Pressure ulcer

A multicenter study of prevalence, risk factors and prevention in a sample of hospitals in Norway

PhD Thesis

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"If he has a bed sore, it's generally not the fault of the disease, but of the nursing."

Florence Nightingale, 1859.

Content

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Abbreviations

AE	Adverse events
BMI	Body mass index
CI	Confidence interval
EPUAP	European Pressure Ulcer Advisory Panel
HAPU	Hospital acquired pressure ulcer
ICC	Intraclass correlation coefficient
LOS	Length of stay
NPUAP	National Pressure Ulcer Advisory Panel
PPPIA	Pan Pacific Pressure Injury Alliance
PU	Pressure ulcer
RCT	Randomized controlled trial
SAQ	Safety Attitudes Questionnaire
SD	Standard deviation
WHO	World Health Organization

List of papers

I Bredesen IM, Bjøro K, Gunningberg L, Hofoss D. (2016) Effect of e-learning program on risk assessment and pressure ulcer classification – a randomized study. *Nurse Educ Today, 40, 191-197.*

II Bredesen IM, Bjøro K, Gunningberg L, Hofoss D. (2015) The prevalence, prevention and multilevel variance of pressure ulcers in Norwegian hospitals: a cross-sectional study. *Int J Nurs Stud, 52(1), 149-56.*

III Bredesen IM, Bjøro K, Gunningberg L, Hofoss D. (2015) Patient and organisational variables associated with pressure ulcer prevalence in hospital settings – a multilevel analysis. *BMJ Open, Aug 27, 5(8).* doi: 10.1136/bmjopen-2015-007584.

Summary

Introduction: Pressure ulcers (PUs) are a serious health care problem in hospitals. Evidence-based guidelines for PU prevention highlight the importance of pressure-redistributing surfaces in beds and chairs as well as heel protection and frequent repositioning. Even though patient risk factors are well known, PU prevalence rates are still high and PUs remain a patient safety problem. The development of a PU is an adverse event and may be associated with characteristics of health care organization, including staffing levels and safety culture.

Aims: The project has three aims: (1) to develop and test an e-learning program for assessment of PU risk and PU classification; (2) to investigate PU prevalence, patient-related risk factors, the use of PU preventive measures, and how much of the hospital acquired PU (HAPU) variance is at patient, ward and hospital level; and (3) to investigate the association of ward-level differences in the odds of hospital acquired PUs (HAPUs) with selected ward organizational-related variables and patient risk factors.

Study I: This study was a randomized controlled study comparing the effect of an e-learning program (intervention group) on registered nurses' risk assessment and PU classification skills compared to classroom lecture training. Forty-four nurses participated. The nurses in the e-learning group (n=23) had better PU classification skills immediately after training compared to the classroom training group (n=21), but this was only a short-term effect. No difference was found between groups in the PU risk assessment tests.

Study II: This study was a cross-sectional study conducted in six hospitals (88 wards, 1209 patients). The PU prevalence for the sample was 18.2% (220/1209 patients) including PU categories I-IV. Most PUs were located on the sacrum (36.4%). Three hundred five patients (25.2%) were considered at risk, having a Braden score of < 17 points and/or a PU. Only 44.3% (135/305) of at-risk patients had a pressure-redistributing mattress. Further, only 22.3% (68/305) received planned repositioning in bed. Implementation of preventive measures recommended in evidence-based guidelines for the at-risk patients was not sufficient. We found significant variance in HAPUs at ward level, which we further investigated in Study III.

Study III: This study used the cross-sectional data from Study II in addition to national patient safety culture study data for the participating hospitals, provided as mean ward scores. The sample in this study consisted of 1,056 patients in 84 wards at four hospitals. We found a significant association between patient safety culture and HAPU odds: better patient safety culture was associated with lower HAPU odds (OR 0.97; 95% CI 0.95-0.99). Study III found an association between odds of HAPUs and other organizational risk factors: lower risk in rehabilitation wards vs surgery/internal medicine (OR 0.17; 95% CI 0.04-0.66) and higher risk when PU prevention was implemented (OR 2.02; 95% CI 1.12-3.64). Significant patient-level factors were age above 70 (OR 2.70; 95% CI 1.54-4.74), Braden total score (OR 0.73; 95% CI 0.67-0.80), and being overweight (OR 0.32; 95% CI 0.17-0.62).

Conclusion: PU present a challenge in Norwegian health care and there is insufficient implementation of evidence-based preventive measures for a large part of at-risk patients. Organizational factors, as well as patient risk factors, were significantly related to the HAPU odds. Increased focus on patient safety is important, as a strong ward patient safety culture was significantly associated with lower odds for HAPUs. An important aspect of good patient safety is the health personnel's knowledge. Knowledge about risk assessment and correct classification of PUs is important for identifying at-risk patients and initiating prevention. Repeated training may lead to improved PU prevention.

Preface

My motivation for this thesis has developed over my long career in healthcare. Already in the early 1990s, when working as a nursing assistant at a nursing home, I encountered PUs for the first time. A patient with hip fracture returned from the hospital with a large PU on the sacrum. The time-consuming process of healing and the patient's pain and discomfort made an indelible impression on me and piqued my interest in PU and wound healing. Since then I have worked for 20 years as a nurse in an orthopaedic ward where nearly all patients are at risk of developing PUs and other complications. I became involved in the pressure ulcer committee at my hospital as a representative for the orthopaedic department and participated in hospital PU prevalence studies conducted from 1997 to 2002. During this time, my interest in the prevention of patient complications, including PUs, really increased, and led me to choose PU prevention as the area of my doctoral research.

As an instruction nurse in the orthopaedic ward, I have also been interested in the development of effective methods to increase staff knowledge. In-service education such as traditional classroom education is particularly problematic in a nursing context. It is often not possible to gather nurses for classroom instruction due to their workload which often makes it difficult for nurses to leave the ward and their patients to attend classes. Alternative ways to introduce new and update existing knowledge in a more efficient way are highly needed in busy nursing contexts.

1. Introduction

In 1863 Florence Nightingale wrote, “It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm.”[1] “Do no harm” is the core ethical principle of the Hippocratic Oath that health professionals have taken since antiquity. The Code of Ethics of the International Council of Nurses is also grounded in the fundamental ethical principle of protecting patients from harm.[2] Yet, today about one in ten hospitalized patients experience an adverse event (AE) that harms them.[3] Pressure ulcers (PUs) are one of the most common AEs that patients experience.

PUs are injuries to the skin: they are a common occurrence in immobilized patients in hospitals. PU prevalence is reported to be between 9% and 18% in European hospitals.[4-7] A study of a single Norwegian hospital[8] found a prevalence of 18% indicating that PUs may also be a serious problem in Norwegian hospitals. However, very few Norwegian hospitals conduct systematic studies to monitor the occurrence of PUs.

PUs cause pain, increase the length of stay in hospital (LOS), delay rehabilitation, and reduce mobility and quality of life.[9] PUs also increase the risk of infection and death.[10] The occurrence of PUs, therefore, has dire consequences for hospitalized patients.

PU treatment is also associated with an estimated excess annual healthcare expenditure of up to 2.59 billion euros according to a recent review.[11] PU prevention costs less than PU treatment.[11] Therefore, prevention makes good sense. The majority of PUs can be avoided if evidence-based preventive measures are implemented at an early stage. Prevention of PUs is an important patient safety goal.[12 13] Epidemiological research is crucial to improving detection and treatment of this harmful and potentially lethal complication of illness and hospitalization.

Nurses are the healthcare professionals closest to patients and they play a key role in identifying and meeting patients’ needs related to the prevention of PUs. Already in 1859, Nightingale noted that “if he has a bed sore, it’s generally not the fault of the disease, but of the nursing.”[14] This statement has been modified as our understanding of the causes of PUs has increased, but quality nursing care must be in place to reduce the occurrence of PU. For decades, nurses have used nursing theories and the nursing process as guidelines to ensure quality patient care.[15 16] PU prevalence is considered a relevant indicator of the quality of nursing care.[12 13 17 18]

There is a general agreement that the occurrence of PUs is multifactorial. No single risk factor can explain PU.[19] The most important patient risk factors for PUs are reduced mobility/activity, reduced peripheral and central circulation, and skin status, including existing PUs.[19] The presence of existing PUs is a risk factor for developing a more severe PU as well as for developing additional PUs. Systematic skin and risk assessments are important for identifying changes in the skin and risk factors that contribute to PU development.

Systematic skin and risk assessment should trigger implementation of early preventive measures tailored to the individual patient.[12] Nurses who lack knowledge concerning risk factors, skin assessment and outcomes may fail to recognize compromised tissue and early signs of PU development. Studies have shown that nurses often fail to identify patients at risk for PUs and to implement preventive measures. A Norwegian study concluded that knowledge deficits regarding PU risk factors and risk assessment may be a major factor underlying the high prevalence of PUs.[8] The study recommended the development of educational tools to effectively teach nurses how to assess PU risk factors and identify PUs; yet little is known about which teaching strategies are most effective in ensuring successful learning.

Nurses' need to know how to assess both skin and PU risk; the high prevalence of PUs in many hospital settings remains a patient safety problem. Increasingly, PU development has been viewed as an AE that may be associated with characteristics of healthcare organization, including staffing levels and safety culture. Nevertheless, only a few studies have been conducted demonstrating the adverse impact of organizational characteristics on PU development. Recent reviews show mixed results for the association between staffing and PUs[20 21] and between safety culture and PUs.[22 23] Thus, the research evidence is still unclear regarding the relationship between organizational characteristics and PUs. Moreover, no studies have investigated the association of PU prevalence and organizational factors in Norwegian hospitals.

There is a gap in the scientific knowledge base regarding the most effective way to teach nurses to assess PU risk, skin assessment, and to classify PU. There is insufficient data on the PU prevalence in Norwegian hospitals; little is known about the risk profiles of patients and the preventive measures they receive. There is also insufficient knowledge regarding the association between the organizational characteristics of hospital wards and PU prevalence. Research is needed to better understand the occurrence of PUs in Norwegian hospitals and the characteristics of patients at risk for PUs.

1.1 Aims

PU prevention is an important element of care quality and patient safety in hospital settings, and it is highly relevant for nursing. The overall aim of this research was to develop a better understanding of the epidemiology of PUs in Norwegian hospitals in the interest of evaluating and ultimately improving nursing care quality and patient safety. Our research establishes a baseline for future research. This thesis has three objectives, which were achieved through three studies.

Study I

The aim of Study I was to develop and test an e-learning program for assessment of PU risk and PU classification.

Study II

The study investigated PU prevalence, patient-related risk factors, the use of PU preventive measures and how much of the hospital acquired PU (HAPU) variance is at patient, ward, and hospital levels.

Study III

The study investigated the association of ward-level differences in the odds of hospital-acquired PUs (HAPUs) with selected ward organizational variables and patient risk factors.

1.2 Significance of this research

Pressure ulcers are a patient safety problem of global importance. Several countries including the United States, the United Kingdom, Scotland, Canada, Australia, Sweden and Denmark have implemented patient safety campaigns that include PUs as an important target.[24 25] A Norwegian national patient safety campaign was launched in 2011; however, no national PU prevalence studies have been conducted to date. Thus, this PU prevalence study provides baseline data regarding the magnitude of the PU problem in Norwegian hospitals prior to initiation of the campaign.

PUs greatly affect the health outcomes and quality of life of hospitalized patients. Research is needed to document the changing needs of patients and potential risk factors. Older patients are at greater risk of developing PUs during episodes of illness and hospitalization, and as the number of older adults increase, the magnitude of the PU problem might also increase. Other vulnerable patient groups include patients with chronic illness and health issues such as obesity and diabetes.[26]

No large PU study had been conducted in Norwegian healthcare settings for nearly twenty years.[27] Therefore, we thought it was important to investigate PUs in a Norwegian setting including the variance of the HAPU outcome. This thesis investigates the frequency and severity of PUs, and PU risk factors in a sample of Norwegian hospitals. We also need information regarding methods of improving nurses' knowledge and their skills in risk assessment and PU classification. Increased knowledge regarding patient and organizational variables may contribute to improving healthcare and patient outcomes in Norway.

The strategy document for the Norwegian patient safety program for 2014–2018, underscores that most research in quality improvement and patient safety has been done in other countries, including Canada, the United Kingdom, the United States, and Australia.[28] More Norwegian research targeting quality improvement and patient safety is needed.[28] This thesis addresses this need.

1.3 Organization of the thesis

Chapter 2 presents the conceptual framework and introduces key terms. Chapter 3 describes data and methods. Chapter 4 presents the findings, which are then discussed in Chapter 5 along with recommendations for future research. Chapter 6 consists of the conclusion of the thesis.

2. Background

PU prevention is an important element of care quality and patient safety in hospitals and is highly relevant to nursing. Quality of care and patient safety are the core of ethical nursing practice, as well as a legal responsibility of nurses and healthcare organizations in Norway, and will be further described in this chapter.

Evaluation of care quality and patient safety are hallmarks of professional accountability. The evaluation of quality in healthcare and nursing has long been approached using a conceptual framework with three concepts: structure, process and outcome. The importance of this triad was first described in the 1960s by Avedis Donabedian.[29] The concepts of structure, process and outcome are used as an overarching framework for this thesis. In this chapter, quality and patient safety in nursing and the conceptual framework will be further described and key terms will be defined.

2.1 Quality and patient safety in nursing

The International Council of Nurses Code of Ethics states that nurses have four fundamental responsibilities: (1) to promote health, (2) to prevent illness, (3) to restore health, and (4) to alleviate suffering.[2] The need for nursing is universal, and nurses' primary professional responsibility is to people requiring nursing care. Inherent in nursing is a respect for human rights, including cultural rights and the right to life, choice, dignity and respect.[2] The quality of nursing care encompasses both the technical and the interpersonal aspects of care.

Several theories and models have been developed to describe the responsibilities of nursing. Virginia Henderson's theory of nursing, developed in the 1950s, focuses on the identification of patients' basic needs and the performances of activities to meet basic needs. Her theory encompasses not only physical but also psychosocial and existential needs.[15]

The healthcare environment in which nurses practice has become increasingly complex. Improved technology has resulted in greater demand for treatment. Healthcare policy makers are concerned about the cost of care, demand increased productivity, and require documentation regarding care provision. Patients spend less time in hospitals. Nurses are expected to provide good care in less time and with fewer staff. There is increasing evidence that nursing tasks are often left undone.[30 31] Nurses and nurse managers spend more time doing administrative tasks and less time caring for patients. When nurses do not have time to make basic observations of patients and implement necessary interventions, patient safety is compromised.[32]

Kitson and colleagues[33] call for a revival of nursing and a refocusing of the nursing profession on the fundamentals of care. Kitson's fundamentals of care comprise the physical, psychosocial, and relational aspects of care (e.g., hygiene, safety, comfort, respect, empathy).[34] Variation in delivery of the fundamentals of care may result in adverse patient outcome and adverse care experiences.[34] To reduce variance and to provide quality nursing care, nurses require a good work environment, leadership, and a culture that is focused on patient safety. Nurses need structure to provide high quality care.

Nursing quality is dependent on qualified nurses. In the Code of Ethics, personal responsibility and accountability are highlighted as qualifications for nursing practice, as is maintaining competence through continual learning.[2] The use of judgment, technology, and scientific advances are other areas that are important for nursing practice.[2] Nurses have a round-the-clock responsibility to their patients in a complex hospital setting. In their work with patients, nurses use a systematic process often referred to as *the nursing process*.[16 35] The nursing process includes both an interpersonal and a problem-solving part.[35] It is a method of approaching and planning patient care that includes assessment, planning, implementation and evaluation.[16 35] The problem-solving part of the nursing process is systematic and is often described as a process linked to coping with patients' basic needs.[35]

The Norwegian Health Personnel Act stipulates the professional responsibility of individual practitioners to provide good care. The definition of good quality care is determined by the nurses' qualifications, the nature of the work, and the situation in general.[36] The Norwegian Specialized Health Services Act requires that hospitals have responsible managers at all levels.[37] Moreover, the law requires that management take responsibility for facilitating education and training required for professionals to carry out their work.[37] The responsibility of management to create room for nurses' professional development is also underscored in the Norwegian Nurses Organization's Ethical Guidelines for Nurses.[38] Hospital and nursing management should focus on the principle of "do no harm", quality, safety, improvement, and teamwork. In this thesis, management, safety climate, and teamwork are incorporated in the term "patient safety culture". The professional, ethical, and legal responsibility of nurses and nurse managers for clinical practice is clearly defined in these ethical guidelines and in Norwegian law. The first step towards improving quality and safety of care is evaluation. The next paragraphs describe the conceptual framework.

2.2 Conceptual framework

The Donabedian model is often used as a framework to investigate quality in hospital care. The Donabedian model includes three interlinked concepts: structure, process and outcome.[29 39] Structure, process and outcome are used as an overarching framework in this thesis.

"Structure" is the context in which care is delivered, including material resources, human resources, and organizational structure. Structure is often considered an indirect measure of quality of care.[40] Structure variables in this thesis reflect nurses' skills and their work context. The assumption is that the provision of good care requires the availability and distribution of resources. Structure variables investigated are staff training, staffing level, ward type, and safety culture (teamwork, safety climate and perception of management).[39 41 42]

The performance of health care personnel can be captured by technical care and interpersonal care.[39] Technical care refers to the knowledge, judgment, skills, and strategies for care based on best-practice knowledge.[39] Interpersonal care refers to the quality of communication and interaction with patients. According to Donabedian, the interpersonal process and outcome should derive from behavioural science, while the relationship between technical care and outcome derives from healthcare science.[39]

"Process" describes how care is actually provided, including activities of health professionals in assessing, diagnosing, and treating of patients. Process encompasses the nursing process (assessment, diagnosis, planning, implementing, evaluating).[16] During assessment, the nurse observes the patient's health status, which further guides the planning of care and implementation of, e.g., preventive measures. Process variables are important components of quality of care as they measure what registered nurses do for, with, or on behalf of patients,[43] for example, whether preventive measures have been implemented for all at-risk patients. Process variables are the activities related to PU prevention. In this thesis, these variables are PU risk and skin assessment and PU preventive measures implemented based on patients' risk profiles.[12 39] These nursing actions are important for preventing PUs.

“Outcome” describes the effect of care on patients’ health.[12 29 39] In this thesis, PU is the outcome variable of interest. The evaluation of nursing care outcomes determines whether nursing actions have been effective. PUs are often used as a quality indicator for nursing care.[12 13 17 18 41 44] Quality indicators are used as measures of the quality of care and are often divided according to the three concepts of the Donabedian model.[45]

A basic premise of the structure, process, and outcome model is that a good structure may increase the probability of a good process, which in turn may increase the probability of a good outcome.[39] A good result is the primary goal of care quality and reflects the degree to which a patient’s needs (health/ function level/treatment/care) are met. Good quality means that specifications are met. Specifications may be the expectations, wishes, and orders from stakeholders, namely patients, relatives, staff, organizations, top management, and public authorities. The association between structure and outcome has been investigated more often than the association between process and outcome.[40 41] AEs are examples of poor outcomes that have often been associated with poor structure or poor process of care.[46] The structure-process-outcome model provides an opportunity to investigate how AEs such as PUs may be affected by risks within the structure and process of care.

Outcome may be a consequence of structure and process, but patient characteristics such as age and diseases can influence outcome as well. PU prevalence cannot be explained by characteristics of health services (structure and process) alone. The Donabedian model does not explicitly mention patient characteristics’ impact on the outcome.[39 47] However, patient characteristics are important factors for PU development (outcome) and for nurses’ assessment and judgment of patients’ risk of developing PU (process). Patient characteristics may vary between wards/hospitals, and influencing PU prevalence. We have therefore added patient characteristics to structure, process, and outcome in Figure 1. Some of the patient characteristics are included in the chosen risk assessment scale, namely the Braden scale. Additional patient characteristics are age, gender, height, and weight. Other studies investigating quality of care in hospitals and nursing homes have added to the model accordingly.[48-50] We chose the concepts of structure, process, and outcome as a guide for our framework because it is a basic model that can be used to measure aspects of different levels of healthcare organization (hospital, ward, and patient levels). We investigated the influence of structure and process on PU outcome.

The variables measured in this thesis (PU/HAPU prevalence, patient characteristics, risk assessment, PU preventive measures, nurses’ skills in assessment and PU classification, patient safety culture, staffing) were selected based on empirical results from earlier research. An overview of main study variables is presented in Figure I classified by structure, process, and outcome. Healthcare is complex, and the chosen variables only present a part of its complexity. In the following sections, each variable will be presented.

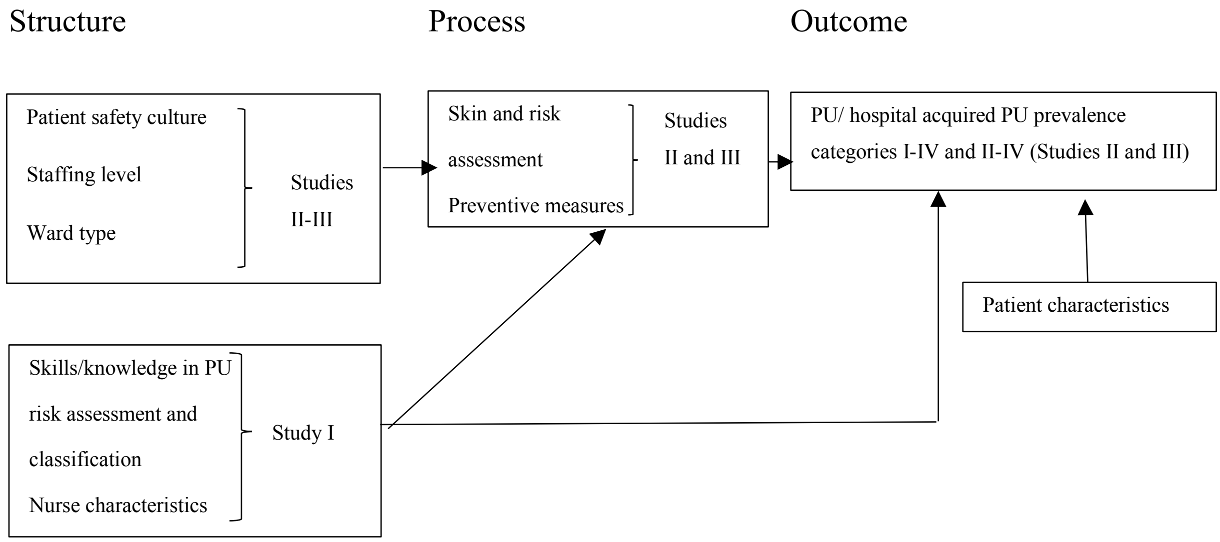


Figure 1. Overview of the main study variables classified by structure, process, or outcome and by study.[39]

2.3 Outcome: pressure ulcer (PU)

The main outcome measure of this thesis is PU prevalence. The outcome is influenced by factors related to the patient, the care the patient has received, and the organization in which the care is given.

2.3.1 Definition of PU and PU classification

In 2009, the National Pressure Ulcer Advisory Panel (NPUAP) and the European Pressure Ulcer Advisory Panel (EPUAP) developed a common definition of PUs, a system for classifying them (Table 1), and an evidence-based guideline.[51] The guideline was updated in 2014, in cooperation with the Pan Pacific Pressure Injury Alliance (PPPIA).[12]

> A PU is localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear. A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated (see p. 38[12]).

As the definition indicates, pressure is the key determinant for the development of a PU. Cell damage can occur within minutes when high strain leads to deformation of tissue and deep tissue injury occurs.[52] The time at which a PU becomes visible to the naked eye varies. The occlusion of blood flow leads to ischemic damage and can take hours.[52] A PU may not be visible until several days after the exposure to pressure.[53 54] In addition, PUs may begin in the epidermis and progressively affect deeper tissue layers. But PUs may also develop at the bony prominences and progress to the skin.[55] However, individual tissue tolerance to pressure varies. Therefore, no specified critical values can be determined for pressure and exposure time needed to produce PUs.[53 56]

Other factors that may contribute to PU development are shear, friction, and microclimate.[12] Shear refers to a force "acting parallel to the skin at the interface with a support surface" (see p. 1[57]) and occurs when a patient slides down in a bed or chair. Friction is "the contact force parallel to the skin surface in case of slip (in technical literature this is called dynamic friction)" (see p. 19[12]). Microclimate refers to the humidity and temperature between skin and support surfaces.[12] High humidity and temperature increase the vulnerability of the skin, but dry skin is also fragile.[12] Confirmatory research is needed to clarify the significance of humidity and temperature for PU development.[12 19]

PUs are classified into four categories. Table 1 shows the definition of each category according to the NPUAP/EPUAP/PPPIA classification system.[12] Unstageable and suspected deep tissue injury were considered category IV PUs in the 2009 evidence-based PU guideline.[51]

Table 1. PU classification as defined by the NPUAP/EPUAP/PPPIA guideline.[12]

Category	Definition
Category I	*Nonblanchable erythema*. Intact skin with nonblanchable redness of a localized area usually over a bony prominence.
Category II	*Partial thickness skin loss*. Partial thickness loss of dermis presenting as a shallow ulcer with a red pink wound bed, without slough. May also be present as an intact or open/ruptured serum-filled blister.
Category III	*Full thickness skin loss*. Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.
Category IV	*Full thickness tissue loss*. Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often including undermining and tunnelling.
	Unstageable: Depth unknown. Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.
	Suspected deep tissue injury: Depth unknown. Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

Illustrations of the different PU categories are shown below. Illustrations downloaded from the NPUAP's website and used in this thesis with permission from the NPUAP.

