

Patient risk factors for pressure ulcer development: systematic review

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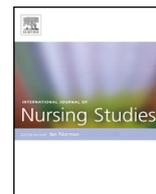
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Review

Patient risk factors for pressure ulcer development: Systematic review

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ABSTRACT

Objective: To identify risk factors independently predictive of pressure ulcer development in adult patient populations?

Design: A systematic review of primary research was undertaken, based upon methods recommended for effectiveness questions but adapted to identify observational risk factor studies.

Data sources: Fourteen electronic databases were searched, each from inception until March 2010, with hand searching of specialist journals and conference proceedings; contact with experts and a citation search. There was no language restriction.

Review methods: Abstracts were screened, reviewed against the eligibility criteria, data extracted and quality appraised by at least one reviewer and checked by a second. Where necessary, statistical review was undertaken. We developed an assessment framework and quality classification based upon guidelines for assessing quality and methodological considerations in the analysis, meta-analysis and publication of observational studies. Studies were classified as high, moderate, low and very low quality. Risk factors were categorised into risk factor domains and sub-domains. Evidence tables were generated and a summary narrative synthesis by sub-domain and domain was undertaken.

Results: Of 5462 abstracts retrieved, 365 were identified as potentially eligible and 54 fulfilled the eligibility criteria. The 54 studies included 34,449 patients and acute and community patient populations. Seventeen studies were classified as high or moderate quality, whilst 37 studies (68.5%) had inadequate numbers of pressure ulcers and other methodological limitations. Risk factors emerging most frequently as independent predictors of pressure ulcer development included three primary domains of mobility/activity, perfusion (including diabetes) and skin/pressure ulcer status. Skin moisture, age, haematological measures, nutrition and general health status are also important, but did not emerge as frequently as the three main domains. Body temperature and immunity may be important but require further confirmatory research. There is limited evidence that either race or gender is important.

Conclusions: Overall there is no single factor which can explain pressure ulcer risk, rather a complex interplay of factors which increase the probability of pressure ulcer development. The review highlights the limitations of over-interpretation of results from individual studies and the benefits of reviewing results from a number of studies to develop a more

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reliable overall assessment of factors which are important in affecting patient susceptibility.

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What is already known about the topic?

- Large number of risk factors related to pressure ulcer development.
- Reduced activity/mobility is a risk factor for pressure ulcer development.
- Large number of risk factor studies.

What this paper adds

- Overall there is no single factor which can explain pressure ulcer risk, rather a complex interplay of factors which increase the probability of pressure ulcer development.
- Three primary risk factors include mobility/activity, perfusion (including diabetes) and skin/pressure ulcer status. There has been over-interpretation of results from individual risk factor studies.

1. Introduction

Pressure ulcers are described as ‘localised injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure or pressure in combination with shear’ (National Pressure Ulcer Advisory Panel and the European Pressure Ulcer Advisory Panel, NPUAP/EPUAP, 2009). Pressure ulcers vary in size and severity of tissue layer affected, ranging from skin erythema to damage to muscle and underlying bone (Witkowski and Parish, 1982) and are classified by tissue layer affected using the NPUAP/EPUAP classification system (2009).

Pressure ulcers are a worldwide problem affecting hospital and community patient populations (Kaltenthaler et al., 2001; O’Dea, 1995; Saito et al., 1999; Vangilder et al., 2008). In practice, the emphasis is on identifying patients at risk and implementing appropriate interventions to prevent pressure ulcer occurrence (AHCPR (Agency for Health Care Policy and Research), 1992; NICE, 2003).

It has been argued consistently that pressure ulcer risk assessment scales need to be developed on the basis of multivariable analyses to identify factors which are independently associated with pressure ulcer development (Bridel, 1994; Cullum et al., 1995; Nixon and McGough, 2001). An improved understanding of the relative contribution risk factors make to the development of pressure ulcers and an improved ability to identify patients at high risk of pressure ulcer development would enable us to better target resources in practice. Early epidemiological evidence identified that reduced activity and mobility is the key risk factor for pressure ulcer development, but the relative contribution other risk factors make cannot be reliably determined from individual studies. To inform an emerging National Institute for Health Research (NIHR) Programme Grant on pressure ulcer prevention (PURPOSE: RP-PG-0407-10056) we

sought to systematically review existing research to identify factors independently associated with pressure ulcer development, that is, “a risk factor that retains its statistical association with the outcome when other established risk factors for the outcome are included in the statistical model” (Brotman et al., 2005). However, it should be noted that being ‘independent’ is a statistical concept, depends on the risk factor variables included in the model and does not imply causality (Brotman et al., 2005). Careful consideration should therefore be given to whether the statistical associations have clinical relevance.

The aim of this study was to identify risk factors independently predictive of pressure ulcer development in adult patient populations.

2. Methods

A systematic review of primary research was undertaken. The approach was based upon the systematic review methods recommended for questions of effectiveness (The Cochrane Collaboration, 2009; Centre for Reviews and Dissemination, 2009), and adapted to identify risk factor studies with consideration of the methodological limitations including bias and confounding associated with observational studies (Egger et al., 2001; Hayden et al., 2006).

2.1. Study eligibility

Methodological quality criteria were integrated into the inclusion and exclusion criteria of the systematic review, developed from principles of good research conduct in observational studies and randomised controlled trials which minimise bias (Altman, 2001; Schulz et al., 2010; Maltoni et al., 2005; STROBE, 2005).

Inclusion criteria: (i) primary research, (ii) adult study populations in any setting (iii) outcome was the development of a new pressure ulcer(s), (iv) prospective cohort, retrospective record review or a controlled trial, (v) length of follow-up at least 3 days, with exception of operating room studies for which no minimal was set and (vi) outcome clearly defined as \geq Grade/Stage 1 (AHCPR, 1992; EPUAP, 1999) or equivalent, (vii) multivariable analyses were undertaken to identify factors affecting pressure ulcer outcome and (viii) the unit of analysis was the patient.

Exclusion criteria: (i) paediatric study populations (ii) cross-sectional, case-study, patient recall, patient self-report or analysis of General Practitioner records and (iii) duplicate publication of patient dataset (iv) cohort studies (prospective and record reviews) were excluded from the review if $>20\%$ of the study sample were excluded from analysis for reasons including withdrawal, death, loss to follow-up and missing records (Altman, 2001; Egger et al., 2001; Maltoni et al., 2005; STROBE, 2005). Controlled trials

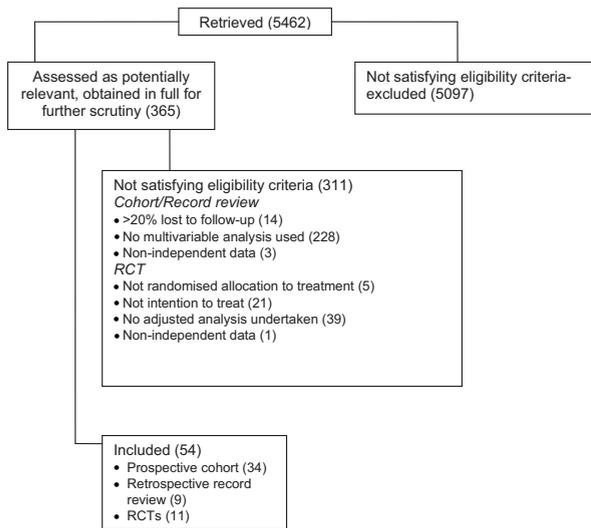


Fig. 1. Flowchart of studies.

were excluded unless all of the following minimum criteria applied: (i) randomised allocation to treatment, (ii) intention to treat analyses (Centre for Reviews and Dissemination, 2009; Schulz et al., 2010).

No language restriction was applied.

Data sources: Fourteen electronic databases were searched, each from inception until March 2010: AMED, British Nursing Index, MEDLINE, Embase, PsycINFO, CINAHL, Cochrane Library, Proquest, Networked Digital Library of Theses and Dissertations, International Theses in Progress, Theses Canada Portal, Australian Digital Theses Program, and Russian Academy of Sciences Bibliographies and Index to Theses. The search strategy sought to identify all published and unpublished research studies investigating risk factors for the development of pressure ulcers. The search strategy was designed with guidance from the collaborative team and includes pressure ulcer search terms (Cullum et al., 2001), OVID maximum sensitivity filters for Prognosis and Aetiology or Harm and OVID maximum sensitivity filter for RCTs (Centre for Reviews and Dissemination, 2009).

In addition we hand searched specialist journals and conference proceedings, contacted 13 experts, searched the UK National Research websites and performed a citation search on all included studies and systematic reviews identified in the search (search strategy is available on request).

2.2. Data extraction

Abstracts were screened for relevance by one reviewer (CG) and checked by a second (JN). Abstracts assessed as potentially relevant were obtained in full and reviewed against the eligibility criteria by one reviewer (CG or SC) and checked by a third (JN). Where the statistical methods were unclear and eligibility could not be determined, statistical review was undertaken (JB). Disagreements were dealt with through consensus.

Where studies fulfilled the eligibility criteria data were extracted by a single reviewer (CG or SC) and checked by a second reviewer (JN). Where data was missing from the publication attempts were made to contact the authors. Where duplicate publications of patient datasets were identified, the most detailed report was used for data extraction. Experts in the field were asked to review/data extract abstracts and articles not published in English.

2.3. Quality assessment

There are no guidelines for the quality assessment of risk factor studies, so we developed an assessment framework based upon guidelines for assessing quality in prognostic studies and methodological considerations in the analysis, meta-analysis and publication of observational studies (Altman et al., 1994; Altman, 2001; Egger et al., 2001; Harrell et al., 1985; Hayden et al., 2006; Maltoni et al., 2005; Peduzzi et al., 1995; Royston et al., 2006; STROBE, 2005). Each study was appraised by two reviewers (JN, SC) and the following methodological limitations were noted where present: baseline characteristics not adequately described, inadequate measurement of risk factors (for example, record review), inappropriate cut-points used for continuous data and time dependent co-variables included in the analysis without appropriate adjustment.

In addition, specific consideration was given to the following criteria:

1. Is there sufficient number of events (rule of thumb, ≥ 10 events per risk factor)?
2. Is there sufficient presentation of data to assess the adequacy of method and analysis?
3. Is the strategy for model building (i.e. inclusion of variables) appropriate and based upon a conceptual framework?
4. Is the selected model adequate for the design?

Each criteria was assessed as being met (yes/no/partial/unsure) and provided a structured approach for the classification of overall study quality.

2.4. Classification of study quality

We classified studies as high, moderate, low and very low quality using the following criteria:

- High quality studies: yes for all criteria;
- Moderate quality studies: yes for criteria 1 and at least 2 other criteria;
- Low quality studies: no for criteria 1 and no or partial for 2 other criteria;
- Very low quality studies: no for criteria 1 and no or partial for all 3 other criteria.

2.5. Data synthesis

Meta-analysis of the data was not feasible for this review because of heterogeneity in the study designs, patient populations, risk factor descriptors, interventions

used and outcomes reported. As the main aim was to identify risk factors, rather than quantify the effect size of the relationship between those factors and pressure ulcer development, a narrative synthesis was carried out (Centre for Reviews and Dissemination, 2009).

For each study all factors entered into multivariable modelling and those which emerged as significant ($p \leq 0.05$) were identified. For studies using stepwise regression we included non-significant factors ($p \geq 0.05$) if these were reported in the final model as being independently associated with pressure ulcer development.

Risk factors were categorised into domains and sub-domains. Evidence tables were generated for each risk factor sub-domain, with a summary narrative synthesis by sub-domain and domain (evidence tables available on request). For each sub-domain the total number of studies entering the variable and the total number where the variable emerges in the multivariable analyses and the quality of studies are summarised. In the evidence tables Grade and Stage are recorded as reported in individual studies.

3. Results

3.1. General study characteristics

Of 5462 abstracts retrieved, 365 were identified as potentially eligible. Of these 54 fulfilled the eligibility criteria (Fig. 1) including 34 prospective cohort, 9 retrospective record reviews and 11 RCTs. A summary of included studies are detailed in Table 1.

The 54 studies include a total of 34,449 patients (median 237 per study). Median pressure ulcer incidence was 16.6 (range 3.2% to 73.5%). Study patient populations include intensive care, surgery, trauma, various mixed specialty acute care environments, long-term rehabilitation and nursing home populations, community populations and specific diagnostic groups (e.g. fractured hip and spinal cord injured Table 1).

