International Journal of Nursing Studies 155 (2024) 104768

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/locate/ns

The effect of pressure injury prevention care bundles on pressure injuries in hospital patients: A complex intervention systematic review and meta-analysis

Wendy Chaboyer [a,b,*], Sharon Latimer [a,b], Udeshika Priyadarshani [a,b,c], Emma Harbeck [a], Declan Patton [d], Jenny Sim [e,h], Zena Moore [d], Jodie Deakin [a,b], Joan Carlini [a,f,1], Josephine Lovegrove [a], Sepideh Jahandideh [a], Brigid M. Gillespie [a,b,g]

[a] NHMRC Centre of Research Excellence in Wiser Wound Care, Griffith University, Gold Coast Campus, Queensland 4222, Australia
[b] School of Nursing and Midwifery, Griffith University, Gold Coast Campus, Queensland 4222, Australia
[c] Department of Nursing and Midwifery, Faculty of Allied Health Sciences, General Sir John Kotelawala Defence University, Sri Lanka
[d] School of Nursing & Midwifery, Royal College of Surgeons Ireland, University of Medicine and Health Sciences, 123 St Stephens's Green, Dublin, 2, Ireland
[e] Faculty of Health, University of Technology Sydney, 235 Jones Street, Ultimo, NSW 2007, Australia
[f] Health Consumer and Department of Marketing, Griffith Business School, Griffith University, Gold Coast Campus, Queensland 4222, Australia
[g] Gold Coast University Hospital and Health Service, Gold Coast, QLD, Australia
[h] School of Nursing, Midwifery & Paramedicine, Australian Catholic University, North Sydney Australia

ARTICLE INFO

Article history:
Received 15 November 2023
Received in revised form 25 March 2024
Accepted 27 March 2024

Keywords:
Pressure injury
Pressure ulcer
Systematic review
Meta-analysis
Care bundle
Complex intervention
Intervention complexity

ABSTRACT

Background: Numerous interventions for pressure injury prevention have been developed, including care bundles.
Objective: To systematically review the effectiveness of pressure injury prevention care bundles on pressure injury prevalence, incidence, and hospital-acquired pressure injury rate in hospitalised patients.
Data sources: The Medical Literature Analysis and Retrieval System Online (via PubMed), the Cumulative Index to Nursing and Allied Health Literature, EMBASE, Scopus, the Cochrane Library and two registries were searched (from 2009 to September 2023).
Study eligibility criteria: Randomised controlled trials and non-randomised studies with a comparison group published in English after 2008 were included. Studies reporting on the frequency of pressure injuries where the number of patients was not the numerator or denominator, or where the denominator was not reported, and single subgroups of hospitalised patients were excluded. Educational programmes targeting healthcare professionals and bundles targeting specific types of pressure injuries were excluded.
Participants and interventions: Bundles with ≥3 components directed towards patients and implemented in ≥2 hospital services were included.
Study appraisal and synthesis methods: Screening, data extraction and risk of bias assessments were undertaken independently by two researchers. Random effects meta-analyses were conducted. The certainty of the body of evidence was assessed using Grading of Recommendations, Assessment, Development and Evaluation.
Results: Nine studies (seven non-randomised with historical controls; two randomised) conducted in eight countries were included. There were four to eight bundle components; most were core, and only a few were discretionary. Various strategies were used prior to (six studies), during (five studies) and after (two studies) implementation to embed the bundles. The pooled risk ratio for pressure injury prevalence (five non-randomised studies) was 0.55 (95 % confidence intervals 0.29–1.03), and for hospital-acquired pressure injury rate (five non-randomised studies) it was 0.31 (95 % confidence intervals 0.12–0.83). All non-randomised studies were at high risk of bias, with very low certainty of evidence. In the two randomised studies, the care bundles had non-significant effects on hospital-acquired pressure injury incidence density, but data could not be pooled.
Conclusions and implications of key findings: Whilst some studies showed decreases in pressure injuries, this evidence was very low certainty. The potential benefits of adding emerging evidence-based components to bundles should be considered. Future effectiveness studies should include contemporaneous controls and the

* Corresponding author at: Building G01, Griffith University Gold Coast Campus, Griffith University, Queensland 4222, Australia.
E-mail address: W.Chaboyer@griffith.edu.au (W. Chaboyer).
Social media: @SharonLLatimer, @jodie_deakin3, @bgillespie6.