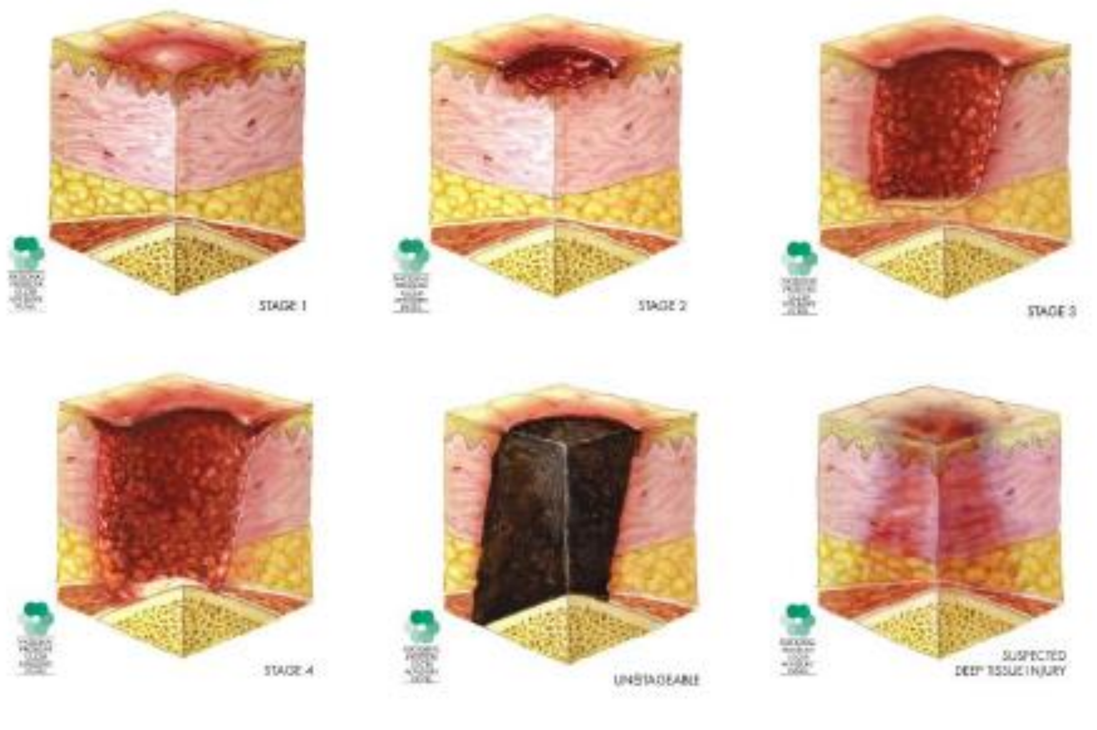


Figure 2. The four PU categories, including "unstageable" and "suspected deep tissue injury".

Illustrations of the skin damage in the lowest category, category I, and highest, category IV, PUs are shown below purchased from the NPUAP website for professional use.

Figure 3. Category I PU.

Figure 4. Category IV PU.

2.3.2 Prevalence and incidence of PUs

Epidemiology is the study of the distribution and determinants of health-related conditions or events in a population and the use of study results to control disease or conditions.[58] Epidemiological studies are often classified as either descriptive or analytic.[58] Descriptive epidemiology examines how percentages and rates vary according to demographic variables, while analytical epidemiology allows the assessment of hypotheses of associations of suspected risk factors exposures with the outcome of interest.[58] Epidemiology of PU measures includes prevalence or incidence. Prevalence measures the frequency of an existing outcome at a given time.[58] Incidence measures the frequency of new events.[58] Prevalence is a snapshot while incidence measures the risk of acquiring the disease or condition. PU prevalence and incidence studies usually include the distribution of PU by categories (I-IV) and most common locations of PUs. PUs may be registered in a number of ways in care settings, as shown below.[12]

<u>PU prevalence measures</u>

- PU point prevalence: the number of patients with at least one PU at a specific time (usually a specific day); usually, both PUs present at admission and PUs developed during hospitalization are counted.
- PU period prevalence: the number of patients with at least one PU during a specific time period rather than at a specific point of time.

In this thesis, we used PU point prevalence as the outcome measure in Study II. Study II took a descriptive epidemiological approach including all PUs present at 7 a.m. on one particular day.

PU incidence measures

- PU incidence: the number of PU free patients at admission who develop a PU during a specific period of time.
- Hospital acquired pressure ulcer (HAPU): number of patients with at least one PU at a specific time that was acquired at the hospital after admission.

PUs developed and documented after admission, HAPUs, are used as an indirect measure of incidence. HAPUs developed during hospitalization but measured at one specific time. HAPU prevalence provides a more accurate indication of the effect of the prevention program provided than does PU prevalence, and HAPUs are therefore used as the dependent variable for the analytical approach controlled with other variables in Study III.[12] HAPUs are less cost- and resource-demanding to measure as an indicator of hospital and ward quality than PU incidence.

Table 2 shows an overview of recent larger PU prevalence studies in Europe. The PU prevalence was as high as 23%. The PU prevalence is lower in some countries than others primarily due to differences in context.[4 6 59]

PU incidence rates in acute care facilities are summarized in the updated NPUAP/EPUAP/PPPIA guideline, which shows incidence ranging from 0% to 12%. The incidence of PUs ranged from 3.3% to 53.4% in critical care facilities and from 1.9% to 59% in aged care.[12] The prevalence and incidence figures indicate that PUs still occur regularly in hospital settings.

In the United States, the government has decided not to reimburse treatment of category III and IV HAPUs.[60] This may have an impact on the incentive to prevent these categories of PUs and achieve zero HAPUs in hospitals by ensuring that early skin and risk assessment are performed.[61-63]

In Norway, only a few PU prevalence studies have been conducted.[8 27 64-66] A 1997 multicenter study, including four hospitals and three long-term care and rehabilitation institutions, found a PU prevalence between 7% in one hospital and 14% in long-term care and rehabilitation.[27] More recently, a pilot study testing the Norwegian EPUAP minimum data set[8] showed a prevalence of 17.6% for categories I-IV in a sample of surgical and medical wards at one hospital. No larger updated studies on PU prevalence have been conducted and no incidence studies have been performed in Norway prior to this thesis. The prevalence and incidence of PUs may provide an indication of the magnitude of the PU/HAPU problem, the proportion of patients affected and of the quality of nursing care in a Norwegian sample.

2.3.3 Patient risk factors and consequences PUs have for patients

Patient risk factors for the development of PUs are well known, but no single factor can explain PU risk.[19] A recent systematic review identified the following three main risk factors: reduced mobility/activity, perfusion-related variables (e.g., diabetes, vascular disease), and skin/PU status (e.g., redness, category I).[19] Other important patient risk factors are age, skin moisture (including urinary/faecal incontinence), hematological conditions (e.g., low albumin, hemoglobin/anemia), poor nutrition, and poor general health status.[19] Even though patient PU risk factors are well known, few PU studies have been conducted in a Norwegian sample as shown in 2.3.2, and additional research is needed to describe the distribution of risk factors in the Norwegian hospital population. Nurses have to be aware of PU patient risk factors and use the information from risk assessments in their care planning. Some of the patient risk factors measured in this thesis are included in the chosen risk assessment scale (see 3.1.4). Other patient risk factors for which we collected data include age, gender, and body mass index (BMI).

PUs are common AEs in hospitals, especially in older patients, patients with reduced general health, patients with multiple diseases, and patients whose mobility is severely restricted.[12 19] PUs are painful;[67 68] they have been shown to reduce patients' quality of life in many ways. Patients with PUs have communicated that they feel that they are a burden to society, have become more dependent on others, feel more anxious, and have become more isolated due to pain, wound odour, and limited activity.[9] Furthermore, PUs often delays rehabilitation and may cause infection, sepsis, and early death.[9 69-73] Finally, PUs are costly, both for patients and for society.[9 11 70] Across care settings, the cost of PU prevention ranged from 2.7 to 87.6 euros per patient per day compared to 1.7 to 470.5 euros for treatment.[11] We do not know the cost of PUs in Norway.

Table 2. Overview of national prevalence studies of PU in European hospitals, 2007-2014.

Author	C*	Sample Hospitals (H), Wards (W), Patients (P)	Prevalence (%)		Risk Scale and cut-point (CP) for at-risk patients	At-risk patients and preventive measures. Mattress (M), Heel protection (H), Planned repositioning (R)			Comments
			I-V	II-IV		M (%)	H (%)	R (%)	
Vanderwee et al., 2007[4]	BE, IT, PT, UK, SE	H: 25, P: 5947	18.1	10.5	Braden scale CP: <17	71.6	-	38.2	Across country PU I-IV variation: 8.3-23%. Patient at risk: 9.7% had fully adequate prevention**
Tannen et al., 2008[6]	NL	H: 60 P: 10237	18.1	-	Braden scale CP: <21 CP: <19 CP: <17	 87.3 89.4 90.7	 - - -	 14.7 20.4 26.2	Odds of having PU in Dutch hospitals were 1.9 higher than in German hospitals.
	DE	H: 39 P: 8515	9	-	Braden scale CP: <21 CP: <19 CP: <17	 29.7 37.8 45.9	 - - -	 29.4 41.9 56.1	
Vanderwee et al., 2011[5]	BE	H: 84, P: 19968	12.1	7	Braden scale CP: < 17	-	-	-	Patient at risk: 25.5% fully adequate prevention**
Halfens et al., 2013[59]	NL	H: 36 W: 924 P: 6486	-	Range*** 3.3-4%	Braden scale CP: <21	94.6	34.7	27.9	Preventive measures numbers from 2011/2012
	AT	H: 33 W: 226 P: 3648	-	Range*** 0.5-1.2%		53.4	38.5	27.4	
	CH	H: 140 W: 884 P: 10098	-	2		51.7	34.1	26.9	
Baath et al., 2014[7]	SE	SI: P: 16466 SII: P: 8265 SIII: P:14540	16.4 14.4 16.1	- - -	Modified Norton scale CP: <21	75.8 81.4 79.3	31.8 30.4 30.6	47 49.7 47.5	

*Countries, BE= Belgium, IT= Italy, PT= Portugal, UK= United Kingdom, SE= Sweden, NL= The Netherlands, DE= Germany, AT= Austria, CH= Switzerland, ** Fully adequate prevention in bed: mattress + planned repositioning + offloaded heels. *** Range between 2009-2012.

2.4 Process of care variables that could prevent PU development

Prevention of PUs requires the assessment of individual patients' risk and the implementation of relevant preventive measures. In this thesis, process variables include skin and risk assessment and implemented preventive measures. The implementation of PU preventive measures is essential: adequately applied preventive measures will reduce patients' risk of developing PUs while failure to implement such measures may lead to patients' developing PUs.

2.4.1 Risk assessment

A structured assessment of a patient's risk of developing a PU is recommended [12] as an important element of the process of care. Risk assessment (including skin inspection) helps nurses identify which patients should receive PU preventive care. Systematic risk assessment and the implementation of recommended interventions based on the risk assessment for at risk patients have been shown to reduce the number of HAPUs significantly.[62] Several risk assessment scales have been developed to support nurses in this process. Some of the most common PU risk assessment scales are the Braden Scale® for Predicting Pressure Sore Risk (the Braden scale), the modified Norton scale and the Waterlow scale.[74] These risk assessment scales include different risk factors to identify patients at high risk of developing PUs.[12]

A recent meta-analysis of risk assessment scales and clinical judgment found that the Braden scale is one of the most used and tested scales in a research context. Thirty-three of 73 studies in the meta-analysis evaluated the Braden scale.[74] The Braden scale showed the highest predictive capacity of the risk assessment scales tested in this meta-analysis with a relative risk of 4.26; 95% confidence interval (CI): 3.27-5.55.[74] The Braden scale was included in the EPUAP minimum data set used in this thesis. The Braden scale and the EPUAP minimum data set are described in more detail in 3.1.4 and 3.2.3. Nursing care planning and implementation of preventive measures are based on skin assessment, risk assessment with a validated instrument, and clinical judgment regarding other patient risk factors. For instance, the Braden risk assessment scale does not include risk factors like age and comorbidity.

The use of structured PU risk assessment scales is not common in Norway.[75] In Norway, PU risk assessment is usually based on nurses' clinical judgment.[75] The Norwegian pilot study of the EPUAP minimum data set found low agreement between nurses in PU classification and Braden total score and recommended the development of educational tools to train nurses in risk assessment and PU classification.[8] The lack of use of structured risk assessment scales and educational tools in Norway were important factors for developing and testing the training program mentioned in 2.5.1 and 3.1.3.

2.4.2 PU preventive measures

The evidence-based PU guideline recommends the implementation of PU preventive measures.[12] Patients at risk of PUs and those who already have PUs should receive preventive measures. One of the most important preventive measures is the use of a pressure-redistributing mattress to relieve pressure. There are many different types of mattresses available. The effect of any specific mattress is largely unknown; however, reviews have found that higher specification foam mattresses are better than standard hospital mattresses for patients at risk of PUs.[76 77] Pressure-redistributing cushions are recommended for at-risk patients while seated.[12]

Repositioning is important for preventing PUs; however, the evidence for sound recommendations regarding the frequency of repositioning is still not clear.[12 78] A repositioning schedule often starts with a two-hour interval, but individual risk factors, skin condition, and the availability of support surfaces must guide the schedule. The patient's health condition, including their respiration and circulation, may pose challenges when trying to determine the frequency of repositioning. However, given the right strategy, even unstable ICU patients can be turned.[79] Turning an unstable patient requires adequate staff. Staff should turn the patient slowly 10-15 degree, pausing for 15 seconds at a time, until reaching full lateral position for skin care. Afterwards, the patient should be returned to a 30-degree position, supported using wedges and pillows, and monitored for 10 minutes following the turn.[79] When the patient is lying in bed, a side-lying 30-degree position is recommended as a variation of the supine position. This distributes pressure over a greater area resulting in lower interface pressure than a side-lying 90-degree position.[12 80]

The most important principle of PU prevention is to offload pressure completely or redistribute skin pressure. Even when patients lie on pressure-redistributing mattresses, repositioning and offloading of heels are mandatory for optimal protection.[12 81] Other important preventive measures include skin care with regular skin assessment, incontinence care, and nutrition.[12 82 83] Most of these preventive measures are also important in PU treatment; therefore, in the updated guideline, the prevention and treatment tasks have been merged.[12 51] Nurses and assistant nurses' awareness of and attitudes regarding when such measures should be implemented, and for which patients, is critical to effective prevention.

The use of preventive measures varies across countries as shown in Table 2. Studies show that at-risk patients often do not receive preventive measures such as pressure-redistributing mattresses, planned repositioning, and heel protection. However, in one Belgian study high numbers of patients not at risk (9709/14055 or 69.1%) were found to have some preventive measures both in bed and in chairs.[5] Even though it is not harmful for patients to receive preventive measures they do not need, it is not cost effective to provide such measures. Therefore, investigating the use of preventive measures is an important part of this thesis. Lack of implementation of preventive measures may reflect the failure of nurses to assess patients and identify those at risk for PUs.

2.5 Structure variables that could influence PU prevalence

The concept of structure variables refers to the environment in which care is provided. There has been increasing interest in the contribution of organizational factors to the PU prevalence problem. The knowledge and skills needed to recognize PUs, patient risk factors, and measures that should be implemented to prevent PUs are crucial to decreasing the number of PUs in healthcare. The hospital environment and the availability of adequate resources to provide safe patient care are important factors in PU prevention. Literature reviews have reported inconsistent results regarding the relationship between structural variables such as staffing and safety culture and PUs.[20-23] Most research on the effects of organizational factors has been conducted in countries with different healthcare cultures and management structures than those found in Norway. Thus, Norwegian studies are required.

2.5.1 Nurses' knowledge and skills in PU risk factors and classification

The human resources under the structure concept include the qualifications of personnel.[39] Nursing staff's knowledge of PU risk factors and their skills in skin and risk assessment are important for PU prevention, as is the use of appropriate preventive measures. Conversely, inadequate knowledge and skills among health personnel may be detrimental to patient safety. Learning is a core element of patient safety and is important for improving nurses' performance in identifying potential PU risk factors and preventing PUs.[84] The

NPUAP/EPUAP/PPPIA guideline recommends interactive education and training in evidence-based prevention, risk assessment, and PU classification.[12]

An overview of studies testing training with the Braden scale for written cases and studies testing training in PU classification is shown in Tables 3 and 4. The literature shows that training in PU risk assessment and classification successfully increases skills.

None of the studies of the Braden scale shown in Table 3 had a control group, nor an RCT design, nor did they investigate the long-term effect of the training. In addition to the studies in Table 3, two studies have compared expert nurses' and registered nurses' Braden scoring on patients in pre-test and post-test. Those not familiar with the scale improved their scores in post-test significantly more than regular users.[85 86] Only one of the studies in Table 4 has examined the long-term effect of the training. This study showed an increase in exact classification immediately after training, but exact classification decreased again after one and two months.[87] Few of the studies in Tables 3 and 4 used the RCT design to test the effect of intervention, and more research is required. In a pilot study of the Norwegian EPUAP minimum data set, low agreement between participating nurses was discovered for both PU risk assessment and PU classification.[8] This highlights the need for developing educational tools for training in the use of a risk assessment scale and classification of PU to ensure high data quality from data collectors in future Norwegian studies and also to ensure high quality, skilful patient care.[8] The implementation of learning programs was an essential part prior to our planned PU data collection in Norway.

Knowledge and skills can be acquired by different methods. The most common methods for expanding nurses and nursing students' knowledge and skills are the traditional classroom instruction method and newer web-based instruction methods.[88-90] Electronic learning programs (e-learning) are becoming more popular due to efficiency requirements, flexibility, cost, and the time available for learning.[87 91] A PU classification e-learning program developed by EPUAP, called PUCLAS2 (Pressure Ulcer Classification 2), was available prior to this thesis.[92] However, we did not considered using a translation of this program because the English version was in the process of being updated. Instead, we decided to develop and examine the effects of our own Norwegian PU classification training program, as well as a program to teach the use of the Braden scale prior to the data collection for this thesis.

Table 3. Overview of primary studies testing the use of the Braden scale with patient cases.

Author	Design	Sample	Program description	Test	Key findings	Comments
Maklebust et al., 2005[93]	Cross-sectional	> 2500 nurses One hospital	**Braden scale** Computer-based learning module	5 patient cases (different risk levels): subscale and total score. Additional 10-14 questions about appropriate PU preventive measures	Correctly rated levels of risk of the cases:75.6%. Subscale: lowest correctly rated: moisture and sensory perception Highest correctly rated: friction/shear	The nurses were familiar with the Braden scale No long-term follow up No control group
Magnan & Maklebust, 2008[94]	Post-test-only design	Nurses (N=1391) at 3 medical centers 2 of 3 centers familiar with Braden scale, newly introduced in the third center	**Braden scale** Computer-based learning module	5 patient cases (different risk levels): subscale and total score Additional 4-5 questions related to PU prevention in each case Two program evaluation questions	Average correctly rated level: 82.6% Subscale: Lowest correctly rated: nutrition Highest correctly rated: activity and mobility New users scored lower than regular users	Post-test design only No long-term follow up No control group

Table 4. Overview of primary studies to improve skills in PU classification.

Author	Design	Sample	Program description	Test	Key findings	Comments
Beeckman et al., 2008[87]	Repeated measure One pre-test and three post-tests (immediately after, 1 mo, 2 mo)	Convenience N=426 nurses + final-year nursing students Random assignment: intervention (n=217) or control (n=209)	PU classification *Intervention (I):* 1h e-learning program, PUCLAS 2 (PU classification, differentiation between PU and moisture lesions, classification training) *Control group (C):* 1h lecture Both programs contained the same content.	Pre-test 20 photos rated Post-tests 20 pre-test photos+ 20 new photos rated	*Total group:* <u>Pre-test:</u> PA*: 35% Ck*: 0.24 in both groups <u>Post-test I:</u> PA*: *I*: 70% vs *C*: 67.5% Ck*: *I*: 0.65 vs *C*: 0.63 <u>Post-test II/III:</u> showed decrease in both analyses	Lost to follow up: 43.2% by last measuring point
Beeckman et al., 2010[92]	RCT pre /post-test the same day	Convenience N=1217 nurses attending a wound care conference	PU classification *Intervention group (I)*: PUCLAS education as 1h classroom lecture with PowerPoint *Control group (C):* 15 min classroom lecture presentation of PU grades	Pre-test 20 photos rated Post-tests 20 pre-test photos+ 20 new photos rated	<u>Pre-test:</u> PA*: 44.5% <u>Post-test:</u> 20 pre-test photos: PA*: *I*: 62.8% vs *C*: 53.0%, $p<0.0001$ 20 new photos: PA*: *I*: 63.7% vs *C*: 53.2%, $p<0.0001$	No long-term effect Potentially biased sample, wound care nurses more knowledgeable per PU classification
Ham et al., 2015[95]	One group, pre/post-test the same day	54 emergency nurses and physicians	PU classification PowerPoint lecture 20 min based on the PUCLAS 2	20 photos two sets (10 + 10)	<u>Pre-test:</u> PA*: 68.5% Mk*: 0.43 <u>Post-test:</u> 10 pre-test photos: PA*: 84.1% Mk*:0.67 All 20 photos: PA*: 79.8%. Mk*: 0.58	No control group Handouts allowed during post-test

*PA= percent agreement, Ck= Cohen’s kappa, Mk= Multirater Kappa

2.5.2 Patient safety culture in relation to PUs

Culture is a context-specific local phenomenon.[96] Patient safety culture is considered a structure variable in this thesis since it is a feature of the wards work environment.

As mentioned earlier, increased knowledge alone is not sufficient to reduce PUs. Organizational and cultural factors are important to understanding how quality and safety enhancements occur.[97] More attention has been directed towards understanding how AEs in healthcare organizations are affected, not only by neglect and mistakes on the part of individual carers, but also by cultural and organizational factors.[98-100] The most commonly used definition of safety culture in healthcare was developed by the British Health and Safety Commission,[96 101] which defines safety culture as

> The product of individual and group values, attitudes, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety programmes. Organisations with a positive safety culture are characterised by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measure.[101]

In healthcare, safety culture is directed towards health personnel and/or patients. The World Health Organization (WHO) defines patient safety as the *"absence of preventable harm to a patient during the process of healthcare."*[102] This sentence shows the possible linkage between the outcome measure in this thesis, PUs, and safety culture. PUs are preventable in most cases and should not develop in environments that privilege patient safety.

The terms culture and climate are often used interchangeably; however, safety climate is an operationalization of safety culture and used as the measurable component of safety culture.[96 103 104] The term safety culture is used in this thesis unless safety climate is used as term in refereed studies. A review of the dimensions of safety culture found the most frequently used dimensions to be leadership, open communication, organizational learning, a non-punitive approach to adverse event reporting and analysis, teamwork and shared belief in the importance of safety.[96] Safety culture dimensions included in this thesis are teamwork, safety climate and leadership. Important leadership duties include ensuring staff are knowledgeable and that there are enough staff and resources available to provide safe care and achieve optimal patient outcomes. Nursing leaders have an ethical responsibility and play a strategic role in patient safety.[105] Reviews show that hospital and nursing leadership may influence the quality and safety of clinical outcomes, processes and accomplishments.[106 107]

Several instruments have been developed to measure patient safety culture and climate.[24 108 109] Some of the best-known and most used instruments are the Safety Attitude Questionnaire (SAQ) and the Hospital Survey on Patient Safety Culture (HSOPSC).[23 96 103 110-113] The SAQ is shorter than the HSOPSC and examines the relationship to outcomes.[114]

Studies of patient safety culture have found that a lower patient safety culture score is associated with a higher risk of sustaining an AE.[115-118] To our knowledge, as of 2012 when this thesis was planned, only four studies had investigated the association between PU and patient safety culture in hospitals.[115 117 119 120] Two of the studies found an association,[115 117] while the others did not. Three additional studies have since been published; however, results are still inconsistent. Table 5 provides an overview of the studies conducted in the hospital setting.

The different findings in the studies investigating the relationship between patient safety culture and PUs may be explained by differences in measurement methods, settings, analysis methods, control variables, and ways of collecting PU data. Few studies have taken a multilevel analysis approach to the data. Several studies were based on personnel-reported patient outcome measures, which can either under- or over-estimate the number of events. Some studies excluded category I PUs. Category I PUs may be more sensitive to organizational factors intervening with preventive measures such as repositioning and providing pressure-redistributing mattress can reverse the progression to a category II PU. The different findings indicate that more research is required to determine whether or not there is a significant association between patient safety culture and PUs since PUs are an important patient safety indicator. Few studies have investigated patient safety culture in Norway[121-123] and no Norwegian study has specifically investigated the association between patient safety culture and patient outcomes.

In addition to the primary studies shown in Table 5, two systematic reviews have been conducted investigating the relationship between safety culture and patient outcomes. Groves[22] did pilot meta-analyses of four articles and six dissertations on the relationship between different patient outcomes and safety culture. Seven of the included reports used aggregated data at ward level, while the remaining three used aggregation at hospital level. Six different safety culture instruments were used in these 10 reports. The author conducted one meta-analysis on PUs, including four dissertation research studies. The heterogenity of the studies was high and the meta-analysis lacked true effect.[22] Another systematic review included 17 studies (10 articles and 7 dissertations);[23] three of the studies used HAPU as one outcome, with two showing no significant relationship between PU and safety culture. One of the dissertations showed a significant relationship; it was later published as an article, which is included in Table 5.[115]

Table 5. Overview of studies investigating association between patient safety culture* (PSC) and PUs in hospitals.

Author	**Design**	**Sample Hospitals (H) Wards (W) Patients (P)**	**Patient safety culture/ climate instrument**	**PU outcome measurement**	**Covariates**	**MLA Yes/ No**	**Assoc. PSC and PU, adjusted**	**Comments**
Stone et al., 2007[120]	Observational study	H: 31 W: 51 P total: 15 847 1059 nurses PU data P: 9554, 191 with PUs	PNWE (composite score for organizational climate, ward average score)	Discharge code for acquired PUs	Patient characteristics, hospital size, teaching status, ICU type and case-mix	No	Organizational climate not significant: OR 1.06; 95% CI 0.83-1.37	ICUs only Only patients > 65 years included Hospital level data
Singer et al., 2009[117]	Cross-sectional	H: 91	PSCHO	MPAR	Organizational characteristic	No	PU incident rate ratio and safety climate overall: 1.064 (SE 0.024), $P < 0.01$	Hospital level data
Bosch et al., 2011[119]	Cross-sectional study	W: 37 P: 235	TCI-SF	PU point prevalence (category II or worse)	Case-mix: age, type of ward, and malnutrition Sum score of 8 indicators for PQM at ward level Sum score of 11 indicators for PQM at institutional level. CVF (4 types of culture)	Yes	Non-significant Team climate: OR 1.0; 95% CI 0.50 - 2.02	Braden scale cut-off ≤ 18. Category I PUs excluded Hospital level data. Multilevel analysis not with ward level
Taylor et al., 2012[115]	Cross-sectional study	H: 1 W: 29 P: 28876 723 nurses	SAQ 5 dimensions	Discharge code 105 PUs included in analysis	Unit turnover Registered nursing hours per patient day Patient and nurse injuries	Yes	"Teamwork": OR 0.56; 95% CI 0.38-0.82 and "Safety climate": OR 0.52; 95% CI 0.29-0.92	Single hospital study. No PU risk scale adjustment No PSC composite score SAQ subscale analysis only

Brown & Wolosin, 2013[124]	Cross-sectional study	H: 9	HSOPSC: 12 dimensions GSC rating: composite of 4 questions	PU prevalence data (CALNOC) HAPU stage 2+)	Process of care variables (i.e. risk assessment and prevention) Structural indicators (staffing measured with six items)	No	Non-significant	HAPU category II-IV and GSC (r = -.349, $p < .05$) Category I PUs excluded Separate regression models for structure variables and process of care variables were non-significant Hospital as level in the analysis
Ausserhofer et al., 2013[125]	Cross-sectional study	H: 35 W: 132 P: 997 1630 nurses	SOS composite score 9 items.	PU category II or worse nurse reported. 5% (occurred few times or more frequent a month)	Nurse staffing level, skill mix patient satisfaction nurse characteristics, patient self-reported health status and educational level, hospital type, unit type and language region	Yes	No significant association SOS: OR 1.491; 95% CI 0.705-3.154	No PU risk scale adjustment. Category I PUs excluded
Wang et al., 2014[118]	Descriptive correlated study	H: 7 W: 28 463 nurses	HSOPSC 12 dimensions	7 AEs included PUs	Nurse characteristics	No	4 of 12 dimensions significant: Organizational learning-continuous improvement (OR: 0.249) Feedback and communication about error (OR: 0.413) Non-punitive response to error (OR: 0.045) Frequency of event reporting (OR: 0.006)	Not controlled for unit or hospital related factors Nurse-reported outcome measures

*Patient safety culture in this table includes both culture and climate.