Twenty-eight studies defined pressure ulcer outcome as Grade ≥ 1 (Baldwin and Ziegler, 1998; Bergstrom et al., 1996; Bostrom et al., 1996; Bourdel-Marchasson et al., 2000; Boyle and Green, 2001; Chan et al., 2005; Cobb et al., 1997; Donnelly, 2006; Ek et al., 1991; Ek, 1987; Feuchtinger et al., 2006; Goodridge et al., 1998; Gunningberg et al., 2001; Halfens et al., 2000; Inman et al., 1999; Kemp et al., 1993; Lindgren et al., 2004; Olson et al., 1996; Perneger et al., 2002; Rose et al., 2006; Salzberg et al., 1999; Sayar et al., 2009; Schnelle et al., 1997; Schultz et al., 1999; Suriadi et al., 2007, 2008; Tourtual et al., 1997; Watts et al., 1998), 22 define pressure ulcer outcome as a Grade ≥ 2 (Allman et al., 1995; Bates-Jensen et al., 2007; Baumgarten et al., 2004; Bergquist and Frantz, 1999; Berlowitz and Wilking, 1989; Brandeis et al., 1994; Compton et al., 2008; De Laat et al., 2007; Fife et al., 2001; Hatanaka et al., 2008; Marchette et al., 1991; Nijs et al., 2009; Nixon et al., 2006, 2007; Okuwa et al., 2006; Ooi et al., 1999; Rademakers et al., 2007; Reed et al., 2003; Schoonhoven et al., 2002; Stordeur et al., 1998; Vanderwee et al., 2009; Yepes et al., 2009), 3 report both (Bergstrom

and Braden, 1992; Defloor and Grypdonck, 2005; Pancorbo Hidalgo and Garcia Fernandez, 2001), and 1 is unknown (Serpa and Santos, 2007).

The majority of studies reported a dichotomous outcome, with fifteen reporting time to the development of new pressure ulcers (Boyle and Green, 2001; Bergquist and Frantz, 1999; Sayar et al., 2009; Allman et al., 1995; Perneger et al., 2002; Cobb et al., 1997; Salzberg et al., 1999; Bourdel-Marchasson et al., 2000; Kemp et al., 1993; Okuwa et al., 2006; Donnelly, 2006; De Laat et al., 2007; Baumgarten et al., 2004; Vanderwee et al., 2009; Hatanaka et al., 2008) in modelling.

Eleven studies reported more than one multivariable analysis (Brandeis et al., 1994; Schnelle et al., 1997; Bergstrom et al., 1996; Bergstrom and Braden, 1992; Pancorbo Hidalgo and Garcia Fernandez, 2001; Salzberg et al., 1999; Lindgren et al., 2004; Ek, 1987; Defloor and Grypdonck, 2005; Bates-Jensen et al., 2007; Nijs et al., 2009). Where more than one model was reported a primary model was identified based upon the following hierarchy: primary endpoint of \geq Grade 1, primary endpoint development of new pressure ulcer(s), model with the most comprehensive range of variables, total sample or largest sub-groups of patients, largest number of pressure ulcers and models with baseline values not time dependent variables.

3.2. Study quality

Seven studies fulfilled all 4 quality criteria and were classified as high quality and a further 10 studies had sufficient numbers of event and were classified as moderate quality studies. The remaining 37 studies (68.5%) had inadequate numbers of pressure ulcers and other methodological limitations and comprised 27 low quality studies and 10 very low quality studies (Table 1).

3.3. Risk factor domains and sub-domains

Forty-seven (87.0%) studies reported the risk factors entered into multivariable modelling and those which emerged as significant (independently predictive of pressure ulcer outcome). Seven studies (Schnelle et al., 1997; Bourdel-Marchasson et al., 2000; Ek et al., 1991; Rose et al., 2006; Marchette et al., 1991; Serpa and Santos, 2007; Hatanaka et al., 2008) only reported the risk factors which emerged from multivariable modelling. The forty-seven studies evaluated a median of 11 (range 3–45) potential risk factors in multivariable analyses and identified a median of 3 (range 1–10) factors as independently predictive of pressure ulcer outcome.

A summary of risk factors entered into multivariable modelling (where known) and those which emerged as significant are summarised by study (Table 1) and by risk factor domain/sub-domain (Table 2).

3.4. Mobility/activity

Mobility/activity variables were classified into 8 sub-domains including activity risk assessment scale subscales, mobility risk assessment scale subscales,

Table 1
Summary of studies.

Study and country	Study population (No. recruited and type)	Other inclusion criteria	Design and analysis method	No. final model (PU%), no. PU dev and stage/grade	Results: No. risk factors (No. in model), model risk factor names	p value	Odds ratio	Confidence intervals	Overall study quality and limitation notes
Allman et al. (1995) USA	286 pts Setting: acute care hospital Speciality: multiple	Admitted to the hospital within previous 3 days, aged 55 or more, expected to be confined to a bed or chair for at least 5 days or had a hip fracture, expected to be in hospital for at least 5 days. Exclusion patients with stage 2 or above PU, Friday admission, active skin disease that would interfere with PU assessment and previous enrolment in the study. Consent required.	Cohort Backward stepwise Cox regression	286 (12.9%), 37 Stage ≥ 2 PU	9 (5) Nonblanchable erythema if intact sacral skin Immobility Dry sacral skin Decreased body weight Lymphopenia	0.05 0.02 0.04 0.03 0.003	7.5 2.4 2.3 2.2 4.9	1.0–59.1 1.1–4.9 1.0–5.2 1.1–4.5 1.7–13.9	LQS Insufficient number of events.
Baldwin and Ziegler (1998) USA	36 pts Setting: acute care hospital Speciality: trauma	Adults aged 15–60 years, previously healthy, hospitalised as a result of severe trauma, did not require burn fluid resuscitation, and had expected length of hospitalisation of at least 1 week	Cohort Forward logistic regression	36 (30.6%), 11 Stage ≥ 1 PU	7 (2) Braden mobility subscore Braden moisture subscore	0.02 0.04	0.3 3.0	0.1–0.8 1.1–8.3	VLQS Baseline characteristics are not reported. The sample size is too small and insufficient number of events.
Bates-Jensen et al. (2007) USA	35 non-surgical pts Setting: nursing home Speciality: elderly/geriatric	Long-stay residents in 2 nursing homes who were eligible for a larger nutrition trial (not referenced) and provided informed written consent	Cohort, Generalised logistic regression	35 (45.7%), 16 Stage ≥ 2 PU	5 (2) Subepidermal moisture (at 1 week) Total Braden score	≤ 0.05 ≤ 0.05	1.0 6.8	1.004–1.012 0.6–72.3	LQS Inadequate sample size resulting in wide confidence intervals.
Baumgarten et al. (2004)	2285 non-surgical pts Setting: long-term nursing care/nursing home Speciality: NR	Random sample of patients, aged 65 or older, newly admitted to NH, black or white skin colour, consent or relative assent. Pts excluded if had previously resided in a NH or chronic care facility for 8 or more days in the year before the NH admission.	Cohort Cox proportional hazards model	1938 (23.2%), 450 Stage ≥ 2 PU	12 (3) Black race No. of ADL dependencies PU on admission	0.032 0.001 0.001	1.3 1.4 1.8	1.0–1.7 1.3–1.5 1.4–2.3	MQS All risk factors are categorical data rather than continuous. 20% missing data from final model.

Bergquist and Frantz (1999) USA	1711 non-surgical pts Setting: community/homecare Speciality: elderly/geriatric	Home healthcare agency, aged 60 or more with no PU on admission, non-hospice, non-IV therapy. Consent not required	Record review Stepwise Cox proportional hazards	1567 (3.2%), 55 Stage ≥ 2 PU	45 (10) Limited to wheelchair ADL dressing Incontinence bowel and/or bladder Braden mobility Anaemia Adult child primary caregiver Male Recent fracture Oxygen use Skin drainage	0.0198 <0.001 0.0195 <0.001 0.0021 <0.001 0.0281 0.0019 <0.001 <0.001	2.8 2.7 2.8 5.2 4.0 5.8 1.9 3.5 3.9 6.6	1.2–6.5 1.5–4.8 1.2–6.8 2.4–11.1 1.6–9.5 2.1–15.9 1.1–3.2 1.6–7.6 2.1–7.6 2.3–19.2	LQS Record review and insufficient number of events. Inadequate measurement of risk factors (record review).
Bergstrom and Braden (1992) USA	200 non-surgical pts Setting: long-term nursing care/nursing home Speciality: elderly/geriatric	Consecutive patient admissions to teaching nursing home were screened and included if over 65 years, at risk of PU development (Braden score < 17), free of existing PU, estimated length of stay more than 10 days. Consent required from patients or family	Cohort, logistic regression (backward elimination)	200 (73.5%), 147 Stage ≥ 1 PU, (38.5%), 77 Stage ≥ 2 PU Model 1 Stage ≥ 1 Model 2 Stage ≥ 2 Model 3 Stage = 1	Model 1 10 (5) Braden score Diastolic BP Temperature Age Protein (%RDA) Model 2 10 (4) Braden score Age Systolic BP Protein (RDA%) Model 3 10 (4) Braden score Diastolic BP Temperature Iron (%RDA)	<0.01 <0.01 ns ns <0.05 <0.001 <0.05 <0.01 ns <0.01 <0.01 <0.05 <0.01	NR NR NR NR NR NR NR NR NR NR NR NR NR NR	NR NR NR NR NR NR NR NR NR NR NR NR NR NR	MQS No confidence intervals reported.
Bergstrom et al. (1996) USA	843 pts Setting: multiple Speciality: multiple	Patients from 2 nursing homes, 2 university hospitals and 2 VAMCs, aged 19 or more, no PU on admission, admitted for care within 72 h	Cohort Logistic regression	843 (12.8%), 108 Stage ≥ 1 PU Model 1 Age, gender, race, Braden scale and preventive measures Model 2 Mobility, activity and primary diagnoses (13) Model 3 Braden total score and primary diagnoses (13)	Model 1 6 (3) Braden scale score Age Race Model 2 15 (3) Braden mobility Braden activity Cardiovascular disease Model 3 14 (1) Braden total	<0.001 <0.001 0.012 <0.001 0.004 0.023 <0.001	1.3 1.0 2.7 1.7 1.5 2.5 1.4	1.2–1.4 0.95–0.98 1.3–6.0 1.3–2.3 1.1–1.9 1.1–5.5 1.3–1.5	HQS

Table 1 (Continued)

Study and country	Study population (No. recruited and type)	Other inclusion criteria	Design and analysis method	No. final model (PU%), no. PU dev and stage/grade	Results: No. risk factors (No. in model), model risk factor names	p value	Odds ratio	Confidence intervals	Overall study quality and limitation notes
Berlowitz and Wilking (1989) USA	185 non-surgical pts Setting: chronic care hospital Speciality: medicine	All patient admissions to chronic care hospital (requiring medical, skilled nursing, rehabilitative services) with chronic medical conditions, Patients excluded from the study if they died or were discharged within 1 week of admission, or required transfer to an acute care hospital within 24 h of admission i.e. had a PU at baseline. Consent not required – record review	Cohort Stepwise logistic regression	185 (10.8%), 20 Stage ≥ 2 PU	11 (3) Cerebrovascular accident Bed or chair bound Impaired nutritional intake	<0.05 <0.05 <0.05	5.0 3.8 2.8	1.7–14.5 1.0–14.0 1.0–17.9	LQS Insufficient number of events. Data collection relied on clinical staff and only partial reporting of baseline characteristics.
Bostrom et al. (1996) USA	112 pts Setting: multiple Speciality: multiple	Medical and surgical patients admitted to three hospitals (tertiary, general and community) aged more than 18 years, able to give consent and anticipated hospital stay of 48 h or more	Cohort Logistic regression	112 (8.04%), 9 Stage ≥ 1 PU	7 (1) No. of layers between pt and mattress	0.001	NR		VLQS Insufficient number of events. Analysis reporting inadequate. No confidence intervals reported. Time dependent variables included in the analysis.
Bourdel-Marchasson et al. (2000) France	672 pts Setting: acute care hospital Speciality: elderly/geriatric	Patients recruited from wards of University hospital and geriatrics units where >40% of inpatients were older than 65years, including neurology, gastroenterology, orthopaedic surgery, vascular surgery, internal and geriatric medicine. Patient inclusions were aged older than 65 years in acute phase of a critical illness, unable to move by themselves, unable to eat independently, and no PU on admission. Consent requirement not reported	RCT Cox proportional hazards model	672 (44.5%), 299 stage ≥ 1 PUs	NR (5) Hypoalbuminemia Lower limb fracture Norton score 5–10 vs. >14 Kuntzman score Control vs. nutritional intervention	<0.001 <0.001 0.04 0.003 0.04	1.1 2.7 1.3 1.2 1.6	1.0–1.1 1.8–4.1 1.0–1.6 0.3–4.6 1.0–2.4	MQS Full details of modelling not provided. Adequate number of events is assumed as large number of events (299).