[1] Consumer.

https://doi.org/10.1016/j.ijnurstu.2024.104768

development of a comprehensive, theory and evidence-informed implementation plan.
Systematic review registration number: PROSPERO CRD42023423058.
Tweetable abstract: Pressure injury prevention care bundles decrease hospital-acquired pressure injuries, but the certainty of this evidence is very low.

What is already known

- Pressure injuries are present in about 8 % of hospitalised adults.
- Evidence-based clinical practice guidelines advocate various strategies for pressure injury prevention.
- Care bundles, generally comprised of three to five evidence-based interventions, are associated with improved patient outcomes.

What this study adds

- Pressure injury prevention care bundles decrease hospital-acquired pressure injuries, but the certainty of this evidence is very low.
- Implementation strategies are important to ensure bundles are used as intended, but there is inconsistency in the way care bundle components are delivered.

1. Background

Pressure injuries are potentially preventable healthcare-acquired complications (European Pressure Ulcer Advisory Panel et al., 2019) and are patient outcomes sensitive to nursing care (Burston et al., 2014; Sim et al., 2018; Twigg et al., 2019). They have recently been termed nursing sensitive indicators of nursing care (Oner et al., 2021). Pressure injuries cause avoidable harm to patients, including psychological distress, pain, compromised quality of life and even death (Gorecki et al., 2012; Jackson et al., 2017, 2018; Kim et al., 2019). Their costs are significant burdens on health systems (Demarré et al., 2015; Nghiem et al., 2022; Padula and Delarmente, 2019). As a result, clinicians, researchers, and patient safety experts have focussed on ways to prevent pressure injuries. Various pressure injury risk assessment and prevention approaches have been trialled (Beeckman et al., 2021; Lovegrove et al., 2021; McLaren-Kennedy et al., 2023). Yet, pressure injuries continue to occur in about 8 % of hospitalised patients (Li et al., 2020) and are likely higher in subgroups of patients, including those who are at high-risk, such as the elderly (Rasero et al., 2015), critically ill (Labeau et al., 2021), and those with spinal cord injuries (Shiferaw et al., 2020).

Several studies have shown that evidence-based pressure injury prevention strategies are inconsistently used, suggesting a gap between knowledge and practice (Chaboyer et al., 2017; Deakin et al., 2023; Latimer et al., 2016; Li et al., 2022; Martinez-Garduno et al., 2019; Tervo-Heikkinen et al., 2023). Care bundles have emerged as an approach to support clinicians in standardising and improving use of preventative care (Institute for Healthcare Improvement, 2023) including for those at risk of pressure injuries (Chaboyer et al., 2016; Jafary et al., 2018). The Institute for Healthcare Improvement describes care bundles as three to five evidence-based interventions that together improve processes of care and patient outcomes (Institute for Healthcare Improvement, 2023). For example, a pressure injury prevention care bundle could include repositioning, skin care and nutrition support.

Care bundles have been used to tackle a variety of health problems, such as ventilator-associated pneumonia (Martinez-Garduno et al., 2019), kidney disease (See et al., 2023), chronic obstructive respiratory disease (Ospina et al., 2017), central line-associated blood stream infection (Lavallée et al., 2017) and urinary tract infection (Lavallée et al., 2017). They have also been used to address hospital-acquired pressure injuries (Lavallée et al., 2017). Four recent reviews have included pressure injury care bundles (Gaspar et al., 2019; Lavallée et al., 2017; Lin et al., 2020; Lovegrove et al., 2021). Lin et al. (2020) focussed on the adult intensive care population, concluding that prevention bundles were beneficial for intensive care unit patients, but a meta-analysis was not undertaken. Lavallée et al. (2017) examined a variety of care bundles targeting various conditions, including pressure injuries. Their meta-analysis identified a risk ratio of 0.33 (95 % confidence intervals 0.21–0.52) in favour of using pressure injury prevention care bundles. However, their analysis included only three pressure injury prevention care bundle studies; one focussed on the general hospital adult population, and the other two were on intensive care patients. Thus, their findings may not apply to the general hospital population. Gaspar et al. (2019) included seven studies in their narrative synthesis of findings, concluding that pressure injury prevention care bundles were effective. However, they did not include some of the studies identified in a previous review (Lavallée et al., 2017); five of the seven studies focussed on specialised populations (four of intensive care patients and one on spinal cord injury patients); and they were unable to conduct a meta-analysis. Finally, Lovegrove et al. (2021) focussed their review on randomised controlled trials of mostly individual pressure injury prevention strategies. The Lovegrove et al. (2021) review only had two care bundle studies, but we are aware of several non-randomised care bundle studies not eligible for their review (Martin et al., 2017; Smith et al., 2018). Thus, the Lovegrove et al. (2021) review does not reflect some of the evidence in the area.