MLA = Multilevel, PNWE = Perceptions of Nurse Work Environment scale, PSCHO =The Patient Safety Climate in Healthcare Organizations, MPAR=The Medicare Provider Analysis and Review, TCI-SF = Team climate Inventory short version, CVF = Competing Values Framework, PQM = preventive quality management, SAQ = Safety Attitude Questionnaire, HSOPSC = Hospital Scores of Patient Safety Culture, GSC = Global safety climate, CALNOC = Collaborative Alliance for Nursing Outcomes, SOS = Safety Organizing Scale.

2.5.3 Staffing level in relation to PUs

Staffing refers to the number of nursing staff (registered nurses) present in the wards during a day shift. Staffing is a structure variable in this thesis as it is a part of the human resource dimension in the structure concept.[39] Staffing level may have consequences for patient safety and for PU development. A 2006 review investigated whether PUs and falls could be linked to nurse staffing. This review found seven studies with mixed results.[20] Most of the studies included administrative PU data and only one of the studies reported prevalence data from patient observation. Administrative data may be influenced by diagnosis codes and is often underestimated. Only three of the studies used multilevel models accounting for the clustering of data. The review recommended that future studies use prevalence data and include category I PUs. Another recommendation was to use a PU risk assessment scale to adjust for patient risk rather than other complexity scores.[20] A recent review with 12 studies investigating PUs found mixed results for the relationship between nurse staffing and PUs, but most of the included studies found lower levels of PUs where there were more nurses.[21]

Studies have found a relationship between staffing, patient safety, and omitted or delayed nursing care.[126 127] Better staffing seems to be a key factor for patient safety and for reducing the PU rate. Staffing is an important factor to investigate in a Norwegian setting, as Norway has fewer patients per nurse than many other countries.[30]

In summary, several research studies have investigated organizational and patient-related variables that may be related to PU development. However, inconclusive findings show that more research is needed, especially to establish which organizational factors contribute to PU development. Hardly any PU or patient safety studies have been conducted in a Norwegian setting and such studies are needed to tailor future improvement strategies to the Norwegian context.

3. Data and methods

The overall aim of this research is to develop knowledge regarding the epidemiology of PUs in Norwegian hospitals in order to evaluate, and ultimately to improve nursing care quality and patient safety. Thus, we used quantitative research methods to address the three aims in three linked studies. This chapter presents the methods used to answer each research aim.

Nurses' knowledge and skill in assessing patients' PU risk and skin status during episodes of hospitalization are important structural factors of care quality. In Study I, we developed a training program focused on PU risk assessment and PU classification, which is an element of the process of care. Study I used an experimental pre-test/post-test design to compare the effect of e-learning on skill improvement with that of classroom instruction. The training program from Study I was used to train the nurses on the data collection teams in Studies II and III. Study I was a pilot study to test the method and the learning effect of the intervention. This gave the researchers the opportunity to test feasibility and to improve the intervention.

To evaluate and ultimately improve care quality it is important to know the rate of PU occurrence in the patient population in Norwegian hospitals, the risk factors for developing PUs, and what preventive care is provided. A descriptive epidemiological design was used to address the aim of Study II: to investigate the prevalence of PUs, patient-related risk factors, and the use of preventive measures (outcome and process). Recent studies indicate that organizational characteristics may be important risk factors for PUs and may vary across hospital and ward levels. Thus, Study II included preliminary analysis of how much of the observed PU variance was at patient, ward and hospital level, and clarified the need for multilevel analysis in further investigations.

The aim of Study III was to investigate the association between selected patient-related and organization-related risk factors and the study outcome HAPUs. Thus, an analytic epidemiological approach was used. Study III investigates the relationship between structure, process, patient characteristics and outcome using multilevel models.

Table 6. Overview of aims, design, sample, data collection and data analysis methods in studies I-III.

Study	Aims	Design	Sample	Data collection	Data analysis methods
I	To develop and test an e-learning program for assessment of PU risk and PU classification	Randomized controlled study	Registered nurses (N=44)	Report form	Percentages/Percent exact agreement Fleiss' kappa Chi-square/Fisher's exact test Mann-Whitney *U* test
II	To investigate PU prevalence, patient-related risk factors, the use of preventive measures and how much of the HAPU variance is at patient, ward and hospital level	Cross-sectional study	Patients (N=1209) Wards (N=88) Hospitals (N=6)	Patient records Physical examination	Percentages Chi-square Mann-Whitney *U* test Intraclass correlation coefficient (ICC) Multilevel logistic regression
III	To investigate the association of ward-level differences in the odds of hospital-acquired PUs (HAPUs) with selected ward organizational variables and patient risk factors	Cross-sectional study	Patients (N=1056) Wards (N=84) Hospitals (N=4)	Patient records Physical examination Web-based survey for health personnel	Percentages Chi-square Cronbach's α Correlation Intraclass correlation coefficient (ICC) Multilevel logistic regression

3.1 Study I *Effect of e-learning program on risk assessment and pressure ulcer classification – a randomized study*

3.1.1 Setting

Study I was conducted at two hospitals and one nursing home with computer laboratory and a classroom or auditorium available.

3.1.2 Sample

For Study I, nurses were recruited from somatic hospital wards or nursing homes. An invitation to participate in this study was sent to the nursing homes and hospital administration. Nurses were randomized to three different groups of 25 nurses each; the group size was based on pilot study recommendations of 10 to 50 participants in each group.[128 129] The intervention group received the e-learning intervention while one control group received traditional classroom lectures and another control group received only a copy of the Braden scale and an illustration of the PU categories. To achieve random distribution of unknown potential confounding factors, we selected a block randomization of six nurses per block. A research coordinator conducted the randomization using a web site randomization program (www.randomization.com) and packed the numbered opaque envelopes containing group allocation. Seven nurses were excluded, six did not show up on testing day and one had not completed the pre-test forms. Sixty-eight nurses participated in the training effect study. Two of the participants were men, the rest women. No significant differences were found between the three groups' background characteristics. Due to the high dropout rate in the three-month follow up (post-test II), we excluded the group with no additional training in the paper. The final sample included 44 nurses assigned to the e-learning (n=23) or classroom (n=21) groups.

3.1.3 E-learning program intervention

As far as we know, prior to this study no Norwegian educational tool existed for teaching nurses the Braden risk assessment scale and PU classification. Thus, we developed an e-learning intervention as a method for teaching nurses risk assessment and PU classification. The training program included two modules, one for the Braden risk assessment and one for PU classification.

To develop the intervention content, a pre-test of 13 patient cases was administrated in two groups of nurses to test the clearness of the cases (content validity). The cases with the highest percent exact agreement were selected to be included in the tests. The patient cases were drawn from an instructional CD (www.bradenscale.com), a web site (http://ced.muhealth.org/resources/bradenCD/), other studies,[93] and our own experience. The gold standard for Braden scores for the written cases was the case author's assessment. The Braden scale module included a general definition of PUs, a presentation of the six Braden scale subscales (Table 7), the scoring system, and the different risk levels.

The classification module was based on the definition and classification categories from the 2009 EPUAP/NPUAP PU guideline (Table 1).[51] In the 2009 NPUAP/EPUAP guideline,[51] the unstageable and deep tissue injury PUs are included in category IV. We used both schematic illustrations and photos for each PU category. We purchased PU photos from the NPUAP web site (http://www.npuap.org/) and we used their classification of the photos as the gold standard. We included one slide, illustrating the differences between incontinence-associated dermatitis and PUs and one slide illustrating how to classify redness of skin.

At the end of each module, the participants were able to test themselves using the information from the programs to score a case according to the Braden scale, as well as to correctly classify four photos of PUs. Participants were given a clue if they ticked the wrong subscale or category.

The control group received traditional classroom training with a PowerPoint presentation presented by an instructor. The program included a presentation of the Braden scale and PU classification equal to the presentation in the e-learning program. This means that the two groups received content that was as similar as possible, only the mode of instruction differed.

3.1.4 Measurements

The Braden scale

The Braden scale was developed by Bergström and Braden in 1987.[130] The EPUAP selected the scale as the risk assessment scale to be used with their PU prevalence form.[4] The scale assesses six risk factors, or subscales (Table 7).

Table 7. Overview of the Braden subscales and scoring of each subscale.

Subscale	1 point	2 points	3 points	4 points
Sensory perception	Completely limited	Very limited	Slightly limited	No impairment
Moisture	Constantly moist	Very moist	Occasionally moist	Rarely moist
Activity	Bedfast	Chair fast	Walks occasionally	Walks frequently
Mobility	Completely immobile	Very limited	Slightly limited	No limitation
Nutrition	Very poor	Probably inadequate	Adequate	Excellent
Friction & shear	Problem	Potential problem	No apparent problem	

The Braden scale measures three subscales related to exposure to pressure: mobility, activity and sensorial perception. Three other subscales measure tissue tolerance. Tissue tolerance is divided into extrinsic and intrinsic factors. Extrinsic factors are humidity (moisture) and friction/shear forces. The intrinsic factor is nutrition.[131] “Sensory perception” measures patient capability to respond to discomfort from pressure. “Moisture” grades the moisture of the skin due to exposure to urine and perspiration. “Activity” measures the patient’s degree of activity. “Mobility” measures the patient’s ability to control and change bodily position. “Nutrition” measures food intake. “Friction and shear” measures the patient’s need for assistance in moving and how the patient manages to maintain his/her position in bed or in a chair. The first five subscales are scored from one (worst) to four (best), while the sixth is scored from one (worst) to three (best). This gives a total score with a range of 6-23 points, lower scores indicating higher PU risk. Total scale score is divided into different risk levels: 6-9 points indicates “Very high risk”, 10-12 “High risk”, 13-14 “Moderate risk”, 15-18 “Mild risk”, and 19-23 points indicates “No risk”. In previous European PU prevalence studies, a score of less than 17 points has been used as an indication that a patient is at risk of developing a PU and therefore in need of attentive follow-up.[4 5]

PU classification

We used the EPUAP classification system with normal skin and four categories based on the wound severity. This system is described in more detail in 2.3.1.

3.1.5 Data collection

This was a randomized pre- and post-test study, which contained a training program for both the use of the Braden scale for identifying patients at risk of PUs and for classification of PU severity. All groups performed a pre-test to provide baseline data. The pre-test included 1) Braden scale scoring of five patient cases (one in each risk level) and 2) a PU classification test consisting of 20 photos that had been classified by experts according to the classification system from NPUAP/EPUAP.[51] Since the Braden scale was not a well-known instrument in Norway, all participants were equipped with a copy of the scale and a schematic illustration of the four categories of PU. Immediately after the pre-test, the two training groups received a 45-minute training session (e-learning or classroom). The nurses then completed a second test. This first post-test contained five patient cases, two of which were different from the pre-test cases. In the first post-test, no case with low risk but two cases for very high risk were included. The classification test contained twice as many photos as the pre-test, i.e., all the pre-test photos plus 20 additional photos.

The second post-test was conducted at three months. All groups were asked to complete a new Braden scale rating of five cases (no low-risk case but two cases for very high risk level) and PU classification of a selection of 20 photos. The study protocol also included a post-test after six months; however, due to the large drop-out at the three month test we decided to not arrange the six month test.

Table 8. Number of photos in each PU category on the pre-test, post-test I, and post-test II respectively.

	Pre-test	Post-test I	Post-test II
PU category photos	Normal skin (1)	Normal skin (4)	Normal skin (1)
	Category I (5)	Category I (5)	Category I (3)
	Category II (4)	Category II (6)	Category II (4)
	Category III (6)	Category III (12)	Category III (6)
	Category IV (4)	Category IV (13)	Category IV (6)

3.1.6 Data analysis

Descriptive data were presented as frequencies for categorical variables. Chi-square or Fisher exact tests were used to assess the significance of categorical variables' group differences within each test. When the expected frequencies in each cell were five or less, the Fisher exact test was used.[132] The Mann-Whitney *U* test was used for non-normally distributed continuous variables. We measured interrater reliability in Study I with both percent exact agreement (number of correct assessment/number of possible correct assessment x 100) and multi-rater Fleiss' kappa.[133-135] Fleiss' kappa values range from -1 to 1. Kappa values over 0.6 show good agreement, whereas values below 0.2 are considered poor agreement.[136] Values below zero indicate agreement less than chance. Contrary to Cohen's kappa, which measures agreement between only two raters, Fleiss' kappa measures group agreement. The variables in Study I were also collapsed into correct/incorrect answers. Missing answers in Study I were coded as "incorrect" answers. No missing scores were replaced by reinterpretations/imputations. The level of significance was set at $p < .05$. We conducted the analysis for Study I with SPSS 21. We used the statstodo.com web-based calculator for the Fleiss' kappa in Study I (https://www.statstodo.com/CohenKappa_Pgm.php). Data collection forms for Study I were read by TeleForm (Cardiff Software, Inc), an electronic forms processing application.

3.2 Study II *The prevalence, prevention and multilevel variance of pressure ulcers in Norwegian hospitals: a cross-sectional study*

3.2.1 Setting

In Study II, nine hospital trusts and two private non-commercial hospitals belonging to the South-Eastern Regional Health Authority of Norway were invited to participate. The South-Eastern Regional Health Authority is the largest health region in Norway and provides acute healthcare services to approximately half of the country's population.[137] Six hospital trusts agreed to participate.

3.2.2 Sample

For the second study, inclusion criteria were inpatients 18 years or older in somatic wards. Exclusion criteria were pediatric ward patients, maternity ward patients, and day surgery patients. A total of 1,334 patients were eligible to participate. 125 patients were excluded because they were either too ill to be bothered by having their skin examined or declined to participate. Thus, a final sample of 1,209 patients on 88 wards was included in the analysis.

3.2.3 Measurements

The Braden scale and PU classification were used in Study I and the Braden scale is described above in 3.1.4. PU classification is presented in 2.3.1.

<u>European Pressure Ulcer Advisory Panel Minimum Data Set</u>

The EPUAP minimum data set data collection form was constructed by the EPUAP to standardize data collection in PU prevalence studies, thus allowing comparison across studies.[4] The data collection form includes five categories of data: general data, patient data, risk assessment (the Braden scale), skin assessment (most severe PU is the highest PU category found at the skin assessment), and prevention.[4] The original EPUAP minimum data set did not include offloading of the heels, but recent research has included this measure, as mattresses alone do not prevent PUs on the heels.

The data collection procedure involved two nurses trained to complete the data collection form and to classify PUs by using the EPUAP classification system (see Table 1) and taught how to assess PU risk using the Braden scale. Interrater reliability, as measured by Spearman's rho, was very high: 0.98 for the Braden scale, 0.96 for the most severe PUs and 0.97 for the location of the most severe PUs.[4] The Norwegian version of the form was tested in a pilot study in 2008.[8] The interrater reliability (Spearman rho's) in the Norwegian study was lower than in the original study: 0.54 for the Braden scale and 0.48 for the location of most severe PUs.[8] This differences highlighted the need for more training in risk assessment and classification for Norwegian nurses and motivated development of the e-learning program in Study I.

Table 9. Variables and categories included in the Norwegian version of the EPUAP data collection form.

Variables	Categories
Age*	18-39, 40-59, 60-69, 70-79, 80-89, >89
Gender	Male, female
Residence**	Own residence, nursing home
Height**	In centimetres
Weight**	In kilograms
PU documented at admission**	Yes, no
Admission to hospital**	Elective, acute
Surgical procedure within previous 14 days**	Yes, no
Length of stay (LOS)*	Number of days from admission to study day
Braden scale	Total score was used in Studies II and III. Cut-point for at-risk patients < 17 points.
PU severity[1]	No PU, or PU category I-IV
PU location	Location of most severe PU: sacrum, heel, hip, other
Number and location of PU	Body map for all existing PUs
Pressure-redistributing support surfaces in bed and chair	No pressure-redistributing device, non-powered pressure-redistributing device, powered pressure-redistributing device
Repositioning in bed/chair	No planned repositioning, every 2 hours, every 3 hours, every 4 hours
Offloaded heels in bed**	Yes, no
Hospital identification number*	Hospital number 1 to 6
Ward identification*	Each hospital's name or number code at each ward

*Variables that have been changed or **added from the original EPUAP form. [1] "Most severe " is the highest PU category found on the skin assessment.

Ward characteristics form

Nurse managers were asked to complete a form to provide information regarding their ward. This information was used in Study II, Study III, or both: hospital and ward identification code (Studies II and III), number of estimated beds of the ward (Study III), number of inpatients on the ward at 7 a.m. on the data collection day (Study II). We also asked for information about the staffing level: the number of registered nurses, practical nurses, and unskilled nursing assistants on the day-, evening-, and night shifts, respectively, for the 24-hour period immediately preceding the data collection (Study III).

3.2.4 Data collection

Each hospital designated a coordinator to organize data collection. Each participating ward assigned at least one nurse to be responsible for the data collection. These nurses received information about the protocol as well as training in the use of Braden scale and PU classification (a program slightly adjusted from Study I). The training lasted between two and three hours and included a test to score five patient cases with the Braden scale (paper-based test) and a PU classification test including 20 photos (web-based test).

Prior to the data collection, each ward received a detailed guideline for the completion of the data collection form. Teams of two nurses, preferably from different wards, assessed each participating patient and extracted data from patient records to complete the study forms (see Table 9). The hospital coordinator collected the anonymous forms and passed them on to the research study team.

3.2.5 Data analysis

Descriptive data were presented as frequencies for categorical variables and mean values and standard deviation for continuous variables. PU prevalence was calculated as the percentage of patients with a PU in the group of all patients (number of patients with PU/total number of patients included x 100). HAPU prevalence was calculated as the percentage of patients with a PU among of all inpatients with no PU at hospital admission. The Chi-square and Mann-Whitney *U* tests are described under Study I. In Study II, missing answers for repositioning and type of mattress were coded as “No planned repositioning” and “Standard mattress”.

We conducted the analysis for Study II with SPSS 18. We conducted the multilevel analysis in Study II with MLwiN 2.28 (University of Bristol Centre for Multilevel Modelling). Data collection forms for Study II were read by TeleForm (Cardiff Software, Inc), an electronic forms processing application.

Multilevel analysis

We wanted to investigate the distribution of HAPUs across the hierarchical levels and used the so called empty model[138] – a model with no explanatory variables – to partition the variance of HAPUs. Due to the hierarchical structure of the data in Study II, the assumption of independence of observations may not hold: patients are assigned to wards and hospitals where they may treated according to routine procedures that may differ from the routines in other wards and hospitals. Patients in the same type of hospital ward have more similarities compared to patients in other types of hospital ward.[139] Logistic regression has few assumptions and does not require normal distribution or a specific level of measurement.[140] Traditional logistic regression does not take into account the hierarchical structure of data.[139 141] Thus, multilevel analysis was required. Multilevel regression model is the preferred method for investigating outcome variation across groups, such as wards.

The dependent variable in the model was HAPU prevalence. In this preliminary investigation we conducted the following analyses: (1) HAPU dichotomized into "No HAPU" and "HAPU (categories I-IV)"; and (2) HAPU dichotomized into "No HAPU/HAPU 1" and "HAPU II-IV". The dependent variable was dichotomized this way so that we could investigate whether the across-level variance was affected by the PU severity.

With MLwiN multilevel logistic regression, the patient-level variance is not part of the regular output and was estimated by hand by the expression $\pi^2/3$ as recommended by Twisk[138] and Rabe-Hekseth and Skrondal.[142] Three to five groups at the highest hierarchical level in the model are probably too few and a preliminary analysis is advisable to consider whether the sample is large enough to estimate variance.[139 143] We applied a three-level (hospital, ward, and patient) empty model (without explanatory variables) in Study II to investigate whether there was variance across all levels.

We partitioned the variance in HAPU by calculating intraclass correlation (ICC) according to this formula: [(hospital variance + ward variance)/(hospital variance + ward variance + patient variance)] x 100. A high ICC calls for multilevel regression.[144]

3.3 Study III *Patient and organisational variables associated with pressure ulcer prevalence in hospital settings – a multilevel analysis*

3.3.1 Setting

Study III used data from Study II as well as data from a national patient safety culture study conducted by the Norwegian Ministry of Health and Care Services as a part of a patient safety campaign. The setting of Study III was the same as that of Study II. However, the sample for Study III was smaller because two of the hospitals had not participated in the patient safety culture study.

3.3.2 Sample

We used the data from our prevalence study (Study II), but excluded the patients with a PU documented at admission or with missing data on that variable. The hospitals in Study II that had collected data for the national patient safety culture study provided their data to us in the form of ward/department averages. The data from the patient safety culture study was handed to us as written reports from the participating hospitals, and ward response rates varied from 33% to 82%. After the exclusion of the 153 patients with a PU at admission (37 patients) or with missing data (51 patients) and hospitals that had not participated in the patient safety culture study (65 patients), a final sample of 1,056 patients in 84 wards remained.

3.3.3 Measurements

Study III used data from the same measurement forms used in Study II, namely the EPUAP minimum data set (PU documented at admission, PU severity, Braden total score, age, gender, height and weight, preventive measures), and the ward characteristic form (ward type, nurse staffing, number of estimated beds). Study III used an analytic epidemiological approach. In Study III, HAPU prevalence was the outcome variable (see section 2.3.2). In addition, the SAQ questionnaire presented below was included in the analysis.

Safety Attitude Questionnaire (SAQ)

The original SAQ measures patient safety culture using six dimensions: safety climate, teamwork climate, stress recognition, perception of management, working conditions, and job satisfaction.[103] The SAQ questionnaire consists of 36 questions, each question measured on a scale of 1 to 5 (disagree strongly to agree strongly) and not applicable.[103 122] The original scale has demonstrated good psychometric properties when applied to critical care units, operating rooms, inpatient settings, and ambulatory clinics.[103] Testing of the Norwegian SAQ version in one Norwegian hospital has also showed satisfactory psychometric properties.[122]

In this thesis, the SAQ was chosen to measure patient safety culture due to availability of data from a national study. The national patient safety culture study in Norway measured health personnel's rating on only three dimensions of the SAQ with 16 questions: safety climate (7 questions), teamwork climate (6 questions) and perception of management (only 3 questions from the dimension were included in the Norwegian national patient safety culture study).[104 145] Dimension sum scores were transformed into mean scores between zero and 100. Higher scores indicate a stronger patient safety culture.

3.3.4 Data collection

The data were collected as described in the section on Study II, the PU prevalence study. In the patient safety culture study used in Study III, health personnel anonymously answered a web-based questionnaire based on the Safety Attitude Questionnaire (SAQ). The questionnaire was distributed by mail, and all Norwegian Health Regional Authorities participated as a part of a Norwegian patient safety campaign. The questionnaire is described in more detail above.

3.3.5 Data analysis

Descriptive data were presented as frequencies for categorical variables and as mean values and standard deviation for continuous variables. We conducted the analysis for Study III with SPSS 21. We conducted the multilevel analysis in Study III with MLwiN 2.30. Regression analysis controls the effect of each explanatory variable for each other variable in the model. The independent variables in Study III were variables that had been identified in other studies as significant PU predictors or, at least, predictors of potential importance. The multilevel logistic regression results are presented as odds ratios (ORs) and confidence intervals (95%). In Study III, we used a model with only two-levels (ward and patient). In Study III, there were only four hospitals, which was insufficient for a three-level model. As the MLwiN multilevel logistic regression output does not include model goodness-of-fit indicators from which the significance of ward level variance can be inferred (like the change in the Chi squared distributed -2LL of multilevel linear regression models), the significance of the ward-level variance as assessed by the size of the ward-level variance relative to its standard error. If the ward level variance divided by its standard error produced a larger quotient than 1.96, a significance level of less than 5% was assumed.

Cronbach's α was used to assess the coherence of the computed construct "patient safety culture" in Study III. Cronbach's α varies between zero and one, where 0.7 is satisfactory.[146 147] The constructs Cronbach's α coefficient was 0.905. The small number of patients with PUs on the outcome variable limited the number of explanation variables included in Study III. To meet this limitation, we collapsed categories to reduce the number of dummy variables in the model. The variable "PU prevention implemented" was constructed from the response to three items: pressure-redistributing mattress, planned repositioning and elevated heels. These items were collected at the patient level, and considered as a process variable in this thesis. The reasoning here is that these preventive measures may reflect the availability of equipment and/or the clinical decision made by the nurse. Therefore, preventive measures are a measure of both material and human resources. Others have included preventive measures as a process variable.[148] Each of these items was first dichotomized into implemented or not implemented. Then the three items were summed. The sum score of 0 to 3 was then dichotomized into 0 = no preventive measures implemented and 1= one, two or three preventive measures implemented.

3.4 Ethics

All three studies were conducted according to principles outlined in the Declaration of Helsinki. The Regional Committee for Medical Research Ethics (REK) in Norway had previously been contacted for the pilot study of the EPUAP form to confirm that the privacy protection officials had sufficient authority to approve the study.[8] The privacy protection officials from the participating hospitals approved each sub-study. The nurses included in Study I participated voluntarily and gave written consent. Study I is registered in Clinical

Trials (http://clinicaltrials.gov/) with register ID NCT01567410. The development of e-learning programs allows nurses to learn how to use the Braden scale and assess PUs in a controlled situation. The alternative would be to involve actual patients, which could pose a considerable burden on them. We used written case descriptions and pictures in Study I instead of a real patient investigation. The risk for the nurse participants was considered low. The advantages of participation, including increased knowledge and the satisfaction of learning, would appear to outweigh the disadvantages, such as time spent in training.

For Studies II and III, the observed patients or their relatives were informed about the study aim both verbally and in writing. The method of data collection had been used in prior studies and was considered safe for both the patients involved and the data collectors.[4 5 8] Hospitalized patients are vulnerable due to illness, age, feelings of powerless, and social status and it is important not to expose them to additional burdens. The study involved very limited, if any, risk for patients: a daily skin examination should be performed for at-risk hospitalized patients as an element of routine nursing care without threatening the patient's integrity. Nevertheless, patients who were considered too ill to participate were excluded. We did not exclude patients with cognitive impairment, as they often have a high risk of PUs. Data was collected only once. Participation was voluntary and patients or their relatives were assured that care would not be affected by a refusal to participate. Data collection was anonymous and scores cannot be traced back to individual patients. We also promised the participating hospitals full anonymity in all presentations and thus did not present single ward and hospital results, instead using data aggregated by ward type.