Boyle and Green (2001) UK	534 pts Setting: ICU	All ICU pts not consented. PU that developed after day 1 admission were included in analysis. PU present on admission were excluded.	Cohort Parametric survival regression (Weibull)	534 (5.2%), 28 Grade ≥ 1 PU	7 (2) Coma/ unresponsiveness/ paralysed and sedated	0.001	4.2	30–77	LQS Baseline characteristics not reported. Insufficient number of events.
					Cardiovascular instability	0.035	2.7	4–70	
Brandeis et al. (1994) USA	4232 non-surgical pts Setting: long-term nursing care/nursing home Speciality: elderly/geriatric	Residents aged over 60, admitted to NHC nursing homes during 1988 and 1989, free of PU on admission and at 3-month follow-up (the baseline assessment) Eligible residents remained in the home for at least 3 months after baseline assessment up to 21 months. Consent not required record review	Cohort Pooled logistic regression	4232 (12.9%), 546 Stage ≥ 2	Model 1 15 (4) Ambulation difficulty	<0.001	3.3	2.0–5.3	HQS Record review.
				Model 1 High incidence Homes 1322 (19.3%), 255 Stage ≥ 2 PU	Faecal incontinence	<0.001	2.5	1.6–4.0	
					Diabetes	<0.006	1.7	1.2–2.5	
					Feeding ADL	<0.001	2.2	1.5–3.3	
Chan et al. (2005) Singapore	666 pts Setting: acute care hospital Speciality: multiple	All hospital in-patients on census date, aged >18 , excluding infectious disease wards, aggressive psychiatric pts, airborne infectious pts, pts with existing ulcers.	Cohort Logistic regression	666 (8.1%), 54 Stage ≥ 1 PU	23 (1) Braden score (Braden score 12–15)	0.001			LQS Only partial reporting of baseline characteristics. Inadequate reporting of analysis and modelling. Inadequate number of events.
					(Braden score 6–11)	0.001	7.0	3.5–17.1	
						0.001	12.5	4.5–34.6	
Cobb et al. (1997) USA	123 pts Setting: acute care hospital Speciality: ICU	Aged over 18 years, weighed 290 pounds or less, did not have a pre-existing PU, expected length of stay one to two weeks, determined to be at-risk based on Braden scale. Consent required. All hospital wards and intensive care units of large military hospital	RCT Wilcoxon test	123 (16.3%), 20 Stage ≥ 1 PU	4 (2) Hypertension Weight	0.03 0.05	NR	NR	VLQS Inadequate reporting of analysis methods. No confidence intervals. Insufficient number of events.
Compton et al. (2008) German	713 Setting: Acute care hospital, non surgical Speciality: ICU	All patients without a PU on admission to the medical ICU between April 2001 and December 2004 were eligible for inclusion. Patient who remained in ICU for less than 72 h were excluded from the analysis.	Record Review	698 (17%) 121 grade 2–4	32 (6) Male gender	0.014	1.8		LQS Record review. Large number of events but it used 32 variables in model. No confidence intervals reported.
					Moist skin	0.001	2.4		
					Oedematous skin	0.002	2.2		
					Centralised circulation	0.001	2.4		
					Mottled skin	0.016	2.0		
					Reddened skin	0.001	2.3		

Table 1 (Continued)

Study and country	Study population (No. recruited and type)	Other inclusion criteria	Design and analysis method	No. final model (PU%), no. PU dev and stage/grade	Results: No. risk factors (No. in model), model risk factor names	p value	Odds ratio	Confidence intervals	Overall study quality and limitation notes
Defloor and Grypdonck (2005) Belgium	1772 non-surgical pts Setting: long-term nursing care/nursing home Speciality: elderly/geriatric	All in-patients in the 11 long-term care facilities during the 4 week study period	RCT Stepwise logistic regression	1458 Model 1 Grade ≥ 1 , 302/1458 (20.7%)	Model 1 19 (3) Braden sensory perception Skin condition Existing PU	0.02 <0.001 <0.001	0.8 1.5 2.3	0.6–1.0 1.2–1.9 1.4–3.5	HQS Limitation partial reporting of baseline.
				Model 2 Grade $\geq 2 = 171/1458$ (11.7%)	Model 2 19 (4) Braden activity Braden sensory perception Skin condition Existing PU	0.03 0.02 <0.001 0.01	0.7 0.7 1.6 1.9	0.5–1.0 0.6–1.0 1.3–2.1 1.1–3.0	
De Laat et al. (2007) Netherlands	399 pts Setting: acute care hospital Speciality: ICU	Pts admitted into ICU, with expected length of stay >48 h, without PU on admission, and screened within 48 h of admission. Consent not required.	Cohort Cox proportional hazards model	399 (35.1%), 140 Grade ≥ 2 PU	11 (3) Preventive transfers Shock/resus Friction/shear	<0.001 <0.001 0.02	0.2 1.5 1.3	NR	MQS Ward staff recording data and no confidence intervals reported. Time dependent covariates included in the analysis.
Donnelly (2006) UK	240 hip fracture pts Setting: acute care hospital Speciality: elderly/geriatric	Aged 65 years or older on the day of injury, new fractured hip (injury <48 h “old”), able to undergo tests and assessment procedures included in the study. Patient consent required.	RCT Cox proportional hazards model	239 (16.3%), 39 Grade ≥ 1 PU	20 (1) Control group (standard mattress)	0.001	4.6	NR	LQS Insufficient number of events and no confidence intervals reported.
Ek (1987) Sweden	515 non-surgical pts Setting: Chronic care hospital Speciality: medicine	Consecutive patients admitted to a long-term medical ward who were hospitalised for more than 3 days. With or without PU at baseline. Consent requirement not reported	Cohort Logistic regression	515 (7.6%), 39 \geq Stage 1 equivalent PU Model 1 Baseline measures	Model 1 8 (1) Norton mobility	<0.05	NR	NR	VLQS Partial reporting of baseline. Inadequate reporting of methods. Insufficient number of events and no confidence intervals reported.
				Model 2 variables on day of PU or if PU free on 4th week of care	Model 2 8 (2) General physical condition Norton activity	<0.01 <0.01	NR NR	NR NR	

Ek et al. (1991) Sweden	501 non-surgical pts Setting: Acute care hospital Speciality: Medicine	Newly admitted long-term medical ward admissions who remained in hospital more than 3 weeks. Patient consent required.	RCT Multiple regression	495 (10.1%), 51 stage ≥ 1 equivalent PU	NR (4) Albumin Norton mobility Norton activity Food intake	<0.001 <0.001 <0.001 <0.05	NR	NR	VLQS Partial reporting of baseline. Inadequate reporting of methods and analysis. No confidence intervals. Adequacy of number of events cannot be assessed.
Feuchtinger et al. (2006) Germany	175 surgical pts Setting: acute care hospital Speciality: cardiac surgery	Aged 18 or over, scheduled for cardiac surgery with ECC, not included in another study, consent required	RCT Logistic regression	175 (14.3%), 25 Grade ≥ 1 PU	13 (1) Renal insufficiency	0.05	NR	NR	LQS Inadequate reporting of analysis and insufficient number of events. No confidence intervals reported.
Fife et al. (2001) USA	186 pts Setting: ICU	All patients admitted to Neuro ICU (acute SCI/head injuries/gunshot wounds/CVAs). No consent required (apart from for photographs). Excluded if a PU > stage 2 on initial assessment, discharge from unit <24 h after admission, diagnosis of brain death on life support pending organ donation, no evaluation by nursing staff within 12 h after admission.	Cohort Stepwise, logistic regression	149 (15.4%), 23 Stage ≥ 2 PU	11 (2) Braden score Age	0.002 0.043	NR	NR	LQS Insufficient number of events. Odds ratios and confidence levels not reported.
Goodridge et al. (1998) Canada	330 non-surgical pts Setting: acute care hospital Speciality: elderly/geriatric	Care-setting: medical/elderly of tertiary care facilities and long-term care facilities >65 years, within 48–96 h of admission Exclusion: pre-existing dermal ulcers, terminal stages of cancer, acute/chronic renal failure	Cohort Stepwise logistic regression	330 (9.7%), 32 Stage ≥ 1 PU	5 (1) No. of prevention strategies used prior to PU appearance	<0.001	1.4	NR	VLQS Partial presentation of baseline data. Nutritional factors collected but not analysed. Analysis reporting inadequate. No confidence intervals or <i>p</i> values reported. Insufficient number of events. Time dependent variable included in the analysis.

Table 1 (Continued)

Study and country	Study population (No. recruited and type)	Other inclusion criteria	Design and analysis method	No. final model (PU%), no. PU dev and stage/grade	Results: No. risk factors (No. in model), model risk factor names	<i>p</i> value	Odds ratio	Confidence intervals	Overall study quality and limitation notes
Gunningberg et al. (2001) Sweden	146 hip fracture pts Setting: acute care hospital Speciality: trauma	Patients with hip fracture, 65 or more years, admitted without a PU carried out in the A&E department and the Department of orthopaedics not sure about consent – assume not	Record review Logistic regression	146 (36.9%), 54 stage ≥ 1 PU	3 (1) Advanced age	0.03	1.1	NR	MQS Partial reporting of baseline characteristics and analysis reporting inadequate. No confidence intervals reported.
Halfens et al. (2000) Netherlands	320 pts Setting: acute care hospital Speciality: multiple	No PU on admittance, Caucasian, probable hospital stay of at least 10 days. Consent required. 3 hospitals including surgical, neurological, orthopaedic, and internal medicine patients	Cohort Stepwise logistic regression	320 (14.7%), 47 Grade ≥ 1 PU	16 (4) Braden sensory perception Age Braden friction/shear Braden moisture	<0.01 <0.01 <0.01	3.7 2.3 2.3	1.4–9.3 1.4–3.9 1.4–4.0	LQS Partial reporting of baseline characteristics and insufficient number of events.
Hatanaka et al. (2008) Japan	149 non-surgical pts Setting: Acute Care Hospital Speciality: Respiratory	Bedridden patients who were hospitalised for a respiratory disorder, and required constant attentive care or needed a considerable amount of assisted care.	Cohort Cox proportional hazards model	149 (25.5%) 38 Grade ≥ 2	NR(5) Hb CRP Alb Age Gender	0.006 0.042 0.021 0.953 0.379	1.2 1.9 0.4 1.0 0.7	1.1–1.4 1.0–3.9 0.2–0.9 0.97–1.03 0.3–1.7	LQS Clinical data collection method not reported and number of factors entered into the stepwise procedure not reported, therefore adequacy of number of events cannot be assessed.

Inman et al. (1999) Canada	149 pts Setting: ICU	Aged 17 years or older, an Acute Physiology and Chronic Health Evaluation (APACHE) II score of at least 15, expected stay in ICU of at least 3 days. Pts excluded if PUs at baseline, not expected to survive, admitted for compassionate care or ICU transfer. consecutive admissions randomised – not concealed allocation, consent procedure not detailed.	RCT Stepwise logistic regression	144 (25.7%), 37 Stage ≥ 1 PU	9 (2) LOS in ICU Increasing SURE score	NR	NR	NR	VLQS Poor quality reporting and insufficient number of events. Limited number of risk factors. Inadequate stats reporting and the independent variable is a composite score which includes the dependent variable. <i>p</i> values, Odds ratios or confidence intervals not reported. Data reporting by ward staff. Time dependent variable included in the analysis (LOS and increase SURE score).
Kemp et al. (1993) USA	84 non-surgical pts Setting: multiple Speciality: elderly/medical	Patients recruited from hospital in-patient (general medicine and geriatric medicine) and long-term care facilities. Patient inclusion were aged 65 years or more, had Braden score of 16 or less and PU free. Eligible patients invited to participate – consent requirements not detailed.	RCT Cox regression	84 (39.3%), 33 Stage ≥ 1 PU	11 (2) Overlay type Average Braden mobility	0.018 <0.001	NR	NR	LQS Inadequate number of events, Confidence intervals not reported.
Lindgren et al. (2004) Sweden	548 mixed pts Setting: acute care hospital Speciality: multiple	Elective and acute medical and surgical patients admitted to 21 wards in University hospital, aged over 17 years of age, an expected hospital stay of at least 5 days, for patients undergoing surgery an expected time on operating table of at least 1 h and PU free. Verbal consent or verbal relative assent required. Consecutive patients admitted in 3 defined days included up to a maximum of 9 per week.	Cohort Multiple stepwise logistic regression	530 (11.7%) 62 Stage ≥ 1 , Model 1 Total sample 530 (11.7%) 62	Model 1 13 (5) Mobility RAPS Length of hospitalisation Age Weight Surgical treatment	0.011 0.002 0.014 0.006 <0.001	0.5 1.0 1.0 1.0 4.8	0.3–0.9 1.0–1.1 1.0–1.1 0.9–1.0 2.0–11.4	LQS Insufficient number of events. Time dependent covariate was included in the analysis.
				Model 2 Medical patients 244 (8.6%) 21	Model 2 13 (3) Mobility RAPS Length of hospitalisation Diastolic BP	0.001 0.029 0.026	0.4 1.0 1.0	0.2–0.6 1.00–1.04 0.9–1.0	
				Model 3 Surgical patients 286 (14.3%) 41	Model 3 13 (3) Serum albumin RAPS Length hospitalisation Weight	0.029 0.027 0.002	0.5 1.0 1.0	0.3–0.9 1.0–1.1 0.9–1.0	

Table 1 (Continued)

Study and country	Study population (No. recruited and type)	Other inclusion criteria	Design and analysis method	No. final model (PU%), no. PU dev and stage/grade	Results: No. risk factors (No. in model), model risk factor names	p value	Odds ratio	Confidence intervals	Overall study quality and limitation notes
Marchette et al. (1991) USA	161 surgical pts Setting: acute care hospital Speciality: ICU	Patients aged over 59 years who were in ICU after a surgery. Consent not required.	Record review Discriminant analysis	161 (39.1%), 63 Stage ≥ 2 equivalent PU	NR (5) Skin redness Days static air mattress for prevention Faecal incontinence Diarrhoea Preoperative albumin	<0.001 <0.001 0.0013 0.0019 0.0028	NR	NR	VLQS Inadequate reporting of methods and analysis. No confidence intervals. Included time dependent variables in the analysis. Adequacy of number of events cannot be assessed.
Nijs et al. (2009) Belgium	520 pts Setting: acute care hospital, surgical Speciality: ICU	Pts expected to stay more than 24 h admitted to the Surgical ICU of an acute hospital. Patient younger than 16 years old and patient admitted for burn injuries were excluded.	Cohort Multivariate logistic regression	463 (28.9%) 134 Grade 2–4	19 (9) Dopamine < 5mcg/km/min Medical history of vascular disease IHD or CVVH Adequate prevention Frequency of turning $\geq 6 \times$ /day or alternating mattress Turning Use of sedatives Body Temp $\geq 38.5^\circ\text{C}$ Sitting in chair	0.003 <0.001 0.045 0.002 <0.001 <0.001 0.006 0.029 <0.001	6.1 4.5 3.8 6.0 30.2 6.7 0.3 0.2 0.1	1.9–19.5 2.0–10.2 1.0–13.9 1.9–18.6 12.2–74.8 2.7–16.4 0.1–0.7 0.2–0.9 0.0–0.3	MQS Full details of modelling not provided. Adequate number of events is assumed as large number of events.
Nixon et al. (2006) UK	1972 pts Setting: acute care hospital Speciality: multiple	Aged 55 or over, admitted to vascular, orthopaedic, medical, or care of elderly people wards, either as acute or elective, expected length of stay at least 7 days and either limitation of activity or mobility or an existing pressure ulcer of grade 2. consent required	RCT, logistic regression	1971 (10.5%), 207 Grade ≥ 2 PU	13 (7) Hospital Acute admission Baseline wound Baseline skin trauma Baseline grade 1 Age Diabetes	0.02 <0.001 <0.001 0.05 0.001 0.03 0.047	3.7 3.0 1.7 2.0 1.0 1.6	2.3–5.9 1.7–5.1 1.0–2.8 1.3–2.9 1.002–1.04 1.0–2.6	HQS Minor limitation – number of patient in final model not reported.

