should receive education and training in PU identification and classification. This should include:
  - the normal appearance of skin, muscle, tendon and bone
  - variances in PUs that may be due to anatomical location, eg Stage IV/Grade 4 PUs that occur over the occiput are shallower than those over the sacrum
  - differentiation of PUs from arterial, venous and neuropathic ulcers, as well as other common skin alterations such as moisture lesions (including IAD), rashes and skin tears
  - identification of more complex pathology
  - how to conduct a full skin assessment, including examination for physical characteristics that may increase risk of overlying pressure damage, eg bony prominences
- Morbidly obese (bariatric) patients may present particular challenges and require an appropriate individualised protocol to address practical assessment issues and resource implications
- Regular inspection of skin folds and behind/under large skin flaps (eg pannus), particularly in morbidly obese patients should be undertaken, and PUs should be differentiated from intertrigo
- Regular inspection of the skin under or in contact with medical devices should be ensured



#### APPLICATION TO PRACTICE

**Variability in the application of PU classification systems can be a major hindrance to comparisons of PU prevalence and incidence studies**

**Use of a standardised data collection instrument can assist study comparisons<sup>33</sup>**

**Programmes to increase awareness of PUs should be accompanied by training of healthcare professionals to improve accuracy of identification and classification, and reduce the likelihood of over-reporting**

# evaluation, interpretation and comparison

The wide-ranging variability of possible approaches to performing prevalence and incidence studies hampers evaluation of trends and comparisons between studies. The box below outlines a systematic approach to evaluating, interpreting and comparing studies. There remains a need for a universally accepted standard approach to such studies to increase transparency and aid understanding of trends.

## Questions to ask

- What was the purpose of the study?
- Was the choice of prevalence or incidence appropriate to the purpose of the study?
- How were the term(s) defined?
- Was the study retrospective or prospective?
- What was the source of the data?
- Who collected the data? What expertise and qualifications do they have?
- How were the data collected?
- What was the care setting?
- How was the study population defined, eg in terms of healthcare setting or level of PU risk?
- What proportion of patients in the initial study group did not agree to participate or dropped out?
- What were the inclusion/exclusion criteria, eg were patients with a particular comorbidity or under a particular level of risk excluded, were children and neonates included?
- How was risk assessed?
- Were patients stratified according to risk?
- What were the cut off points for 'at risk' and 'not at risk'?
- Did incidence studies include patients who had a PU on study entry?
- When was the study conducted, eg might an apparent increase be related to data collection from a study period during winter months?
- Was a PU classification system used? If so, which one?
- Were Stage I/Grade 1 PUs included or analysed separately?
- How was DTI counted in the PU classification system used, or was it counted separately?
- Were medical device-related PUs identified and were they analysed separately?
- How were NPUAP unstageable PUs considered?
- Did prevalence studies include healed PUs? If included, how were they classified?
- Were data available from time of admission on all patients?
- Were patients with evidence of PU on admission included/excluded/analysed separately?
- How were patients with more than one PU considered?
- What happened to data from patients whose PU deteriorated or healed during the study period?
- What prevention protocol was in place during the study?
- How was adherence to the prevention protocol assessed?
- What conclusions were drawn from the study? Are they valid and what implications do they have?
- Were the results compared with those of other studies? If so, were the patient populations and study methodology similar enough to allow for meaningful comparison?



**Caution is advised in the comparison of PU prevalence or incidence studies because of the large number of variables involved**





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