Study III used data from Study II as well as ward/department data from a national patient safety culture study provided to us by the participating hospitals in Study II. Health personnel at wards had answered the patient safety culture study anonymously using a web-based questionnaire. We were not involved in the planning, data collection, or primary analysis of the patient safety culture study. That study was run as a part of the activity of the regional health authorities.

4. Results

This chapter briefly summarizes the results of the three studies.

4.1 Study I *Effect of e-learning program on risk assessment and pressure ulcer classification – a randomized study*

Twenty-three nurses were randomized to the e-learning group and 21 nurses to the traditional classroom lecture group. Most of the nurses worked in hospital wards (81.8%) and the majority were female (97.7%). Over half of the participants had more than 6 years of work experience (range 0 to 32 years). There were no differences between the two groups for these characteristics.

The Braden subscale test did not reveal any differences between the groups on the pre-test, post-test I or post-test II. The e-learning subscale scores ranged from 74.8% to 89.6% agreement in the pre-test, while in post-test I the range dropped to 61.7% to 71.3% agreement. The classroom subscale scores ranged from 75.2% to 86.7% agreement in the pre-test, falling to 55.2% to 69.5% agreement in post-test I. The Fleiss' kappa values ranged from -0.05 to 0.59 across the tests. In the post-test II, some of the subscales achieved medium strength of agreement.[136]

The PU classification test showed differences between the groups on post-test I. The e-learning group scored better than the classroom group for all categories except category IV for the same photo set as in the pre-test. For this photo set, there was also a difference between the groups' sum scores (U = 126.0, z = -2.738, p = .006). For post-test I (new photo set) and post-test II, hardly any differences were found between the groups. None of the groups reached 80% exact agreement when all test photos were included, but for some of the PU categories both groups reached over 80% exact agreement. The Fleiss' kappa values ranged from 0.13 to 0.29, indicating fair strength of agreement.[136]

4.2 Study II *The prevalence, prevention and multilevel variance of pressure ulcers in Norwegian hospitals: a cross-sectional study*

The sample in this study included 1,209 patients from 88 wards in six hospitals. 220 patients (18.2%) had a category I-IV PU on the day our data was collected. Most PUs were in category I (60.5%), while 7.7% and 8.2% of PUs were category III and IV, respectively. The most common location was the sacrum (36.4%). The highest prevalence was found in the ICUs (31.8%) and the lowest in the rehabilitation wards (13.1%). The prevalence of category II-IV PUs was 7.2% (87/1209) for the total sample. Of the 220 patients with a PU, 38 presented with a PU at admission. One thousand one hundred nineteen patients (92.6%) had no PU at admission. For 52 patients (4.3%) we had no information on the presence of PU at the time of admission. The hospital-acquired PU (HAPU) prevalence was about 15% for categories I-IV (182 PUs not documented at admission).

Most patients were not at risk of developing PUs on the data collection day. Only 17% of the sample had a Braden total score below the cut-off point of 17, indicating “at risk”. However, about one-fourth of the patients (305 patients) were considered at risk, with a Braden score below 17 and/or a PU. Over half of these patients (156 patients) had not been allocated a pressure-redistributing mattress, nor had they received planned repositioning in bed. Fewer than one-fifth of the patients at risk and/or with a PU (54/305 patients) were allocated both a pressure-redistributing mattress and planned repositioning in bed. Only 44.3% (135/305) of the at-risk patients had received a pressure-redistributing mattress and 22.3% (68/305) had planned repositioning in bed. Few patients with increased risk of PU received preventive measures when seated in a chair. Of the 904 patients considered not at risk on data collection day, 147 (16.3%) had a pressure-redistributing mattress.

We conducted an empty multilevel logistic regression model with hospital, ward, and patient levels to investigate the level-specific variance for HAPUs that included the patients with PUs not present at admission. The variance was mostly at the patient-level, but we also found considerable ward-level variance. The result from the empty model warranted further investigation of selected patient and organizational variables, which we undertook in Study III.

4.3 Study III *Patient and organisational variables associated with pressure ulcer prevalence in hospital settings – a multilevel analysis*

Four hospitals, 84 wards, and 1,056 patients were included in Study III. The HAPU prevalence for categories I-IV was 14.3% for the total sample (151/1056). The prevalence of HAPUs ranged from 5.7% in the rehabilitation wards to 27.6% in the ICU wards.

In the model with only organizational variables, the significant HAPU predictor variables were the mean patient safety culture score (OR 0.98; 95% CI 0.96-0.99), ward type (rehabilitation OR 0.26; 95% CI 0.08-0.87), and PU prevention implemented (OR 3.74, 95% CI 2.49-5.63). This model still left a significant variance (ICC 17.39) in HAPUs across wards. However, once the selected patient variables were added to the model in the next step, the significant across-ward variance was eliminated.

A significant association was found between the mean patient safety culture score and the odds of HAPU; an increase of a single point on the 0-100 mean patient safety culture scale reduced the odds of HAPU by a factor of 0.97. The rehabilitation wards had lower odds of HAPU than the surgery and internal medicine wards reference group. When PU preventive measures were implemented, patients had twice the odds of HAPU as those not allocated any PU preventive measures. In the final model, age, Braden scale total score, and being overweight were significant patient variables. Patients 70 years of age or above had almost three times as high risk of HAPU as patients below 70 years. A higher Braden total score reduced the risk of HAPU; a one-point increase on the Braden total score reduced the risk by a factor of 0.73 (95% CI 0.67-0.80). Overweight patients (BMI 25-29.99) had significantly lower HAPU odds (OR 0.32; 95% CI 0.17-0.62) than patients with normal weight (BMI 18.5-24.99).

The finding that the HAPU risk increased when preventive measures were implemented required further analysis. This finding may indicate that preventive measures were implemented only after a PU was visible. We had Braden total score data for 1,004 patients. Comparing patients at risk of and/or with a PU to patients not at risk, we found significantly higher use of preventive measures among those at risk and/or with a PU. Of the patients at risk, 136/222 (61.3%) received preventive measures. Of those not at risk, 181/782 (23.1%) received such measures.

5. Discussion

In this chapter, the main findings will be discussed including the significance of study findings for nursing practice and education, and recommendations for further research will be proposed. This is followed by a discussion of the strengths and limitations of the studies.

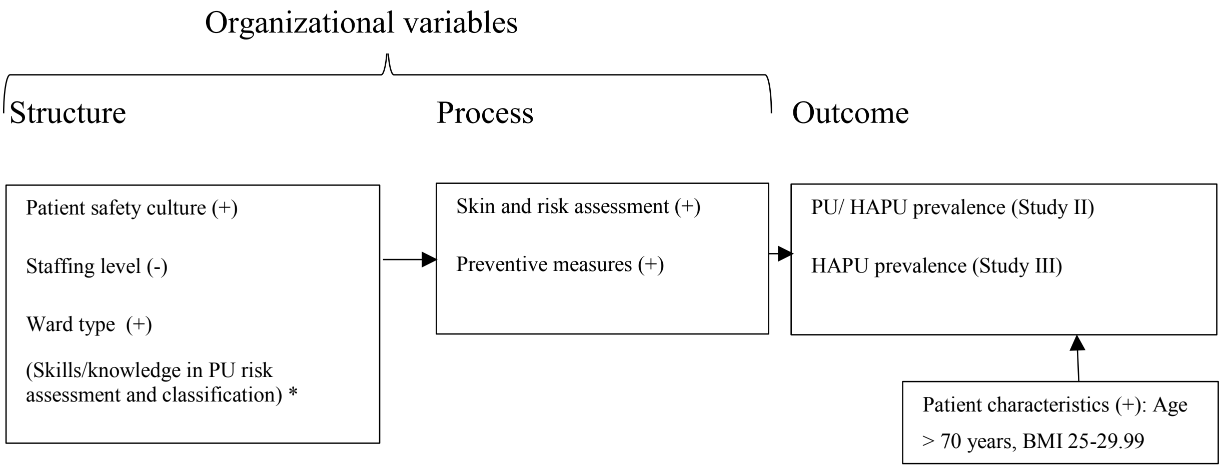
5.1 Main findings

This research found that compared to traditional classroom lectures, an e-learning program improved nurses' ability to accurately classify PU (**Study I**). However, the e-learning program did not improve nurses' ability to correctly assess risk of PU development using the Braden scale (**Study I**).

This research shows that PU prevalence was 18.2%, indicating that the prevalence of PUs in Norwegian hospitals is as high as or higher than in other European hospitals (**Study II**). Patients identified to be at risk with a Braden score below 17 and/or with a PU did not receive the preventive measures recommended in the international evidence-based guideline. This finding documents that prior to implementation of PU as a target in the Norwegian patient safety campaign, a high number of patients at risk and/or with a PU did not receive optimal care (**Study II**). Organizational factors may contribute to PU prevalence, as there was a significant variance of HAPUs at ward level (**Study II**).

Further, in multilevel analysis, **Study III** detected a significant association between PU development during hospitalization (HAPUs) and six variables: low patient safety culture score, PU prevention implemented, rehabilitation ward, high age, low Braden total score, and BMI 25-29.99 (**Study III**). Both structural and process factors, as well as patient characteristic variables, had an impact on the odds of developing a PU during hospital stay (**Study III**). Figure 5 shows the significant associations between structure, process and patient characteristic variables and the PU outcome.

The intervention study (**Study I**) will be discussed first and then major study results from **Study II** and **III** will be highlighted and discussed based on our structure, process, and outcome model. The model allows data input of multiple structural factors that could affect the process of care, which in turn affect outcome. In this thesis, structure refers to ward characteristics while process refers to the nursing care provided, including assessment of patients, planning, implementation of prevention measures, and evaluation. Outcome refers to the prevalence of PUs and HAPUs in Studies II and III, respectively.



* Study I shows that there are gaps in staff skills even though these variables were not included in the regression models in Study III. (+) indicates significant variables, (-) indicates nonsignificant variables.

Figure 5. Overview of the structure and process variables that had an impact on odds of PU development during hospitalization.

5.2 Training programs to improve risk assessment and PU classification skills

Assessment of patients' PU risk using a specific risk assessment scale is not a routine procedure in Norwegian hospital wards.[75] Moreover, the pilot study of the EPUAP data collection form confirmed that nurses were not familiar with the Braden scale and classification.[8] As no training program was available in Norwegian to teach nurses to conduct risk assessment with the Braden scale and to classify PUs, we developed an e-learning program with two modules for this purpose. Our study was the first Norwegian study to evaluate the effect of an e-learning program on the use of a risk assessment scale and PU classification. Previous studies in other contexts found such training to be successful.[86,87,92,94,95] We found a short-term improvement for the e-learning training group for the classification program. The e-learning training group scored better on post-test I immediately after training than the classroom training group did. However, we did not achieve satisfactory results for the Braden scale module of the program or a long-term effect for the classification training module (**Study I**).

The exact agreement on the Braden subscales dropped in post-test I for both groups. In the pre-test both groups had 80% or more exact agreement on three of the subscales, while neither group achieved this high result on the post-test I. The negative result in post-test I may be due to the introduction of two new cases and to fatigue among the participants. The agreement increased again in post-test II, three months after intervention: 80% exact agreement was achieved in four of the six subscales for the e-learning group and in five of the six in the classroom group.

Only one other study has compared the effect of an e-leaning program on PU classification skills with a control group that received classroom training with the same content.[87] Both groups in that study increased the percent agreement from pre-test to post-test. There were no significant differences between e-learning and classroom training for the nurse group in the Beeckman et al. study, while nursing students achieved better results in the e-learning training group.[87] The fact that nursing students achieved better results with e-learning may be related to their having greater familiarity with web-based programs. Despite showing no significant long-term effect, e-learning training did improve PU classification skills. Thus, our study corroborates earlier findings regarding short-term improvement following an e-learning program. Work experience might have had an impact on our results, as indicated in the Beeckman et al. study.[87] We did look into work experience, but we found few differences probably due to small sample size. Therefore, we decided to leave out this information in the paper.

The Fleiss' kappa results were generally low overall, which indicates low agreement, i.e., differing interpretations of PU photos and Braden subscales, in both groups. For the Braden subscale ratings, the classroom group improved their kappa from pre-test to post-test. The classroom group showed greater agreement after training, but agreement was still low. As has been pointed out by e.g., Polit & Beck,[149] kappa values should not be presented alone because they are dependent on the sample at hand. Therefore, it is important to show kappa measures together with another measure of agreement. In our case, we complemented the kappa with information on percent exact agreement. Kappa is a measure of consistency between raters. Kappa measures may show high agreement even when the agreement is based on an incorrect answer.

None of the previous studies of the Braden scale have compared e-learning to a control group receiving classroom training in a randomized study. RCT is the gold standard for evaluating the effect of interventions, such as the e-learning program. Earlier studies compared web-based training for regular and new users unfamiliar with the scale, none of these studies included a long-term follow-up.[85 86 93 94] The new users of the Braden scale could be compared to our participants as they were also not familiar with the scale. The studies showed different results: regular users of the Braden scale had more correct assessments for both risk level and subscale scoring compared to new users in one post-test only study using patient cases.[94] In another pre- and post-test study, new users showed improved agreement with the experts' assessments compared to regular users of the Braden scale.[85] However, this study was conducted on patients and the expert and nurse ratings were obtained within a 24-hour window. The correct agreement may have been affected by a possible change in the patient's condition during those 24 hours. New users of the Braden scale in the Magnan and Maklebust study[85] achieved higher scores on the post-test after training compared to the nurses participating in our study. Despite inconsistencies across studies, it is clear that training is important. It might be easier for new users to assess real patients using the Braden scale than to assess written cases. Regular users of the Braden scale achieved better results in the study using cases.[94]

The e-learning intervention in **Study I** did not improve assessment skills for the use of Braden scale and had only a short-term effect for PU classification. Equivalency of results for both training methods indicated that both methods could be used in future studies with some adjustments. In fact, we adjusted the programs and used them in the training procedure for the data collectors in **Study II.** The adjustments are described in greater depth in the strengths and limitations of methods section. As in **Study I**, both e-learning and classroom sessions were offered to the hospitals. Because the training was a part of the preparation for data collection and was given at the same time review of the study protocol, classroom training was the only option at some participating hospitals due to limited availability of PC terminals. The data collectors in **Studies II** and **III** achieved satisfactory results prior to data collection.

Assuming equivalent skill acquisition between e-learning and classroom training, the easy accessibility of e-learning may be an important factor when selecting a training mode. Staff training interventions that can effectively improve knowledge and skills are important in a hectic nursing ward. E-learning programs support flexible learning with the possibility of repeating the courses frequently to maintain proficiency. Continuous professional development and maintenance of competence are important. Even though the nurses did the program only once in **Study I,** we recommend e-learning as a better tool than classroom instruction for continuing education since the method is less resource demanding. Further, the Norwegian National Health and Hospital Plan calls for increased use of e-learning as an efficient training method.[150]

A combination of evidence-based knowledge, clinical judgment and risk assessment scales is needed to prevent the development of PUs.[12 151 152] According to Donabedian, knowledge and judgment are important for performance and in comparison of practice.[39] Competent nurses with knowledge and skills (structure) are also key aspects of safety culture (see 2.5.2). Increased knowledge (structure) about PU risk factors and categories will probably improve risk and skin assessment performance (process) which may result in increased implementation of preventive measures (process) and in turn cause a decrease in the development of PUs (outcome). Knowledge, attitude, and skills are important elements of nurses' critical thinking and observation. The assessment of a patient's vulnerability, skin status, and risk of developing negative outcomes are all important to consider at the starting point of the nursing process because they provide information on which to base the prevention plan. Risk assessment is the very core of nursing care and enables nurses to protect their patients and avoid damage. Assessment helps nurses determine which nursing interventions are needed. Assessment information helps caregivers and patients achieve patient targets. The poor pre-test results in **Study I** showed that the participating nurses lacked skills in risk and skin assessment. If this result reflects a lack of competence in assessment among Norwegian nurses in general, this would in part explain why many at-risk patients in **Studies II** and **III** did not receive preventive measures.

5.3 Main outcome variable

Our findings showed a PU prevalence of 18.2% (**Study II**) and a HAPU prevalence of 14.3% (**Study III**) indicating that the Norwegian hospitals in our study have an equally high or higher prevalence of PUs as European hospitals. Norway spends relatively more of its gross national product (GNP) on healthcare and has a lower patient-to-nurse ratio than other comparable countries;[26 153 154] one might therefore expect the prevalence of PUs to be lower than in other European hospitals. Nevertheless, the prevalence of PUs in Norway is as high as it is elsewhere (Table 2). As indicated by Table 2, many countries focus on PU as a national quality indicator; however, in Norway there is no national data on PU prevalence. **Study II** included all PUs identified on the data collection day, while **Study III** used only the HAPUs, i.e. not documented at admission indicating that the PU developed after admission during hospital stay.

The majority of patients with PUs in **Study II** had category I as the most severe PU (60.5%). There were few PUs in category III (17 patients) and category IV (18 patients). An additional analysis showed that of the patients with categories III and IV PUs, they often were presented with PUs at admission (11 PUs in category III and 11 in category IV, data not shown). However, over one-third of these ulcers (categories III and IV) were not present at admission. The fact that most PUs were less severe (categories I and II) may also affect nurses' ability to recognize such PUs. On the other hand, categories III and IV are highly visible ulcers, which should be easier to identify as PUs than redness that does not blanch (category I). Category III was, however, one of the PU categories with the lowest agreement in **Study I**. The location of category III and IV ulcers may affect the accuracy of classification. The depth of these categories (categories III and IV) differs by location, e.g., the ear versus the buttocks, due to variations in the thickness of the subcutaneous layer.[12]

The most common location of the most severe PUs in our study was the sacrum (36.4%), followed by the heels (26.8%). Our findings are comparable to other large PU prevalence studies.[4 5 7] The studies from Vanderwee et al.[4 5] found the sacrum to be the most common PU location with frequencies of 44.8% and 48.1%, respectively, which are higher than we found in our study. The heels and sacrum are exposed to high pressure patients lie in bed, thus it is not surprising that these bony prominences are the most common sites of PUs. Therefore, skin assessment of these locations and implementation of preventive measures such as pressure-redistribution mattresses, heel protection, and repositioning of bedridden patients, are important.

HAPU measures the occurrence of new PUs that develop after admission to hospital. HAPU is commonly used as an indirect measurement of incidence. Measuring PU incidence takes more time and costs more than a HAPU prevalence study. In **Study III,** HAPU was the outcome of interest since the purpose was to investigate the association between PUs and organizational factors. PUs documented at hospital admission cannot be attributed to poor care provided at this particular hospital. Therefore, patients with PU present at admission or those whose PU status at admission could not be ascertained (i.e., due to missing information) were excluded from the sample analyzed in **Study III**.

Three Norwegian PU prevalence studies have been published since our study results were published (**Study II**).[155-157] The hospital patient sample in these studies showed a prevalence of 18% (12 of 66 patients),[155] 22.5% (14 of 62 patients),[156] and 11.9% (37 of 328 patients),[157] respectively. Even though these studies had smaller sample sizes than our study, they support our findings of a rather high PU prevalence in Norwegian hospitals. The hospitals and wards included may also be a factor when comparing prevalence data, as some wards, such as ICUs, have more at-risk patients. We included ICUs and various other ward types in our sample, while the other three small Norwegian studies included few wards and mostly surgical and medical ones.[155-157]

The healthcare systems in the Nordic countries have many similarities such as universal health coverage and publicly financed healthcare and hospitals.[158] Compared to the Swedish results of 14.4-16.4%,[7] our prevalence rate is slightly higher. In Sweden, several national PU prevalence studies have been conducted in recent years as a part of a Swedish patient safety initiative.[7 159] Repeated measurement of PU prevalence may contribute to improving PU prevention. When the PU problem is recognized, quality improvement initiatives are probably easier to establish and maintain.

PU prevalence/incidence rates should be a major concern since PUs negatively affect the quality of life of patients.[9 160] Even though not all PUs are avoidable,[161] most can be prevented. PUs affect physical, social, psychological, and financial aspect of health related quality of life. Therefore, reducing the prevalence and incidence of PUs is important. However, according to a Norwegian government white paper,[162] the number of days elapsing between discovery of a new PU has increased from three to nine days in the two pilot wards (one orthopaedic and one internal medicine) that tested PU as a target of the patient safety campaign. The patient safety campaign pilot wards have shown improved results. This indicates that it is important to focus on PUs to improve PU prevention. The PU prevalence and incidence may have dropped since the patient safety program began nationwide. Even though the occurrence of PUs is a target of the ongoing patient safety program since spring 2013,[163] no large PU research studies have been published.

5.4 Organizational variables (process and structure variables)

We found variation in PU prevalence and prevention measures across different ward types in **Study II**. We also found a significant ward variance in the empty models (with no explanatory variables), including all four PU categories, as well as categories II-IV only (**Study II**). The variance was smaller for the HAPU outcome variable including categories II-IV than for the outcome with all four categories, indicating that organizational factors may have an impact on PU prevalence. Organizational factors are important, but the patient case mix will still have an impact on PU prevalence, even if organizational improvement is initiated. Using the structure-process-outcome model, we investigated the relationship between selected organizational factors and HAPUs in the final study (**Study III**).

5.4.1 Process variables associated with PU development

Failure to implement preventive measures for at-risk patients is a troubling finding. In our **Study II,** 25.2% of the patients had a Braden score of less than 17 points and/or a PU. Less than half of these at-risk patients had a pressure-redistributing mattress and only one-fifth had planned repositioning (every 2-4 hours) documented in their patient record or a turning schedule at their bedside (**Study II**). When preventive measures were applied, the odds of a HAPU were twice as high (**Study III**). A reason for this may be that the prevention was implemented only after nurses had identified a PU and not as primary prevention measures based on risk assessment. Not all at-risk patients received preventive measures, but significantly more patients at risk and/or with PUs received preventive measures compared to patients who were not at risk (**Studies II and III**).

Our findings raise a number of questions. Why are patients not receiving needed preventive measures? Was a risk assessment conducted prior to the data collection day? Is prevention lacking because nurses do not know the importance of repositioning? Is it because repositioning often requires two or more nurses to perform? Were there not enough pressure-redistributing mattresses available or do nurses lack competency to allocate relevant prevention to meet the individual needs of patients? Our study was not designed to answer questions as to why patients do not receive appropriate prevention. These questions need to be investigated in future research. In other studies, insufficient material resources has been found to be an important underlying cause of omitted or delayed nursing care, including PU prevention.[164 165]

Failure to implement preventive measures such as providing support surfaces, repositioning, and offloading heels reflects poor nursing care (**Studies II** and **III**). Failure to implement preventive measures is not an issue only in Norwegian hospitals; even in countries that have conducted several PU prevalence studies, the number of at-risk patients not receiving optimal prevention is high.[5 7 59] A recent case-control study found an association between quality of preventive care and PU prevalence. The study investigated a quality score that graded suboptimal factors for PU, PU risk score, and PU development.[166] The adjusted odds of PU/incontinence-associated dermatitis were nearly double (OR 1.9) when the quality score was deteriorated by one point.[166] This result indicates that the variation in PU prevalence reflects variation in the care quality.[166] Other studies showed that omitted or delayed care increased the odds of nurse-reported PUs by 1.2 to 3.4.[32 167]

However, important factors when comparing results in multicenter studies include what risk assessment scale was used and what risk level (cut-off) was chosen. For instance, Halfens et al.[59] used a Braden score below 21 to indicate risk in their multi-country study. This is a higher risk level cut-off score than in many other studies, which use cut-off scores below 17 points. Their cut-off level may be a reason for the result that nearly all of the at-risk patients had a pressure-redistributing mattress in bed in participating Dutch hospitals (see Table 2). However, in the Austrian and Swiss hospitals only half of the at-risk patients had a pressure-redistributing mattress.[59] Comparing results across countries can be challenging since there are differences in healthcare systems. However, international evidence-based PU prevention guidelines have been available for many years and implementation of preventive measures should improve. As shown in Table 2, planned repositioning is implemented even less frequently than the provision of pressure-redistributing mattress for at-risk patients.[4 6 7 59]

Early risk assessment may decrease the odds of HAPUs. The evidence-based PU guideline recommends a risk assessment within eight hours.[12] One study including 789 wards found fewer HAPUs when risk assessment was completed at admission.[62] The study showed low HAPU prevalence for categories I-IV (2.94%), and almost all patients were risk- and skin-assessed within 24 hours of admission. The same study found that nearly 90% of the at-risk patients had prevention protocols. Risk assessment may trigger such protocols.[62] Knowledge about classification, risk factors, and evidence-based preventive measures is important to reduce PU development and especially target at-risk patients.[12] With the implementation of evidence-based checklists and guidelines, healthcare is expected to demonstrate a stronger culture of safety.[84] The results of our studies indicate that the international guideline for PU prevention has not been successfully implemented in the participating Norwegian wards. One other reason may be lack of risk assessment at patient admission and reassessment when conditions change to determine whether preventive measures are necessary.

PU risk assessment scales provide decision support to nurses by directing attention to risk factors known to contribute to PU development. Nurses are expected to use the nursing process as a tool to assess patient problems and the need for action.[16] PU prevention is an integral part of the nursing process and includes systematic assessment, diagnosis, planning, implementation of interventions, and evaluation.[168] Our results may indicate failure of nurses to use a systematic approach to assessment and prevention prior to our data collection day. However, systematic risk assessment scales do not include all patient risk factors and should be combined with clinical judgment and skin assessment.[12] Risk assessment must be carried out skilfully to avoid faulty subscale ratings that may lead to inappropriate care plans. Training in use of assessment scales are therefore important. Magnan and Maklebust[168] concluded that "the absolute best defense against pressure ulceration is a capable and caring nursing staff that is committed to the patient's welfare".(Page 91)[168]

Some nurses are skeptical of available risk assessment scales because of their limited validity and reliability. Recently, Coleman et al. have developed a new PU framework based on previous conceptual frameworks and updated science.[169] This new framework limits risk assessment to assessing mobility (can the patient walk without help and change position) and PU status (current PU, history of PU) with a yes/no option in the first assessment. The framework is currently under clinical evaluation.[169] The new framework will be efficient because it will enable caregivers to quickly identify low-risk patients while patients at-risk and/or with PUs will be allocated to secondary prevention and treatment pathways.[170]

The term "preventive measures" in **Study III** encompasses planned repositioning, offloaded heels, and pressure-redistributing mattresses. Data on this variable were collected at patient level, but we treated these variables as ward-level process variable, as the implementation of preventive measures depends strongly on the nurses' assessments. Patient risk, availability of pressure-redistribution mattresses/cushions, nurse knowledge, and staffing affect whether preventive measures are implemented or not. According to the PU prevention guideline, preventive measures should be implemented for all at-risk patients.[12]

The reasons nurses fail to implement relevant prevention to patients is poorly understood. More research is needed on the barriers and facilitators to implementation of evidence-based nursing practice and preventive measures.[171 172]

5.4.2 Structure variables associated with PU development

Studies have shown that work environment and staffing level may affect quality of care.[30 31 165 173 174] With our framework, we investigated the potential relationship between patient safety culture, other organizational variables, and PUs. Patient safety culture was considered a structural characteristic of hospital wards. Our results indicate that the structure variables ward type and patient safety culture were significantly associated with HAPU while staffing level was not. Significantly lower odds of HAPUs were found for the rehabilitation wards than for the surgery and internal medicine wards (**Study III**). The rehabilitation wards had relatively fewer patients aged 70 years or older than the other wards (**Study II**). Older patients have a higher risk of PUs.[19] Nearly half of the PUs in the rehabilitation wards were documented at admission (Table 2 in **Study II** paper). The rehabilitation wards had higher implementation of preventive measures as pressure-redistribution mattresses and planned repositioning compared to surgical and medical wards (Table 3 in **Study II** paper).