Nixon et al. (2007) UK	109 surgical pts Setting: acute care hospital Speciality: multiple	Aged over 55, expected length of stay 5 or more days, scheduled for elective major general surgery or vascular surgery OR acute orthopaedic (average surgical time of 90 min or more), vascular and general surgical admission, with or without PU at baseline. Consent required	Cohort Forward stepwise logistic regression	97 (15.5%), 15 Grade ≥ 2 PU	8 (4) Pre-op albumin Grade 1 equivalent Weight loss Diastolic Bpmin	0.009 0.008 0.092 0.205	0.8 7.0 0.3 1.0	0.7-1.0 1.7-29.5 0.1-1.2 0.9-1.0	LQS Inadequate number of events. Included time dependent variables in the analysis.
Okuwa et al. (2006) Japan	259 non-surgical pts Setting: long-term nursing care/nursing home Speciality: elderly/geriatric	Patients admitted to long-term care facility, aged 65 or older, bedfast, without lower extremity PU, length of hospital stay 14 or more days, identified at risk of developing PU. Consent required from patients or family	Cohort Forward stepwise Cox regression	259 (12.7%), 33 stage ≥ 2 PU	9 (3) Ankle brachial index Length of bedfast period Male gender	<0.001 0.003 0.001	0.1 3.0 1.0	0.0-0.2 1.5-6.0 1.004-1.015	LQS Inadequate number of events. Time dependent variables reported.
Olson et al. (1996) USA	149 pts Setting: acute care hospital Speciality: multiple	Medical and surgical inpatients aged 18 and above with no pressure ulcers on admission, expected hospital stay of 5 or more days, consent required	Cohort Stepwise logistic regression	143 (13.9%), 20 Stage ≥ 1 PU	11 (3) Haemoglobin Hours in bed Pulse pressure	0.0731 0.0551 0.3022	NR NR NR	NR NR NR	LQS Insufficient number of events.
Ooi et al. (1999) USA	5518 non-surgical pts Setting: long-term nursing care/nursing home Speciality: elderly/geriatric	Nursing home residents free from Pus at baseline and 3 month f-up assessment. Excluded residents in homes < 50. Consent not required record review	Record review Logistic regression backward elimination	5518 (11.4%), 629 Stage ≥ 2 PU	6 (6) Age Diabetes Faecal/urine incontinence Transfers Medicaid payments Facility effects (Facility effects intermediate) (Facility effects high risk)	0.0081 0.0106 <0.001 <0.001 0.0623 <0.001 <0.001	1.0 1.4 1.6 1.5 1.2 1.6 1.9	1.00-1.03 1.1-1.7 1.2-2.0 1.2-1.8 1.0-1.4 1.3-2.0 1.5-2.4	MQS Record review and limited range of risk factors considered (e.g. do not have mobility in the model).

Table 1 (Continued)

Study and country	Study population (No. recruited and type)	Other inclusion criteria	Design and analysis method	No. final model (PU%), no. PU dev and stage/grade	Results: No. risk factors (No. in model), model risk factor names	p value	Odds ratio	Confidence intervals	Overall study quality and limitation notes
Pancorbo Hidalgo and Garcia Fernandez (2001) Spain	187 pts Setting: acute care hospital Speciality: multiple	Pts at risk of PUs (Gosnell score of equal to or less than 12) and aged more than 70 years, admitted to internal medicine, ICU, general surgery, and orthopaedic wards	Cohort Logistic regression	187 (16.6%), 31 Stage ≥ 1 Model 1 Stage ≥ 1	Model 1 16 (9)				LQS Article was translated so unable to undertake detailed quality assessment. Limitations based on inadequate number of events. Time dependent variables included in the analysis.
					Length of stay	<0.05	1.1	1.1–1.2	
					Gosnell score	<0.05	1.2	1.1–1.2	
					Incontinence	<0.05	2.2	1.7–2.9	
					Skin alterations diminished	<0.05	1.4	1.0–1.9	
					Highest systolic BP	<0.05	1.0	0.9–1.0	
					Lowest diastolic BP	<0.05	1.1	1.06–1.13	
					Low skin fold thickness	<0.05	1.3	1.0–1.6	
					Diminished lymphocytes	<0.05	1.2	1.0–1.5	
					Low haemoglobin	<0.05	2.2	1.3–3.9	
					Model 2 Stage ≥ 2				
					Model 2 (10)				
					Length of Stay	<0.05	1.2	1.1–1.2	
					Gosnell score	<0.05	1.1	1.1–1.2	
					Incontinence	<0.05	1.2	1.1–1.2	
					NOVA activity diminished	<0.05	2.0	1.2–3.5	
					Highest systolic BP	<0.05	1.0	0.9–1.0	
					Lowest diastolic BP	<0.05	1.1	1.0–1.1	
					Low skin fold thickness	<0.05	1.4	1.0–1.9	
Diminished lymphocytes	<0.05	1.5	1.1–2.0						
Low haemoglobin	<0.05	3.0	1.5–6.1						
Use of alternating overlay (for at risk pts)	<0.05	2.7	1.0–6.9						
Perneger et al. (2002) Switzerland	1190 pts Setting: acute care hospital Speciality: multiple	All newly admitted patients admitted to mixed specialties within a teaching hospital (with or without PU at baseline). Consent not required	Cohort Multivariate proportional hazards model	1190 (10.8%), 129 stage ≥ 1 PU	10 (3)				HQS Limitation partial reporting of baseline.
					Braden/Norton mobility	0.006	1.4	1.1–1.8	
					Braden friction/shear	0.034	1.5	1.0–1.8	
					Age (16–59)				
					(Age 60–69)		1.5	0.8–2.2	
					(Age 70–79)		2.5	1.5–4.4	
					(Age 80–89)		3.8	2.3–6.4	
					(Age 90–96)		5.2	2.6–10.6	

Rademakers et al. (2007) Netherlands	722 hip fracture pts Setting: acute care hospital Speciality: Trauma	All hip fracture patients admitted to a level one trauma centre. Exclusion: age < 60 years, (multiple) high energy trauma (defined as a fall from higher than ground level, or road traffic accidents), initial conservative treatment, inter-hospital transfer, presence of PUs on admission, pathological fractures and recurrent fractures	Record review, Multivariate logistic regression	722 (29.6%), 214 Stage ≥ 2 PU	10 (5) Diabetes Post-op urinary tract infection Post-op hip dislocation ASA class III/IV Time to surgery >12h	0.021 0.004 0.009 0.001 0.008	1.7 1.9 2.7 4.2 1.7	1.1–2.7 1.2–2.9 1.3–5.6 2.9–6.1 1.2–2.6	MQS Large sample size but limited number of risk factors considered and not based on a conceptual framework (no nutrition or skin moisture factors). Inadequate measurement of risk factor. (Record review).
Reed et al. (2003) USA	2771 non-surgical pts Setting: chronic care hospital Speciality: medicine	Record review identifying: mobility impaired, admitted to the chosen hospital wards between July 1st, 1994 through until October 1 1997, length of stay of at least 1 week. Consent not required – record review grade 3's and 4's reported	Record review Forward stepwise logistic regression	2771 (14.7%), 406 Stage ≥ 2 PU	7 (6) Low albumin levels Confusion DNR Urinary catheter on admission Malnutrition Stage 1 PU	0.014 0.001 <0.001 <0.001 <0.001 <0.001	1.4 1.5 1.5 1.6 1.7 3.1	1.1–1.8 1.2–1.8 1.2–1.9 1.4–1.8 1.3–2.2 2.4–4.1	HQS Record review.
Rose et al. (2006) Canada	111 pts Setting: acute care hospital Speciality: ICU	Consecutive admissions to university hospital intensive care unit. Consent not reported	Cohort Multiple regression	111 (43.2%), 48 stage ≥ 1 PU	NR (3) Skin quality Restricted movement Temperature	NR NR NR	NR NR NR	NR NR NR	VLQS Abstract only. Inadequate information on methodology and analysis. No p values or confidence intervals.
Salzberg et al. (1999) USA	226 SCI pts Setting: acute care hospital Speciality: trauma	SCI with a neurological deficit attributable to damage of the spinal cord; excluding the cortices and brainstem, defined by ICD-9CM, acute SCI due to a trauma, survival of at least 14 days following acute SCI, and level of SCI between C4-S1.	Record review Model 1 forward stepwise linear regression Model 2 Cox proportional hazards	226 (38.5%), 87 Stage ≥ 1 PU	Model 1 8 (3) Extent of paralysis Moisture Serum creatinine Model 2 8 (8) Extent of paralysis Moisture Serum creatinine Incontinence Albumin Mobility Pulmonary disease Level of activity	<0.001 <0.001 0.007 <0.001 0.003 0.006 <0.001 0.028 0.002 0.014 0.036	NR NR NR NR NR NR NR NR NR NR NR	NR NR NR NR NR NR NR NR NR NR NR	MQS Limited because of record review and no confidence intervals reported.
Sayar et al. (2009) Turkey	140 Setting: acute care hospital Speciality: ICU	Surgical and medical ICU patients. Within 1–2 h after admission to ICU, the waterlow was administered to determine PU risk. Patients who were given scores that were 'at risk' and very high risk' limits were taken into the study	Cohort Multiple stepwise logistic regressions	140 (14.3%) 20 Stage ≥ 1 PU	6 (2) Length of stay Activity level	<0.001 0.005	1.2 0.3	1.1–1.3 0.2–0.7	LQS Insufficient number of events.

Table 1 (Continued)

Study and country	Study population (No. recruited and type)	Other inclusion criteria	Design and analysis method	No. final model (PU%), no. PU dev and stage/grade	Results: No. risk factors (No. in model), model risk factor names	p value	Odds ratio	Confidence intervals	Overall study quality and limitation notes
Schnelle et al. (1997) USA	105 non-surgical pts Setting: long-term nursing care/nursing home Speciality: elderly/geriatric	Incontinent nursing home residents, consent required, exclusion criteria presence of stage 2 or above PU at baseline, catheters, <60 day length of stay	Cohort Stepwise multiple regression	91 (20.9%), 19 Stage ≥ 1 PU Model 1 Stage ≥ 1 severity index = NR Model 2 Stage ≥ 1 only = NR	Model 1 NR (2) Bed mobility Blanchable erythema severity Model 2 NR (1) Blanchable erythema severity	NR	NR	NR	LQS Insufficient number of events and analysis reporting inadequate. No p values or confidence intervals reported.
Schoonhoven et al. (2002) Netherlands	223 surgical pts Setting: acute care hospital Speciality: multiple	Patients scheduled for surgery expected to exceed 4 h (post recruitment exclusion if surgery lasted less than 4 h)	Cohort, multiple logistic regression	208 (10.1), 21 Grade ≥ 2 PU	12 (1) Length of surgery (in minutes)	<0.05	1.0	1.0035–1.0087	LQS Baseline characteristics not reported. Insufficient number of events.
Schultz et al. (1999) USA	413 surgical pts Setting: acute care hospital Speciality: mixed	Pts scheduled for inpatient care, aged 18 and over, with surgery scheduled to last longer than 2 h in the lithotomy or supine position, Pts excluded if had a PU present at baseline, pts with severe chronic skin problems, or patients receiving only local anaesthesia	RCT Logistic regression	413 (21.5%), 89 Stage ≥ 1 PU	7 (5) Age Presence of diabetes Less body mass Use of the study mattress Admission Braden score	0.005 0.013 0.015 0.044 0.013	1.1 2.5 0.9 1.9 0.8	1.0–1.1 1.2–5.3 0.9–1.0 1.0–3.7 0.7–1.0	HQS Risk factors were recorded by OR and ward staff, although outcome data was assessed by research assistants.
Serpa and Santos (2007) Brazil	170 pts Setting: private hospital Speciality: NR	Age ≥ 18 years, no PU at time of admission, hospitalised for minimum 24 h, total Braden Score Patients admitted to two private hospitals who were ≤ 18 and agreement to participate. Exclusion: presence of chronic renal failure, dialysis treatment for more than one month, and/or presence of hepatic insufficiency accompanied by ascites.	Cohort Multivariate logistic regression	170 NR	16 (5) Sub Global Nut Assess Albumin Ureas Age Institution	<0.001 <0.001 <0.001 <0.001 <0.001			LQS Unable to assess in detail, abstract and author communication available only. Low quality study based on assumed inadequate no events. Stage of PU definition unknown.

