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What Is the Impact of Care Bundles on the Prevalence or Incidence of Pressure Ulcers Among At-Risk Adults in the Acute Care Setting? A Systematic Review

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ABSTRACT

A pressure ulcer is an injury to the skin and underlying tissues caused by pressure, shear or a combination of the two. In Europe, the mean prevalence rate of pressure ulcers is 10.8%, in Ireland, it is less than 12%. Using systematic review methodology, original research studies written in English were included, employing pre- and post-studies, quality improvement initiatives or projects, randomised controlled trials and experimental studies. Data was extracted using a pre-designed data extraction tool and quality appraisal was undertaken using the Evidence-Based Librarianship (EBL) tool. Where appropriate, a meta-analysis was undertaken using RevMan. The study protocol was pre-registered with the International Prospective Register of Systematic Reviews (PROSPERO CRD42023442711). Following the search, 628 records were returned, of which 25 met the inclusion criteria. The studies were conducted in a variety of acute healthcare settings. Of the included studies, 16 presented data on incidence and 12 presented data on prevalence of pressure ulcers post-implementation of a care bundle. A meta-analysis of 10 studies discussing incidence indicates the RR of PU is 0.40 (95% CI: 0.21–0.78; $p = 0.007$), supporting the use of a care bundle. A meta-analysis of seven studies discussing prevalence indicates the RR of PU is 0.34 (95% CI: 0.21–0.56; $p = 0.0001$), demonstrating the reduction in the RR of PU development in favour of the care bundle group. A variety of care bundle elements were found in the studies. Although results indicated the use of a care bundle was advantageous in preventing a pressure ulcer in the acute care setting, it was unclear which of these elements were most effective.

1 | Introduction

A pressure ulcer (PU), defined as localised damage to skin, underlying tissue or both, arises due to pressure, shear or a combination of the two [1]. PUs are also known as pressure injuries, pressure sores or bedsores and are most commonly found on areas such as the heels, base of the spine, hips or elbows [2]. The mean prevalence rate of PU in Ireland is less than 12%, whereas the mean

Summary

- PU (pressure ulcer) care bundles (CB) are associated with a reduction in PU rates.
- There was a statistically significant reduction in the risk of PU development among those cared for using a specific PU prevention care bundle.
- Use of a care bundle is advantageous in preventing PUs; however, it is unclear which elements of the bundle are most effective, either individually or collectively.
- The terms pressure ulcers and pressure injuries will be used interchangeably throughout this paper.

prevalence rate in Europe is 10.8% [3]. Globally, over one in 10 adult patients admitted to hospitals are affected by preventable PUs [4].

Given the right circumstances, that is, prolonged, unrelieved exposure to pressure and shear, anyone is at risk of, or can acquire a PU. However, those confined to a bed or those who sit in a wheelchair for prolonged periods are more often affected [5]. Of concern is that although PUs usually develop gradually, they can also develop over a few hours [5]. Thus, despite efforts to reduce PUs in America, 2.5 million patients continue to acquire PUs each year in acute care facilities [6].

Risk assessment is a crucial first step towards planning for timely PU prevention [7]. Following this, the use of specific care strategies is recommended in an effort to aid PU prevention [8]. Care bundles (CB) are inclusive of such strategies and these are a structured set of evidence-based practices that are specifically designed to improve patient outcomes and the process of care [9]. The set of practices (usually between three and five) is performed together when administering care to patients with the same illness or condition within a health care setting [9]. PU prevention is a vital contributor to the overall safety of patients in acute care within hospitals [10]

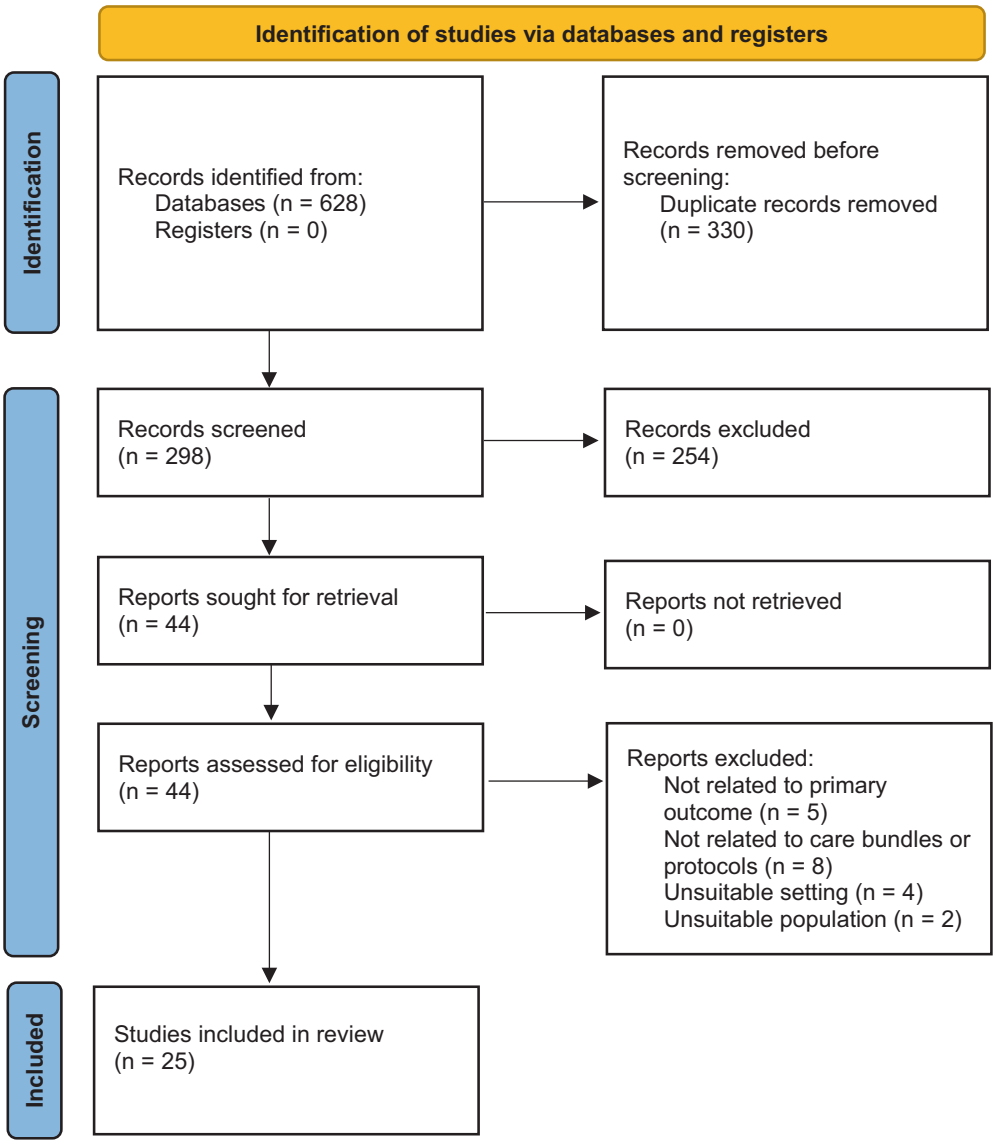


FIGURE 1 | PRISMA flow diagram.

and PU care bundles are associated with a reduction in PU rates [11].