Few studies have investigated the association between HAPU prevalence and patient safety culture prior to our data collection for **Study III**.[115 117 119 120] Our results showed a significant association between the composite score of patient safety culture based on three dimensions (safety climate, teamwork, perception of management) from the SAQ and HAPUs. Better patient safety culture scores were associated with lower HAPU odds. Our results match a number of other studies that have shown an association between safety culture measures and lower risk of experiencing a PU.[115 117 118 124] One earlier study found an association between two SAQ subscales, safety and teamwork, and PUs.[115] For each 10-point increase of the average safety or teamwork score, the odds of PUs declined by 44-48%.[115] Our result was a decrease in PU odds of 26% for each 10-point increase in the composite score of patient safety culture (**Study III** paper, page 5). Our composite patient safety culture score included safety climate, teamwork and perception of management. One can assume that wards with strong patient safety cultures make PU prevention a higher priority than those with weaker cultures. As learning is an important issue under patient safety culture,[84] one can assume that wards with strong patient safety cultures also prioritize staff knowledge and skills. While some studies have found a significant relationship between safety culture and PUs, others have not.[119 125 175]

Our results may be affected by the inclusion of category I PUs. However, category I PUs are important in patient safety research because they are often predictors of more severe PUs.[19] The ward-level intraclass correlation was also higher when category I PUs were included in calculation of the HAPU outcome variable (empty models **Study II**). Most of the studies investigating patient safety culture and PUs included only PU categories II-IV (see Table 5), which limits comparison with our study. The relationship between patient safety culture and PUs is still not clear. The variation across studies shown in Table 5 appears to be due to the different methods and instruments used in the studies.[112] Studies use varying definitions of safety culture,[96] which may limit the ability to draw conclusions. Our study is one of few studies investigating the relationship between organizational variables including patient safety aspects, and patient outcomes in Norway. One other recent Norwegian study used nurse-reported estimates from a large European nurse study (RN4CAST study) and found that quality system, nurse-physician relations, patient safety management, and staff adequacy, which all were part of work environment process in the study, were organizational measures associated with nurse-reported work- and patient-related outcomes.[176] Organizational variables seem to be important to patient outcomes in Norway.

Quality of care is related to work environment factors such as adequate resources, sufficient staffing, and competent leadership.[84 107 126 177-180] At all levels, managers play a critical role in incorporating governmental, hospital, and ward strategies and procedures to safeguard care quality and in allocating necessary resources for adequate nursing care. [84 179] Building ward safety culture requires engagement of managers and staff at the organizational level closest to the patient. Studies have shown nursing leadership to be positively related to patient outcome.[107 180] Findings on the relationship between PUs and leadership are inconclusive: only one of the three studies of PUs and leadership showed a significant association with lower PU incidence.[107] We have not investigated the specific effect of "perception of management" on HAPU outcome, as this is only one of three dimensions in the overall patient safety culture construct we used, considering the restriction of variables we could include in the model. However, "perception of management" had the lowest score of the three single SAQ dimensions, as shown in the paper for **Study III**. Low satisfaction with leadership or lack of leadership may indicate a threat to patient safety.[84] Studies have shown that competent and visible nursing leadership may be related to better patient safety.[126] When nursing leaders communicate with a more person-centred approach and focus on the patients' well-being, staff become more independent, which may influence their own work and working conditions.[181 182] Nursing leaders who promote the individual competencies of staff are an important aspect of person-centred leadership.[181] This approach might lead the nurses to deliver more person-centered care. Ultimately, focus on the quality of care and nursing will increase.

When staffing is inadequate, or there is high workload, nursing tasks must be prioritized. Not all tasks can be completed; however, the choice of which tasks to prioritize may affect care and PU development. A recent review of nurse-sensitive patient outcomes found inconclusive evidence to support a relationship between staffing and PUs.[21] The review requested more research from countries besides the United States as most studies they found were based on North American data.[21] A review including 465 US hospitals showed that the incidence of unit-acquired PUs was lower with higher staffing ratios.[183] The patient-to-nurse ratio was not a significant organizational factor related to HAPUs in our study when adjusted for other structure and process variables and patient characteristics (**Study III**). Our findings may be due to a rather low patient-to-nurse ratio in Norway compared to other countries.[26 158 178] This raises the question of whether Norwegian nurses do not prioritize PU prevention or whether the low implementation of preventive measures is solely due to lack of resources.

The quality of nursing care depends on ability of patients to cope with their basic needs. Moreover, it depends on nurses' attitudes towards assessment and whether or not they have the opportunity to perform assessment prior to initiating nursing action as a preventive measure in their interaction with the patient.[35] Knowledge, skills, and care are important core elements in patient safety.[84] Missed nursing care may be the results of an individual nurse's knowledge and attitude, but it can also result from organizational factors and context.[31 32] The nursing process is affected by nurses' values, attitudes, competencies, and patterns of behaviour which are an essential part of safety culture.[35 101] Our studies provide no information about patient-nurse communication related to PU prevention. With the nursing shortage and the focus on cost of care, nursing care has become more technical and nurses' workloads have increased; new indirect nursing tasks take more time, which means that nurses have less direct contact with the patients. Rather than providing holistic nursing care, nurses work in an increasingly fragmented manner, and this may influence care quality and represent a threat to patient safety. Nursing observations are sometimes either not made or skipped completely due to, for instance, increased workload. A recent review shows unfinished care predicts decreased nurse-reported care quality, decreased patient satisfaction; increased adverse events, increased turnover, decreased job and occupational satisfaction, and increased intent to leave.[32] This is a significant problem in acute care hospitals.[32] Our findings in **Studies II** and **III** show the evidence-based guideline for PU prevention was not used. Given the expectation that nursing practice is based on evidence, the quality of care is unsatisfactory.

The Donabedian model has been used for decades to assess quality of care. Our model with patient characteristics was inspired by the Donabedian model and facilitated evaluation of PU prevention as an element of quality of care. Multiple factors that might affect the outcome could be included in the model because each concept of the model (structure, process and outcome) influences the next step. The conceptual framework showed the relationship between structure, process, and outcome in this thesis. The concepts of structure, process, and outcome borrowed from the Donabedian model are also used as the guiding framework in an international prevalence measurement of care problems that includes PU prevalence as a measure.[148]

The concept of the fundamentals of care was introduced in the last decade in response to an increasing awareness of the consequences to patients of nursing tasks left undone. Healthcare has also started paying more attention to person-centered care.[34] To provide person-centered care, the nurses need to know how to meet the patients' basic needs.[33] A return to the basics of nursing care has to be considered for the sake of patient safety.[34] The fundamentals of care may also refer to activities of daily living such as eating and drinking, personal cleansing, and dressing.[33 34] The fundamentals of care concept might be a more appropriate concept to use in future PU research as it directs attention to the patient's needs to a greater extent than does the chosen modified model, which addresses the quality of health services. The fundamentals of care model can be presented as concentric circles. The central circle is the relationship between patient and nurse.[33] The next circle includes environmental, physiological, and self-care assessment, which influence the practical actions taken. Knowledge, skills, and competence are necessary to see the whole person. The outer circle incorporates the context of care at both policy level and the system level.[33] The fundamentals of care model is similar to the Donabedian model in that it incorporates structure and process, as well as both the interpersonal and technical aspects of care. However, the patient is more in focus in the fundamentals of care model than in the Donabedian model. In interpersonal care it is important to see the whole patient. In many cases, however, nurses lacks technical skills, for example, how to assess patients' skin.

5.5 Significance of the findings to nursing practice and education and recommendations for future research

With its focus on pressure ulcer prevention in hospitalized patients, this thesis has addressed an important phenomenon that is central to nursing practice. Several areas for improvement of care with important implications for nursing practice and education have been identified as outlined in the following.

The high prevalence of PUs in this thesis indicates that PUs present an ongoing challenge to the provision of effective nursing care in hospitals that meets the needs of vulnerable individuals. PU is one of the most common AEs patients experience during hospitalization; however, our results show that prevention is not given priority. The failure to implement preventive measures for at-risk patients requires more research. One important aspect that needs further investigation is the knowledge and attitudes of nurses regarding PU prevention and how they utilize their professional knowledge in clinical practice. Nurses at the bedside must acquire the knowledge and the skills necessary to perform skin assessments, identify risk factors, and implement effective preventive measures and early treatment strategies. Ideally, education and training to this end should begin at the bachelor's level. In addition, clinical master's programs should focus on PUs in relation to the special needs of particular patient groups, i.e. critical and intensive care nurse specialist, operating room nurse specialists, geriatric nurse practitioners, clinical specialists in orthopaedics, etc.

An important follow-up of these findings would be to look at how nursing schools address patient safety, and PUs in particular. To what extent do schools focus on PU prevention and patient safety? Do graduating students have the necessary competence in skin assessment and PU classification, risk assessment, and preventive measures? Nurse educators need to identify what knowledge and skills must be included in the nursing curriculum, and clinical nurse educators need to develop educational programs for nurses at all levels to prepare nurses to meet the challenges of every day clinical practice.

The e-learning intervention developed and evaluated in this research is an important contribution to improve nursing education. The program includes modules to teach risk factor assessment using a formal tool and assessment of skin and PU classification. Although more work should be done to further improve the modules, this e-learning program already contributes to improving the knowledge and skills of nurses in PU prevention.

Creating a patient safety culture at ward level in which PUs are prevented demands several resources and activities. Even with more knowledge about prevention, it is not possible for nurses to implement necessary activities such as mobilizing the patient and changing patient position if there is not enough staff and pressure-redistributing equipment such as mattresses and cushions. Further investigation is required to better understand why preventive measures are not implemented. Is there enough staff with the necessary competence? Are there enough mattresses and cushions? What are the logistics of their use and replacement? We know less about the functionality of support surfaces such as mattresses over prolonged use. Another interesting issue is whether the national patient safety program has increased PU prevention awareness in Norway and whether the prevalence of PUs has decreased. Few qualitative studies have been conducted in the assessment of patient safety culture. Such studies may uncover a deeper insight of the patient safety culture.

The development and implementation of policies, standards, and procedures is necessary to support good nursing care. The evidence-based PU guideline provides guidance for developing more specific policies for particular care settings and patient populations. How to best implement and use of evidence-based guidelines in wards is another area of interest. Ward management is a critical factor in establishing a patient safety climate that is focused on prevention. Nurse managers play a key role in implementing evidence-based guidelines as important tools for good nursing care. They also are responsible for patient safety in their wards and thus need to assess barriers and facilitators before implementing guidelines.[12] A multi-faceted, unit-tailored intervention study found that the presence of a facilitator and repeated quality measurements with quick feedback on results had a positive effect on PU prevention.[184] Even though the prevalence of PUs did not decrease, more at risk patients received prevention after the intervention.[184]

Based on our findings, a recommendation for a Norwegian setting would be to ensure that nursing leaders understand their responsibilities and the importance of implementing evidence-based nursing initiatives as an approach to improve patient safety. One way to increase leadership participation in patient safety could be to implement leadership rounding, or in other words, having leaders visit wards to observe the "clinical reality". Rounding gives leaders the opportunity to talk with patients and staff and to observe first-hand which aspects of patient safety initiatives are working well and which need to be improved. To ensure good quality care preventing PUs, all personnel included in patient care must be knowledgeable about evidence-based interventions, such as risk assessment, pressure-redistributing mattresses, regular repositioning, and how to provide good skin care and good nutrition for patients.

5.6 Strengths and limitations of methods

In **Study I**, the purpose was to test the training programs and the RCT design was chosen because it is considered the gold standard of study design for evaluating an intervention and the best approach when possible.[136 185 186] An RCT is an experimental study design used for a prospective purpose. The design is well suited to finding differences between groups, investigating the effect of different types of interventions, and determining the effectiveness of interventions.[187 188]

Different types of design checklists have been developed to create more consistency in reporting results, The CONSORT 2010 check list is a minimum set of recommendations for reporting RCT results.[189] We used this check list to guide our presentation of the results in **Study I**. Even though RCTs are the gold standard in research, the design is not suited to all research questions. Since the main goal of this thesis was to develop knowledge regarding the epidemiology of PUs in a Norwegian sample, we chose a cross-sectional design for **Studies II and III**. Cross-sectional design is good for determining prevalence.[190] Further, cross-sectional studies are less expensive than other designs and we wanted our PU prevalence study to have the largest possible sample of hospitals participate. A limitation of the cross-sectional study design is that one cannot assume causal relationships, only infer associations in correlation and regression analysis. The STROBE statement, a check-list for cross-sectional studies, was used to guide the research reports for **Studies II** and **III**.[191] The use of such checklists is helpful for sorting information and assures a standard for reporting findings in manuscript.

We used a convenience sample in all studies (**Studies I-III**). We did not perform a power analysis in any of the studies. This would have been a strength especially for **Study I**. However, **Study I** was considered a pilot test of the training programs. For sample size in pilot studies, a group size of between 10 and 50 is recommended.[128 129] In **Study I**, the nurses were randomized into three groups initially (one group with e-learning, one with a classroom lecture, and one without additional training). The purpose of **Study I** was to examine whether one training method was superior; further, to test feasibility of the process and find areas for improvement in the programs before up-scaling them for training data collectors in a PU prevalence study. In **Study I,** we underestimated the time it would take to recruit the planned number of nurses in each group. Small sample size is a threat to the external validity in **Study I** and the generalizability of the results is limited. However, inclusion of nurses from different institutions is a positive attribute. It is questionable whether a pilot study such as **Study I** is appropriate for testing the effect of an intervention. One might argue that we should have limited our study to descriptive data.[192] Data from testing interventions can be published if researchers clarify that the study is based on small samples and if results are reported with caution.[192 193] Performing many separate statistical tests may create potential false positive results due to chance and show relationships that do not exist. We probably should have been more cautious in claiming significant findings, as this was a pilot study with a small sample. However, Polit and Beck argue that a pilot study with an intervention may be considered not only a test of the method but also of the intervention itself and of opportunities to improve it.(page 214)[149] A CONSORT extension for randomized pilot and feasibility trials has recently been published with guidance of the type of information that should be reported for pilot RCT versus standard RCT.[194] This check list was published after our paper.

If recruitment went flawlessly, we planned to increase the sample to 30 in each group but ended recruitment with 25 per group due to the slow inclusion. Because of the large number of dropouts at the three-month test, the group with no additional training was excluded from the analysis. Relatively small samples can be a problem if participants differ in characteristics that can affect the results. However, there were no significant differences in background characteristics of the groups. In the protocol for **Study I**, we also planned a test at six months, which would have been a longer follow-up timeframe than other studies. Due to the large number of dropouts at the three month test, the six month test was not conducted. A reason for the high dropout rate could be that the three-month period was too long to hold the participants' interest, and a test after one month should probably have been included as well. On the other hand, one other study[87] also had a large dropout rate of 43.2% at the two-month mark, even with one test conducted after one month. A two-group design from the beginning would have been more appropriate based on the experience from the long inclusion time and the high dropout rate. In retrospect, we could also have let the group without additional training perform the post-test I instead of the pre-test (**Study I**).

The intervention in Study I: The results and feedback from the participating nurses indicated that the training programs needed some improvement (**Study I**). The main reason for our study was to test if one educational tool (e-learning) was more effective than the other (PowerPoint lecture in classroom) at teaching nurses how to classify PUs and how to use a risk assessment tool. We did not achieve a large improvement with either training method, which may be related to several factors. First, we may have included more material than the nurses could handle in one day. Participants communicated that there was too much to do in one sitting (pre-test, training, and post-test I) and too many tasks – especially in the post-test I classification test with 40 photos. The amount of information and testing presented in one day may have affected the post-test I results (**Study I**). We allowed helping aids during pre-test, which may have contributed to higher pre-test scores. The small sample size may have contributed to the lack of significant findings. Based on the feedback, some of the slides/pages in the adjusted program used in **Study II** were clarified linguistically. The largest differences between the methods used in **Studies I and II** were that the data collectors did a post-test only after training and the classification tests were web-based so the 20 photos were probably clearer than on the paper version of the test (**Study II**). The results of the intervention study (**Study I**) suggest that it might be more efficient to test each module in separate studies as other studies have done with more success (Tables 3 and 4).

For the sample in **Study II**, all hospitals in the South-Eastern Norway Regional Health Authority were invited to participate. Of the 11 hospitals invited, six agreed to participate. A total of 1,334 forms were collected on the data collection day. The 125 patients excluded in **Study II** were 9.4% of the eligible sample in the study. However, the excluded patients were younger and probably at less risk of PUs and would likely not have increased the prevalence rate found in the study. In other words, if all patients were included and none of the excluded patients had a PU, the overall prevalence would still be 16.5%.

All three studies used voluntarily participating nurses and hospitals. Even though the participating nurses in **Study I** were from different locations and the hospitals participating in **Studies II** and **III** differed in terms of size and wards included, the convenience sample may have introduced a selection bias.[195] We have no data on the hospitals that did not participate or on those who did not answer the patient safety culture study questionnaire. We were therefore not able to conduct a non-response analysis. It is possible that the hospitals, wards, and nurses that participated in the studies were already interested in PU prevention and patient safety.

In **Study III** some of the included wards had a low response rate on the SAQ-questions. This is a limitation, and the low response rate may have influenced the external validity of the results. We had no opportunity to increase the response rate with reminders since we received the data as reports after the study was conducted. We included all the wards, even those for which response rates were low.

Even though our sample was small compared to national studies, the sample used in **Studies II** and **III** consisted of 84 to 88 wards and 1,056 to 1,209 patients, making it possible to achieve statistically significant findings. However, the HAPU patient number was too small to include a large number of predictor variables in the explanatory models of **Study III**. The rule of thumb for logistic regression is 10 cases (HAPUs) per included independent variable.[196] The list of variables included in the studies is not exhaustive and other factors not investigated may have an important impact on the investigated association. However, the included variables have been found significant or with inconclusive findings in other studies. Furthermore, some of the variables included in this thesis may not strictly be a part of structure or process; there may be overlap between these categories.

Patients were recruited from several hospital sites, which is a strength. No variance was found at the hospital level (**Study II**) indicating equal PU odds across hospitals. The use of PU prevalence data may also be a strength when testing the relationship with organizational risk factors such as patient safety culture. Many other studies have used discharge codes[115 175] or nurse-reported estimates[118 125] as data when investigating the association between PUs and patient safety. Nurse-reported estimates may be subject to recall bias and PU discharge codes may underestimate the PUs, as many PUs are probably not documented in patient records.[197 198]

Study II shows descriptive statistics for all PUs, localisation and number of PUs in each category, and whether preventive measures were implemented for at-risk patients. This was a point prevalence study that provided a snapshot of the situation at a particular point in time, at 7 a.m. on one day. The point of using an empty model in **Study II** was to investigate whether there was across-unit or hospital variance in the material or whether all the variance was at patient level. We did not ask what caused such variation; this question was approached only in **Study III**. Thus, **Study II** considered whether multilevel regression was required for the subsequent explanatory analysis in **Study III**. **Study II** only showed the variance partitioned by level and may be seen as a preliminary analysis for **Study III**. **Study III** includes only PUs that became visible during hospital stay (HAPUs). This is a proxy measure for a PU incidence. This study was designed to investigate the association between patient and organizational variables and HAPU development.

Training in risk assessment and classification is an important part of the EPUAP method as it assures more reliable data collection. The nurses who collected the data used in **Studies II** and **III** were trained to assess risk and classify PUs in the different categories. This training is a strength in our research. Even with training, potential bias in finger-press tests and the differentiation of blanching and nonblanching erythema may have occurred as shown in other studies.[199] If an area of skin blanches under pressure from a finger and turns red again when pressure is released, this area has good circulation.[200] As our results showed 60% category I PUs, which is a higher rate than in other studies, it is possible that some nurses misclassified blanching erythema as category I PUs. The results from the classification test in

Study I showed that the percentage of correct assessments of "normal skin" and "category I PUs" increased after training, especially for the e-learning training group. A review of research on the reliability of PU staging showed limited and variable reliability of PU identification and classification in the 10 studies included[201] and discussion is ongoing about whether the number of PU categories should be limited to reduce classification failure. Incorrect PU classification could have been revealed with a more thorough test-retest with some of the patients. No such test was undertaken in this thesis. Including category I, with the possible misclassifications may be a limitation for the models in **Study III**; however, reviews have recommended inclusion of category I PUs in multilevel models.[20]

A 2008 review addresses how organizational structure and processes affect quality of care and discusses several limitations of the included studies.[40] One recommendation from this review was to increase the use of multilevel analysis to adjust for nesting/clustering in data. Another recommendation was to include all three components of structure, process, and outcome measures in studies. Studies that measured only structure and process or process and outcomes had more significant findings than structure-outcome studies.[40] We have therefore included multilevel analysis, used ward-level aggregation, and adjusted the outcome measure for both structure and process variables in the model in **Study III**. As quality of care and patient safety are local phenomena, ward level analysis is important. Multilevel analysis including ward level has also been used in other recent studies investigating patient safety culture and association with PUs.[115 118 124 125] However, two of these studies used nurse-reported outcome measures[118 125] and another used discharge data.[115]

To collect prevalence data, we used a well-documented method that was developed and tested by PU experts in the EPUAP collaboration. We used pairs of nurses in our data collection as recommended by the EPUAP. One study of nursing homes, including data from 5,493 patients, did not find significant differences in PU prevalence when data was collected by single collectors (n=1269 patients) or teams (n=4224 patients).[202] The effect of using single collectors or teams should be further investigated as the management in the participating wards in our study gave feedback that our data collection method was staffing demanding.

The overall aim of this research was to develop knowledge regarding the epidemiology of PU in Norwegian hospitals. Such knowledge is necessary to evaluate quality of care and ultimately to improve nursing care quality and patient safety. However, quality involves both the technical and interpersonal aspect of care. Thus, epidemiological studies should be supplemented with studies focused on the interpersonal aspects of care to provide a more thorough evaluation of care quality.

We could have chosen a qualitative approach to investigate the acceptability and feasibility of the intervention in **Study I**. A focus group interview in each group in **Study I** could have substantiated the results, and the nurses could have suggested changes to the e-learning program. This would have been more valuable to program improvement than the voluntary written feedback we received. Interviews with nurses and nurse leaders participating in **Study II** and **III** could have identified activities that might promote safety culture within the wards. A qualitative approach could have been used to explore factors that affect the PU prevalence and the level of knowledge and skills in greater detail.[40] Mixed methods approaches that combine quantitative and qualitative methods are becoming more common in scientific research. In retrospect, including a qualitative approach may have strengthened the design of this thesis.

6. Conclusion

PUs present a challenge in Norwegian healthcare and there is insufficient implementation of evidence-based preventive measures for a large number of at-risk patients. Organizational factors, as well as patient risk factors, were significantly related to the HAPU odds. Increased focus on patient safety is important, as a strong ward patient safety culture was significantly associated with lower odds for HAPUs. An important aspect of good patient safety is the health personnel's knowledge. Knowledge about risk assessment and correct classification of PUs is important for identifying at-risk patients and initiating prevention. Repeated training may lead to improved PU prevention.

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PAPERS I-III

I

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Effect of e-learning program on risk assessment and pressure ulcer classification — A randomized study

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ABSTRACT

Background: Pressure ulcers (PUs) are a problem in health care. Staff competency is paramount to PU prevention. Education is essential to increase skills in pressure ulcer classification and risk assessment. Currently, no pressure ulcer learning programs are available in Norwegian.
Objectives: Develop and test an e-learning program for assessment of pressure ulcer risk and pressure ulcer classification.
Methods: Design, participants and setting: Forty-four nurses working in acute care hospital wards or nursing homes participated and were assigned randomly into two groups: an e-learning program group (intervention) and a traditional classroom lecture group (control). Data was collected immediately before and after training, and again after three months. The study was conducted at one nursing home and two hospitals between May and December 2012.
Analysis: Accuracy of risk assessment (five patient cases) and pressure ulcer classification (40 photos [normal skin, pressure ulcer categories I–IV] split in two sets) were measured by comparing nurse evaluations in each of the two groups to a pre-established standard based on ratings by experts in pressure ulcer classification and risk assessment. Inter-rater reliability was measured by exact percent agreement and multi-rater Fleiss kappa. A Mann–Whitney U test was used for continuous sum score variables.
Results: An e-learning program did not improve Braden subscale scoring. For pressure ulcer classification, however, the intervention group scored significantly higher than the control group on several of the categories in post-test immediately after training. However, after three months there were no significant differences in classification skills between the groups.
Conclusion: An e-learning program appears to have a greater effect on the accuracy of pressure ulcer classification than classroom teaching in the short term. For proficiency in Braden scoring, no significant effect of educational methods on learning results was detected.

1. Introduction

Pressure ulcers (PUs) are a problem in health care with a PU prevalence ranging from 0% to 46% in acute care and 4.1% to 32.2% in nursing home settings (National Pressure Ulcer Advisory Panel, 2014). Most PUs can be prevented. Staff competency in skin assessment and identification of patient risk factors are paramount to prevention (National Pressure Ulcer Advisory Panel, 2014). Yet a Norwegian PU prevalence pilot study showed deficient knowledge among nursing staff in terms of reliable classification of PU and PU risk assessment (Bjøro and Ribu, 2009). However, currently no PU learning programs are available in Norwegian, thus development of a program for PU classification and risk assessment is deemed necessary.

E-learning programs are commonly considered an efficient and effective means of training large numbers of nurses, yet few studies have been conducted to develop and test the effect of e-learning programs on PU risk assessment and classification. Reviews have found that web-based training/e-learning program and traditional classroom instruction require equal administration time, and no differences have been found in staff knowledge or skills acquisition (Cook et al., 2008,

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2010, Lahti et al., 2014, Militello et al., 2014). Thus, more research is needed to test the effectiveness of e-learning programs as a mode of teaching nurses PU classification and risk factor identification.