Overall, the main limitations of previous reviews include very specific populations (Gaspar et al., 2019; Lavallée et al., 2017; Lin et al., 2020) that cannot be generalised to the hospital population and the inclusion of only 2–3 pressure injury prevention care bundle studies in the review (Lavallée et al., 2017; Lovegrove et al., 2021). Additionally, information on the extent to which the care bundles were implemented as intended was not reported in any review. But there is good theoretical and empirical evidence on implementation strategies and the effect implementation fidelity can have on intervention fidelity and ultimately effectiveness (Carroll et al., 2007; Gillespie and Ziemba, 2024; Lynch et al., 2018; Walton, 2024). A more contemporary and comprehensive synthesis and meta-analysis of pressure injury prevention care bundles and their implementation strategies used with a wide variety of hospitalised patients is needed to provide further guidance for researchers and clinicians tasked with implementing and evaluating pressure injury practice improvements hospital wide.

To address this gap, we undertook a systematic review and meta-analysis to answer the question, "What is the effect of pressure injury prevention care bundles on the pressure injury prevalence and incidence and hospital-acquired pressure injury rates in hospital patients?" In addition, two sub-questions were included: "What are the components of the care bundles?" and "What strategies are used to implement the care bundles?". Answers to the latter question will provide guidance to others who are challenged with changing pressure injury practice, including how to ensure new practices are implemented as intended. In particular, this review reflects a more comprehensive and up-to-date synthesis, (including meta-analyses) of the research in the area and extends understanding beyond that of effectiveness, recognising that

approaches to implementation influence both intervention fidelity and effectiveness (Carroll et al., 2007).

2. Methods

2.1. Design

Our systematic review and meta-analysis was guided by the Cochrane approach to intervention complexity reviews (Thomas et al., 2022). Pressure injury prevention care bundle intervention complexity reflects the number of components and their possible interactions, and the possible interaction with context of care delivery. Our review protocol was registered in PROSPERO (CRD42023423058), the international prospective register of systematic reviews. We used the Preferred Reporting Items for Systematic Reviews and Meta-analyses - Complex Interventions statement (Guise et al., 2017) to guide our reporting of this review. A consumer was actively involved in the research process as an author (Carlini and Robertson, 2023). The reporting of health consumer engagement in this review was guided by the Guidance for Reporting Involvement of Patients and the Public Short Form (Staniszewska et al., 2017). It includes five items on how this involvement can occur including the aims, methods, results, discussion and conclusions, and a critical reflection of the experience. Our health consumer author (JC) contributed to all except the first item.

2.2. Selection criteria and search strategy

The Population, Intervention, Comparator, Outcome, Timeframe and Study design approach was used to plan the selection criteria (Table 1) and search strategy. The population for our review question was hospitalised adults and not subgroups such as intensive care patients. Therefore, we included the requirement that the studies had to have been conducted in more than one hospital service. We also recognised that some care bundles would be developed to reflect unique issues such as immobile patients or patients with specific skin issues, but we aimed to better understand care bundle effectiveness that would be more generalisable. Hence, we excluded specific subpopulations and specific types of pressure injuries. The intervention in this review, care bundles, was defined as groups of evidence-based interventions, comprised of at least three components (Institute for Healthcare Improvement, 2023). Due to resource constraints, studies had to be published in English. We included non-randomised studies because, previous reviews, our knowledge of the field, and the resources required to conduct trials, meant we anticipated that few randomised trials would be published, which we thought might give an incomplete understanding of the potential effects of pressure injury prevention care bundles.

The search strategy was developed with the assistance of a health librarian. Databases searched included Medical Literature Analysis and Retrieval System Online (MEDLINE) (via PubMed), the Cumulative Index to Nursing and Allied Health Literature (CINAHL), EMBASE, Scopus, and the Cochrane Library. Two registries (World Health Organization International Clinical Trials Registry Platform and US National Institutes of Health Ongoing Trials Register) were also searched. Search terms included combinations of: pressure ulcer, pressure injury, decubitus ulcer, care bundle, intervention, prevention, hospital. Medical subject headings, keywords and free text words were searched, depending on the database, using Boolean AND and OR terms. Search term strategies for the databases are included in Supplementary File Table 1. The search was conducted on the 14th of September 2023. The Search Refiner (Clark et al., 2020) was used to assist the search process. It checks the number of relevant and irrelevant studies found for each search term in a visual display that can be quickly used to determine search terms to remove, ultimately decreasing the number of publications to screen. Refining the search helps to shorten the length of time it takes to undertake a review whilst ensuring the quality of the review is not compromised (Beller et al., 2018; Clark et al., 2021; O'Connor et al., 2019). Forwards and backwards citation screening was employed including the reference lists of six systematic reviews (Gaspar et al., 2019; Lavallée et al., 2017; Lovegrove et al., 2021; Niederhauser et al., 2012; Soban et al., 2011; Sullivan and Schoelles, 2013) for possible papers for inclusion.