2 | Research Question

'What is the impact of pressure ulcer care bundles on the prevalence or incidence of pressure ulcers among at-risk adults in the acute care setting?'

3 | Methods

3.1 | Aim

The aim of this systematic review (SR) was to ascertain the impact of PU CBs on PU prevalence or incidence among at-risk adults cared for in the acute care setting. The PICO model [12] was used to formulate the research question as follows:

- *Population*: Adult patients at risk of PUs cared for in the acute care setting.
- *Intervention*: A PU prevention care bundle.
- *Comparison*: Usual care.
- *Outcome*: *Primary*: PU prevalence or PU incidence; *Secondary*: Stage of PU development, time to PU development, and nature of the care bundle.

3.2 | Inclusion and Exclusion Criteria

Only published studies were deemed eligible for inclusion, comprising the following: quantitative studies including randomised control trials (RCTs), cluster trials, cohort studies, cross-sectional studies and before and after studies. Studies from intensive care or coronary care settings, studies exploring the impact of CBs on medical device-related PU, and qualitative studies were excluded.

3.3 | Electronic Searches

Electronic searches of the following databases were undertaken from inception to June 2024: Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library) (latest issue), Ovid MEDLINE, Scopus and EBSCO CINAHL Plus. A manual search of Google Scholar and the grey literature to acquire further studies was also undertaken in addition to scanning the reference lists of already identified studies.

3.4 | Search Limits

There were no restrictions applied to the year of publication. Limitations included publications in the English language and publications in full text.

TABLE 1 | Excluded papers.

Author	Reason for exclusion
Wilborn et al. [16]	Not related to the impact of care bundle
Walsh and Plonczynski [17]	Not related to the impact of care bundle
McElhinny and Hooper [18]	Not related to impact of care bundle
Buttery [19]	Not related to impact of care bundle
Denby and Rowlands [20]	Not related to impact of care bundle
Ackerman [21]	Not related to impact of a care bundle
Gunningberg et al. [22]	Not related to impact of care bundle
Jankowski and Nadzam [23]	Primary outcome not measured
Bergquist-Beringer et al. [24]	Not related to impact of care bundle
Downie et al. [25]	Primary outcome not measured
Harrsion et al. [26]	Unsuitable population: Primarily high dependency care patients
Anderson et al. [27]	Unsuitable setting: ICU
Gallagher et al. [28]	Unsuitable setting: Primarily targeting ICU
Awad [29]	Unsuitable population: Burns patients
Al-Mutair et al. [30]	Unsuitable setting: Primarily ICU
Santamaria et al. [31]	Primary outcome not measured
Gupta et al. [32]	Unsuitable setting: CCU and cardiac setting
Stanberry et al. [33]	Primary outcome not measured
Johnson et al. [34]	Primary outcome not measured

3.5 | Keywords

The key words used for the search were, pressure ulcers or pressure injury, or pressure sores or decubitus ulcers or bed sores; acute care or acute care settings or hospital settings; care bundles; evidence-based care bundles; pressure ulcer prevention protocol.

3.6 | Study Selection

Two reviewers independently screened the selected study abstracts for applicability. Following this, full text articles of the

TABLE 2 | Author, country, setting, sample size and design of included studies.

Author	Country	Setting	Sample size	Design
Cole and Nesbitt [41]	Canada	Surgical, medical/palliative, chronic/rehabilitation, telemetry and ICU	261	Quality improvement
Gibbons et al. [44]	USA	All nursing units	Not given	PU prevention programme
Hiser et al. [45]	USA	Academic medical centres and Acute care	978	PU prevention programme
Catatania et al. [40]	USA	All hospital units/departments	1247	PU prevention programme
Baldelli and Paciella [39]	USA	Critical care/ICU/Medical/Surgical	Not given	PU prevention programme
Van Gaal et al. [57]	Netherlands	Medical/Surgical	2888	Cluster RCT
Sendelbach et al. [53]	USA	Large health care system	Not given	PU prevention programme
Young et al. [36]	USA	Multiple medical services	254	Quality improvement
Mallah et al. [48]	Lebanon	Medical/surgical, oncology, paediatrics, ICUs	486	Pre/post study
Padula et al. [52]	USA	Academic medical centres	1 590 022	Quasi-experimental
Cano et al. [35]	USA	Acute care units	Partial = 305	PU prevention programme
Meehan et al. [51]	USA	Peri-operative, Theatre, postanesthesia, postoperative nursing care unit	699	Quasi- experimental
Fabruzzo-Cota et al. [42]	Canada	Academic health care facility	Not given	Quality improvement
Chaboyer et al. [11]	Australia	Acute, surgical and rehab units	1598	Cluster RCT
Martin et al. [49]	Canada	Community hospital	561	Pre/post test
Smith et al. [54]	Australia	Acute/subacute inpatient setting	3937	Cross-sectional
Jafary et al. [46]	Iran	Surgical, ICU, internal units	3798	Cluster RCT
Fremmelevholm and Soegaard [43]	Denmark	All hospital units/departments	Not given	PU prevention programme
Kimsey [47]	USA	Peri-operative	Not given	PU prevention programme
Al-Otaibi et al. [37]	Saudi Arabia	Hospital	1905	Quality improvement
Staines et al. [55]	Switzerland	All wards with the exception of OPD, obstetrics and gynaecology, paediatrics and theatre	34 732	Quality improvement
Sving et al. [56]	Sweden	General hospital, medical and surgical units	763	Quasi-experimental
Edwards et al. [6]	USA	ED and acute care units	Not given	PU prevention programme
Mayhob and Amin [50]	Egypt	Orthopaedic	80	Quasi-experimental
Aloweni et al. [38]	Singapore	Surgical inpatient nursing units	944	Quasi-experimental

selected abstracts were assessed and were excluded if they were not relevant or did not meet eligibility criteria.

3.7 | Data Collection and Data Extraction

Data was extracted using a pre-designed data extraction tool using the following headings: author, year, country, setting, design, population, sample size, risk assessment, frequency of intervention, fidelity of intervention, duration of quality improvement project (QIP)/study, result for the primary outcome and secondary outcomes. A second reviewer validated this data independently.

3.8 | Data Analysis

Where appropriate, meta-analysis was conducted using RevMan [13] and results are presented as risk ratios (RR) with the 95% confidence intervals (CI). Otherwise, a narrative synthesis of the remaining data is provided.

3.9 | Quality Appraisal

Glynn's EBL critical appraisal checklist was used to assess the methodological quality of the studies [14] and this was carried out independently by two authors. This instrument assesses a

TABLE 3 | Duration of QI programme or study.