2. Background

Few studies have investigated the effect of training in use of a PU risk assessment tool. The Braden Scale for Predicting Pressure Ulcer Risk (Braden scale) was developed to help health professionals; especially nurses assess a patient's risk of developing a PU (Bergstrom et al., 1987a, 1987b). Braden scale is the most used and tested PU risk assessment tool. The scale includes six subscales (sensory perception, moisture, activity, mobility, nutrition and friction/shear). Each subscale is rated from one (worst condition) to four, with the exception of friction/shear rated one to three. This gives a sum score from six to 23, the lower the sum score, the higher the risk. Web-based training in risk assessment with the Braden scale increased performance (Magnan and Maklebust, 2008, 2009). New users of the Braden scale increased the accuracy of their subscale scoring significantly after training, whereas regular users of the scale did not increase their subscale scorings significantly (Magnan and Maklebust, 2009). Furthermore, in a post-test only study, regular users of the Braden scale correctly identified significantly more patient cases with high risk and moderate risk than new users (Magnan and Maklebust, 2008).

Studies investigating the effect of training on PU classification have shown that training improves performance (Beeckman et al., 2008, 2010, Ham et al., 2015). In a repeated measures design study, Beeckman and colleagues compared the effect of an e-learning (PUCLAS2, Pressure Ulcer Classification tool) and a classroom program with the same content on PU classification in a sample of nurses and nursing students (Beeckman et al., 2008). While both programs increased PU classification skills, the nursing students achieved better results with the e-learning program. In the nurse group, no differences between the methods were found (Beeckman et al., 2008). Beeckman et al. (2010) compared the classification skills of a group receiving PUCLAS2 as a one-hour classroom training with another group receiving a 15-min standardized rehearsal of the EPUAP classification system. Results showed increased classification skills in both groups, but significantly more so for the group receiving PUCLAS2. A one-group study involving classroom training found significant improvement in PU classification skills after training of emergency staff (Ham et al., 2015).

Most studies of training in risk assessment and classification have compared either an e-learning program or classroom training to a control group with no additional training or an alternative method of training. As far as we know, few studies have used a program with the same content to compare an e-learning program and classroom training in an RCT (Beeckman et al., 2008). Furthermore, we have found no studies testing both skills in PU classification and the use of a PU risk assessment scale in the same study.

Regularly updating knowledge is a challenge in health care. Often hospital wards experience high turnover and health care personnel have problems finding time to leave the ward for in-service education due to workload demands. Therefore, efficient methods of training nurses are needed.

3. Purpose and research questions

The purpose of this intervention study was to develop and test an e-learning program for assessment of PU risk factors and PU classification in a Norwegian setting. The research questions for the study were: 1) Is an e-learning program more effective than classroom lecture training for learning the use of a risk assessment scale and 2) Is an e-learning program more effective than classroom lecture training for learning PU classification?

4. Methods

4.1. Design

Participants were randomly assigned to one of two groups: the intervention group (e-learning program) and a control group (classroom lecture training). Three tests were carried out: a baseline pre-test before training, a post-test immediately after training (post-test I), and a three month follow-up test (post-test II). The effect of the intervention was measured by the post-test immediately after training.

The study protocol included a third group without additional training and a test six months after training, but because of massive dropout, we excluded this group and test from this study. Data were collected between May and December 2012.

4.2. Ethics

The privacy protection officials of each investigating hospital approved the study. All participating nurses gave written consent.

4.3. Setting and sample

Nurses from two hospitals and four nursing homes participated. Inclusion criteria: 1) registered nurse 2) employed in acute care hospital or nursing home. Testing was conducted at one nursing home and two hospitals.

We included 25 nurses in each group. We used block randomization with six in each block to ensure even distribution within the groups (Lin et al., 2015). A study coordinator prepared the randomization using closed, opaque numbered envelopes to conceal group allocation. When a participant who met the inclusion criteria agreed to participate, the principal investigator opened an envelope to assign group. The participant received information regarding the time and place of the testing. Information about their group allocation was given the day they performed testing. The study has reference number NCT01567410 in the Clinical Trials.gov Protocol Registration System (http://clinicaltrials.gov/).

Before the pre-test, the participants completed a form with questions about personal information including gender, work place, education and work experience. Five participants did not show up on test day, and one of those who came had not completed the necessary pre-test forms. Forty-four participants completed the pre-test. All forty-four nurses in the two groups completed the post-test immediately following the training. Eighteen nurses completed the post-test after three months (Fig. 1).

4.4. Development of the training programs

No training program was available in Norwegian for either the use of the Braden risk assessment scale or PU classification. Therefore, we developed two individual training programs, one for the use of the Braden scale and one for PU classification.

Pedagogical principles guided the development of the training programs including motivation for learning, active engagement of the learner, concrete material facilitate learning and individualization allowing learners to work at their own space (Hiim and Hippe, 2004).

4.5. The Braden scale program

One of the co-authors (KB) had previously translated the Braden scale into Norwegian. The Braden scale training program was based on patient cases published in an instructional CD purchased from the Braden scale homepage (www.bradenscale.com), other studies (Maklebust et al., 2005) and from a web site based on the Braden scale instructional CD (http://ced.muhealth.org/resources/bradenCD/menu.html), as well as on cases from our own experience. Each case

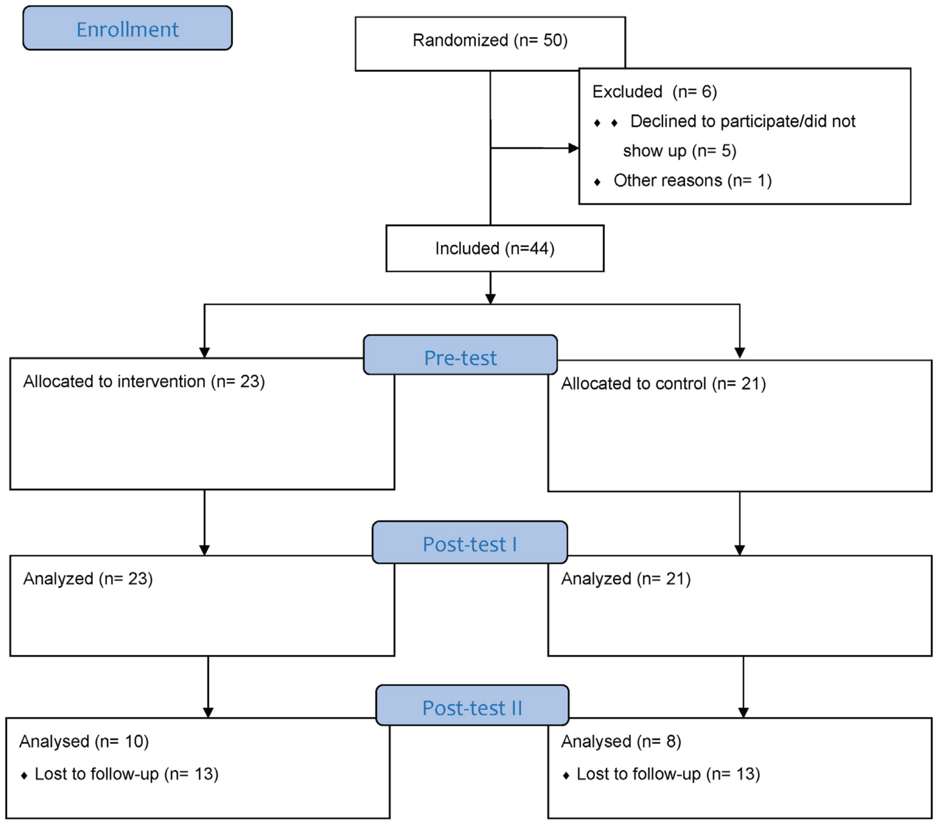

Fig. 1. Flow chart of participants for the current study.

contained patient information necessary to score each of the six subscales of the Braden scale. For the cases from the CD and website and from other studies, the cases' authors gave the correct assessment. For the cases from our own experience, our research group determined the correct assessment. The initial set included 13 cases illustrating different risk levels.

We validated the patient cases in two phases of testing. We recruited a group of five experienced nurses to score 13 cases each. We then compared the expert nurses' responses to the correct response. The exact percent agreement for the mean subscale scores for each case ranged from 53.3% to 90%. We revised case texts on the basis of nurses' responses.

We validated the revised version of the 13 cases in a new group of four expert nurses, all experienced in PU prevention. This second group of nurses had a higher exact percent agreement than the first group with scores ranging from 62.5% to 95.8%. This step was primarily designed to select the cases that were most clear-cut and interpretable. The final set of patient cases used in the program and testing included the eight cases (at different risk levels) that received the highest agreement scores from the second test group.

The Braden scale training program included a general definition of PU, followed by a presentation of the Braden scale with individual slides to present each of the six subscales, the scoring system and the scale risk levels ("Not at risk" to "Very high risk") (Bergstrom et al., 1987a, 1987b). We used one case to illustrate the scoring levels of each subscale and to demonstrate the scoring of the subscale and total score.

4.6. The PU classification program

The training program for PU classification contained a definition of PU and the four PU categories (National Pressure Ulcer Advisory Panel, 2014), as well as a description of suspected deep tissue injury and unstageable PUs as category IV. We used photos as well as a schematic illustration for each ulcer category. We included instructions on how to classify redness of skin. We also presented the differences between PUs and Incontinence-Associated Dermatitis (IAD). We used PU photos purchased from the National Pressure Ulcer Advisory Panel (NPUAP), the categories of which had been determined by NPUAP experts.

4.7. E-learning system

The e-learning program was mounted on the Mohive e-Learning Publishing System (http://www.crossknowledge.com/en_US/elearning/technologies/mohive.html) used by the South-Eastern Norway Regional Health Authority and familiar to hospital nurses participating in the study. The e-learning program was not available online during the testing period. Therefore, a link to the program was placed on the desktop of each computer and the program was only available to the participating nurses in the e-learning group during the testing.

4.8. The testing of the intervention

We constructed three test sets for the Braden scale, each consisting of five cases. All three test sets included three cases: one very high risk, one medium risk and one not at risk. We replaced two cases and changed the order of the cases in each test set to reduce the effect of learning bias.

The competence test for the classification program consisted of 40 photos of PUs representing different categories (normal skin, categories I–IV). We used NPUAP photos both in the training program and in the tests. In order to ensure comparability of test results between the groups, the test photos as well as the competence tests were printed on paper. We divided the photos into two sets, as shown in Table 1. In post-test II we used a random selection of 20 of the 40 photos

Table 1
Number of photos per PU category in the in the photo tests.

	Set A (20)	Set B (20)	Set A + B (40)	3 months
Normal skin	1	3	4	1
Category I	5	0	5	3
Category II	4	2	6	4
Category III	6	6	12	6
Category IV	4	9	13	6

(Table 1). To minimize recognition, the order of photos was changed in each of the tests.

Because the Braden scale is not a well-known assessment tool in Norway, an explanation of the Braden scale and an illustration of the PU categories were included as an aid during testing. After the pre-test, the intervention group and classroom group proceeded immediately to the training modules. The intervention and classroom training groups received training identical in content. The participants in the e-learning program group worked independently with their program in a computer room, each on his/her own terminal. A research assistant oversaw the training and made sure participants did not communicate with each other while completing the program. The classroom group received a traditional lecture delivered by an experienced nurse using a PowerPoint presentation. The lecture lasted about 45 min and allowed for questions from the participants.

4.9. Outcome measures

The outcome measures were the number of correct Braden subscale scores of patient cases and the number of PU photos correctly classified before and after training.

4.10. Data analysis

All the test variables were dichotomized into correct or incorrect answers compared to the predetermined correct answer. Missing data was registered as an incorrect answer. We calculated the exact percent agreement (number of observed agreements that match exactly the gold standard divided by the number of possible agreements × 100) for the six Braden subscales and for the PU photos (normal skin and the four categories) respectively. We focused on the Braden subscale scores since the total score may camouflage variation in risk scores across subscales. Due to small sample size, comparisons between groups were analyzed with a Chi-square test or a Fisher Exact test for categorical variables and a Mann–Whitney U test for continuous variables. The chosen significance level was $p < .05$.

To adjust for chance agreement, the multi-rater Fleiss' kappa were calculated for the Braden subscales and for all the photos in each photo set. We used the Fleiss' kappa because it measures group agreement, whereas Cohen's kappa only measures the agreement between two participants. The values of the Fleiss' kappa vary from −1 to 1, where kappa values below 0.2 are considered poor, while values above 0.60 are good agreement (Altman, 1991). Data were analyzed using SPSS 21 and the Statstodo web-based calculator for the Fleiss' kappa (https://www.statstodo.com/CohenKappa_Pgm.php).

5. Results

The majority of participants were female (97.7%) and worked at hospitals (81.8%). The nurses' work experience ranged from zero years to 32 years, and over half of the participants had six years work experience or more. Slightly more than 10% of the participating nurses had postgraduate specialization. There were no significant differences in these characteristics across the two groups (Table 2).

The dropout rate for the three-month test for the total sample was 59%. The dropout rate was high in both groups (Fig. 1).

Table 2
Characteristics of study participants.

	E-learning n = 23 n (%)	Classroom n = 21 n (%)	Total N = 44 n (%)
Education			
Bachelor	22 (95.7)	17(81)	39 (88.6)
Postgraduate specialization	1 (4.3)	4 (19)	5 (11.4)
Workplace			
Hospital	20 (87)	16 (76.2)	36 (81.8)
Nursing home	3 (13)	5 (23.8)	8 (18.2)
Work experience			
0–2 years	2 (8.7)	3 (14.3)	5 (16.4)
3–5 years	9 (39.1)	3 (14.3)	12 (27.3)
>6 years	12 (52.2)	15 (71.4)	27 (61.4)

Chi-square/Fisher Exact test not significant between the two groups.

5.1. Braden scale risk assessment

No significant Braden subscale score differences were found between the groups in any of the three tests, either for categorical variables (Table 3) or for subscale sum scores between the groups in pre-test and post-test I (data not shown). We calculated the Fleiss' kappa for each subscale for both groups in all tests. The Fleiss' kappa had a range from −0.05 to 0.59.

5.2. PU classification

In post-test I immediately after the training, the e-learning program group scored significantly higher than the classroom group on all categories except category IV when comparing the same photo set used in the pre-test (photo set A) (Table 4). A Mann–Whitney U test showed significant differences between the group sum scores for the same photo set used in pre-test and post-test 1 U = 126,0, z = −2738, $p = .006$. In the set with the 20 photos used only in post-test I (photo set B) and for the scores in post-test II, there were no significant differences between the two groups (Table 4). The Fleiss' kappa scores for all photos in each photo set ranged from 0.13 to 0.29.

6. Discussion

No significant differences were found in Braden subscale scores between the e-learning program group and the classroom group in any of the three tests. For the PU classification program, the e-learning program group scored significantly better than the classroom group in some of the categories in the post-test immediately after training.

6.1. Braden scale risk assessment

The Braden training program had no effect on the risk assessment of subscales in our study. Magnan and Maklebust (2009) found that a web-based Braden training program increased assessment accuracy, measured by exact percent agreement, in the post-test compared to the pre-test for new users of the Braden scale. According to our results, the nurses did quite well in the pre-test but did not increase their accuracy scores in the post-test immediately after training. In comparison, our intervention group had lower accuracy scores for the subscales than did the new users in the sample from Magnan and Maklebust (2009).

6.2. PU classification

In our study, the PU classification training program had a short-term effect for the intervention group compared to the classroom group in post-test I. Beeckman et al. (2008) also compared classroom and e-learning programs, and found that both groups improved significantly

Table 3
Exact agreement and Fleiss' kappa scores for Braden subscales in pre- and post-tests by groups.

Pre-test	E-learning (n = 23)		Classroom (n = 21)		p-Value	Total (N = 44)
	Agreement (%)	Fleiss' kappa (95% CI)	Agreement (%)	Fleiss' kappa (95% CI)		Agreement (%)
Sensory perception	86/115 (74.8)	0.22 (0.17–0.28)	82/105 (78.1)	0.08 (0.02–0.14)	.563	168/220 (76.4)
Moisture	90/115 (78.3)	0.03 (0.02–0.09)	85/105 (81)	0.01 (−0.06–0.07)	.621	175/220 (79.5)
Activity	92/115 (80)	−0.01 (−0.07–0.04)	79/105 (75.2)	0.01 (−0.05–0.07)	.396	171/220 (77.7)
Mobility	99/115 (86.1)	0.01 (−0.05–0.07)	85/105 (81)	0.12 (0.06–0.18)	.304	184/220 (83.6)
Nutrition	89/115 (77.4)	0.10 (0.05–0.16)	79/105 (75.2)	0.22 (0.16–0.28)	.707	168/220 (76.4)
Friction/shear	103/115 (89.6)	0.03 (−0.03–0.08)	91/105 (86.7)	0.05 (−0.01–0.11)	.506	194/220 (88.2)
Post-test I	(n = 23)		(n = 21)		p-Value	(N = 44)
Sensory perception	82/115 (71.3)	0.07 (0.02–0.13)	69/105 (65.7)	0.25 (0.19–0.31)	.372	151/220 (68.6)
Moisture	76/115 (66.1)	0.04 (−0.01–0.10)	63/105 (60)	0.15 (0.06–0.21)	.350	139/220 (63.2)
Activity	73/115 (63.5)	0.05 (−0.01–0.10)	62/105 (59)	0.16 (0.10–0.22)	.500	135/220 (61.2)
Mobility	79/115 (68.7)	0.08 (0.02–0.13)	73/105 (69.5)	0.21 (0.15–0.27)	.894	152/220 (69.1)
Nutrition	71/115 (61.7)	0.15 (0.09–0.20)	58/105 (55.2)	0.25 (0.19–0.31)	.328	129/220 (58.6)
Friction/shear	79/115 (68.7)	−0.01 (−0.07–0.04)	65/105 (61.9)	0.15 (0.09–0.21)	.290	144/220 (65.5)
Post-test II	(n = 10)		(n = 8)		p-Value	(n = 18)
Sensory perception	40/50 (80)	0.19 (0.06–0.33)	33/40 (82.5)	0.13 (−0.03–0.30)	.763	73/90 (81.1)
Moisture	42/50 (89)	−0.03 (−0.16–0.11)	32/40 (80)	0.24 (0.08–0.41)	.622	74/90 (82.2)
Activity	35/50 (70)	−0.05 (−0.18–0.08)	29/40 (72.5)	0.19 (0.03–0.36)	.795	64/90 (71.1)
Mobility	40/50 (80)	0.53 (0.40–0.66)	35/40 (87.5)	0.05 (−0.11–0.22)	.343	75/90 (83.3)
Nutrition	38/50 (76)	0.59 (0.46–0.72)	35/40 (87.5)	0.51 (0.34–0.68)	.166	73/90 (81.1)
Friction/shear	41/50 (82)	−0.04 (−0.17–0.09)	35/40 (87.5)	0.12 (−0.05–0.28)	.474	76/90 (84.4)

Chi-square/Fisher Exact test for p-value between the groups exact agreement.

in the post-test compared to the pre-test and significantly more in their e-learning program group. However, this study had a mixed sample of nursing students and registered nurses. In contrast to findings in the total sample, a sub analysis of only the registered nurses group found no differences between training methods in either of their post-tests (Beeckman et al., 2008). An explanation of the better results for the e-learning program in our study compared to the sub group of nurses in the Beeckman et al. (2008) study may be the high number of newly graduated nurses in our e-learning program group. The seven-year difference between data collection in these two studies has to be taken into account. Our nurses may have been more familiar with e-learning programs as well as with using a computer.

A one-group study also found significant improvement in classification skills for the group receiving a power-point presentation based on the PUCLAS2 tool (Ham et al., 2015). In their study Ham et al. (2015) had higher exact agreement in their post-test than we did in our classroom group. However, they had only half the number of photos included in their test and only tested staff working in an emergency ward, which may have influenced the scoring accuracy.

The comparison of results must take into account the elements of different settings (single and multicenter samples) and the sample sizes in the other studies. Both the Ham et al. (2015) and Beeckman et al. (2008) studies had larger group samples than our study did.

The exact agreement was rather good in our study, but the Fleiss' kappa showed mostly poor agreement across the raters. The kappa values remained low after training, indicating that more training and/or program change is essential for improvement.

The different findings for training effect for PU risk assessment and classification in this study may indicate that a task such as PU classification was easier to learn than the use of the risk assessment instrument. We used written patient cases with limited information, yet PU risk assessment in general is a comprehensive assessment that includes a validated risk assessment scale, skin assessment and clinical judgment (National Pressure Ulcer Advisory Panel, 2014). All these factors help nurses to identify the risk of developing PU and further determine which preventive measures the patient should take, such as type of pressure-redistributing mattress and regular repositioning. This assessment may be more complex than what can be taught by an e-learning program or in traditional classroom training. Magnan and Maklebust (2008) found that when the patient cases were very high or moderate risk, new users with Braden scale training alone were less likely to reliably assess risk compared to regular users with both training and experience working with Braden scale. Training as well as reflection are essential for proficiency in patient risk assessment. In organizations with high turnover and little time for in-service training, e-learning programs could be a good alternative to classroom lecture in-service. However, a variety of training methods should also be used including simulation and group discussion of PU categories and different PU risk patient cases, to increase competency and focus on patient safety.

The non-significant differences between the two risk assessment training methods are similar to findings of systematic reviews. No statistical differences were found between e-learning programs and classroom lecture groups in skills and knowledge improvement in health professions (Cook et al., 2008, Lahti et al., 2014). However, our results for classification training showed significant differences between the training methods, which suggest that more studies are required in the field of e-learning programs, especially for long-term effect.

6.3. Strengths and limitations of the study

The two training programs had the same content. Most training studies have studied one type of training or compared training programs with a slightly different content or a training group to one with no training at all. Our study also included training in both risk assessment and PU classification.

There were limitations to our study. First, we did not do a power calculation prior to this study, thus increasing the risk of Type II error: our sample size was probably too small to detect clinically important differences between the groups for the Braden scale. Confounding factors may have affected the results, but small sample size limits the opportunity for multivariate analysis. Furthermore, the exact percent agreement does not correct for chance agreement and may overestimate the level of agreement. On the contrary, it is easier to compare exact percent agreement with other study results than kappa statistics.

The exclusion of the control group with no additional training (necessitated by the large dropout) limits the long-term effect comparison. Moreover, those who completed the post-test II might have been more interested in PU prevention and more familiar with risk assessment and classification of PU than the dropouts; if correct, this hypothesis would underestimate the training effects. Using real patients instead of photos

Table 4
Percent exact agreement and Fleiss' kappa for the PU classification scores in pre- and post-tests by group.

	Agreement (%)	Agreement (%)	p-Value	Agreement (%)
Pre-test	E-learning (n = 23)	Classroom (n = 21)		Total (N = 44)
Photo set A				
Normal skin	10/23 (43.5)	8/21 (38.1)	.717	18/44 (40.9)
Category I	71/115 (61.7)	64/105 (61)	.905	135/220 (61.4)
Category II	73/92 (79.3)	61/84 (72.6)	.296	134/176 (76.1)
Category III	73/138 (52.9)	80/126 (63.5)	.081	153/264 (58.0)
Category IV	83/92 (90.3)	75/84 (89.3)	.839	158/176 (89.8)
All photos	310/460 (67.4)	288/420 (68.6)	.708	598/880 (68.0)
Fleiss' kappa all photos (95% CI)	0.21 (0.18–0.24)	0.13 (0.09–0.16)		
Post-test I	(n = 23)	(n = 21)	p-Value	(N = 44)
Photo set A				
Normal skin	19/23 (82.6)	10/21 (47.6)	.014	29/44 (65.9)
Category I	85/115 (73.9)	50/105 (47.6)	<.001	135/220 (61.4)
Category II	71/92 (77.2)	52/84 (61.9)	.027	123/176 (69.9)
Category III	90/138 (65.2)	64/126 (50.8)	.018	154/264 (58.3)
Category IV	86/92 (93.5)	78/84 (92.9)	.870	164/176 (93.2)
All photos	351/460 (76.3)	254/420 (60.5)	<.001	605/880 (68.8)
Fleiss' kappa all photos (95% CI)	0.17 (0.14–0.20)	0.24 (0.21–0.27)		
Photo set B				
Normal skin	54/69 (78.3)	45/63 (71.4)	.365	99/132 (75)
Category I	–	–	–	–
Category II	36/46 (78.3)	36/42 (85.7)	.365	72/88 (81.8)
Category III	65/138 (47.1)	66/126 (53.4)	.391	131/264 (49.6)
Category IV	157/207 (75.8)	161/189 (85.2)	.019	318/396 (80.3)
All photos	312/460 (67.8)	308/420 (73.3)	.074	620/880 (70.5)
Fleiss' kappa all photos (95% CI)	0.22 (0.19–0.35)	0.29 (0.26–0.32)		
Photo set A + B				
Normal skin	73/92 (79.4)	55/84 (65.5)	.039	128/176 (72.7)
Category I	85/115 (73.9)	50/105 (47.6)	<.001	135/220 (61.4)
Category II	107/138 (77.5)	88/126 (69.8)	.155	195/264 (73.9)
Category III	155/276 (56.2)	130/252 (51.6)	.292	285/528 (54)
Category IV	243/299 (81.3)	239/273 (87.5)	.039	482/572 (84.3)
All photos	663/920 (72.1)	562/840 (66.9)	.019	1225/1760 (69.6)
Fleiss' kappa all photos (95% CI)	0.20 (0.18–0.22)	0.27 (0.25–0.29)		
Post-test II	(n = 10)	(n = 8)	p-Value	(n = 18)
Normal skin	6/10 (60)	7/8 (87.5)	.196	13/18 (72.2)
Category I	14/30 (46.7)	9/24 (37.5)	.498	23/54 (42.6)
Category II	28/40 (70)	28/32 (87.5)	.076	56/72 (77.8)
Category III	36/60 (60)	35/42 (83.3)	.012	71/102 (69.6)
Category IV	44/60 (73.3)	32/42 (76.2)	.745	76/102 (74.5)
All photos	128/200 (64)	111/160 (69.4)	.283	239/360 (66.4)
Fleiss' kappa all photos (95% CI)	0.22 (0.16–0.29)	0.17 (0.09–0.25)		

Chi-square/Fisher Exact test for p-value between groups exact agreement.

and written cases could have strengthened the study, but would also have prolonged the data collection period. Because a further adjusted version of these training programs was to be included in a larger PU prevalence study later the same year, a prolonged data collection period was not possible.

In retrospect, the Braden scale test should have included the same five cases in each test. Moreover, in the PU classification test, all photos should have been included in post-test II for improved analysis. The replacement of two cases in each of the Braden scale tests may have had an impact on the poor accuracy of the results. The cases may require more refinement to achieve more accurate scoring between the nurses.

We did not ask the nurses about their computer knowledge and preferred learning method. As most hospitals and nursing homes have implemented electronic documentation systems long ago, one may assume the respondents were not unfamiliar with computer output and input. Nurse participation was voluntary, and this may affect the external validity: the participating nurses may be more PU-conscious than the average nurse, which could be a possible reason for the small skill improvement findings.