2.3. Study selection

After removing duplicates, clearly irrelevant studies were excluded. Two reviewers then independently screened titles and abstracts, with disagreements resolved through discussion or an adjudicator. Then, full-text studies were screened independently by two reviewers with disagreements resolved either through discussion or an adjudicator. Covidence (Covidence systematic review software, 2017) was used for the screening process. A PRISMA flow chart of study selection was constructed.

2.4. Data extraction

Data extracted included study characteristics (geographic location, design, sample characteristics, length of follow-up, funding source, conflicts of interest, etc.), intervention characteristics such as number and

Table 1
Inclusion and exclusion criteria using PICOTS.

Inclusion	Exclusion
Population: Hospitalised patients who may or may not be at risk of a PI. Patients to be recruited from ≥2 services such as medical, surgical or ICU	Specific single subgroups of patients such as day surgery and patients who are nursed in the prone position because the care bundles developed for specific subgroups with unique risk factors do not reflect the general hospital population
Intervention: PI prevention care bundles targeted towards direct patient care with ≥3 components, reflecting bundle complexity and the Institute for Healthcare Improvement definition of care bundles	Educational programmes exclusively targeting healthcare professionals because these do not meet the definition of a care bundle; bundles targeting specific types of PI (e.g., mechanical device PI) because they would be reflective of unique aetiologies and contexts and not reflect the general hospital population
Comparator: Other interventions or routine care, however defined by authors	No comparisons undertaken (such as after only studies) because we wanted to determine bundle effectiveness, which requires some comparison
Outcome: PI point or period prevalence (number of patients with a PI divided by total number of patients), Hospital-acquired PI rate (number of patients with a PI that developed in hospital divided by total number of patients), cumulative incidence (number of patients with a new PI divided by the total number of patients) or incidence density (number of patients with a PI per 1000 person days) of PI (any stage)	Studies reporting on the frequency of PI, where the number of patients is not the numerator or denominator, or where the denominator is not reported because we wanted to identify patient level effectiveness
Timeframe: Studies published after 2008, which is after many clinical practice guidelines were published (Gillespie et al., 2021) and the Institute of Healthcare Improvement care bundle approach had been developed, to better reflect more contemporary practice	Grey literature including abstracts if full text is not available because of the possibility of limited description of the research and these may not have undergone peer review
Study design: Randomised trials (including cluster-randomised trials and crossover trials) or non-randomised studies (before and after studies, time series and cohort studies)	Uncontrolled studies with no comparison group because we wanted to determine bundle effectiveness, which requires some comparison

Note. ICU, intensive care unit; PI, pressure injury.

types of components and the extent to which components were compulsory or discretionary (Thomas et al., 2022), their foundation (such as previous research evidence, local data and theory), implementation strategies, intervention fidelity and outcomes. Two reviewers extracted all data independently, with disagreements resolved through discussion or an adjudicator. Two study authors provided additional information via e-mail. The data extraction tool was piloted with three studies, and minor revisions made to the extraction tool including instructions for reviewers. A summary of findings table was constructed.

The complexity of the causal pathway, termed 'pathway complexity' (Guise et al., 2017), reflected how we thought the care bundle components could affect the development of a pressure injury (Supplementary File Fig. 1). Guided by Donabedian's (1988) structure, process, outcome framework and the aetiology of pressure injury development (Coleman et al., 2014; European Pressure Ulcer Advisory Panel et al., 2019), we envisioned that some components would improve the identification of at-risk patients and thought components would be directed at decreasing mechanical load and improving tissue tolerance, as previously suggested (Coleman et al., 2014; European Pressure Ulcer Advisory Panel et al., 2019). We anticipated that other components, such as the use of nutrition support and incontinence products, would be used in subgroups of individuals. We also proposed that some bundle components would be aimed at improving staff competence, capability, and commitment to pressure injury prevention. Finally, we thought that access to and use of pressure injury prevention resources would be improved.