Study	Duration of QI/study
Cole and Nesbitt [41]	3 years
Hiser et al. [45]	3 years
Gibbons et al. [44]	2 years
Catatania et al. [40]	2 years
Baldelli and Paciella [39]	6 years
Van Gaal et al. [57]	2 years and 2 months
Sendelbach et al. [53]	1 year
Young et al. [36]	4 months
Mallah et al. [48]	15 months
Padula et al. [52]	5 years and 5 months
Cano et al. [35]	5 years and 6 months
Meehan et al. [51]	2 years and 1 month
Fabruzzo-Cota et al. [42]	2 years
Chaboyer et al. [11]	11 months
Smith et al. [54]	6 years
Martin et al. [49]	1 year
Fremmelevholm and Soegaard [43]	6 years
Jafary et al. [46]	10 months
Kimsey [47]	5 years
Al-Otaibi et al. [37]	9 months
Staines et al. [55]	1 year and 8 months
Sving et al. [56]	3.5 years
Edwards et al. [6]	2.5 years
Mayhob and Amin [50]	6 months
Aloweni et al. [38]	15 months

study across four domains: population, data collection, design and result. Each domain is scored based on the assessment and in order for the overall study to be considered valid, the overall score must be ≥75% [14].

4 | Results

4.1 | Overview of Included Studies

A PRISMA flow chart [15] (Figure 1) outlines the flow of articles through this SR. As can be seen, 628 citations were identified from database searches, and 330 were removed as duplications prior to screening, then a further 254 papers were excluded as not meeting the inclusion criteria. Following a review of the abstracts, 44 full papers were sought for retrieval. Following a full review of these papers, 19 were rejected (see Table 1), 8 studies were not related to CB or protocols [16–22, 24]. Five studies were not related to the primary outcome [23, 25, 31, 33, 34]. Four studies were from an unsuitable setting, relating primarily to the ICU/CCU or a high dependency setting [27, 28, 30, 32] and two studies were from an unsuitable population [26, 29]. Finally, 25 studies met the inclusion criteria and these formed the basis of this systematic review [6, 11, 35–57] (see Table 2).

4.2 | Study Design

Five studies were quality improvement (QI) or quality initiative projects [36, 37, 41, 42, 55]. Nine studies were PU prevention programmes or involved use of a PU prevention protocol [6, 35, 39, 40, 43–45, 47, 53]. A further five studies were quasi-experimental [38, 50–52, 56]. Three studies were cluster RCTs [11, 46, 57]. Two studies employed a pre/post design [48, 49] and one study was cross-sectional [54] (see Table 2).

4.3 | Geographical Location

The studies were published between 2004 and 2023. The geographical location of the studies was diverse and included the United States of America (USA) [6, 35, 36, 39, 40, 44, 45, 47, 51–53], The Netherlands [57], Australia [11, 54], Denmark [43], Sweden [56] Iran [46], Saudi Arabia [37], Lebanon [48], Canada [41, 42, 49], Singapore [38], Switzerland [55] and Egypt [50] (see Table 2).

4.4 | Study Settings

The studies were conducted within a variety of acute health care settings. These include all hospital units/departments/rehab/acute care [11, 35–37, 40, 43, 44, 49, 53, 55], varied nursing units including critical care/ICU, medical and surgical [38, 39, 41, 46, 48, 54, 56, 57], orthopaedic units [50], the emergency department [6], peri-operative unit/theatre [47, 51] and academic medical centres [42, 45, 52] (see Table 2).

4.5 | Participants and Sample Size

Sample sizes were given in 17 studies [11, 36–38, 40, 41, 45, 46, 48–52, 54–57]. A partial sample size was given in 1 study [35]. The total sample was 1 645 458 and varied between 80 participants [50] and 1 590 022 patients [52]. The mean sample size was 91 414 participants (SD = ±374 087) (see Table 2).

4.6 | Risk Assessment

All studies discussed the use of a risk assessment tool. The most common was Braden with 80% ($n = 20$) [6, 35, 36, 38–53, 55] of studies using this tool. Other tools included the Norton scale, employed in 12% ($n = 3$) studies [37, 54, 56], while one study [54] used both the Norton scale and the Waterlow scale. Furthermore, 16% ($n = 4$) of studies used other methods of risk assessment, namely surgical PU risk score [38], the Prevention PU Risk Score Evaluation (PrePurse) scale [57], limited mobility [11] and finally, one study [50] also used a patient observation checklist adapted from Willborn and Dassen [58].

TABLE 4 | EBL checklist using Glynn [14].

Study	Section A: Population	Section B: Data collection	Section C: Study design	Section D: Results	Overall validity
Cole and Nesbitt [41]	57% (not valid)	75% (valid)	62.5% (not valid)	50% (not valid)	61% (not valid)
Hiser et al. [45]	57% (not valid)	63% (not valid)	60% (not valid)	67% (not valid)	62% (not valid)
Gibbons et al. [44]	57% (not valid)	63% (not valid)	60% (not valid)	67% (not valid)	62% (not valid)
Catatania et al. [40]	57% (not valid)	63% (not valid)	60% (not valid)	67% (not valid)	62% (not valid)
Baldelli and Paciella [39]	57% (not valid)	63% (not valid)	60% (not valid)	67% (not valid)	62% (not valid)
Van Gaal et al. [57]	100% (valid)	100% (valid)	100% (valid)	100% (valid)	100% (valid)
Sendelbach et al. [53]	71% (not valid)	50% (not valid)	80% (valid)	50% (not valid)	63% (not valid)
Young et al. [36]	71% (not valid)	75% (valid)	80% (valid)	66% (not valid)	73% (not valid)
Mallah et al. [48]	85% (valid)	75% (valid)	80% (valid)	83% (valid)	81% (valid)
Padula et al. [52]	71% (not valid)	63% (not valid)	100% (valid)	83% (valid)	79% (valid)
Cano et al. [35]	57% (not valid)	75% (valid)	63% (not valid)	67% (not valid)	66% (not valid)
Meehan et al. [51]	75% (valid)	75% (valid)	80% (valid)	83% (valid)	78% (valid)
Fabruzzo-cota et al. [42]	57% (not valid)	50% (not valid)	60% (not valid)	66% (not valid)	58% (not valid)
Chaboyer et al. [11]	88% (valid)	100% (valid)	100% (valid)	100% (valid)	97% (valid)
Martin et al. [49]	85% (valid)	75% (valid)	100% (valid)	67% (not valid)	82% (valid)
Smith et al. [54]	85% (valid)	63% (not valid)	100% (valid)	67% (not valid)	79% (valid)
Jafary et al. [46]	100% (valid)	100% (valid)	100% (valid)	67% (not valid)	92% (valid)
Fremmelevholm and Soegaard [43]	71% (not valid)	63% (not valid)	80% (valid)	67% (not valid)	70% (not valid)
Kimsey [47]	57% (not valid)	63% (not valid)	80% (valid)	67% (not valid)	67% (not valid)
Al-Otaibi et al. [37]	71% (not valid)	50% (not valid)	60% (not valid)	50% (not valid)	58% (not valid)
Staines et al. [55]	71% (not valid)	87% (valid)	80% (valid)	67% (not valid)	76% (valid)
Sving et al. [56]	71% (not valid)	100% (valid)	100% (valid)	67% (not valid)	85% (valid)
Edwards et al. [6]	57% (not valid)	63% (not valid)	80% (valid)	50% (not valid)	63% (not valid)
Mayhob and Amin [50]	100% (valid)	75% (valid)	100% (valid)	83% (valid)	90% (valid)
Aloweni et al. [38]	75% (valid)	87% (valid)	100% (valid)	67% (not valid)	82% (valid)