Stordeur et al. (1998) Belgium	174 surgical pts Setting: acute care hospital Speciality: cardiac/vascular	Consecutive patients 16 years or older, who underwent cardiac or vascular surgery, with min length of hospital stay > 5. Exclusion criteria pts who died. Not sure about consent – assume not	Cohort Stepwise logistic regression	163 (29.5%), 48 Stage ≥ 2 PU	16 (3) Postoperative Braden score Haemoglobin concentration at admission Postoperative steroid therapy	<0.001 <0.001 0.020	NR	NR	LQS Insufficient number of events and confidence intervals not reported.
Suriadi et al. (2008) Japan	253 pts: Acute care hospital Speciality: ICU	Age > 18years, ICU patients, admitted at least 24 h before enrolment in the study, bedfast, no existing PU, have the ability to give informed consent and Indonesian origin.	Cohort Logistic regression model	253 (28.4%) 72 Stage ≥ 1	Unknown (3) Interface pressure Body Temperature Cigarette smoking		2.2 2.0 1.6	1.6–2.9 1.7–2.5 1.1–2.5	MQS Inadequate reporting of analysis and modelling. Adequate number of events is assumed as large number of events.
Suriadi et al. (2007) Indonesia	105 pts Setting: ICU	Patients admitted to ICU, bedfast or could not walk, free from PUs, ICU patient for at least 24 h and expected length of ICU stay at least 3 days, informed consent (by patient or family). Exclusion: patients physically incapable of participating (difficult to identify the skin condition everyday because patient could not be manipulated) or any patient who did not wish to participate.	Cohort Multivariate logistic regression	105 (33.3%), 35 stage ≥ 1 PU	6 (4) Interface pressure Skin moisture Smoking > 10/day Body temperature	<0.001 0.002 0.001 0.001	17.6 8.2 12.7 102.0	4.1–74.3 2.2–30.9 2.8–56.7 7.7–98.8	LQS Insufficient number of events.
Tourtual et al. (1997) USA	291 non-surgical pts Setting: acute care hospital Speciality: medicine: elderly/geriatric	All patients admitted to the 4 nursing units within an acute hospital and gave consent, Baseline PU status not recorded	Cohort Forward stepwise logistic regression	291 (21.6%), 63 Stage ≥ 1 heel PU	17 (2) Braden friction and shear Braden moisture	0.01 0.007	NR	NR	LQS Insufficient number of events and confidence intervals not reported.
Vanderwee et al. (2009)	235 Setting: nursing home Speciality: elderly non surgical	Nursing home patients with no PU lesion (grade 2–4, EPUAP), if they could be repositioned, if they were expected to stay for more than 3 days in the nursing home and if they had non-blanchable erythema at a pressure point on the skin.	RCT Multivariate Cox regression analysis	235 (18.7%) 44 Grade ≥ 2 PU	16 (6) Age > 80–90 Age > 90 CVA Urinary inc Dual inc Contractures Hypotension	0.16 0.015 0.042 0.004 0.086 0.04 0.002	0.6 0.4 1.9 0.2 0.5 2.0 3.4	0.3–1.2 0.2–0.8 1.1–3.7 0.1–0.6 0.2–1.1 1.0–4.0 1.6–7.5	LQS Insufficient number of events.
Watts et al. (1998) USA	148 pts Setting: acute care hospital Speciality: trauma	Victims of blunt or penetrating injury, age 15 or older, with traumatic injuries, who had a length of stay of at least 2 days and no pre-existing pressure ulcers.	Cohort Logistic regression	148 (20.3%), 30 Stage ≥ 1 PU	20 (1) Braden mobility	NR	7.5	NR	VLQS Baseline characteristics not reported. Insufficient number of events. Insufficient presentation of analysis. Inadequate measurement of risk factors. No confidence intervals or <i>p</i> values reported.

Table 1 (Continued)

Study and country	Study population (No. recruited and type)	Other inclusion criteria	Design and analysis method	No. final model (PU%), no. PU dev and stage/grade	Results: No. risk factors (No. in model), model risk factor names	p value	Odds ratio	Confidence intervals	Overall study quality and limitation notes
Yepes et al. (2009)	150 Setting: acute care hospital Specialty: ICU	Pts without PU on admission who were hospitalised more than 48 h in ICU and who had any of the following risk factors for pressure ulcers: intubated and on mechanical ventilation, with vasopressor support.	Cohort Multivariate logistic regression	150 (26.7%) 40 stage ≥ 2	8 (3) Infection ICU LOS APACHE II	0.023 0.005 0.044	2.9 1.1 1.1	1.2–7.2 1.1–1.2 1–1.1	LQS Insufficient number of events. Time dependent variable included in the analysis.

RCT, randomised controlled trial; PU, pressure ulcer; ADL, activities of daily living; ICU, intensive care unit; SCI, spinal cord injury; LOS, length of stay; NR, not report.
Overall study quality: HQS (high quality study), MQS (moderate quality study), LQS (low quality study), VLQS (very low quality study).
p values <0.001 reported as such. Odds ratio and confidence intervals reported to one decimal place (where appropriate).

activity descriptors (bedfast/chair fast/immobility), mobility/activity ADL (Activities of Daily Living), general ADL, friction and shear, factors affecting mobility and interface pressures. Activity subscales categorise patients as bedfast, chair fast, walking with limitations, walking with no limitations, whilst mobility subscales tend to categorise frequency or magnitude of movement.

Overall 36 studies entered one or more mobility/activity related variables into their statistical models (Table 2). In 29 (80.5%) of these studies a mobility/activity related variable emerged as statistically significant (this included 2 large, high quality studies). The variables that emerged most consistently were mobility sub-scales (8 of 14 studies), mobility/activity ADL (4 of 7 studies) and activity (bedfast/chairfast/immobile descriptors (6 of 11 studies)). In all studies the direction of the relationship was that poorer mobility/activity increased the risk of pressure ulcer development.

Study specific activity descriptors were used in 11 studies and the use of non-standardised measures also impacts upon interpretation and clinical application of findings. A distinction is found in the literature between measures of activity which are at the macro level (that is, bedfast, chairfast, ambulation) and mobility which capture frequency and magnitude of movement. An important observation is that 14 studies used standardised measures (risk assessment scale subscales) and included both activity and mobility subscales in multivariable modelling. Both subscales emerged in 1 very poor quality study (Ek et al., 1991), in 7 the mobility subscale rather than the activity subscale emerged (Bergquist and Frantz, 1999; Baldwin and Ziegler, 1998; Watts et al., 1998; Perneger et al., 2002; Lindgren et al., 2004; Ek, 1987; Kemp et al., 1993), illustrating that mobility measures are more able to distinguish between patients who will or will not develop pressure ulcers.

3.5. Skin/pressure ulcer status

Skin/pressure ulcer status were categorised into 5 areas comprising general skin status (relating to factors which may make the skin more vulnerable to pressure ulcer development, e.g. redness, blanching erythema, dryness), stage/grade 1 equivalent, existing pressure ulcers, and previous pressure ulcers.

Overall sixteen studies entered one or more skin/pressure ulcer status related variables into their statistical models (Table 2). In 12 (75.0%) of these studies skin/pressure ulcer status related variables emerged in multivariable modelling as independently predictive of pressure ulcer development, and this included 3 high quality studies (Reed et al., 2003; Nixon et al., 2006; Defloor and Grypdonck, 2005).

There is strong association between Stage/Grade 1 pressure ulcers (Allman et al., 1995; Reed et al., 2003; Nixon et al., 2006, 2007) and subsequent \geq Stage/Grade 2 pressure ulcers. All of the studies reported odds ratios and confidence intervals and the 2 large high quality studies (Reed et al., 2003; Nixon et al., 2006) suggest that the presence of a Stage/Grade 1 pressure ulcer increases the odds of subsequent Stage/Grade 2 by 2–3 fold.

Table 2

Summary of evidence for risk factor domains/sub-domain.

Domain summary variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non significant in multivariable model
Mobility/activity sub-domains		
RAS mobility subscale 8 of 14 studies (57.1%)	1 HQS – Perneger et al. (2002) 3 LQS – Bergquist and Frantz (1999), Lindgren et al. (2004) and Kemp et al. (1993) 4 VLQS – Baldwin and Ziegler (1998), Watts et al. (1998), Ek (1987) and Ek et al. (1991)	1 MQS – Salzberg et al. (1999) 4 LQS – Vanderwee et al. (2009), Tourtual et al. (1997), Pancorbo Hidalgo and Garcia Fernandez (2001) and Halfens et al. (2000) 1 VLQS – Bostrom et al. (1996)
RAS activity subscale 1 of 16 studies (6.2%)	1 VLQS – Ek et al. (1991)	3 HQS – Defloor and Grypdonck (2005), Perneger et al. (2002) and Nixon et al. (2006) 1 MQS – Salzberg et al. (1999) 7 LQS – Bergquist and Frantz (1999), Vanderwee et al. (2009), Tourtual et al. (1997), Pancorbo Hidalgo and Garcia Fernandez (2001), Halfens et al. (2000), Lindgren et al. (2004) and Kemp et al. (1993) 4 VLQS – Baldwin and Ziegler (1998), Watts et al. (1998), Bostrom et al. (1996) and Ek (1987)
Activity (bed/chairfast/ immobile) descriptors 6 of 11 (54.5%)	1 MQS – Nijs et al. (2009) 5 LQS – Schnelle et al. (1997), Olson et al. (1996), Allman et al. (1995), Berlowitz and Wilking (1989) and Okuwa et al. (2006)	2 MQS – De Laat et al. (2007) and Baumgarten et al. (2004) 3 LQS – Fife et al. (2001), Bergquist and Frantz (1999) and Donnelly (2006)
Mobility/activity ADL 4 of 7 (57.1%)	1 HQS – Brandeis et al. (1994) 1 MQS – Ooi et al. (1999) 1 LQS – Sayar et al. (2009) 1 VLQS – Rose et al. (2006)	1 MQS – Rademakers et al. (2007) 2 LQS – Bergquist and Frantz (1999) and Donnelly (2006)
General ADL 2 of 4 (50%)	1 MQS – Baumgarten et al. (2004). 1 LQS – Bergquist and Frantz (1999)	1 HQS – Brandeis et al. (1994) 1 LQS – Berlowitz and Wilking (1989)
RAS friction and shear 4 of 12 (33.3%)	1 HQS – Perneger et al. (2002) 1 MQS – De Laat et al. (2007) 2 LQS – Tourtual et al. (1997) and Halfens et al. (2000)	1 HQS – Defloor and Grypdonck (2005) 4 LQS – Bergquist and Frantz (1999), Vanderwee et al. (2009), Lindgren et al. (2004) and Kemp et al. (1993) 3 VLQS – Baldwin and Ziegler (1998), Watts et al. (1998) and Bostrom et al. (1996)
Factors affecting mobility 6 of 13 (46.1%)	3 MQS – Rademakers et al. (2007), Salzberg et al. (1999) and Bourdel-Marchasson et al. (2000) 3 LQS – Boyle and Green (2001), Bergquist and Frantz (1999) and Vanderwee et al. (2009)	1 HQS – Defloor and Grypdonck (2005) 1 MQS – De Laat et al. (2007) 5 LQS – Fife et al. (2001), Sayar et al. (2009), Tourtual et al. (1997), Berlowitz and Wilking (1989) and Feuchtinger et al. (2006)
Interface pressures 2 of 2 (100%)	1 MQS – Suriadi et al. (2008) 1 LQS – Suriadi et al. (2007)	
Skin/PU status sub-domains		
Stage/grade 1 4 of 4 (100%)	2 HQS – Reed et al. (2003) and Nixon et al. (2006) 2 LQS – Allman et al. (1995) and Nixon et al. (2007)	
Existing pressure ulcer 2 of 5 (40%)	1 HQS – Defloor and Grypdonck (2005) 1 MQS – Baumgarten et al. (2004)	1 HQS – Nixon et al. (2006) 2 LQS – Tourtual et al. (1997) and Stordeur et al. (1998)
Previous pressure ulcers 0 of 2 (0%)		2 LQS – Allman et al. (1995) and Halfens et al. (2000)
General skin status 9 of 10 (90%)	2 HQS – Defloor and Grypdonck (2005) and Nixon et al. (2006) 5 LQS – Compton et al. (2008), Schnelle et al. (1997), Allman et al. (1995), Pancorbo Hidalgo and Garcia Fernandez (2001) and Bates-Jensen et al. (2007) 2 VLQS – Rose et al. (2006) and Marchette et al. (1991)	1 LQS – Boyle and Green (2001)
Perfusion sub-domains		
Diabetes 5 of 12 (41.6%)	3 HQS – Schultz et al. (1999), Brandeis et al. (1994) and Nixon et al. (2006) 2 MQS – Rademakers et al. (2007) and Ooi et al. (1999)	7 LQS – Compton et al. (2008), Vanderwee et al. (2009), Berlowitz and Wilking (1989), Stordeur et al. (1998), Halfens et al. (2000), Feuchtinger et al. (2006) and Donnelly (2006)
Vascular disease 4 of 6 (66.6%)	1 MQS – Nijs et al. (2009) 3 LQS – Vanderwee et al. (2009), Berlowitz and Wilking (1989) and Feuchtinger et al. (2006)	2 LQS – Tourtual et al. (1997) and Donnelly (2006)