2.5. Quality appraisal

The Cochrane Collaboration Risk of Bias tools for randomised trials version 2 (Sterne et al., 2019) and the Risk of Bias Assessment for Non-randomised Studies (Kim et al., 2013) were used to assess the methodological quality of included studies. The Risk of Bias tools for randomised trials version 2 (Sterne et al., 2019) assesses the following five bias domains: the randomisation process, deviations from the intended intervention, missing outcome data, measurement, and selective reporting of results. The Risk of Bias Assessment for Non-randomised Studies assesses six domains, including selection of participants, confounding variables, measurement of exposure, blinding of the outcome assessments, incomplete outcome data, and selective outcome reporting. These tools have been used together in other reviews of complex interventions (Karrer et al., 2021; Yamaguchi et al., 2020). Quality appraisal was completed independently by two reviewers and adjudicated by a third if required.

2.6. Data synthesis

Study characteristics were summarised in tables and synthesised narratively based on outcomes (pressure injury prevalence, incidence, and hospital-acquired pressure injury rate). Meta-analyses were planned to improve the estimation of care bundle effects. Because we were interested in the effect of care bundles on review outcomes and not the effect of specific care bundles and their components, we pooled data from studies that had the same design (non-randomised studies of interventions with historical controls) and at least three common care bundle components in our meta-analyses. It is not surprising that care bundles had some minor differences because bundles are generally implemented to address an evidence-practice gap at the local level. Additionally, some 'discretionary' components would only be applicable to certain individuals such as incontinence care. Other reviews of care bundles have also taken this approach to meta-analysis with inclusion of bundles that have various components (see for example Lavallée et al., 2017; Martinez-Reviejo et al., 2023; Ospina et al., 2017; See et al., 2023; Tanner et al., 2015). Cochrane's Q test (significance set at $p < 0.05$) and the I^2 statistic were used to quantify heterogeneity amongst studies. Large Cochrane's Q test with a p value of <0.05 suggests significant heterogeneity. Random effects meta-analytic models were used to pool the data because the heterogeneity was substantial, indicated by an $I^2 > 50$ % (Deeks et al., 2022). The prediction interval was calculated to present the expected range of true effects, and aid clinical interpretation of heterogeneity (IntHout et al., 2016). We report pooled results as risk ratio and 95 % confidence intervals. Funnel or Hunter plots were planned to be used to assess publication bias if there were 10 or more studies in the meta-analysis, but as the meta-analyses only included five studies, these plots were not constructed. The software package RevMan version 5.4 was used for all analyses (Review Manager 5 (RevMan 5), 2020).

2.7. GRADE or certainty of the body of evidence

The certainty of the body of evidence was assessed using Grading of Recommendations, Assessment, Development and Evaluation approach (Balshem et al., 2011; Schünemann et al., 2013). In Grading of Recommendations, Assessment, Development and Evaluation, five domains are considered, including risk of bias, inconsistency, imprecision, indirectness, and publication bias. The body of evidence is then graded as high, medium, low, or very low certainty. We used GRADEpro (McMaster University, 2020) to undertake the Grading of Recommendations, Assessment, Development and Evaluation assessments.

3. Results

3.1. Study characteristics

A total of 15,175 papers were screened, and nine studies were included in the review (Al-Otaibi et al., 2019; Chaboyer et al., 2016; Elliott, 2010; Jafary et al., 2018; Keen and Fletcher, 2013; Martin et al., 2017; Smith et al., 2018; Stausberg et al., 2010; Young et al., 2015). The PRISMA flow diagram of studies included in the review is displayed in Fig. 1. Supplementary File Table 2 provides the reasons for the exclusion for 20 studies that were full-text screened. Table 2 provides a summary of the study characteristics. These nine studies were conducted in eight countries; in three countries English was not the primary language (Al-Otaibi et al., 2019; Jafary et al., 2018; Smith et al., 2018). Two studies were cluster randomised, one a parallel cluster-randomised trial (Chaboyer et al., 2016) and the other, a stepped wedge (Jafary et al., 2018). Authors of the seven other studies labelled their studies in various ways (case study, action research etc.) but all were non-randomised studies of interventions with historical controls. The two randomised trials recruited at-risk patients for pressure injury, whereas the other seven included all patients from the recruited wards, regardless of risk. The total sample size in the nine studies was 106,721; 52.2 % (n = 55,721; range 35–49,904) in the control groups and 47.8 % (n = 51,000; range 46–43,143) in the intervention groups. Screening of patients for study inclusion only occurred in two studies (Chaboyer et al., 2016; Jafary et al., 2018), and the intervention was assigned without consent in six studies (Al-Otaibi et al., 2019; Keen and Fletcher, 2013; Martin et al., 2017; Smith et al., 2018; Stausberg et al., 2010; Young et al., 2015). All but three studies (Chaboyer et al., 2016; Jafary et al., 2018; Martin et al., 2017) measured pressure injury once during each time period.