4.7 | Pressure Ulcer Grading Tool

The National Pressure Injury Advisory Panel (NPIAP), formerly the National Pressure Ulcer Advisory Panel (NPUAP) PU grading tool was used in 20% ($n = 5$) of studies [40, 41, 44, 45, 54]. The NPUAP (now known as NPIAP) and The European Pressure Ulcer Advisory Panel (EPUAP) guideline was used in one study [48]. The EPUAP pressure ulcer grading tool was used in 12% ($n = 3$) of studies [46, 56, 57]. The National Pressure Ulcer Advisory Panel/European Pressure Ulcer Advisory Panel/Pan Pacific Pressure Injury Alliance (NPUAP/EPUAP/PPPIA) was used in 24% ($n = 6$) of studies [6, 11, 38, 43, 52, 56]. Further, one study refers to the Agency for Healthcare Research (AHRQ) in the development of their bundle [39] and one study used a PU grading sheet [50]. The Hill-Rom PU Prevalence Survey Scranton form was used in 1 study [35] while a PU algorithm was used in a further study [53]. One study does not mention skin assessment within the elements [37]. Although the remaining 24% ($n = 6$) of studies include skin assessment in the bundle, they did not mention the use of any PU grading tool [36, 42, 47, 49, 51, 55].

4.8 | Frequency and Fidelity of the Intervention

The frequency of the intervention administration was discussed in 84% ($n = 21$) of studies [6, 35–40, 42–51, 53–55, 57]. Conversely, this was not mentioned in 16% ($n = 4$) of studies [11, 41, 52, 56]. The fidelity of the intervention was discussed in 96% ($n = 24$) of studies [6, 11, 35–40, 42–57]. This was not mentioned in 1 study [41]. Chaboyer et al. [11], noted that testing the feasibility and development of the patient component was published in previous studies [8, 59] and a trial protocol was also previously published [60]. Van Gaal et al. [57], also discuss the development of their cluster RCT in a previously published paper [61].

TABLE 5 | Studies indicating PU incidence as cases per patient 1000 patient days or cases per 1000 inpatient discharges.

Author	Year	PU incidence
Gibbons et al. [44]	2006	Cases per 1000 patient days 2004: 1.94 2005: 1.85 2006: 0.81
Padula et al. [52]	2015	Cases per 1000 inpatient discharges Rates: 2007: 14.1 2008: 8.0 2009: 1.9 2010: 1.5 2011: 0.9 2012: 0.8 Pre-intervention 2007 (October–December): 1084/76 929; 1.4% Post-intervention 2012 (January–June): 150/187 926; 0.08%
Edwards et al. [6]	2019	Cases per 1000 patient days Baseline: 3.56 Post intervention period: 1.31
Sendelbach et al. [53]	2011	Cases per 404 237 patient days October 2008: 15 October 2009: 10
Fabruzzo-cota et al. [42]	2016	Cases per total number of patient discharges 1st quarter 2013/2014: 0.24% 2nd quarter 2013/2014: 0.08% 2010: 6 2014: 1
Jafary et al. [46]	2018	Cases per 1000 patient days Control: 203/1855; 10.9% Intervention: 158/1657; 9.5%
Staines et al. [55]	2020	Cases per 1000 patient days Baseline: 414/5044; 8.2% Post intervention period: 199/4765; 4.2%
Van Gaal et al. [57]	2011	Cases per patient weeks Control group 2006: 18/341; 5.27% Intervention group 2006: 14/346; 4.04% Control group 2008: 66/1120; 5.89% Intervention group 2008: 45/1081; 4.16%

4.9 | Duration of QIP/Study

The shortest duration of QIP/study was 4 months [36], while the longest studies were carried out over 6 years [39, 43, 54] (see Table 3). One study [56] is a long-term follow-up to a previous exploration of a multi-faceted intervention [62].

TABLE 6 | Studies indicating pressure ulcer incidence (number of cases per population studied).

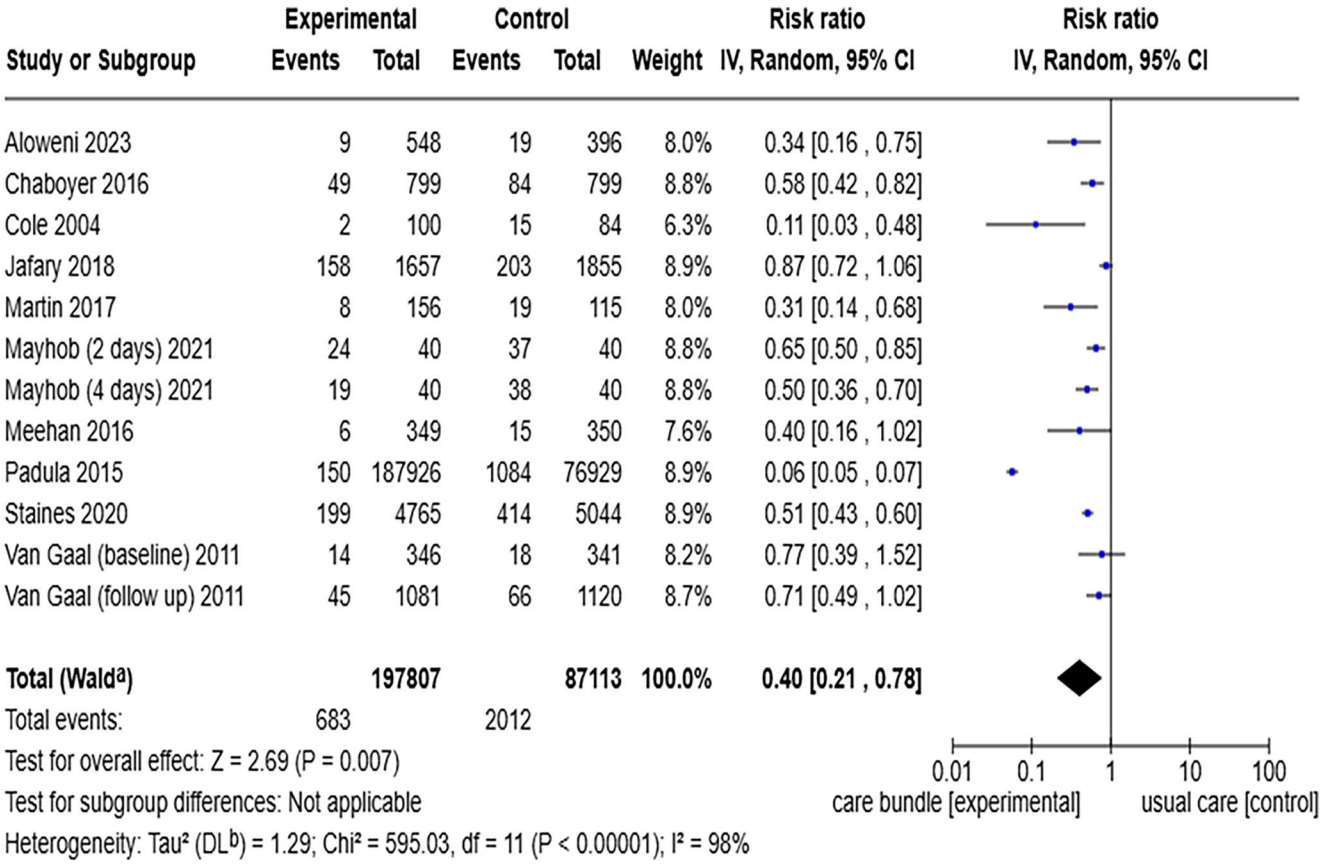
Author	Year	PU incidence
Cole et al. [41]	2004	Pre: 15/84; 17.9% Post: 2/100; 2%
Baldelli and Paciella [39]	2008	2000: 15% 2006: 7%
Chaboyer et al. [11]	2016	Control group: 84/799; 10.5% Bundle group: 49/799; 6.1%
Meehan et al. [51]	2016	Control: 15/350; 4.3% Intervention: 6/349; 1.7%
Martin et al. [49]	2017	Pre: 19/115; 16.5% Post: 8/156; 5.13%
Kimsey [47]	2019	2015: 8 PU 2019: 0 PU
Mayhob and Amin [50]	2021	*Did not develop PU*: After 2 days: *I*: 16/40; 40%; *C*: 3/40; 7.5% After 4 days: *I*: 21/40; 52.5%; *C*: 2/40; 5.0%
Aloweni et al. [38]	2023	Pre: 19/396; 4.8% Post: 9/548; 1.6%