6.4. Clinical implications

In order to ensure patient safety and meet patients' fundamental care needs, fundamental knowledge, practical skills and techniques of nursing, along with interaction between nurse and patients, are important (Kitson et al., 2014). Knowing how to assess risk and skin is important in patient care and for patient safety issues. Several studies have shown that fundamental PU knowledge is lacking among nurses, and it is important to find efficient ways to both increase and maintain knowledge; this remains a challenge. Nursing schools have a responsibility to increase nurses' knowledge about PU assessment and prevention. In addition, hospital wards and other health care institutions need to include PU assessment and prevention training in their orientation of new hires and continue it with in-service education. Pocket cards listing the most important PU risk factors as well as the different PU categories may also be a reminder supplementing continuing education. Training is essential for valid and reliable data collection in studies. Implementation of PU risk assessment and correct classification of PUs is essential since a PU is an indicator of the quality of care (National Pressure Ulcer Advisory Panel, 2014). As it is readily available, an e-learning program may be preferable as a method for continuous improvement subsequent to a test of accuracy.

7. Conclusion

Continuing education is essential for maintaining and increasing nurse proficiency in PU risk assessment and PU classification. The high workload on wards may represent a challenge to attendance at traditional classroom lectures, as they require more planning, an educator, and a lecture room. We found equal or better results for our e-learning program compared to classroom lectures. An e-learning program may be a more efficient method as the nurses can take the program at their own convenience. Moreover, they can repeat the program and testing until they achieve a proficient level.

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Competing interest

The authors declare that they have no competing interests.

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The prevalence, prevention and multilevel variance of pressure ulcers in Norwegian hospitals: A cross-sectional study

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ABSTRACT

Background: Pressure ulcers are preventable adverse events. Organizational differences may influence the quality of prevention across wards and hospitals.
Objective: To investigate the prevalence of pressure ulcers, patient-related risk factors, the use of preventive measures and how much of the pressure ulcer variance is at patient, ward and hospital level.
Design: A cross-sectional study.
Setting: Six of the 11 invited hospitals in South-Eastern Norway agreed to participate.
Participants: Inpatients ≥18 years at 88 somatic hospital wards ($N = 1209$). Patients in paediatric and maternity wards and day surgery patients were excluded.
Methods: The methodology for pressure ulcer prevalence studies developed by the European Pressure Ulcer Advisory Panel was used, including demographic data, the Braden scale, skin assessment, the location and severity of pressure ulcers and preventive measures. Multilevel analysis was used to investigate variance across hierarchical levels.
Results: The prevalence was 18.2% for pressure ulcer category I–IV, 7.2% when category I was excluded. Among patients at risk of pressure ulcers, 44.3% had pressure redistributing support surfaces in bed and only 22.3% received planned repositioning in bed. Multilevel analysis showed that although the dominant part of the variance in the occurrence of pressure ulcers was at patient level there was also a significant amount of variance at ward level. There was, however, no significant variance at hospital level.
Conclusions: Pressure ulcer prevalence in this Norwegian sample is similar to comparable European studies. At-risk patients were less likely to receive preventive measures than patients in earlier studies. There was significant variance in the occurrence of pressure ulcers at ward level but not at hospital level, indicating that although interventions for improvement are basically patient related, improvement of procedures and organization at ward level may also be important.

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What is already known about the topic?

- Hospital patients are at risk of pressure ulcer development.
- Reduced activity and mobility are the most powerful predictive risk factors, as well as high age.
- Few studies have examined the impact of organizational structures on pressure ulcer prevalence.

What this paper adds.

- Data on pressure ulcer prevalence of a large sample in Norway.
- Indications that organizational differences across ward units may explain some of the variance in pressure ulcer prevalence.

1. Background

Pressure ulcer (PU) prevention has been included as a quality indicator for nursing care in many patient safety campaigns. It is also a target for the reduction of adverse events in the ongoing Norwegian Patient Safety Programme under the direction of the Ministry of Health and Care Services in Norway. A PU is a skin injury that affects hospitalized patients with impaired health and reduced mobility. Elderly patients are at particularly high risk (National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009).

Patient-related PU risk factors are well documented, but no single patient risk factor can alone explain the risk (Coleman et al., 2013; National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009). However, most PUs can be prevented if effective measures are implemented. Evidence-based guidelines recommend the use of preventive measures including systematic skin examination, risk assessment, bed and chair support surfaces, repositioning and mobilization, and nutritional support (National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009; Reddy et al., 2006). Despite increasing research on the effectiveness of preventive measures of the recent decades, there is still a knowledge deficit in PU prevention among health personnel (Beeckman et al., 2011; Gunningberg et al., 2013b; Meesterberends et al., 2014) and PUs are an all-too-common clinical problem (Dealey et al., 2013; National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009).

There is some evidence that organizational characteristics of hospitals and wards may increase the risk of PU. Sving et al. (2014) found significant differences between both hospital type and ward type and PU prevention. More at-risk patients in a university hospital received pressure-redistributing mattresses than in a general hospital, but more patients in a general hospital received planned repositioning. Furthermore, patients at medical units were more likely to have planned repositioning, but less likely to have pressure-redistributing mattresses than geriatric wards. Bosch et al. (2011) investigated the relationship between organizational culture, team climate and quality of management at ward level and the PU prevalence. They used a model of PU quality management (QM) with 11 QM indicators at institutional level and 8 indicators at ward level. The QM sum scores for institutional and ward levels were positively correlated. However, they were unable to show an association between QM at institutional and ward level and the PU prevalence. Thus more research is needed to clarify whether characteristics of hospitals and wards affect the risk of PU.

Recent European studies have shown PU prevalence rates from 8.3 to 26.7% (Gallagher et al., 2008; Gunningberg et al., 2013a; James et al., 2010; Tannen et al., 2008; Vanderwee et al., 2007, 2011). We are unaware of any recent multi-centre studies from Norwegian hospitals. However, a 2008 pilot study conducted in medical and surgical wards in one university hospital showed a PU prevalence of 18%, indicating that the PU prevalence in Norwegian hospitals may be a significant clinical problem (Bjøro and Ribu, 2009).

Moreover, prior to implementation of the prevention of PU as a target in the National Patient Safety Campaign in Norway in 2012, the description of PU prevalence and current practice in a larger sample of hospitals was deemed appropriate. The main objectives of this study were (1) to describe patient risk factors, the prevalence of PUs and measures to prevent them in a sample of Norwegian hospitals, and (2) to investigate if there is a variance in hospital acquired PU prevalence at patient level and organizational levels (ward and hospital).

2. Methods

2.1. Design

The study was a cross-sectional multi-centre study.

2.2. Setting and sample

Six of the 11 invited hospitals (nine trusts and two private hospitals) in the South-Eastern Norway Regional Health Authority agreed to participate, supplying data from 88 somatic wards. South-Eastern Norway is Norway's largest health region, covering some 50% of the Norwegian population (Helse Sør-Øst, 2013). Data were collected in one day between 9 and 11 October 2012 at each hospital. Inpatients 18 years and above admitted to somatic hospital wards at 07:00 on the data collection day were invited to participate. Day surgery, paediatric and maternity wards were excluded since PUs are rarely observed on such wards (Bours et al., 2002).

As the hospitals varied in organizational structure and size, the concept *ward* was not unambiguous. At some of the participating hospitals, wards are specialized by patient group, disease or conditions, e.g. orthopaedic ward. At other hospitals, wards are more general and include a mixed group of patients, e.g. general surgical ward. Thus, we analyzed descriptive data stratified by the type of ward classified as surgical, medical, intensive care units including postanaesthesia recovery (ICU), oncology and rehabilitation as well as a group called *other*.

2.3. Outcomes

The outcome of primary interest was the prevalence of patients with PUs category I–IV. The secondary outcome was PUs category II–IV. PUs were classified according to the European Pressure Ulcer Advisory Panels (EPUAP)/ National Pressure Ulcer Advisory Panel's (NPUAP) classification: category I: non-blanchable erythema; category II: partial thickness skin loss; category III: full thickness skin loss; and category IV: full thickness tissue loss including also unstageable and suspected deep tissue injury (National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009). To calculate hospital-acquired PU (HAPU) prevalence we included in the numerator only those patients with no documented PU on admission to hospital.

2.4. Variables/instruments

We used the EPUAP methodology (Vanderwee et al., 2007). The adjusted Norwegian version of the EPUAP data collection form was tested in a pilot study (Bjøro and Ribu, 2009). The form includes the following data:

- General information (treatment centre, ward, length of stay (LOS)).
- Patient characteristics included age, gender, residence, height and weight, PUs present or not on hospital admission, elective or emergency admission, and surgical procedure or not within the previous 14 days. Of these variables the original EPUAP form included only age and gender.
- The Braden scale was used to assess risk factors including sensory perception, nutrition, mobility, activity, moisture and shear/friction (Bergstrom et al., 1987). The six subscales produce a total risk score from 6 to 23 with lower scores indicating a higher risk. We used a cut point of below 17 to indicate increased risk as this is the generally accepted cut point in European studies (Vanderwee et al., 2007, 2011). Further we constructed an increased risk-level group including patients with a Braden total score below 17 and/or patients with a PU. Furthermore, the incontinence subscale of the Norton scale was included.
- Skin observation for PU location and category (see Section 2.3).
- PU preventive measures included the type of any pressure-redistributing support surfaces (no special equipment, non-powered or powered device) and the frequency of repositioning in bed and chair (no planned repositioning or repositioning planned every 2, 3 or 4 h). Furthermore, we added a variable regarding elevation of the heels or not in bed.

2.5. Procedure

Each hospital appointed a coordinator responsible for internal logistics. The head nurse of each participating ward appointed at least one registered nurse to perform the data collection.

Data collectors received training by an e-learning program or by a classroom session. The two programs were similar and included training in the classification of PUs (including differentiating PU and incontinence associated dermatitis), risk assessment with the Braden scale, and a review of the study protocol. The training lasted between 2 and 3 h depending on the type of program and the amount of time spent on the tests. For training and calibration purposes all data collectors from the 88 wards completed a Braden scale test scoring five patient cases. Additionally they scored 20 PU pictures for category. The mean exact percent agreement between the data collectors and the set formula ranged from 81.7% to 93.3% on the Braden subscale scores of the five cases. Not all of our data collectors achieved the targeted goal on the classification test of 80% correct classification. However, only 2 of the 44 (4.5%) teams were not adequately prepared.

To further ensure better identification of PUs, we assembled teams of two nurses, assessing each patient on their wards and auditing the patient records, preferably from different wards to reduce the potential for assessment bias. We also developed a detailed guideline for completion of the EPUAP form. The coordinator collected completed anonymous patient registration forms and submitted the forms to the research study team. The forms were scanned and stored on the research server at a university hospital. Participating hospitals received a report with the main results for their own hospital from the research study team.

3. Analysis methods

Descriptive data were analyzed using SPSS (version 18). We used the Chi-square test to compare the age distribution of excluded and included patients. We compared patients with and without PUs using the Chi-square test for gender and age and the Mann–Whitney *U* test for LOS and total Braden score. We interpreted missing data for mattress and repositioning as no pressure redistributing mattress and no planned repositioning respectively.

In order to investigate whether there were differences across hospitals and/or wards regarding the occurrence of HAPUs, the variance of the dependent variable HAPU was partitioned by multilevel analysis using the MLwiN program 2.26 (University of Bristol's Centre for Multilevel Modelling) (Twisk, 2006). Two dichotomous versions of the HAPU outcome variable were analyzed: (1) *No HAPU* versus *HAPU categories I–IV* and (2) *No HAPU or category I HAPU* versus *HAPU categories II–IV*. The three-level model with hospital, ward and patient levels included only five of the six hospitals in the study as one hospital that participated with only one ward was excluded. The two-level model with ward and patient levels included all 88 wards.

The appropriateness of multilevel analysis was investigated by calculating the Intraclass Correlation Coefficient (ICC) of *the empty model* containing no explanatory variables. This model investigates the distribution of the variance of the dependent variable across levels (i.e. hospital/ward/patient) (Field, 2009; Rasbash et al., 2012; Twisk, 2006; Tabachnick and Fidell, 2013). The ICC is the higher level variance fraction of the total variance in HAPU: (hospital variance + ward variance)/(hospital variance + ward variance + patient-level variance). A high ICC indicates that organizational factors may be important in exploring variability in HAPU (Field, 2009). As patient-level variance does not automatically appear in multilevel logistic regression output, we estimated it by using the idea of looking at the logistic model as a latent response model, as suggested by Rabe-Hesketh and Skrondal (2012) and Twisk (2006), who recommend approximating the patient-level variance by the expression $\pi^2/3$.

4. Ethical review

The Norwegian pilot study in 2008 was considered by the Regional Ethics Committee for Medical Research in Eastern Norway to be a quality control study, thus not requiring ethical review board approval. The privacy protection official for each participating hospital approved the multicentre study protocol. Although this study was conducted as an internal quality audit at each hospital, the patients or their relatives received verbal and written information about the study and were informed that they could choose not to participate and that the decision would not affect the care they were given. Data were collected according to the standards laid down by the Declaration of Helsinki. The participating hospitals provided written approval allowing the authors to publish data from the study.

5. Results

A total of 1334 patients were eligible for the study. One hundred and twenty-five patients were excluded because they were on leave from the hospital, did not wish to participate, had not had their skin examined, or were considered too ill to participate. Thus, the final sample included 1209 patients (90.6%) for further analysis. Excluded patients were younger than the included patients (χ^2 = 17.169, p = 0.004).

Approximately 40% of the sample were 70 years or above, over 70% of the patients were admitted to surgical or medical wards (Table 1) and most patients were admitted from home (94.6%). The mean total Braden score was 19.7 (SD 3.4) with a median of 21 (range 8–23). The lowest Braden mean score was 16.7 (SD 4.4) registered in the ICUs. Seventeen percent of all the participating patients were at risk of PU development with a Braden total score less than 17 (Table 1). For the patients with PUs, half were at risk on data collection day based on their total Braden score. About 80% of the patients were continent for both urine and feces.

There was no gender difference between patients with and without PUs (χ^2 = 0.862, p = 0.353); however, age 70 or above (χ^2 = 70.347, $p < 0.001$) differed significantly. Furthermore, the total Braden score for patients with and without PUs differed (PU 16.0 (SD 3.5) versus no PU 20.5 (SD 2.8) ($p < 0.001$)). Patients with PUs had significantly longer LOS (9.7 (SD 12.0) days) than patients with no PUs (8.6 (SD 17.5) days) ($p < 0.001$).

The overall prevalence was 18.2% (220/1209) for PU category I–IV and 7.2% (87/1209) for category II–IV. The HAPU prevalence rate was 15% (182/1209). Intensive care units had the highest prevalence, followed by medical wards. Almost 75% of the patients with PU were admitted to medical or surgical wards (Table 2). In total, 220 patients had 359 PUs, yielding an average of 1.6 PU per patient (range 1–7).

The sacrum and heel were the most common locations of the most severe PUs (Table 2). The elbow, ankle or head were the most common anatomical locations in the category *other location*. For those with the most severe PU on the heel, only 24 of 59 (40.7%) had a cushion/heel protection for elevating the heels in bed.

A total of 305 patients (25.2%) were at risk with a Braden score below 17 and/or with a PU (Table 3), and 51.1% (156 patients) received neither pressure-redistributing mattress nor planned repositioning and 17.7% (54 patients) received both. Of the at-risk patients not

Table 1
Patient characteristic by ward

(N = 1209).

	Surgical wards, n = 480		Medical wards, n = 389		Rehab. wards, n = 99		Oncology wards, n = 139		ICU[a], n = 88		Other wards, n = 14		Total, N = 1209	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Age	476	99.2	384	98.7	99	100	139	100	85	96.6	14	100	1197	99
18–39	71	14.9	51	13.3	18	18.2	11	7.9	13	15.3	1	7.1	165	13.8
40–59	123	25.8	89	23.2	32	32.3	31	22.3	26	30.6	8	57.1	309	25.8
60–69	101	21.1	64	16.7	29	29.3	35	25.2	21	24.7	2	14.3	252	21.1
70–79	89	18.7	81	21.1	12	12.1	41	29.5	15	17.6	2	14.3	240	20.1
80–89	77	16.2	78	20.3	7	7.1	19	13.7	9	10.6	0		190	15.9
>89	15	3.2	21	5.5	1	1	2	1.4	1	1.2	1	7.1	41	3.4
Gender	468	97.5	377	96.9	98	99	138	99.3	88	100	13	92.9	1182	97.8
Female	229	48.9	162	43	30	30.6	76	55.1	32	36.4	4	30.8	533	44.1
Male	239	51.1	215	57	68	69.4	62	44.9	56	63.6	9	69.2	649	55.8
Braden score	465	96.9	355	91.3	97	98	121	87	86	97.7	14	100	1138	94.1
(<17)	58	12.5	69	19.4	17	17.5	11	9.1	38	44.2	1	7.1	194	17

[a] Intensive care units includes both postanaesthesia recovery and intensive care units.

Table 2
PU prevalence, location and category of most severe PU by ward ($N = 1209$).

	Surgical wards, $n = 480$		Medical wards, $n = 389$		Rehab. wards, $n = 99$		Oncology wards, $n = 139$		ICU[a], $n = 88$		Other wards, $n = 14$		Total, $N = 1209$	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
PU prevalence														
Category I–IV	77	16.0	85	21.9	13	13.1	17	12.2	28	31.8	0	0	220	18.2
Category II–IV	30	6.2	30	7.8	8	8.0	7	5.0	12	13.6	0	0	87	7.2
PU documented at admission to hospital	12	15.6	13	15.3	6	46.2	2	11.8	5	17.9	0	0	38	17.3
Location of most severe PU														
Sacrum	26	33.8	34	40.0	5	38.5	6	35.3	9	32.1	0	0	80	36.4
Heel	27	35.1	18	21.2	2	15.4	4	23.5	8	26.8	0	0	59	26.8
Hip	4	5.2	4	4.7	2	15.4	2	11.8	2	7.1	0	0	14	6.4
Other location	20	26.0	29	34.1	4	30.8	5	29.4	9	32.1	0	0	67	30.5
Category of most severe PU														
Category I	47	61.0	55	64.7	5	38.5	10	58.8	16	57.1	0	0	133	60.5
Category II	17	22.1	19	22.4	3	23.1	5	29.4	8	28.6	0	0	52	23.6
Category III	4	5.2	8	9.4	1	7.7	1	5.9	3	10.7	0	0	17	7.7
Category IV	9	11.7	3	3.5	4	30.8	1	5.9	1	3.6	0	0	18	8.2

[a] Intensive care units includes both postanaesthesia recovery and intensive care units.

confined to bed (201 patients), few had preventive measures while seated in a chair. Only 13.9% (28 patients) had a cushion and 2% (4 patients) had planned repositioning while seated. For those patients not at risk, 83.7% (757/904 patients) received no pressure-redistributing mattress.

Multilevel analysis showed that the variance in the presence of HAPUs was primarily at patient level. Still, there was considerable variance at organizational levels: this variance was at ward level and not at hospital level (Table 4). There was less across-ward variance for the dichotomous variable for HAPUs with categories II–IV collapsed into one group, indicating more severe skin damage, compared to the models including all four categories of PUs as one group (ICC 8.12 versus 21.51) (Table 4).

6. Discussion

The 18.2% PU prevalence documented in this Norwegian sample is similar to the prevalence rates of 16.6–18.5% found in comparable European studies (Gallagher et al., 2008; Gunningberg et al., 2013a; Vanderwee et al., 2007). In a Dutch and German study, the Dutch hospitals reported 18.1% PU prevalence whereas in the German the prevalence was only 9% (Tannen et al., 2008). Also other studies have showed a lower PU prevalence than ours. A UK study showed 14.8% (Briggs et al., 2013) and a Belgian national study had 12.1% PU prevalence (Vanderwee et al., 2011).

The PU prevalence at ward level was highest in ICUs, as was the case in the Belgian study (Vanderwee et al., 2011). Even though a high prevalence on these wards is not surprising given the low activity and mobility level and high severity of illnesses of the patients, the Norwegian ICU prevalence was much higher (31.8% vs. 19.9%). The reason for this result is unclear. However, Lahmann et al. (2012) showed that when controlled for surface, repositioning, immobility, shear forces, age and gender, the ICU unit is no longer a high-risk factor for the development of PU. Preventive measures such as mattress and repositioning were documented for over 70% of the patients at risk on ICU wards; however, given their high risk level, all ICU patients at risk should have preventive measures. PU prevalence studies have not been systematically conducted in Norwegian hospitals and thus continuous monitoring and prevention efforts may need to be

Table 3
Preventive measures for patients at risk (Braden score < 17 and/or with PU) by ward ($N = 305$).

	Surgical wards		Medical wards		Rehab. wards		Oncology wards		ICU[a]		Other wards		Total	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Patients at risk	102	21.3	110	28.3	25	25.3	21	15.1	46	52.3	1	7.1	305	25.2
Prevention in bed														
Pressure redistributing mattress	35	34.3	32	29.1	14	56.0	18	85.7	35	76.1	0	0	135	44.3
Heel protection/floating heels	43	42.2	30	27.3	10	40.0	6	28.6	20	43.5	0	0	109	35.7
Planned repositioning	12	11.8	11	10.0	9	36.0	3	14.3	33	71.7	0	0	68	22.3

[a] Intensive care units includes both postanaesthesia recovery and intensive care units.

Table 4
Variance components of the logistic multilevel analysis for (1) no HAPU versus HAPU I–IV and (2) no HAPU/HAPU I versus HAPU categories II–IV.

Model	No HAPU versus HAPU I–IV		No HAPU/HAPU I versus HAPU II–IV	
	Three level ($N = 1136$)	Two level ($N = 1168$)	Three level ($N = 1136$)	Two level ($N = 1168$)
Hospital variance (SE)	0.000 (0.000)[a]		0.000 (0.000)[a]	
Ward variance (SE)	0.921 (0.240)[b]	0.901 (0.227)[b]	13.516 (2.049)[b]	14.225 (2.097)[b]
Patient variance	3.287	3.287	3.287	3.287
Total variance	4.208	4.188	16.803	17.512
ICC ward	21.89	21.51	8.04	8.12

ICC = organizational level variance/total variance × 100.
[a] $p = 0.399$.
[b] $p < 0.001$.

intensified. Older patients are at high risk and two-thirds of the patients with PUs in our study were 70 years or above. Considering the expected increase in the number of elderly patients, hospitals must tailor care to meet the needs of these vulnerable patients (Coleman et al., 2013; National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009).

In our study 60.5% of the PUs were category I. This is a higher rate than shown in comparable studies, which demonstrate a rate of 50.2% or less (Gunningberg et al., 2013a; Vanderwee et al., 2007). This may mean that blanchable erythema or deep tissue injury (DTI) were incorrectly identified as non-blanchable erythema (category I) in our study. Accurate classification of PUs is difficult and studies have shown varying degrees of inter-rater reliability for classification (Bruce et al., 2012). A review article concluded that category I is a major predictor for greater PU severity, and ultrasound has shown evidence of deeper tissue injury in category I PUs than may be identified clinically (Coleman et al., 2013; Low et al., 2010). Thus, in clinical practice it is better to over-diagnose blanchable erythema and implement prevention than to under-diagnose non-blanchable erythema since category I may quickly progress to more serious PU. However, classification of PU in nursing education and in furthering clinical education should be emphasized to improve accuracy in practice and research.

International guidelines (National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009) and a Cochrane review (McInnes et al., 2011) conclude that the use of pressure-redistributing support surfaces in beds and chairs as well as repositioning is important PU preventive measures, especially for those with low mobility. In two previous studies utilizing the EPUAP methodology 71.6% and 91.2% of the patients at risk had either planned repositioning or support surfaces or both in bed (Vanderwee et al., 2007, 2011) but in our study less than half of the patients at risk did. Other studies have also found a much higher percentage of repositioning alone (38.2% and 47%) than our study (Gunningberg et al., 2013a; Vanderwee et al., 2007). Support surfaces are important preventive measures but should be utilized together with repositioning. Our study shows a lack of both indicating an increased risk that these patients may develop more severe categories of PU during their hospital stay. Repositioning is thought to be time-consuming and perhaps this is one reason for the low rate of planned repositioning in our patients.

About 17% of the most severe PUs were documented on admission, showing that not all PUs should be considered a reflection of the quality of care and preventive effort of the patient's current unit. Nevertheless, most PUs develop during the hospital stay: the prevalence of HAPUs was 15% in this study, which may be explained by the infrequent use of preventive measures. Guidelines recommend the use of a valid risk assessment scale together with skin assessment and clinical judgement (National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009) on admission with reassessment conducted when health condition changes during hospitalization. Implementation of these recommendations could probably reduce the PU problem in Norwegian hospitals.

Only half of the patients with PUs were identified as being at risk by the Braden scale on data collection day. However, since this was a point prevalence study, we were not able to determine if the patients had had lower Braden total scores earlier during their hospital stay. The hospital as well as the ward management must facilitate improvements in level of PU attention and knowledge among staff in relation to preventive measures including the use of pressure redistributing support surfaces and repositioning. Some patients are at higher risk than others, and it is important to identify them and tailor their care to their increased susceptibility (National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009).

The dominating result of the multilevel analysis was that most variance was at patient level. Still there was also significant variance at ward level, and the high ICC indicates that multilevel analysis is appropriate.

Ward-related factors might have an impact on the PU problem. Studies show that nurses place PU prevention low on the list in order to prioritize more urgent tasks (Aiken et al., 2013; Samuriwo, 2010). Sving et al. (2014) found a significant difference for type of hospital and ward, showing that PU prevention may be related to the hospital and ward to which one is admitted. However, we found only variance at patient and ward levels. To limit the PU problem, interventions must not aim solely at improving the care of the individual patient but also at developing ward-nursing routines which focus more closely on PU prevention. Wards with a lower prevalence may be regarded as an example of good care that others may learn from. The ward-level variance may also indicate that PU-improvement interventions should not be aimed indiscriminately at entire hospitals. However, there was less variance at ward level for the dichotomous variable collapsing category II–IV (ICC 8.12) than when all four categories were collapsed (ICC 21.51). This difference in variance could be explained by difficulties in classifying category I PU. Outright skin damage, such as a blister, a skin wound or necrosis, is easier to classify as a PU than redness in the skin.

Few PU prevalence studies have used a multilevel approach to take into account the nested structure in health care organizations (Wilborn et al., 2010) and our study shows that the PU prevalence may be associated with organizational differences. It is, however, an empirical question whether the variance in the PU odds at ward level reflects inter-ward differences in organization and quality of care factors such as a higher staff-to-patient ratio or better patient-safety culture on some wards than on others. The variance at ward level may also reflect differences in case mix; some wards may just have more PU high-risk patients than other wards. Further research is warranted to more fully understand the importance of organizational characteristics at hospital and ward level.