Only four studies reported receiving funding (Chaboyer et al., 2016; Jafary et al., 2018; Martin et al., 2017; Young et al., 2015), one of which was funded by industry (Young et al., 2015). In five studies, no conflicts of interest were declared (Al-Otaibi et al., 2019; Chaboyer et al., 2016; Jafary et al., 2018; Keen and Fletcher, 2013; Stausberg et al., 2010), and in the remaining four, there was no mention of conflicts of interest (Elliott, 2010; Martin et al., 2017; Smith et al., 2018; Young et al., 2015). Four studies did not report information on ethics committee approval (Al-Otaibi et al., 2019; Elliott, 2010; Stausberg et al., 2010; Young et al., 2015); and approval was waived in one study (Keen and Fletcher, 2013); and ethics approval was obtained in the remaining four studies (Chaboyer et al., 2016; Jafary et al., 2018; Martin et al., 2017; Smith et al., 2018). The risk of bias for all non-randomised studies of interventions (all of which had historical controls) was high, and there were

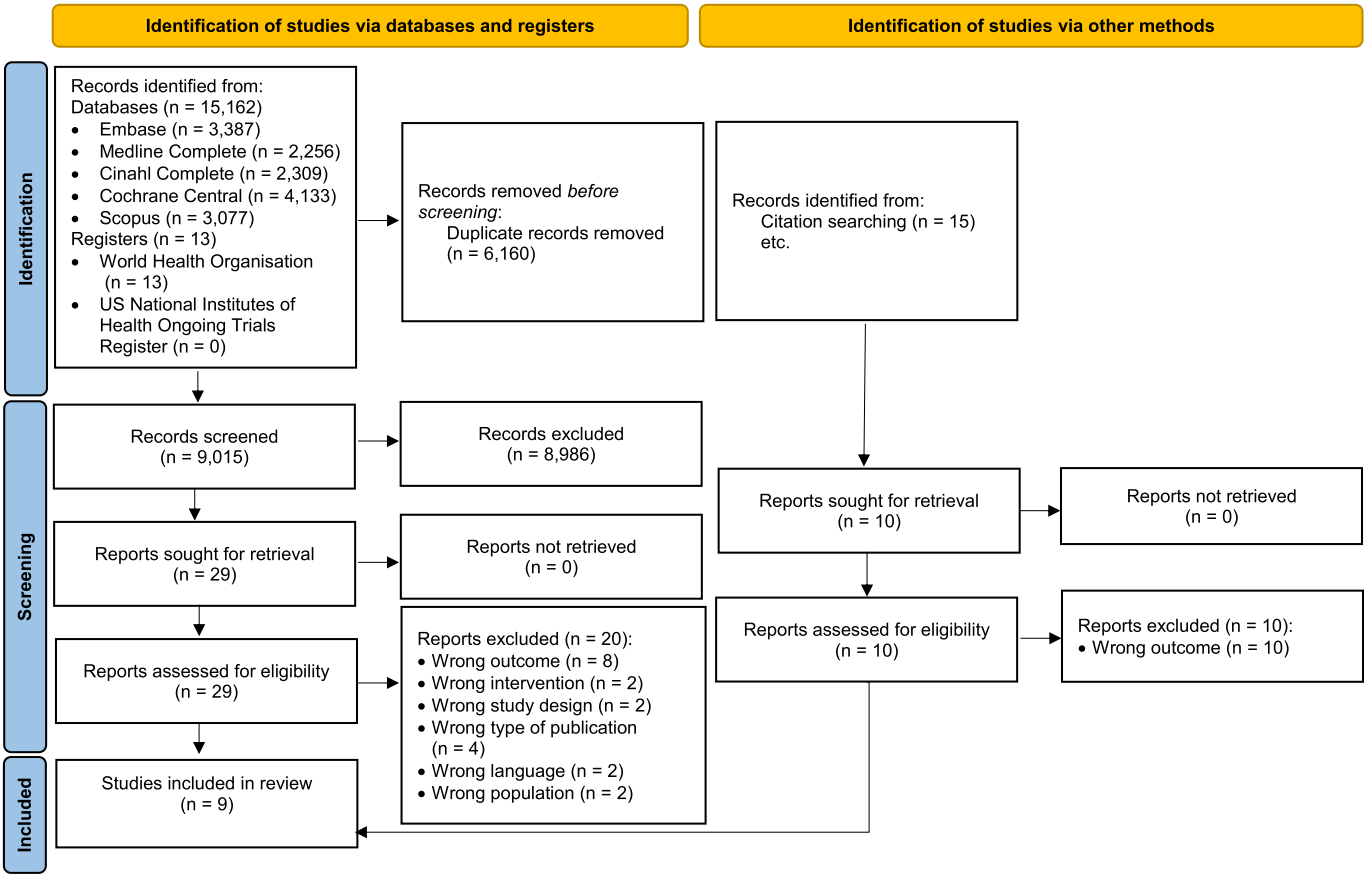

Fig. 1. PRISMA flowchart of study selection.

some bias concerns for both randomised trials. Detailed bias assessments for all studies are reported in Tables 3 and 4.

3.2. Bundle components and implementation

Table 5 summarises the care bundles, including core and discretionary components and study outcomes (pressure injury prevalence, incidence, and hospital-acquired pressure injury rate). The number of bundle components in the included studies ranged from four to eight (median six). Some bundles identified discretionary components, generally reflective of individual patient needs such as incontinence care. They were aimed at patients and staff and were delivered by various staff. Bundle components often included risk assessment, repositioning, the use of appropriate support surfaces, skin care and staff or patient education. The foundations for the bundles were generally based on local evidence, research evidence and/or guidelines and theory in three studies (Chaboyer et al., 2016; Martin et al., 2017; Smith et al., 2018).