4.10 | Quality Appraisal

The results of the quality appraisal of the included studies using Glynn's EBL critical appraisal checklist [14] can be seen in Table 4. For all studies [6, 11, 35–57] the mean validity score was 73.92% (SD: 12.55; min: 58% [37, 42] max: 100 [57]).

In section A, population, 66.6% ($n = 16$) studies [6, 35–37, 39–45, 47, 52, 53, 55, 56] scored ≤75 and therefore did not meet the validity criterion score. Many of these studies did not include inclusion/exclusion criteria or obtain consent. In section B, data collection, 48% ($n = 12$) of studies [6, 37, 39, 40, 42–45, 47, 52–54] scored ≤75%, thus did not meet the validity criteria. Many of the studies did not affirm if inter-observer or intra-observer bias was reduced, it was unknown if the data collection instrument was validated and it was not always clear if those collecting the data were also delivering direct care to the participants.

In section C, study design, 68% ($n = 17$) of studies [6, 11, 36, 38, 43, 46–57] scored ≥75%, and were therefore considered valid in this section. Many studies did not require ethical approval due to the nature of the QI in the studies and in some studies face validity was questionable. In section D, results, 76% ($n = 19$) of studies [6, 35–47, 49, 52, 53, 55, 56] scored ≤75% and did not meet the validity criteria. Confounding was not accounted for in many of the studies, and due to the overall nature of the studies, external validity was also unclear.



Footnotes

[a]CI calculated by Wald-type method.

[b]Tau² calculated by DerSimonian and Laird method.

FIGURE 2 | Meta-analysis, risk ratio of PU development, care bundle versus usual care.

4.11 | Primary Outcomes Measured

All studies measured the primary outcomes of interest, PU incidence or PU prevalence. Two [37, 57] included grade 2 PUs and above, one [52] included stage 3 and 4 PUs and one [53] included stage 3, 4 and unstageable.

4.12 | Secondary Outcomes Measured

A total of 44% ($n = 11$) of studies presented the stage of PU development [11, 35, 38, 43, 44, 46, 47, 50, 54–56]. No studies discussed the time to PU development. Finally, all studies presented information about the nature of the care bundle or protocol of care.

4.13 | Results for Primary Outcome: PU Incidence

Five studies [6, 44, 46, 53, 55] reported the data as cases per 1000 patient days, whereas two studies [42, 52] report data as cases per 1000 inpatient discharges. One study reports the data as per patient weeks [57] (see Table 5). Three papers [6, 42, 53] did not present a sample size.

One study indicates a rate of 5208 hospital-acquired pressure ulcer (HAPU) cases from 1 590 022 participants measured between 2007 and 2012 [52]. Other studies include 37 732 participants with a HAPU rate of 1945 cases [55] and 3798 participants with a HAPU rate of 5 in 1000 patient days [46]. One paper includes the combined results of HAPU and pre-existing PU from audits over 4 years. These results indicate the PU incidence rate dropped from 6% in 2010 to 1% in 2014. HAPU rates decreased from the first to the second quarter in 2013/2014 from 0.24% to 0.08% [42]. One study reported that PU rates dropped from 15 to 10 in 404 237 days indicating a 33% reduction of PU incidence [53].

Two studies presented the data year on year [44, 52], noting that the incidence of PU reduced from 1.94% in 2004 to 0.81% in 2006 [44] and from a rate of 14.1 in 2007 to 0.8 in 2012 [52]. Another study compared the difference in incidence from the start of the intervention to the study end, reporting a reduction from 3.56 per 1000 patient days at baseline to 1.31 per 1000 patient-days at the end of the data collection period. There was an incidence of 25 PUs in the baseline group compared to 7 in the intervention group, indicating a 72% reduction in incidence [6]. Eight studies [11, 38, 39, 41, 47, 49–51] presented incidence data by calculating the number of persons who developed a PU over the study period,

divided by the number of persons included in the study (see Table 6). One study indicates PU dropped from 15% to 7% [39].

Figure 2 presents the results for the meta-analysis of 10 studies [11, 38, 41, 46, 49–52, 55, 57] using a random effects model. One study [50] includes data for PU development at 2 and 4 days, and another includes the baseline and follow-up rates [57]. As can be seen in Figure 2, the RR is 0.40 (95% CI: 0.21–0.78; $p = 0.007$). This indicates that there is a 60% reduction in the RR of PU development in favour of the CB group, with the true population parameter lying between a 22% reduction and a 79% reduction.

4.14 | Results for Primary Outcome: PU Prevalence

Twelve studies presented data on prevalence [35–37, 39, 40, 42, 43, 45, 48, 49, 54, 56] (see Table 7). Four studies do not give the total sample size [35, 39, 42, 43].

In one study, the PU prevalence pre-intervention was 29% and post-intervention was 15% [39]. In a further study [35] in 2009 the PU prevalence was 11.7% (sample size not given), whereas in 2014 the PU prevalence was 2/305; 0.65%. In a Danish study, the pre-intervention figures were 10% and 11% and post-intervention figures are 2% and 2% respectively [43]. Another study [48] indicates a prevalence rate of 6.63% in 2012, pre-intervention compared to 2.96% in 2013. Audit results from another study [42] indicate aggregated results from HAPU and pre-existing PU dropped from 17% in 2010 to 10% in 2014.

Figure 3 represents the results of a meta-analysis from 7 studies [36, 37, 40, 45, 49, 54, 56] using a random effects model. One paper reflects the prevalence of PU in all patients and in those at risk [56] and is included in this meta-analysis. As can be seen in Figure 3, the RR is 0.34 (95% CI: 0.21–0.56; $p = 0.0001$). This indicates that there is a 66% reduction in the RR of PU development in favour of the CB group, with the true population parameter lying between a 44% reduction and a 79% reduction.