Table 2 (Continued)

Domain summary variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non significant in multivariable model
Circulation 3 of 6 (50%)	3 LQS – Compton et al. (2008), Olson et al. (1996) and Okuwa et al. (2006)	1 HQS – Defloor and Grypdonck (2005) 2 LQS – Tourtual et al. (1997) and Feuchtinger et al. (2006)
Blood pressure 6 of 11 (54.5%)	1 MQS – Bergstrom and Braden (1992) 4 LQS – Boyle and Green (2001), Vanderwee et al. (2009), Pancorbo Hidalgo and Garcia Fernandez (2001) and Nixon et al. (2007) 1 VLQS – Cobb et al. (1997)	5 LQS – Fife et al. (2001), Suriadi et al. (2007), Olson et al. (1996), Lindgren et al. (2004) and Donnelly (2006)
Smoking 2 of 4 (50%)	1 MQS – Suriadi et al. (2008) 1 LQS – Suriadi et al. (2007)	2 LQS – Feuchtinger et al. (2006) and Donnelly (2006)
Oedema 1 of 4 (25%)	1 LQS – Compton et al. (2008)	1 MQS – Nijs et al. (2009) 2 LQS – Bergquist and Frantz (1999) and Donnelly (2006)
Haematological measures sub-domains		
U&Es 2 of 4 (50%)	1 MQS – Salzberg et al. (1999) 1 LQS – Serpa and Santos (2007)	2 LQS – Berlowitz and Wilking (1989) and Okuwa et al. (2006)
Protein 1 of 3 (33.3%)	1 LQS – Hatanaka et al. (2008)	1 LQS – Sayar et al. (2009) 1 VLQS – Marchette et al. (1991)
Albumin 7 of 11 (63.6%)	1 HQS – Reed et al. (2003) 1 MQS – Bourdel-Marchasson et al. (2000) 3 LQS – Serpa and Santos (2007), Hatanaka et al. (2008) and Nixon et al. (2007) 2 VLQS – Ek et al. (1991) and Marchette et al. (1991)	2 MQS – Bergstrom and Braden (1992) and Salzberg et al. (1999) 2 LQS – Lindgren et al. (2004) and Kemp et al. (1993)
Lymphopenia 2 of 2(100%)	2 LQS – Allman et al. (1995) and Pancorbo Hidalgo and Garcia Fernandez (2001)	
Haemoglobin (Hb) 6 of 11 (54.5%)	1 HQS – Nixon et al. (2006) 5 LQS – Hatanaka et al. (2008), Bergquist and Frantz (1999), Olson et al. (1996), Stordeur et al. (1998) and Pancorbo Hidalgo and Garcia Fernandez (2001)	1 MQS – Gunningberg et al. (2001) 4 LQS – Serpa and Santos (2007), Feuchtinger et al. (2006), Nixon et al. (2007) and Okuwa et al. (2006)
Moisture sub-domains		
Moisture subscales 4 of 12 (33.3%)	1 MQS – Salzberg et al. (1999) 2 LQS – Tourtual et al. (1997) and Halfens et al. (2000) 1 VLQS – Baldwin and Ziegler (1998)	2 HQS – Defloor and Grypdonck (2005) and Perneger et al. (2002) 3 LQS – Bergquist and Frantz (1999), Vanderwee et al. (2009) and Kemp et al. (1993) 3 VLQS – Watts et al. (1998), Bostrom et al. (1996) and Ek (1987)
Urinary incontinence 1 of 7 (14.3%)	1 LQS – Vanderwee et al. (2009)	1 HQS – Brandeis et al. (1994) 2 MQS – Salzberg et al. (1999) and Baumgarten et al. (2004). 3 LQS – Bergquist and Frantz (1999), Halfens et al. (2000) and Donnelly (2006)
Faecal incontinence 2 of 11 (18.2%)	1 HQS – Brandeis et al. (1994) 1 VLQS – Marchette et al. (1991)	1 HQS – Reed et al. (2003) 1 MQS – Baumgarten et al. (2004). 7 LQS – Boyle and Green (2001), Fife et al. (2001), Suriadi et al. (2007), Olson et al. (1996), Allman et al. (1995), Halfens et al. (2000) and Donnelly (2006)
Dual incontinence 3 of 5 (60.0%)	1 MQS – Ooi et al. (1999) 2 LQS – Bergquist and Frantz (1999) and Vanderwee et al. (2009)	1 MQS – Baumgarten et al. (2004). 1 LQS – Tourtual et al. (1997)
Incontinence other 1 of 1 (100%)	1 LQS – Pancorbo Hidalgo and Garcia Fernandez (2001)	
Urinary catheter 1 of 3(33.3%)	1 HQS – Reed et al. (2003)	2 LQS – Compton et al. (2008) and Berlowitz and Wilking (1989)
Skin moisture 3 of 5 (60.0%)	3 LQS – Suriadi et al. (2007), Compton et al. (2008) and Bergquist and Frantz (1999)	1 MQS – De Laat et al. (2007) 1 LQS – Halfens et al. (2000)
Body temperature domain		
Body temperature 5 of 8 (62.5%)	3 MQS – Nijs et al. (2009), Suriadi et al. (2008) and Bergstrom and Braden (1992) 1 LQS – Suriadi et al. (2007) 1 VLQS – Rose et al. (2006)	2 LQS – Vanderwee et al. (2009) and Feuchtinger et al. (2006) 1 VLQS – Ek (1987)

Table 2 (Continued)

Domain summary variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non significant in multivariable model
Nutrition sub-domains		
Nutritional scales 1 of 14 (7.1%)	1 LQS – Serpa and Santos (2007)	3 HQS – Defloor and Grypdonck (2005), Perneger et al. (2002) and Nixon et al. (2006) 6 LQS – Vanderwee et al. (2009), Tourtual et al. (1997), Pancorbo Hidalgo and Garcia Fernandez (2001), Halfens et al. (2000), Lindgren et al. (2004) and Kemp et al. (1993) 4 VLQS – Baldwin and Ziegler (1998), Watts et al. (1998), Bostrom et al. (1996) and Ek (1987)
Food intake 4 of 7 (57.1%)	1 HQS – Brandeis et al. (1994) 1 MQS – Bergstrom and Braden (1992) 1 LQS – Berlowitz and Wilking (1989) 1 VLQS – Ek et al. (1991)	1 HQS – Defloor and Grypdonck (2005) 1 MQS – De Laat et al. (2007) 1 LQS – Bergquist and Frantz (1999)
Malnourishment 1 of 3 (33.3%)	1 HQS – Reed et al. (2003)	2 LQS – Schoonhoven et al. (2002) and Donnelly (2006)
Weight 4 of 12 (33.3%)	3 LQS – Allman et al. (1995), Lindgren et al. (2004) and Nixon et al. (2007) 1 VLQS – Cobb et al. (1997)	1 MQS – Bergstrom and Braden (1992) 5 LQS – Yepes et al. (2009), Boyle and Green (2001), Compton et al. (2008), Olson et al. (1996) and Kemp et al. (1993) 2 VLQS – Inman et al. (1999) and Watts et al. (1998)
BMI 2 of 9 (22.2%)	1 HQS – Schultz et al. (1999) 1 LQS – Fife et al. (2001)	2 HQS – Defloor and Grypdonck (2005), Brandeis et al. (1994) 5 LQS – Serpa and Santos (2007), Compton et al. (2008), Vanderwee et al. (2009), Feuchtinger et al. (2006), Lindgren et al. (2004)
Arm measurements 1 of 3 (33.3%)	1 LQS – Pancorbo Hidalgo and Garcia Fernandez (2001)	2 LQS – Serpa and Santos (2007) and Allman et al. (1995)
Other measures 0 of 4 (0%)		2 LQS – Yepes et al. (2009) and Compton et al. (2008) 2 VLQS – Inman et al. (1999) and Watts et al. (1998)
Age domain		
Increasing age 12 of 32 (37.5%)	4 HQS – Schultz et al. (1999), Perneger et al. (2002), Bergstrom et al. (1996) and Nixon et al. (2006) 3 MQS – Ooi et al. (1999), Bergstrom and Braden (1992) and Gunningberg et al. (2001) 5 LQS – Serpa and Santos (2007), Hatanaka et al. (2008), Vanderwee et al. (2009), Halfens et al. (2000) and Lindgren et al. (2004)	2 HQS – Defloor and Grypdonck (2005) and Brandeis et al. (1994) 2 MQS – De Laat et al. (2007) and Baumgarten et al. (2004) 12 LQS – Chan et al. (2005), Yepes et al. (2009), Fife et al. (2001), Compton et al. (2008), Bergquist and Frantz (1999), Tourtual et al. (1997), Olson et al. (1996), Allman et al. (1995), Berlowitz and Wilking (1989), Feuchtinger et al. (2006), Kemp et al. (1993) and Nixon et al. (2007) 4 VLQS – Inman et al. (1999), Watts et al. (1998), Goodridge et al. (1998) and Cobb et al. (1997)
Sensory perception domain		
Sensory perception Braden subscale 2 of 9 (22.2%)	1 HQS – Defloor and Grypdonck (2005) 1 LQS – Halfens et al. (2000)	1 HQS – Perneger et al. (2002) 3 LQS – Vanderwee et al. (2009), Tourtual et al. (1997) and Kemp et al. (1993) 3 VLQS – Baldwin and Ziegler (1998), Watts et al. (1998) and Bostrom et al. (1996)
Mental status sub-domains		
Mental status subscales 1 of 5 (20%)	1 HQS – Perneger et al. (2002)	1 HQS – Defloor and Grypdonck (2005) 2 LQS – Pancorbo Hidalgo and Garcia Fernandez (2001) and Donnelly (2006) 1 VLQS – Ek (1987)
Mental status study specific measures 1 of 8 (12.5%)	1 HQS – Reed et al. (2003)	1 HQS – Brandeis et al. (1994) 1 MQS – Baumgarten et al. (2004). 5 LQS – Bergquist and Frantz (1999), Sayar et al. (2009), Pancorbo Hidalgo and Garcia Fernandez (2001), Halfens et al. (2000) and Donnelly (2006)
Race domain		
Race 2 of 5 (40%)	1 HQS – Bergstrom et al. (1996) 1 MQS – Baumgarten et al. (2004).	1 HQS – Brandeis et al. (1994) 2 LQS – Bates-Jensen et al. (2007) and Chan et al. (2005)

Table 2 (Continued)