Implementation strategies were used prior to (six studies), during (five studies) and after implementation to embed the practices (two studies). Some information on intervention fidelity was reported in all but three studies (Keen and Fletcher, 2013; Martin et al., 2017; Young et al., 2015). A range of specific implementation strategies were used such as education or awareness campaigns (Chaboyer et al., 2016; Elliott, 2010; Jafary et al., 2018; Keen and Fletcher, 2013; Martin et al., 2017; Young et al., 2015), redesign of systems, processes and documentation (Al-Otaibi et al., 2019; Elliott, 2010; Keen and Fletcher, 2013), audits (Al-Otaibi et al., 2019; Keen and Fletcher, 2013), and access to experts for support and coaching (Al-Otaibi et al., 2019; Young et al., 2015).

3.3. Study outcomes

Pressure injury prevalence was reported in five studies (Elliott, 2010; Keen and Fletcher, 2013; Martin et al., 2017; Smith et al., 2018; Stausberg et al., 2010) and hospital-acquired pressure injury rate reported in five studies (Al-Otaibi et al., 2019; Keen and Fletcher, 2013; Smith et al., 2018; Stausberg et al., 2010; Young et al., 2015). Pressure injury cumulative incidence was reported in three studies (Chaboyer et al., 2016; Martin et al., 2017; Stausberg et al., 2010) and could be calculated in one other (Jafary et al., 2018). It ranged from 0.6 % to 16.5 % in the control groups and 0.7 % to 6.1 % in the intervention groups but because of the two differing designs (randomised and non-randomised), meta-analysis was not undertaken. Pressure injury incidence density (number of patients with a PI per 1000 person days) was reported in two studies (Chaboyer et al., 2016; Jafary et al., 2018). After adjustment, an incident rate ratio of 0.78 (95 % confidence intervals 0.60–1.0) was reported in Jafary et al. (2018); we calculated a risk ratio of 0.87 (95 % confidence intervals 0.72–1.06). Chaboyer et al. (2016) found an unadjusted rate ratio of 0.48 (95 % confidence intervals 0.33–0.69) with an adjusted hazard ratio of 0.58 (95 % confidence intervals 0.25–1.33). Because there were only two randomised studies, we did not undertake a meta-analysis for this outcome. Time to pressure injury was not reported in any studies.

3.4. Meta-analysis

Meta-analyses (Fig. 2) were conducted on pressure injury prevalence (five studies) and hospital-acquired pressure injury rate (five studies), all of which had at least three common components as per the Institute of Healthcare Improvement definition (Institute for

Table 2
Study characteristics.