TABLE 7 | Studies indicating pressure ulcer prevalence.

Author	Year	Primary outcome: PU prevalence
Hiser et al. [45]	2006	2002: 41/458; 9.2% 2004: 33/520; 6.6%
Catatania et al. [40]	2007	2004: 34/264; 12.87% 2006: 12.1/283; 4.3%
Baldelli and Paceilla [39]	2008	2000: 29% 2006: 15%
Cano et al. [35]	2015	2009: 11.7% 2014: 2/305; 0.65%
Young et al. [36]	2015	Pre: 41/135; 30.15% Post: 1/119; 0.85%
Mallah et al. [48]	2015	Pre: 2012 1Q: 6.63% 2012 2Q: 7.05% Post: 2012 3Q: 5.72% 2012 4Q: 2.09% 2013 1Q: 2.96%
Fabruzzo et al. [42]	2016	2010: 17 2014: 10
Smith et al. [54]	2017	2008: 329/1407; 23% 2010: 106/1331; 7.5% 2014: 83/1199; 6.9%
Martin et al. [49]	2017	2013: 83/242; 34.3% 2014: 18/239; 7.53%
Al-Otaibi et al. [37]	2019	Pre: 29/368; 7.8% Post: 12/1537; 0.78%
Fremmelevholm and Soegaard [43]	2019	*Odense*: 2012: 10% 2018: 2% *Svendborg*: 2012: 11% 2018: 2%
Sving et al. [56]	2020	*At risk*: Baseline: 18/53; 33% Follow up: 27/100; 27% *All patients*: Baseline: 28/251; 11.1% Follow up: 48/512; 9.3%

4.15 | Results for the Secondary Outcome

4.15.1 | Stage of PU Development

The stage of PU development is presented only for studies that report both pre and post PU stages. Eight studies presented this data [11, 38, 43, 46, 50, 54–56]. As can be seen in Table 8 and Figure 4, the stages of PU are varied. Of these, one study [55] indicates pre-intervention figures of 5.9% for all PU and 1.6% for grade 2–4, and post-intervention figures of 2.1% for all PU and 0.4% for grades 2–4. In a Danish study [43], five category 3 PUs and one category 4 PU were found in 2012 and 2013. In 2016 and 2017, no PU of category 3 or above was identified. In 2018, there was one category 3 PU identified.

Pressure ulcer stages are presented in Figure 4, which includes six studies [11, 36–38, 40, 43, 45, 46, 49, 54–56]. One paper included a 2 and 4 days follow up [50] and another reflects the prevalence of PU from those deemed at risk of PU in the study [56]. In Figure 4, for both the pre-intervention and post-intervention phases, the development of stage 1, 2, 3 and 4 PU is notable, with a minimal amount of deep tissue or unstageable PU identified. One study has a rate of 0.6% unstageable PU in both pre- and post-intervention [11] of 0.6%, while another study found a rate of 0.33% [54] of unstageable PU post-intervention.

4.16 | Results for the Secondary Outcome: Nature of the Care Bundle

All studies provided data pertaining to the nature of the CB or protocol employed in the studies. As can be seen in Table 9, the

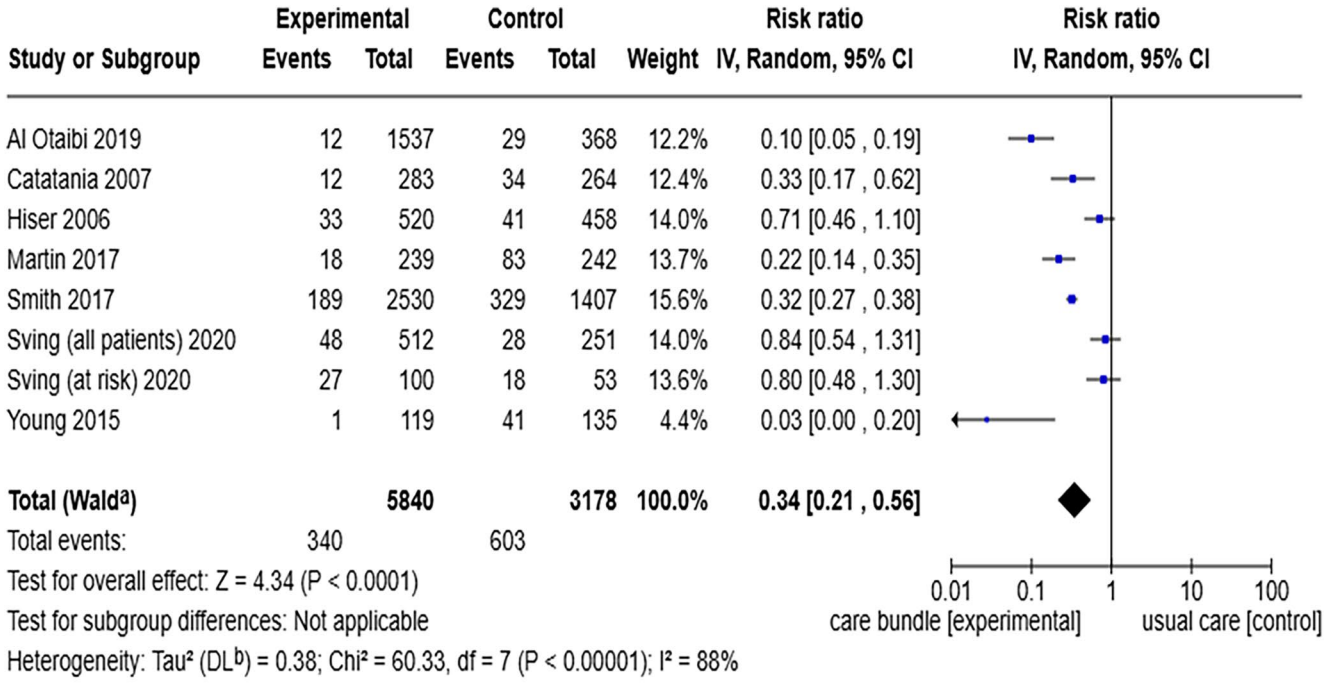


FIGURE 3 | Meta-analysis, risk ratio of PU development, care bundle versus usual care.

most commonly used elements include risk assessment, staff education, IT and IT technology and were discussed in all 25 studies [6, 11, 35–57]. These were followed by skin assessment used in 24 studies [6, 11, 35, 36, 38–57]. The least common elements include the use of serum albumin levels [40, 44, 47], patient-led focus [11, 38, 57], and head of bed elevation ≤30 [39, 40, 48], which were included in 3 studies. The element of turning/repositioning was mentioned in 21 studies [6, 11, 35–40, 42–44, 46–52, 54–56], while the element of surface was considered in 20 studies [6, 35–42, 44–49, 51, 52, 54–56]. The inclusion of a specialist or wound nurse was included in 19 studies [35–40, 42–49, 51–53, 55, 56], the elements of leadership [35, 37–45, 47–49, 51–53, 55, 56] and nutrition were reflected in 18 studies [6, 11, 35, 36, 38–42, 44, 46–50, 52, 53, 55]. Please see Table 9, where the remainder of the most frequent and least employed elements can be seen and include incontinence, mobility, sensory perception, moisture, activity, heel elevation, friction and shear, prophylactic dressing, patient education and skin products.