Domain summary variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non significant in multivariable model
Gender domain		
Gender 4 of 15 (26.6%)	4 LQS – Compton et al. (2008), Bergquist and Frantz (1999), Okuwa et al. (2006) and Hatanaka et al. (2008)	2 HQS – Brandeis et al. (1994) and Bergstrom et al. (1996) 1 MQS – Baumgarten et al. (2004). 6 LQS – Chan et al. (2005), Serpa and Santos (2007), Boyle and Green (2001), Fife et al. (2001), Lindgren et al. (2004) and Donnelly (2006) 2 VLQS – Inman et al. (1999) and Goodridge et al. (1998)
General health status sub-domains		
ASA 1 of 2 (50%)	1 MQS – Rademakers et al. (2007)	1 LQS – Donnelly (2006)
APACHE 2 1 of 4 (25%)	1 LQS – Yepes et al. (2009)	1 MQS – Nijs et al. (2009) 1 LQS – Compton et al. (2008) 1 VLQS – Inman et al. (1999)
Norton score measures 0 of 3 (0%)		2 HQS – Defloor and Grypdonck (2005) and Perneger et al. (2002) 1 VLQS – Ek (1987)
Chronic wounds 1 of 2 (50%)	1 HQS – Nixon et al. (2006)	1 LQS – Nixon et al. (2007)
Other factors 8 of 26 (30.8%)	3 HQS – Schultz et al. (1999), Reed et al. (2003) and Nixon et al. (2006) 2 MQS – Rademakers et al. (2007) and Nijs et al. (2009) 2 LQS – Yepes et al. (2009) and Lindgren et al. (2004) 1 VLQS – Marchette et al. (1991)	2 HQS – Defloor and Grypdonck (2005) and Brandeis et al. (1994) 2 MQS – Salzberg et al. (1999) and De Laat et al. (2007) 12 LQS – Bates-Jensen et al. (2007), Chan et al. (2005), Serpa and Santos (2007), Schoonhoven et al. (2002), Fife et al. (2001), Compton et al. (2008), Bergquist and Frantz (1999), Halfens et al. (2000), Feuchtinger et al. (2006), Nixon et al. (2007), Okuwa et al. (2006) and Donnelly (2006) 2 VLQS – Inman et al. (1999) and Watts et al. (1998)
Medication domain		
Medication 3 of 10 (30%)	1 MQS – Nijs et al. (2009) 2 LQS – Bergquist and Frantz (1999) and Stordeur et al. (1998)	1 HQS – Brandeis et al. (1994) 6 LQS – Yepes et al. (2009), Schoonhoven et al. (2002), Compton et al. (2008), Vanderwee et al. (2009), Olson et al. (1996) and Donnelly (2006)
Risk factor sub-domains		
Braden scale total score 7 of 16 (43.75%)	2 HQS – Schultz et al. (1999) and Bergstrom et al. (1996) 1 MQS – Bergstrom and Braden (1992) 4 LQS – Bates-Jensen et al. (2007), Chan et al. (2005), Fife et al. (2001) and Stordeur et al. (1998)	6 LQS – Yepes et al. (2009), Serpa and Santos (2007), Bergquist and Frantz (1999), Tourtual et al. (1997), Kemp et al. (1993) and Donnelly (2006) 3 VLQS – Baldwin and Ziegler (1998), Watts et al. (1998) and Goodridge et al. (1998)
Other scales 3 of 7 (42.8%)	1 MQS – Bourdel-Marchasson et al. (2000) 1 LQS – Pancorbo Hidalgo and Garcia Fernandez (2001) 1 VLQS – Inman et al. (1999)	4 LQS – Compton et al. (2008), Sayar et al. (2009), Stordeur et al. (1998) and Lindgren et al. (2004)

HQS (high quality study), MQS (moderate quality study), LQS (low quality study), VLQS (very low quality study).

General skin status also appears to be important and emerged in 9 of the 10 studies which considered it (Schnelle et al., 1997; Allman et al., 1995; Pancorbo Hidalgo and Garcia Fernandez, 2001; Nixon et al., 2006; Rose et al., 2006; Marchette et al., 1991; Defloor and Grypdonck, 2005; Compton et al., 2008; Bates-Jensen et al., 2007) including 2 high quality studies (Nixon et al., 2006; Defloor and Grypdonck, 2005). However, the large number of descriptors and more recent technologies to quantify underlying inflammation (e.g. SEM Bates-Jensen et al., 2007), make interpretation difficult. The presence of existing pressure ulcers emerged only in long-term elderly patient populations (Baumgarten et al., 2004; Defloor and Grypdonck, 2005), whilst the presence of existing pressure

ulcer and previous pressure ulcer did not emerge in acute hospital patient studies.

3.6. Perfusion

Perfusion related variables were categorised into diabetes, vascular disease, circulation, blood pressure, smoking and oedema. Overall twenty-seven studies considered 1 or more perfusion related variables within their analysis (Table 2). Of these, in 19 studies (70.4%) a perfusion related variable emerged.

There is strong evidence that diabetes increases the probability of pressure ulcer development. Twelve studies (Brandeis et al., 1994; Berlowitz and Wilking, 1989; Ooi

et al., 1999; Stordeur et al., 1998; Halfens et al., 2000; Feuchtinger et al., 2006; Nixon et al., 2006; Donnelly, 2006; Schultz et al., 1999; Rademakers et al., 2007; Vanderwee et al., 2009; Compton et al., 2008) included the diagnosis of diabetes in multivariable modelling. Of these 5 studies comprising of 3 high quality studies (Brandeis et al., 1994; Nixon et al., 2006; Schultz et al., 1999) and 2 moderate quality studies (Ooi et al., 1999; Rademakers et al., 2007), including both acute and long-term care patient populations found diabetes to be associated with pressure ulcer development. The 7 studies where diabetes did not emerge were all of low quality having serious limitations, including insufficient number of events. Where diabetes emerged, the odds ratios associated with diabetes ranged from 1.35 to 2.52.

Evidence from the wide range of other 'perfusion-related' variables suggest that factors which impair circulation increase the probability of pressure ulcer development, but the evidence is limited by study quality – only 4 of 20 studies are high/moderate quality studies and interpretation is limited by the large range of variable descriptors. Further confirmatory research in this area is required.

3.7. Haematological measures

Haematological measures were categorised into U&Es, Protein, Albumin, Lymphopenia and Haemoglobin (Hb). Overall, twenty-two studies considered 1 or more haematological measures within their analysis (Table 2).

Eleven studies (Reed et al., 2003; Bergstrom and Braden, 1992; Salzberg et al., 1999; Lindgren et al., 2004; Bourdel-Marchasson et al., 2000; Kemp et al., 1993; Ek et al., 1991; Marchette et al., 1991; Nixon et al., 2007; Serpa and Santos, 2007; Hatanaka et al., 2008) included albumin as a variable in multivariable modelling. In 7 studies (63.6%) (Reed et al., 2003; Bourdel-Marchasson et al., 2000; Ek et al., 1991; Marchette et al., 1991; Nixon et al., 2007; Serpa and Santos, 2007; Hatanaka et al., 2008) albumin emerged as significant, the direction of the relationship suggesting that lower albumin levels are associated with pressure ulcer development. Analyses are limited by the use of categorical data.

Eleven studies (Bergquist and Frantz, 1999; Olson et al., 1996; Gunningberg et al., 2001; Stordeur et al., 1998; Pancorbo Hidalgo and Garcia Fernandez, 2001; Feuchtinger et al., 2006; Nixon et al., 2006, 2007; Okuwa et al., 2006; Serpa and Santos, 2007; Hatanaka et al., 2008) involving acute hospital, community and nursing home patient populations included haemoglobin or anaemia as a variable in multivariable analyses and in 6 studies (54.5%) (Bergquist and Frantz, 1999; Olson et al., 1996; Stordeur et al., 1998; Pancorbo Hidalgo and Garcia Fernandez, 2001; Nixon et al., 2006; Hatanaka et al., 2008) haemoglobin/anaemia emerged as a significant factor. The direction of the relationship reported in 6 studies, which comprised of 1 high quality study and 5 low quality studies was that reduced haemoglobin/anaemia is associated with pressure ulcer development. However, in one study (Hatanaka et al., 2008) the relationship was reversed but the study population comprised of respiratory patients where an increased

haemoglobin level is indicative of severity of respiratory disease.

Four studies (Berlowitz and Wilking, 1989; Salzberg et al., 1999; Okuwa et al., 2006; Serpa and Santos, 2007) included a variety of serum blood measures (creatinine, urea, chloride, and sodium) as variables in multivariable analysis and in 2 studies (Salzberg et al., 1999; Serpa and Santos, 2007) the variable emerged as significant (creatinine and urea). C-reactive protein was modelled in 2 low quality studies (Sayar et al., 2009; Hatanaka et al., 2008) and emerged in 1 (Hatanaka et al., 2008). Another very low quality study (Marchette et al., 1991) considered pre op protein but this did not emerge in the multivariable analyses. Two low quality studies (Allman et al., 1995; Pancorbo Hidalgo and Garcia Fernandez, 2001) included the variables lymphopenia and diminished lymphocytes within their multivariable analysis and both emerged as significant. Both studies were in acute hospital patient populations.

3.8. Moisture

Moisture related variables were categorised as moisture subscales of risk assessment scales, urinary incontinence, faecal incontinence, dual incontinence, incontinence other, urinary catheters and measures of skin moisture. Overall twenty-seven studies entered one or more moisture related variables into their statistical models. In 13 (48%) of these studies a moisture related variable emerged as statistically significant (Table 2). Overall, there is some evidence that moisture is a factor in pressure ulcer development with the measures relating to dual incontinence and skin moisture emerging more consistently compared to moisture risk assessment sub-scales, urinary and faecal incontinence.

3.9. Body temperature

Eight studies included temperature within their multivariable analysis (Table 2). In 5 studies (Suriadi et al., 2007, 2008; Bergstrom and Braden, 1992; Rose et al., 2006; Nijs et al., 2009) temperature emerged in multivariable modelling as independently predictive of pressure ulcer development. In 3 of these studies the direction of the relationship linked increased body temperature with pressure ulcer development; in 1 study increased temperature reduced the risk, and in 1 study the direction of the relationship was not reported. It is noteworthy that temperature emerged in all 4 ICU patient studies (Suriadi et al., 2007, 2008; Rose et al., 2006; Nijs et al., 2009). There are methodological limitations with the studies which limit interpretation. The majority of studies defined the temperature variable categorically. Only 3 of the 4 studies reporting statistical significance included odds ratios and confidence intervals (Suriadi et al., 2007, 2008; Nijs et al., 2009).

Overall, there is some evidence that increased body temperature may be an important predictor of pressure ulcer development, but further confirmatory research is required.

3.10. Nutrition

Nutrition related variables were categorised into nutritional scales, food intake, malnourishment, weight, BMI, arm measurement and other measurement. Overall 34 studies included 1 or more nutrition related variable in their analyses and in 13 (38.2%) a nutrition related variable emerged as an important predictor of pressure ulcer development (Table 2).

There are a number of limitations associated with this area of the epidemiological evidence and it is not clear that nutrition is a primary risk factor. However, the variables that emerged most consistently were related to food intake (4 of 7 studies) and weight (4 of 12 studies). Fourteen (Baldwin and Ziegler, 1998; Watts et al., 1998; Tourtual et al., 1997; Bostrom et al., 1996; Perneger et al., 2002; Pancorbo Hidalgo and Garcia Fernandez, 2001; Halfens et al., 2000; Lindgren et al., 2004; Ek, 1987; Kemp et al., 1993; Nixon et al., 2006; Defloor and Grypdonck, 2005; Serpa and Santos, 2007; Vanderwee et al., 2009) studies involving (in the main) acute care hospital patient populations, included nutritional scales which comprised of the Braden Nutrition subscale (10 studies), other nutrition subscales (3 studies) and one study that considered both the Subjective Global Nutrition Assessment (SGNA) and the Braden subscale. In only one low quality study (Serpa and Santos, 2007) did the nutrition scale (SGNA) emerge as independently associated with pressure ulcer development. The studies where nutritional scales did not emerge in multivariable modelling included 3 large high quality studies.

Of note is that 13 studies entered other subscales of the risk assessment scales in the multivariable analysis and the nutrition subscale was not found to be important in the presence of other key risk factors. In three studies none of the risk assessment subscales emerged in the model (Bostrom et al., 1996; Pancorbo Hidalgo and Garcia Fernandez, 2001; Vanderwee et al., 2009), and in 10 studies one or more other subscales including mobility (Baldwin and Ziegler, 1998; Watts et al., 1998; Perneger et al., 2002; Lindgren et al., 2004; Ek, 1987; Kemp et al., 1993), moisture (Baldwin and Ziegler, 1998; Tourtual et al., 1997; Halfens et al., 2000), friction and shear (Tourtual et al., 1997; Halfens et al., 2000) and sensory perception (Halfens et al., 2000; Defloor and Grypdonck, 2005) did emerge as important predictors of pressure ulcer development.

3.11. Increasing age

Thirty-two studies evaluated age as a variable in their analysis (Table 2). Of these increased age emerged in 12 (37.5%) studies (Perneger et al., 2002; Gunningberg et al., 2001; Ooi et al., 1999; Bergstrom et al., 1996; Bergstrom and Braden, 1992; Halfens et al., 2000; Lindgren et al., 2004; Nixon et al., 2006; Schultz et al., 1999; Serpa and Santos, 2007; Vanderwee et al., 2009; Hatanaka et al., 2008). It was anticipated that age would not emerge in homogenous study populations, however, reporting of mean age and age range of study populations is not comprehensive. The trend is noted in the high and

moderate quality studies. Seven high and moderate quality studies included heterogeneous study populations and in six (Perneger et al., 2002; Ooi et al., 1999; Bergstrom et al., 1996; Bergstrom and Braden, 1992; Nixon et al., 2006; Schultz et al., 1999) age emerged in multivariable modelling as an important predictor of pressure ulcer development, whilst in two high quality studies of very aged homogenous patient populations (Brandeis et al., 1994; Defloor and Grypdonck, 2005), age did not emerge as an important factor in the presence of other risk factors in multivariable modelling.

3.12. Sensory perception

Nine studies involving acute care hospital, long-term and ICU patient populations included the sensory perception subscale of the Braden scale within their multivariable analysis (Table 2). In two studies (Halfens et al., 2000; Defloor and Grypdonck, 2005) this factor emerged as statistically significant. However, it did not emerge in the remaining 7 studies.

3.13. Mental status

Overall eleven studies considered mental status, using a range of measures and descriptors in multivariable analysis and 2 (18.2%) studies found mental health variables to be of significance (Table 2). Mental status did not emerge as a key risk factor in pressure ulcer development.