One strength of our study is that both smaller and larger hospitals with patients from wards of different specialities were included, even though the study sample includes only one health region and thus cannot be generalized to the entire country. Another strength is the common study protocol based on the well documented methodology from EPUAP used at all participating hospitals and that the data collectors underwent the same training session. However, many variables which might explain PU development were not assessed, such as blood samples (serum hemoglobin, albumin, total protein), the date of PU discovery, the ward where the patient was admitted when the PU first appeared, the use of nutritional supplements, the patient's diagnosis and co-morbidities, and staff knowledge about and attitude to the PU prevention.

About 10% of patients were excluded and these patients were significantly younger. Since older patients have increased risk of PU, our prevalence result may be slightly inflated. However, even if all of the excluded patients had been included as PU free, the prevalence would still be as high as 16.5%.

We tried to limit bias by using a standardized training and testing program in the Braden scale scoring and PU classification prior to data collection. All the data collectors achieved the targeted goal of 80% agreement on the Braden subscale scores of the five cases. Further, in 95.5% of the 44 data collection teams at least one nurse in the teams did achieve the targeted goal of 80% correct classification. However, it may be a limitation that not both the nurses of the teams achieved the targeted goal on the PU classification test.

This prevalence study was a snapshot of one day providing important PU baseline data prior to commencement of the Patient Safety Campaign on PUs. One must bear in mind that there are natural fluctuations in prevalence rates and prevalence does not provide the insight that can be gained from incidence studies (Baharestani et al., 2009). For our purpose of providing baseline data, a prevalence study was time-saving and less labor intensive for the participating hospitals than an incidence study would have been, and PU prevalence studies can be the first step in improving hospital quality of PU prevention and care (Halfens et al., 2013).

7. Conclusion

Overall the prevalence of PUs in Norwegian hospitals was similar to the prevalence found in other European hospitals. It is a serious concern that so many at-risk patients did not receive evidence-based preventive measures. Future improvement work in Norwegian hospitals should probably include emphasizing better implementation of PU preventive guidelines, in particular use of support surfaces and planned repositioning of patients at risk of developing PUs. Even though interventions for improvement are mostly patient related, improvement of procedures and organization at ward level may also be important since a variance of PU occurrence was found at ward level. Further research should study the effects of organizational factors on the odds of developing HAPUs as well as the effects of patient risk factors.

Conflict of interest

None.

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Ethical approval

The privacy protection official of each participating hospital provided sufficient formal approval to conduct this multi-centre study.

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III

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Patient and organisational variables associated with pressure ulcer prevalence in hospital settings: a multilevel analysis

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ABSTRACT

Objectives: To investigate the association of ward-level differences in the odds of hospital-acquired pressure ulcers (HAPUs) with selected ward organisational variables and patient risk factors.
Design: Multilevel approach to data from 2 cross-sectional studies.
Settings: 4 hospitals in Norway were studied.
Participants: 1056 patients at 84 somatic wards.
Primary outcome measure: HAPU.
Results: Significant variance in the odds of HAPUs was found across wards. A regression model using only organisational variables left a significant variance in the odds of HAPUs across wards but patient variables eliminated the across-ward variance. In the model including organisational and patient variables, significant ward-level HAPU variables were ward type (rehabilitation vs surgery/internal medicine: OR 0.17 (95% CI 0.04 to 0.66)), use of preventive measures (yes vs no: OR 2.02 (95% CI 1.12 to 3.64)) and ward patient safety culture (OR 0.97 (95% CI 0.96 to 0.99)). Significant patient-level predictors were age >70 vs <70 (OR 2.70 (95% CI 1.54 to 4.74)), Braden scale total score (OR 0.73 (95% CI 0.67 to 0.80)) and overweight (body mass index 25–29.99 kg/m^2) (OR 0.32 (95% CI 0.17 to 0.62)).
Conclusions: The fact that the odds of HAPU varied across wards, and that across-ward variance was reduced when the selected ward-level variables entered the explanatory model, indicates that the HAPU problem may be reduced by ward-level organisation of care improvements, that is, by improving the patient safety culture and implementation of preventive measures. Some wards may prevent pressure ulcers better than other wards. The fact that ward-level variation was eliminated when patient-level HAPU variables were included in the model indicates that even wards with the best HAPU prevention will be challenged by an influx of high-risk patients.

Strengths and limitations of this study

- This study contributes to research of the association between pressure ulcers and patient safety culture.
- The study was conducted in a single Regional Health Authority, which may reduce the generalisability of the findings.
- The study sample limits the number of variables included in the analysis.

INTRODUCTION

Organisational culture is a critical factor for successful implementation of quality improvement and development of patient safety culture.[1 2] Safety culture is often defined as the product of individual and group values, attitudes, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety programmes.[3 4] Safety culture involves leadership, teamwork, shared belief in the importance of safety and learning.[4]

Quality and safety have become important healthcare policy objectives in many countries.[2] In Norway, a patient safety campaign was initiated in 2011 that embraces a number of adverse events including pressure ulcer (PU) prevention, commonly considered an indicator of nursing care quality. A recent study in Norwegian hospitals found a PU prevalence of 18%, a finding equal to or higher than prevalence rates in other European countries.[5] This result is particularly disturbing considering that Norway has the highest expenditure on healthcare among European countries.[6] Moreover, Norwegian hospitals were reported to have the lowest patient-to-nurse ratio in a large multicountry study in Europe,[7] although a single-country analysis for Norway did show variation in staffing ratios across Norwegian hospitals.[8] Still, the bottom line is that higher expenditure and greater number of nurses do not necessarily guarantee high-quality or safe patient care.

Despite extensive research and increased knowledge regarding patient-related PU risk factors and increased availability of evidence-based guidelines on PU prevention, the prevalence and incidence of PU have often proved resistant to change efforts.[9–11] Many organisational factors, such as ward safety culture, could inhibit change. Some studies suggest that there is a link between stronger patient safety culture and lower PU rate.[12 13] Taylor *et al*[12] found lower scores for patient safety domains in units with adverse events (patient falls, PU, pulmonary embolism/deep vein thrombosis) than in units without. However, other studies have found no association between PU and organisational factors such as patient safety climate, team climate and preventive quality management at ward level.[14 15] Skin care, frequent repositioning, elevated heels and allocation of pressure redistributing mattresses are important nursing interventions to prevent PU according to an evidence-based PU guideline.[11] Still, a large European study found a rather high prevalence of nursing tasks left undone, including documentation, skin care and repositioning due to lack of time, poor staffing levels and poor work environment.[16] Increased productivity demands have led to greater patient turnover rates, leaving more tasks to be performed in less time, often by fewer staff. Further, the increased number of older patients and the increased prevalence of obesity and diabetes will probably lead to increased prevalence of PU.[17]

Studies of how organisational factors at ward level affect hospital-acquired PU (HAPU) prevalence have produced inconsistent results,[12–15] indicating a need for further research.[18] Moreover, policymakers at all levels are seeking research results to better understand how the quality of healthcare can be improved.[19] The aim of this study was to study, within a multilevel statistical framework, the partition of the variance in the odds of HAPU into ward-level variance and patient-level variance, and investigate the association of selected ward organisational variables and patient risk factors on across-ward differences in HAPU odds in a sample of Norwegian hospitals.

METHODS

Design

This study uses two cross-sectional data sets collected from four Norwegian hospitals. One thousand and fifty-six patients from 84 somatic wards were included.

The patient safety culture data were obtained from a study conducted in all Norwegian Regional Health Authorities (RHAs) as part of the national patient safety campaign in Spring 2012.[20] All health personnel at all hospitals in the country were asked to participate and complete a web-based questionnaire. Data were collected anonymously. The researchers were given the results, aggregated by ward, as written reports from the hospitals.

The PU prevalence study was conducted in voluntarily participating hospitals in the South-Eastern RHA in October 2012. Inclusion criteria for this study were inpatients 18 years or above in somatic wards. Day surgery, psychiatric, maternity and paediatric wards were excluded from the study because of the low frequency of PU in such units.[21] We excluded the patients with a PU at hospital admission as well as those patients with missing data for the *PU present at hospital admission* variable in the current study. The wards were surgery, internal medicine, rehabilitation and intensive care units (ICUs) (including postanaesthesia recovery). The data collection procedure for the PU prevalence study was the European Pressure Ulcer Advisory Panel's (EPUAP) methodology and trained nurse teams collected the data. The procedure has been described in greater detail elsewhere.[5] Furthermore, the ward management completed an additional form including the number of patient beds on the ward, the number of staff and skill mix on each shift on the day prior to the prevalence study data collection and the number of inpatients at 07:00 on the prevalence study day.

Measures

The main outcome variable in this study was the prevalence of HAPU categories I–IV (table 1). The data collection teams identified patients admitted with a PU from the hospitals' patient record admission notes. In this study, HAPUs were defined as PUs not documented at hospital admission. HAPUs were classified according to the international classification: category I: non-blanchable erythema, category II: partial thickness skin loss, category III: full thickness skin loss, and category IV: full thickness tissue loss including also unstageable and suspected deep tissue injury.[11]

Table 1 Overview of the study variables

Outcome variable	
HAPU prevalence	▸ Categories I–IV
Independent variables	
Organisational variables	▸ Teamwork mean score (0–100) ▸ Safety climate mean score (0–100) ▸ Perception of management mean score (0–100) ▸ Ward type (surgery/internal medicine, rehabilitation, ICU) ▸ Patient/nurse ratio (number of patients per nurse) ▸ Repositioning (no/yes) ▸ Support surfaces (no/yes) ▸ Elevated heels (no/yes)
Patient variables	▸ Gender ▸ Age (<70/≥70) ▸ Braden total score (6–23) ▸ BMI (<18.5, 18.5–24.99, 25–29.99, >30 kg/m^2)

BMI, body mass index; HAPU, hospital-acquired pressure ulcers; ICU, intensive care unit.

The organisational variables were ward type, patient-to-nurse ratio (number of patient beds on the ward/number of nurses on the day shift), PU prevention implemented and ward patient safety culture. The PU prevention implemented variable was based on three items: repositioning (no planned, every 2, 3 and 4 h), support surfaces (standard mattress, non-powered or powered redistributing mattress) and elevated heels (no/yes). Since PU prevention is dependent on the availability of pressure-redistributing mattresses and health personnel for repositioning, we defined PU prevention implemented as an organisational variable. Patient safety culture was measured by the Safety Attitudes Questionnaire (SAQ). The SAQ has been translated into Norwegian and has been found to have satisfactory psychometric properties in the Norwegian hospital setting.[22] SAQ measures 36 items in six dimensions: teamwork (6), safety climate (7), perceptions of management (10), job satisfaction (5), stress recognition (4) and working conditions (4).[22 23] The national patient safety culture study used only the first three dimensions from the SAQ to measure patient safety culture. Teamwork measures the perceived quality of collaboration between personnel. Safety climate measures the perceptions of a strong and proactive organisational commitment to safety. Perception of management measures approval of managerial action.[23] Only three items from this dimension were used in the Norwegian patient safety study. In the SAQ data reports, negatively worded sentences were recoded. Moreover, scores for each item and mean score were converted from a 5-point Likert scale to a 100-point scale with 0 points indicating the most negative score and 100 the most positive. Staff mean scores were used to characterise the patient safety culture of the wards. Higher scores indicate stronger safety-mindedness. For one hospital that only provided department-level data, the department mean score was used in lieu of ward-level data.

Patient background characteristic variables included gender, age, Braden total score and body mass index (BMI), which have all been found to be significant predictor variables in earlier studies.[9 11] The Braden scale has six subscales (sensory perception, moisture, activity, mobility, nutrition, friction/shear); each subscale ranges from 1 (worst) to 4 (best), except the friction/shear subscale, which is rated from 1 to 3. The Braden total score thus ranges from 6 to 23, where a lower total score means higher risk.[24]

Statistical analysis

Analysis was conducted by using SPSS (V.21). Missing data on repositioning and pressure redistributing support surfaces were interpreted as no planned repositioning and no pressure redistributing support surfaces. The variable *PU prevention implemented* was constructed using the three items: mattress, repositioning and elevated heels. The items were first dichotomised to indicate whether the preventive measure was implemented or not. The three items were then summed and the sum score (0–3) was then dichotomised using the cut point 0 = preventive measures not implemented/score 1–3 = preventive measures implemented. The sum of the three SAQ dimensions was divided by three and labelled *patient safety culture mean score*. The patient safety culture constructs Cronbach's coefficient α was 0.905. We checked for multicollinearity between the predictor variables and none correlated above 0.50.

Owing to the hierarchical structure of the data, the assumption of independence of observations may not hold, thus requiring multilevel analysis.[25] It has been argued that even an intraclass correlation coefficient (ICC) as small as 1% may have design effects that should not be ignored,[26] and most statisticians agree that an ICC of 10% or higher calls for multilevel analysis.[27] Our ICC result was higher than 10%, and we therefore conducted multilevel analysis by MLwiN 2.30. With an MLwiN multilevel logistic regression, the patient-level variance does not automatically appear and we used $\pi^2/3$ for this estimation, as suggested by Rabe-Hesketh and Skrondal[28] and Twisk[29]. We applied a two-level model (ward and patient levels) due to the limited number of participating hospitals; four hospitals were too few for a model including a hospital level.[27 30 31] Further, we found no hospital-level variance in the PU prevalence study.[5] The level of significance was set to $p<0.05$.

To determine how much of the variance in the odds of HAPU was at ward level, that is, across wards, we first applied an *empty model*, a model with no explanatory variables.[32 33] We then added organisational variables to the model to investigate the association with HAPU. Finally, we included the patient-related risk factors in the model.

Ethics

All participating patients or relatives received oral and written information and gave verbal consent to participate. The patient safety culture study was a part of a national campaign for which each RHA was legally responsible. Both studies have been conducted in accordance with the Declaration of Helsinki.

RESULTS

Most participating wards were surgery or internal medicine. The HAPU prevalence was highest for ICU wards and lowest for rehabilitation wards (table 2).

Variable scores differed by ward type (table 3). The highest patient safety culture mean score was found in ICU wards. The patient safety culture mean score ranged from a low score of 52.7 in one rehabilitation ward to the highest score of 81.3 measured for one ward within the surgery and internal medicine group. For the single dimensions, perception of management was lower than teamwork and safety climate. ICU wards had the lowest patient-to-nurse ratio and a higher use of preventive measures than the other two ward types. Likewise,

Table 2 Patients included and prevalence of HAPU (categories I–IV) by ward type (N=1056)

	Surgery, internal medicine n=62	ICU* n=15	Rehabilitation n=7	Total N=84
Patients included (n (%))	892 (84.5)	76 (7.2)	88 (8.3)	1056 (100)
HAPU categories I–IV (n (%))	125 (14.0)	21 (27.6)	5 (5.7)	151 (14.3)

*Both postanaesthesia recovery wards and ICUs.
HAPU, hospital-acquired pressure ulcers; ICU, intensive care unit.

the patients in ICU wards had the lowest Braden total score indicating higher risk patients. The number of patients 70 years or above was highest in the surgery and internal medicine wards.

The multilevel analysis produced an ICC at ward level above 20% for HAPUs in the model with no explanatory variables (table 4). When controlled for organisational variables, the average ward patient safety culture score was significantly related to the HAPU odds: one single point up on the 0–100 patient safety scale was associated with a reduction in the odds by a factor of 0.98. The odds of HAPU for patients in rehabilitation wards were almost one-fourth of the odds of the reference type of ward. There were no significant differences in the odds of HAPU between ICUs and the reference type of ward; nor was the patient-to-nurse ratio significantly associated with HAPU. When PU prevention was implemented, patients had almost four times higher odds of HAPU as patients who were not allocated any PU prevention. The model with ward-level variables only did not eliminate the across-ward variation in HAPU odds.

The addition of the patient variables (gender, age, Braden total score and BMI) did not affect the significance and the direction of the effects of the organisational variables. Moreover, the associations between HAPU odds and hospitalisation on a rehabilitation ward and better ward patient safety culture, respectively, were actually strengthened. The association of HAPU odds with PU preventive measures was weakened. However, the odds of HAPU were still twice as high in cases where PU preventive measures had been applied.

When controlled for the other variables in the final model, age was significantly related to HAPU. Patients above 70 years of age had almost three times as high odds of developing an HAPU compared with younger patients. Moreover, the Braden total score was a significant HAPU predictor: one single Braden point reduced the HAPU odds by a factor of as much as 0.73. The somewhat overweight patient had significantly lower HAPU odds. The other BMI groups did not differ significantly from the reference BMI group. Gender was not significantly related to the odds of developing PU during hospitalisation. Further, in the final model, there was no longer a significant across-ward variance in HAPU odds.

On the basis of the findings for implemented preventive measures, we conducted an additional analysis based on the patient's risk level (Braden score below 17 and/or a PU). The Braden total score was calculated for 1004 patients, and 222 patients (22.1%) were considered at

Table 3 Descriptive statistics for organisational and patient variables (N=1056)

	Surgery, internal medicine	ICU*	Rehabilitation	Total
Organisational variables				
Patient safety culture mean score (mean(SD)) (n=1042)	70.1 (5.1)	71.6 (3.6)	68.5 (9.5)	70.1 (5.6)
Teamwork	75.8 (5.4)	77.3 (3.9)	74.1 (9.9)	75.8 (5.9)
Safety climate	73.7 (5.4)	76.9 (4.0)	70.4 (7.6)	73.6 (5.6)
Perception of management	60.8 (6.2)	60.5 (3.6)	60.9 (9.5)	60.8 (6.7)
Patient/nurse ratio (mean(SD)) (n=1024)	2.8 (0.8)	1.2 (0.8)	2.6 (0.4)	2.6 (0.9)
PU prevention implemented (yes, %) (n=1056)	27.4	75.0	35.2	31.4
Patient variables				
Braden total score (mean(SD)) (n=1004)	20.2 (3.1)	16.8 (4.5)	19.6 (2.7)	19.9 (3.3)
Gender (female, %) (n=1031)	47.9	34.2	28.7	45.3
Age (>70 years, %) (n=1045)	40.8	26.0	21.6	38.2
BMI, kg/m^2 (n (%))	707 (100)	65 (100)	87 (100)	859 (100)
Underweight (<18.5)	41 (5.8)	4 (6.2)	6 (6.9)	51 (5.9)
Normal (18.5–24.99)	320 (45.3)	24 (36.9)	48 (55.2)	392 (45.6)
Overweight (25–29.99)	243 (34.4)	25 (38.5)	24 (27.6)	292 (34.0)
Obesity (>30)	103 (14.6)	12 (18.5)	9 (10.3)	124 (14.4)

*Both postanaesthesia recovery wards and ICUs.
BMI, body mass index; ICU, intensive care unit; PU, pressure ulcer.

Table 4 Multilevel models with organisational and patient variables associated with HAPU (N=1056)

Risk factors	Empty model N=1056	Organisational variables n=1010 OR (95% CI)	Organisational and patient variables n=757 OR (95% CI)
Patient safety culture mean score		**0.98 (0.96 to 0.99)**	**0.97 (0.96 to 0.99)**
Ward type (reference group: surgery and internal medicine)			
ICU		1.19 (0.43 to 3.33)	1.14 (0.33 to 3.96)
Rehabilitation		**0.26 (0.08 to 0.87)**	**0.17 (0.04 to 0.66)**
Patient/nurse ratio		0.82 (0.56 to 1.21)	0.99 (0.63 to 1.54)
PU prevention implemented (reference group: no)		**3.74 (2.49 to 5.63)**	**2.02 (1.12 to 3.64)**
Gender (reference group: female)			0.97 (0.57 to 1.65)
Age (reference group: <70 years)			**2.70 (1.54 to 4.74)**
Braden scale total score			**0.73 (0.67 to 0.80)**
BMI (reference group: normal 18.5–24.99 kg/m^2)			
Underweight			1.46 (0.61 to 3.46)
Overweight			**0.32 (0.17 to 0.62)**
Obesity			0.51 (0.22 to 1.18)
ICC (%)	**21.16**	**17.39**	10.60

Bold numbers significant ORs and ICCs. ICC=ward-level variance/total variance×100.
BMI, body mass index; HAPU, hospital-acquired pressure ulcers; ICC, intraclass correlation coefficient; ICU, intensive care unit; PU, pressure ulcer.

risk; of those, 136 (61.3%) received preventive measures compared with 181 (23.1%) for those considered not at risk (χ^2=116.27, p>0.000).

DISCUSSION

The multilevel analysis found significant associations between HAPU odds and both organisational and patient variables. One finding in our study was the significant association between the patient safety culture score and the presence of HAPU: the higher the patient safety culture score, the lower the HAPU odds. An OR of 0.97 means a 10-point increase in patient safety score result would correspond to a 26% ($1–0.97^{10}$) reduction in HAPU odds. Ward patient safety scores in the data set varied by as much as 28,7 points, from a low of 52.7 to a high of 81.3. This significant association between higher patient safety and lower odds of HAPU echoes earlier studies that found an association between global safety score, safety climate and team work, and the odds of PU.[12 13] On the other hand, other researchers have reported no association between organisational culture, team climate, preventive quality management at the ward level and safety culture climate and the presence of PU.[14 15] This study supports a significant association between patient safety culture and PU prevalence; however, further research is warranted to conclude with greater certainty.

Further, the rehabilitation wards had significantly lower odds for HAPUs than the surgery and internal medicine wards. Additional analysis showed that one-fifth of the patients in the rehabilitation wards were considered to be at risk and/or had PU (data not shown). The patients at rehabilitation wards are probably more mobilised and in a healthier state than the hospitalised patients in surgical and internal medicine wards.

One further significant result was the counterintuitive finding that implementation of PU prevention seemed to increase the odds of HAPU. We interpret this to mean that such measures were often implemented after the HAPU had occurred and not solely based on an a priori risk assessment. Further, the additional analysis revealed that patients at risk and/or with a PU were significantly more likely to receive such measures compared with those not at risk. About 60% of those at risk and/or with a PU had preventive measures implemented. The international guideline recommends that all at-risk patients should have preventive measures.[11] For those not at risk, about one-fourth had preventive measures. However, we do not know if these patients had been considered at risk prior to the data collection day and not been reassessed as not at risk. It may also be argued that some patients were allocated PU prevention unnecessarily. This practice may be questioned considering that prevention also is costly, an issue also raised by Vanderwee *et al*.[34] We also do not know whether the preventive measures were implemented as primary or secondary prevention. An ICU study also found a significant association between preventive measures and PU outcome (category II–IV).[35] The researchers explained that patients were correctly identified as at risk, but preventive measures were applied too late or first after the PU became visible.[35] Likewise, in our study, the nurses had probably not implemented the international evidence-based guideline that is available in Norwegian.[36] Assessment of patient risk of compromised skin integrity is a fundamental nursing responsibility. Yet studies have shown that nurses do not give prevention the necessary attention and priority to avoid PU from developing.[37]

The single items included in the collapsed preventive measures variable were measured in individual patients, but the collapsed variable was considered to be an organisational variable used as a measurement of nursing care. In a large multicountry study, nurses identified skin care and frequent changing of patient position as nursing activities care left undone.[16] Moreover, if preventive measures had been considered as a patient variable, the relationship between the significant organisational variables and HAPU would remain (patient safety culture mean score OR 0.94 (95% CI 0.90 to 0.99) and rehabilitation ward OR 0.29 (95% CI 0.09 to 0.93)).

The organisational variables were important explanatory factors in the models, but patient variables were also important. Even in wards with a good record of successful prevention of HAPUs, an influx of high-risk patients may affect the HAPU prevalence. Wards have little influence on the number of high-risk patients, but they do have an opportunity to decide the quality of care their patients receive.

These findings raise questions about quality incentives in hospitals. Increased competency among staff in taking preventive measures may reduce the prevalence of HAPU. However, the culture and attitude on the individual wards may influence the implementation of new knowledge and the wards should therefore focus on improved teamwork. Moreover, there is a need for greater focus on safety in clinical practice to protect patients at risk. Finally, the results indicate that nursing staff do not always perceive the management as focusing on safety and quality of care. We need to measure nursing quality outcomes in order to set benchmarks, as these outcomes relate to the organisational quality of care. Moreover, the number of vulnerable patients will increase due to the expected increase in the number of older patients with higher comorbidity and higher patient turnover with shorter length of stay in hospital. It is important to prevent PUs because they affect the individual patient's quality of life as well as increase the cost of care.

Limitations

A limitation of this study is the use of department-level data for one of the hospitals for the variable *mean ward patient safety culture*. There were significant differences in the mean ward scores by ward type across the hospitals (data not shown), but this may be due to the range in the number of wards per hospital. We do not know exactly when the PUs in our study occurred: some of the PUs we considered to be acquired in hospitals may have occurred prior to admission, but were not clinically visible at admission.[38]

Further, the limited number of HAPU cases in our data set limited the number of included variables in the multilevel logistic regression models. We adjusted for this limitation by collapsing categories on the variables so that the independent variables could be presented by fewer dummy variables, even though the collapsing of categories results in less information. We also tested for interactions between the variables prior to the model fitting, but none of these were statistically significant (patient safety culture×preventive measures, patient safety culture×Braden total score, Braden total score×age, age×gender, patient/nurse ratio×preventive measures, patient/nurse ratio×patient safety culture, patient safety culture×type of ward).

It would have been interesting to use the same models with the more severe HAPUs, HAPU II–IV, and to check whether the variables that predicted all HAPUs also predicted the more severe HAPUs. Our data set only included 47 patients with HAPUs II–IV (data not shown), and that was too few for the analysis using our set of HAPU variables.

The results that patients with preventive measures had higher odds for HAPU may be due to confounding. In many cases, preventive measures were probably implemented prior to PU development based on PU risk assessment or only after a PU was visible and, moreover, information about the quality and availability of mattresses that may vary from ward to ward. Owing to the study design, we do not have data to assess these potential confounding factors. Future studies should endeavour to further investigate these variables. The preventive measures could also be considered as an intermediate variable between organisational variables and HAPUs. Owing to the sample size, collapsing variables into one variable reduced the amount of information provided, especially preventive measures and ward type. Larger studies are required to enable inclusion of the individual variables in the models.

A cross-sectional study with limited variables is inadequate to demonstrate causality. However, the purpose for our study was to describe the association between selected predictors and HAPU, not a causal relationship.

CONCLUSION

The fact that the odds of HAPU varied across wards, and that across-ward variance was reduced when the selected ward-level variables entered the explanatory model, indicates that the HAPU problem may be reduced by ward-level organisation of care improvements, that is, by improving the patient safety culture and implementation of preventive measures. Some wards may prevent PU better than other wards. The fact that ward-level variation was eliminated when patient-level HAPU variables were included in the model indicates that even wards with the best HAPU prevention will be challenged by an influx of high-risk patients.

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DH contributed to the data analysis. All coauthors have contributed to the development of the concept and design of the study, interpretation of data and manuscript drafting, as well as provided comments and ideas during the process, and gave their final approval to the final manuscript.

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