5 | Discussion

As stated, CBs are a structured set of evidence-based practices that are specifically designed to improve patient outcomes and the process of care [9]. The effectiveness of a CB arises as they are based on the supporting evidence and should be performed as a package [63]. Within a PU CB, a number of critical elements need to be considered. These include skin assessment, PU risk assessment, care planning and implementation [64].

This SR aimed to explore the impact of PU CB on the incidence or prevalence of PU among at-risk adults cared for in the acute care setting. A total of 64% ($n = 16$) of studies discussed incidence and 48% ($n = 12$) discussed prevalence. The primary outcomes have been presented and using meta-analysis, a statistically significant difference in both PU prevalence and incidence was identified. This suggests that, in some cases, PU CBs may be valuable in reducing the incidence and prevalence of PU. Notably, the CB elements were diverse within the included studies of this SR, from 6 elements [54, 57] up to 19 elements [40]. The findings here support those of another SR and meta-analysis [65], which included studies encompassing CB's with four to eight components. The SR authors [65] found the pooled RR for PU prevalence from five non-randomised studies was 0.55 (95% CI: 0.29–1.03), and for hospital acquired PUs (also from five non-randomised studies), was 0.31 (95% CI: 0.12–0.83).

As mentioned, the CB elements were diverse within the studies included in this review. These findings are comparable to other studies conducted in different healthcare settings of varied specialties. For example, a SR reviewing the value of CB's for the prevention and/or treatment of post-partum haemorrhage also found that CB's are beneficial, but it was unknown what composition of the bundle was ideal [66]. A study exploring the efficacy of a CB for preventing central line-associated bloodstream infections (CLABSI) in the ICU [67] found that when the CB practice was not followed by the healthcare worker, the rate of infection increased. This study also found that the rate of CLABSI did not decrease throughout the first 6 months of the analysis due to the complexities of CB compliance. However,

TABLE 8 | Studies indicating the stages of PU development.

Author	Year	Stage of pressure ulcer development
Chaboyer et al. [11]	2016	*Intervention*: Stage I: 28/799; 3.5%. Stage 2: 16/799; 2%; unstageable: 5/799; 0.6%. *Control*: Stage 1: 60/799; 7.5%. Stage 2: 19/799, 2.4%; unstageable: 5/799; 0.6%.
Smith et al. [54]	2018	*2008*: Stage 1: 492/1407; 35%, Stage 2: 260/1407; 18.5%, Stage 3: 63/1407; 4.5%, Stage 4: 69/1407: 4.9%, Deep tissue: 0, Unstageable: 0. *2010*: Stage 1: 188/1331; 14.1%, Stage 2: 108/1331; 8.1%, Stage 3: 27/1331; 2%, Stage 4: 21/1331; 1.6%, Deep tissue 0, Unstageable: 0. *2014*: Stage 1: 78/130; 60%, Stage 2: 39/130; 30%, Stage 3: 7/130; 5%, Stage 4: 1/130; 1%, Deep tissue: 1/130; 1%, Unstageable: 4/130; 3%.
Jafary et al. [46]	2018	*Pre-intervention*: Stage 1: 1.5%, Stage 2: 83.6%, Stage 3: 11.4%, Stage 4: 3.5%. *Training*: Stage 1: 3.4%, Stage 2: 79.3%, Stage 3: 17.2%. *Post-intervention*: Stage 1: 5.1%, Stage 2: 75.9%, Stage 3: 16.4%, Stage 4: 2.6%.
Fremmelevholm and Soegaard [43]	2019	2012/2013: 5 category 3 PU, 1 category 4 PU. 2018: 1 category 3 PU.
Staines et al. [55]	2020	*Pre-intervention*: Grade 2–4 PU: 1.6. All PU: 5.9. *Post-intervention*: Grade 2–4 PU: 0.4. All PU: 2.1.
Sving et al. [56]	2020	*At Risk* *Baseline*: Stage 1: 11/53; 21%, Stage 2: 4/53; 7%, Stage 3: 2/53; 4%, Stage 4: 1/53; 2%. *Short-term*: Stage 1: 12/52; 23%, Stage 2: 4/52; 8%, Stage 3: 0; 0%, Stage 4: 1/52; 2%. *Long term*: Stage 1: 6/48; 13%, Stage 2: 4/48; 8%, Stage 3: 0; 0%, Stage 4: 0; 0%.
Mayhob and Amin [50]	2021	*Grade 1*: After 2 days I: 21/40, 52.5%; C: 6/40; 15%. After 4 days: I: 13/40, 32.5%; C: 5/40; 12.5%. *Grade 2*: After 2 days I: 2/40, 5%; C: 20/40; 50%. After 4 days I: 6/40, 15%; C: 5/40; 12.5%. *Grade 3*: After 2 days I: 0/40, 0%; C: 11/40; 27.5%. After 4 days; I: 0/40, 0%; C: 28/40; 70%.
Aloweni et al. [38]	2023	*Pre-intervention*: Stage 1: 11/396; 2.8%. Stage 2: 5/396; 1.3%, Stage 3: 0, Stage 4: 2/396; 0.5%, Deep tissue: 1/396; 0.3%. *Post-intervention*: Stage 1: 6/548; 1.1%, Stage 2: 3/548; 0.5%, Stage 3: 0, Stage 4: 0, Deep tissue: 0.

the rates of CLABSI reduced considerably upon practice and regular meetings during the 2nd and 3rd stages of this study [67]. A growing body of evidence confirms that care can be improved by using a bundle approach [9]. It is evident that across healthcare in general, CB's are widely used; however, even within one speciality the included elements of the bundle are diverse and not necessarily consistent within specific specialities. This makes it a challenge to identify which elements of the

FIGURE 4 | Stage of PU development.

bundle are essential and in which combination they should be offered to the patient.

It is recommended to include all elements of the bundle and to apply these consistently to the patient unless there is a medical contraindication [9]. This is the case, for example, in the care of central lines [67]. However, in the care of patients at risk of PUs, the CB should be directed towards addressing the modifiable risk factors [1]. Commonly packaged in the SSKIN acronym, PU prevention will not necessarily be the same for all patients. For example, if the patient is not malnourished or not incontinent, then these elements of the care bundle would not be appropriate for

TABLE 9 | Elements found in the care bundles.