3.14. Race

Five studies considered race as a variable in modelling (Table 2). In two studies (Bergstrom et al., 1996; Baumgarten et al., 2004) race emerged as an independent predictor of pressure ulcer development, however findings were contradictory, since in one study white race was associated with increased risk (Bergstrom et al., 1996) and in the other black race was associated with increased risk (Baumgarten et al., 2004). In the remaining three studies race did not emerge as being significant. Overall there is limited evidence relating to the relationship between race and pressure ulcer development.

3.15. Gender

Fifteen studies included gender in multivariable modelling (Table 2). Only 4 studies (Bergquist and Frantz, 1999; Okuwa et al., 2006; Hatanaka et al., 2008; Compton et al., 2008) demonstrated a relationship between gender and pressure ulcer development, with 3 (Bergquist and Frantz, 1999; Okuwa et al., 2006; Compton et al., 2008) identifying males at increased risk and 1 (Hatanaka et al., 2008) suggesting that males were at reduced risk. Eleven studies, including 2 high quality and 1 moderate quality did not find gender to be a significant factor in pressure ulcer development. Overall there is minimal evidence to suggest that gender is a risk factor associated with pressure ulcer development.

3.16. General health status

We categorised General Health Status into ASA (American Society of Anaesthesiologists) classification, APACHE 2 (Acute Physiology and Chronic Health Evaluation), Norton measures, chronic wounds and other factors. Overall twenty-eight studies considered 1 or more general health status measures within their analysis (Table 2). In 8 studies (28.6%) a general health status measure emerged as important in modelling. The presence of chronic wound also emerged in 1 of the 2 studies that included it in the statistical model. The variety of measures used has made it difficult to consider the overall importance of the findings.

3.17. Medication

Ten studies included various medication therapies in multivariable modelling (Table 2). In three studies (Bergquist and Frantz, 1999; Stordeur et al., 1998; Nijs et al., 2009) medication emerged as a significant variable and these included, use of sedatives, dopamine 5 mcg/kg/min, oxygen use and post operative steroid therapy. In one study (Nijs et al., 2009) of an ICU population use of sedative emerged as significant, however, the direction of the relationship was that it acted as a protective factor.

Overall there is limited evidence that any particular medication predisposes patient to develop pressure ulcers, rather they are likely to be a surrogate indicator of underlying disease pathology which may contribute to risk.

3.18. Risk assessment scale

Overall, 22 studies included a risk assessment scales total score within their analysis and in 10 (45.4%) the risk assessment scale total score emerged as statistically significant (Table 2). The risk assessment total score emerged in all the high quality (Bergstrom et al., 1996; Schultz et al., 1999) and moderate quality (Bergstrom and Braden, 1992; Bourdel-Marchasson et al., 2000) studies which included this variable. However, it is also noteworthy that in general, where studies included both total score and subscales of the risk assessment scale (Bergquist and Frantz, 1999; Baldwin and Ziegler, 1998; Watts et al., 1998; Tourtual et al., 1997; Pancorbo Hidalgo and Garcia Fernandez, 2001; Lindgren et al., 2004; Kemp et al., 1993) a subscale emerged as independently predictive of pressure ulcer development (Bergquist and Frantz, 1999; Baldwin and Ziegler, 1998; Watts et al., 1998; Tourtual et al., 1997; Lindgren et al., 2004; Kemp et al., 1993) rather than the total score.

4. Discussion

This is the first systematic review of risk factors related to pressure ulcer development. Results are consistent with pressure ulcer aetiology conceptual frameworks confirming major domains of mobility/activity, and perfusion (Defloor, 1999), whilst acknowledging the importance of skin/pressure ulcer status and diabetes. A strength of the review was that each of the included studies were subject

to a detailed quality assessment allowing limitations to be identified and taken into consideration in interpretation.

However, the review also highlights important limitations with the current evidence and methodological challenges associated with the conduct and interpretation of risk factor reviews in the absence of clear guidelines. A key limitation is the large number of descriptor variables used to describe risk factors which impacts upon interpretation and further use of the data in meta-analysis, highlighting the need for an internationally agreed minimum data set. Study quality is also generally poor (sample size considerations, analysis methods and standards of reporting). In general, sample size considerations for multivariable analyses have not been used to inform study design and only seventeen studies fulfilled the 'rule of thumb' sample size estimate of 10 events (or pressure ulcers) per variable in the multivariable model (Harrell et al., 1985; Peduzzi et al., 1995). The impact of this is demonstrated in studies which report Confidence Intervals (CIs). For example, four studies report non-blanchable erythema as an independent predictor of Grade ≥ 2 pressure ulcer development (Allman et al., 1995; Reed et al., 2003; Nixon et al., 2006, 2007). Two studies had inadequate numbers of pressure ulcers and reported large odds ratios with wide CIs (Allman et al., 1995; Nixon et al., 2007), whereas the two larger studies (Reed et al., 2003; Nixon et al., 2006) with adequate numbers of pressure ulcers reported lower odds ratios and narrow CIs. Future research should ensure adequate numbers of pressure ulcers to maximise the validity and generalisability of study results.

Continuous data has been analysed as continuous data (Olson et al., 1996; Stordeur et al., 1998; Nixon et al., 2006, 2007; Hatanaka et al., 2008), but also as categorical data (Bergquist and Frantz, 1999; Reed et al., 2003; Pancorbo Hidalgo and Garcia Fernandez, 2001; Bourdel-Marchasson et al., 2000; Serpa and Santos, 2007; Nijs et al., 2009), with no standardisation of category values. Continuous data allows comparability of results from various studies. Categorisation of continuous data should be avoided in regression models since it leads to a loss of power and residual confounding. In addition, the use of data-derived cut points can lead to serious bias (Altman et al., 1994; Royston et al., 2006).

A further consideration is the recommendation that systematic reviews of prognostic factors studies are limited to those with patients at the same 'starting point' in the disease trajectory (Altman, 2001). In this review we included studies of patients with and without pressure ulcers at baseline, from acute, rehabilitation, long-term care and community populations, including heterogeneous and homogeneous patient populations. Interpretation was complicated by poor reporting of patient baseline characteristics and hence difficulty in assessing heterogeneity. It is important to note that the heterogeneity of study populations will impact upon multivariable analysis and also other factors entered into models for example, some studies included only bed/chairfast/mobility restricted patients (Defloor and Grypdonck, 2005; Reed et al., 2003; Nixon et al., 2006; Rademakers et al., 2007; Nijs et al., 2009; Suriadi et al., 2007, 2008; Gunningberg et al.,

2001; Salzberg et al., 1999; De Laat et al., 2007; Bourdel-Marchasson et al., 2000; Yepes et al., 2009; Hatanaka et al., 2008; Boyle and Green, 2001; Fife et al., 2001; Compton et al., 2008; Sayar et al., 2009; Vanderwee et al., 2009; Allman et al., 1995; Kemp et al., 1993; Okuwa et al., 2006; Donnelly, 2006; Inman et al., 1999) therefore it is unlikely that a relationship between mobility/activity and pressure ulcer development would be observed, as all patients were similarly immobile. Future work should be undertaken to identify a sub-set of studies deemed similar enough and of good quality, and the potential for meta-analysis explored with or without individual patient data.

In general researchers did not consider a comprehensive range of key risk factors in multivariable analyses and this limits interpretation and overall conclusions. For example, the study by Serpa and Santos includes 10 descriptors relating to nutrition, but no variables relating to activity/mobility or perfusion (Serpa and Santos, 2007). Similarly a large number of studies do not include a mobility/activity factor in their analysis even where the study population is heterogeneous for activity/mobility (Chan et al., 2005; Cobb et al., 1997; Goodridge et al., 1998; Ooi et al., 1999). Furthermore, the primary studies of the review do not test for statistical interaction between risk factors within their regression models. The review is therefore limited to the confines of the original study analysis. Future primary research should consider which risk factor interactions are most predictive of pressure ulcer development.

A number of studies use only the risk assessment scale total score in the multivariable analysis (Stordeur et al., 1998; Bergstrom and Braden, 1992; Bourdel-Marchasson et al., 2000; Chan et al., 2005; Fife et al., 2001; Inman et al., 1999; Schultz et al., 1999; Bates-Jensen et al., 2007; Yepes et al., 2009; Compton et al., 2008). This does not enable the dominant risk factors to be identified. Future research should ensure that key risk factors are included in multivariable analyses, so that validation of the core set of risk factors can be achieved and prognostic variables can be utilised widely.

In addition general standards for the reporting of risk factor studies do not meet basic criteria recommended by international guidelines on the reporting of observational studies (STROBE, 2005). A large number of studies were excluded due to two key criteria – loss to follow-up rates and use of multivariable analysis. Of the 45 cohort studies and RCTs included in the review only eighteen fulfilled basic reporting requirements (Hayden et al., 2006; STROBE, 2005), including reporting of baseline study population characteristics, levels of significance and CIs (Brandeis et al., 1994; Bergquist and Frantz, 1999; Sayar et al., 2009; Allman et al., 1995; Ooi et al., 1999; Lindgren et al., 2004; Nixon et al., 2006; Okuwa et al., 2006; De Laat et al., 2007; Baumgarten et al., 2004; Fife et al., 2001; Schultz et al., 1999; Bates-Jensen et al., 2007; Rademakers et al., 2007; Suriadi et al., 2007; Yepes et al., 2009; Vanderwee et al., 2009; Hatanaka et al., 2008). These are essential components for the interpretation of results. Future researchers should ensure adequate reporting of risk factor studies to improve the validity and generalisability of study results.

The methodological limitations are further complicated by the use of different outcome measures, that is both Grade ≥ 1 and Grade ≥ 2 outcomes are utilised. Some might suggest that risk factors associated with Grade 1 pressure ulcers are different to risk factors associated with Grade 2 pressure ulcers but this was outside the scope of this review and requires formal review and further analysis to inform future research and clinical practice. The majority of pressure ulcer development in the studies of the review are superficial pressure ulcers since cohort studies fail to recruit patients who develop severe pressure ulcers; therefore the review is limited to risk factors associated with superficial pressure ulcer development.

The strong association between Stage/Grade 1 pressure ulcers and subsequent \geq Stage/Grade 2 pressure ulcers resonates with what is experienced in clinical practice and nurses often see the presence of non-blanching erythema as a warning of potential further deterioration. Additionally the presence of an existing \geq Stage/Grade 2 pressure ulcer would alert the nurse of the possibility of additional pressure ulcer development and the need for secondary prevention.

Another potential area of uncertainty is whether the superficial pressure ulcers reported in the studies of the systematic review are incontinence associated dermatitis (IAD) rather than pressure ulcers. Historically trunk wounds have been labelled as pressure ulcers but there is confusion between IAD and superficial pressure ulcers (Beekman et al., 2011; Doughty, 2012). Only 1 study specifically reported that the training of staff undertaking skin assessment incorporated the differentiation of IAD and pressure ulcers (Vanderwee et al., 2009). Moreover, there is a possibility that the importance of pressure ulcer risk factors may vary in relation to specific skin sites and this is still to be elucidated.

The methodological limitations within the pressure ulcer literature are similar to those reported in other areas of medicine (Altman, 2001; Egger et al., 2001; Maltoni et al., 2005; Riley et al., 2009). Whilst it is recognised that as multiple similar studies accumulate it is important to identify and evaluate all of the relevant studies to develop a more reliable overall assessment (Altman, 2001), the methodological limitations of the studies identified precluded combining study results using meta-analysis.

Finally, whilst there is a general literature on the considerations in the assessment of limitations and bias in the review of risk factor and prognostic factor studies (Altman, 2001; Egger et al., 2001; Hayden et al., 2006; Maltoni et al., 2005), there is no framework for classifying study quality to support the narrative synthesis in a risk factor systematic review. We included key quality criteria in the inclusion criteria (loss to follow-up and multivariable analysis), considered general issues affecting confounding and bias and developed a review specific quality classification based upon the key aspects of the analysis methods, to support interpretation.

5. Conclusions

Overall there is no single factor which can explain pressure ulcer risk, rather a complex interplay of factors

which increase the probability of pressure ulcer development. The review highlights the limitations of over-interpretation of results from individual studies and the benefits of reviewing results from a number of studies to develop a more reliable overall assessment of factors which are important in affecting patient susceptibility.

The risk factors which emerge most frequently as independent predictors of pressure ulcer development in studies using multivariable analyses are consistent with pressure ulcer aetiology conceptual frameworks, confirming major domains of mobility/activity and perfusion (including diabetes). In addition skin/pressure ulcer status particularly relating to stage/grade 1, emerged as a major risk variable and this is an important finding of this systematic review.

Other factors including skin moisture, age, haematological measures, nutrition and general health status are also important, but do not emerge as frequently as the three main domains. Other factors which may be important but were included in only a small number of studies include body temperature and immunity and these require further confirmatory research. Our review shows that there is minimal or limited evidence that either race or gender is important.

The review provides a foundation for the further development of a conceptual framework of pressure ulcer development to bridge the gap between the epidemiological, physiological and biomechanical evidence and enhance our understanding of the role of individual risk factors in pressure ulcer development. This will facilitate the development of a pressure ulcer minimum standard dataset to inform future risk factor research and the development of improved risk assessment methods. This work is being taken forward by a National Institute for Health Research (NIHR) Programme Grant (Pressure Ulcer Programme Of ReSEarch (PURPOSE): RP-PG-0407-10056).

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