Author	Year	Surface	Keep Turning/reposition	In-continence care	Nutrition	Mobility	Sensory perception	Moisture	Activity:	Friction and shear	Risk assessment	Skin assessment	Head of bed ≤ 30	Heel elevation	Leadership	Staff Education:	Information & Information Technology	Patient led	Prophylactic dressing	Albumin levels	Skin products	Specialist/wound nurse	Patient educated
Cole et al. [42]	2004	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓	✗	✗	✗	✓	✗	✗
Hiser et al. [46]	2006	✓	✗	✗	✗	✗	✗	✗	✗	✗	✓	✓	✗	✗	✓	✓	✓	✗	✗	✗	✓	✓	✗
Gibbons et al. [45]	2006	✓	✓	✓	✓	✗	✗	✓	✗	✗	✓	✓	✗	✓	✓	✓	✓	✗	✗	✓	✓	✓	✗
Catatania et al. [41]	2007	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓	✗
Baldelli & Paciella [40]	2008	✓	✓	✓	✓	✗	✗	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✗
Van Gaal et al. [58]	2011	✗	✗	✗	✗	✗	✗	✗	✗	✗	✓	✓	✗	✗	✗	✓	✓	✓	✗	✗	✗	✗	✓
Sendelbach et al. [54]	2011	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✗	✗	✗	✗	✓	✓
Young et al. [37]	2015	✓	✓	✓	✓	✗	✗	✓	✗	✗	✓	✓	✗	✗	✗	✓	✓	✗	✗	✗	✓	✓	✗
Mallah et al. [49]	2015	✓	✓	✓	✓	✗	✗	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗	✓	✓	✓
Padula et al. [53]	2015	✓	✓	✓	✓	✗	✗	✗	✗	✗	✓	✓	✗	✗	✓	✓	✓	✗	✗	✗	✓	✓	✗
Cano et al. [36]	2015	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓	✗	✗	✗	✓	✓	✗
Meehan et al. [52]	2016	✓	✓	✓	✗	✓	✓	✓	✗	✗	✓	✓	✗	✓	✓	✓	✓	✗	✓	✗	✗	✓	✓
Fabruzzo-cota et al. [43]	2016	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓	✗	✗	✗	✗	✓	✓
Chaboyer et al. [12]	2016	✗	✓	✗	✓	✓	✗	✗	✓	✗	✓	✓	✗	✗	✗	✓	✓	✓	✗	✗	✓	✗	✓
\ et al. [50]	2017	✓	✓	✓	✓	✓	✗	✓	✗	✓	✓	✓	✗	✓	✓	✓	✓	✗	✗	✗	✗	✓	✗
Smith et al. [55]	2018	✓	✓	✗	✗	✗	✗	✗	✗	✗	✓	✓	✗	✗	✗	✓	✓	✗	✗	✗	✗	✗	✗
Jafary et al. [47]	2018	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✗	✗	✗	✗	✓	✓
Fremmelevhom & Soegaard [44]	2019	✗	✓	✗	✗	✗	✗	✗	✗	✓	✓	✓	✗	✗	✓	✓	✓	✗	✗	✗	✗	✓	✗
Kimsey [48]	2019	✓	✓	✗	✓	✓	✗	✓	✗	✓	✓	✓	✗	✗	✓	✓	✓	✗	✓	✓	✓	✓	✓
Al-Otaibi et al. [38]	2019	✓	✓	✗	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗	✓	✓	✓	✗	✓	✗	✗	✓	✗
Staines et al. [56]	2020	✓	✓	✓	✓	✓	✗	✓	✗	✗	✓	✓	✗	✗	✓	✓	✓	✗	✗	✗	✗	✓	✓
Sving et al. [57]	2020	✓	✓	✗	✗	✓	✗	✗	✓	✓	✓	✓	✗	✓	✓	✓	✓	✗	✗	✗	✗	✓	✗
Edwards et al. [6]	2021	✓	✓	✓	✓	✓	✗	✓	✓	✗	✓	✓	✗	✗	✗	✓	✓	✗	✓	✗	✓	✗	✗
Mayhob & Amin [51]	2021	✗	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✗	✗	✗	✗	✗	✓
Aloweni et al. [39]	2023	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓	✓	✓	✗	✓	✓	✓
Elements total		20	21	13	18	15	8	16	11	13	25	24	3	7	18	25	25	3	6	3	13	19	11

that patient [1]. This poses an additional challenge in interpreting the data from studies exploring the impact of CBs on PU development. Not only are the included components diverse, but their application is not consistent, meaning that it is unclear which elements of the bundle are most important or if, indeed, the concept of a bundle of care is the key to success or not. In fact, one paper followed up the effect of preventative care from a previously performed cluster RCT [57] and questioned if all PU preventative measures are required all of the time, or if the combination of prevention actions are necessary [68]. One could argue that individual elements of the bundle could be explored in RCTs; however, that too is challenging. For example, a recently updated Cochrane review exploring the impact of dressings and topical agents on PU prevention found that in all cases participants in both arms of the trials were offered standard PU prevention [69].

Many factors influence CB implementation, such as resources and training, sustainability and leadership [70]. Although the quality of evidence is low in one SR and meta-analysis studying the effects of CBs on patient outcomes, CBs might be more successful in areas such as ICUs or trauma units in comparison to the other heterogeneous groups [71]. A recent scoping review has found most studies assess specific homogeneous clinical issues, but appraising CB as a concept is unavoidably heterogeneous [72]. However, another SR including 47 studies has found audit and feedback, reminders and education are the most used

strategies that facilitate CB implementation [73]. In order to determine the facilitation and difficulties that lead to the success of CB implementation in acute care, a mixed methods scoping review [72] indicates the likelihood that fidelity may be increased when the CB consists of a few elements that are simple [72].

5.1 | Quality Appraisal

A total of 48% of studies ($n = 12$) met the criterion score of $\geq 75\%$. Each study has discussed the findings and the varied elements that are used within a CB, and offers knowledge with regard to the CB it implements. Similarly, an SR conducted in the intensive care setting found many PU prevention programmes have been carried out as QI projects [74]. Such projects have also offered limited rigour. Nevertheless, these studies prove useful and offer outcomes that are positive. Several papers recommend further studies [6, 48, 50, 51] while many authors state more research is required to recognise other elements which can contribute to supporting the implementation of evidence-based practices [38, 46, 52, 54]. Chaboyer et al. [11] acknowledge their study was the first rigorous multi-site cluster RCT of a PU prevention CB which was inclusive of both patient and staff behaviours. In order to assess the value of interventions which have multiple elements and implementation strategies, high-quality research is necessary [74]. Specifically, one study recommends further research to determine the applicability of the PU CB in the form of control groups using multiple sites [38]. A further study advocates for research regarding the factors as to why PU interventions are successful or not [46].

6 | Limitations

The main limitation of this SR is that QI projects offer limited rigour [74], and cause and effect are not acknowledged within the QI design [36]. In order to ensure a QI project is effective and to advance learning, collaboration is needed between health workers and researchers [75]. Studies from intensive care or coronary care settings and studies exploring the impact of CBs on medical device-related PU and qualitative studies were excluded from this review. However, due to the nature of the QIPs or studies discussed, it was not always possible to separate the data relating to those areas from the results. Additionally, this review explores the use of CB in the prevention of HAPU, but considering the nature of prevalence studies, some of the results may include PU that were not hospital-acquired.

7 | Conclusion

Overall, the results from the studies included in this SR indicate that CBs can result in a reduction of both incidence and prevalence of PU. The studies were conducted in a variety of acute health care settings and the elements within the bundles were diverse. Although many of the studies follow the International guidelines, they did not all do so consistently. Furthermore, not all patients will need all elements of the CBs. Therefore, it is not possible to decipher which of the elements are effective, and indeed, if these would be consistently effective among all cohorts of patients within the acute care setting.

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Ethics Statement

The authors have nothing to report.

Consent

The authors have nothing to report.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The authors have nothing to report.

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