Author (year) Country	Design Year(s) of data collection	Setting Number of hospitals; types of wards Population	Sample	Timing (when screened and consented)	Frequency of outcome assessment; length of follow-up	Risk of bias assessment
Al-Otaibi et al. (2019) Saudi Arabia	NRSI with historical controls Control: Dec 2016–June 2017 Intervention: July 2017–Oct 2017	• Single site • Adults and paediatrics • All patients	Total: n = 1905 Control: n = 368 Intervention: n = 1537	1. No screening 2. Intervention assigned without consent	Outcomes assessed once control and intervention No follow-up	High
Chaboyer et al. (2016) Australia	Cluster RCT (2014–2015)	• 8 hospitals • Various wards (7 wards median per hospital) • At-risk adults	Total: n = 1598 Control: n = 799 Intervention: n = 799	1. Individual patients screened prior to recruitment 2. Intervention assigned before consent	Daily starting 24 h after recruitment Follow-up 28 days (or other study endpoints)	Some concerns
Elliott (2010) United Kingdom	NRSI with historical controls Control: 2009 Intervention: 2010	• 3 hospitals • All inpatients	Total: n = 1906 Control: n = 976 Intervention: n = 930 At risk Control: n = 497/976 Intervention: n = 492/930	1. No screening 2. Intervention assigned without consent	Once each year No follow-up	High
Jafary et al. (2018) Iran	Stepped-wedge cluster-RT 45 weeks June – Nov 2015	• Single site (16 units) • All high-risk hospital patients	Total: n = 3719 Control: n = 1855 Intervention: n = 1657	1. Eligibility assessed prior to recruitment 2. Intervention assigned after randomisation	Daily PI assessment Follow-up to discharge or death	Some concerns
Keen and Fletcher (2013) United Kingdom	NRSI with historical controls No dates given Control × 1: Intervention 1 (1 year after) Intervention 2 (2 years after)	• Two community hospitals (1 ward from each hospital) • Mixed adults (need for rehabilitation, surgery, palliative care, chronic conditions)	Total: n = 81 Control: n = 35 Intervention ×1: n = 33 Intervention ×2: n = 13 Older patients ≥60 years: n = 77 (91.4 %) At risk not reported	1. No screening 2. Intervention assigned without consent	Once each year control and intervention ×2 No follow-up	High
Martin et al. (2017) Canada	NRSI with historical controls Control: 2013 Intervention: 2014	• Single site • All hospital patients ≥18 years	Total: n = 481 Control: n = 242 Intervention: n = 239	1. No screening 2. Intervention assigned without consent	Prevalence assessment day 1 Control and Intervention: Incidence assessment 6 days after recruitment	High
Smith et al. (2018) Australia	NRSI with historical controls Control: 2008 Intervention 1: 2010 Intervention 2: 2014	• 41 inpatient facilities (of 80 total facilities) • All acute adult wards	Total: n = 3937 Control: n = 1407 Intervention ×1: n = 1331 Intervention ×2: n = 1199 At risk Control: n = 1049 Intervention ×1: n = 1001 Intervention ×2: n = 933	1. No screening 2. Intervention assigned without consent	Once each year control and intervention ×2 No follow-up	High
Stausberg et al. (2010) Germany	NRSI with historical control Control: 2003/2004 Intervention: 2006/2007	• Single site • All inpatients	Total: n = 93,047 Control: n = 49,904 Intervention: n = 43,143 Older patients >70 years Control: n = 8644 (17.3 %) Intervention: n = 8823 (20.5 %)	1. No screening 2. Intervention assigned without consent	Unclear	High
Young et al. (2015) USA	NRSI with historical controls Control: 2008 Intervention: 4 months later	• Two metropolitan hospitals • 11 acute care medical and surgical wards • All patients	Total: n = 254 Control: n = 135 Intervention: n = 119 Hospitals 1 n = 165 Hospitals 2 n = 89 At risk not reported	1. No screening 2. Intervention assigned without consent	Outcomes assessed once control and intervention No follow-up	High

NRSI, non-randomised study of interventions.

Healthcare Improvement, 2023). Supplementary File Table 3 details the common components of the care bundles for these two analyses. We were unable to undertake adjusted meta-analyses because only unadjusted rates were provided in the studies we meta-analysed. The risk ratio for pressure injury prevalence was 0.55 (95 % confidence intervals 0.29–1.03) and for hospital-acquired pressure injury rate it was 0.31 (95 % confidence intervals 0.12–0.83), but all studies were at high risk of bias. The prediction intervals were 0.05–5.64 and 0.00–43.05 for prevalence and hospital-acquired pressure injury rates, indicating high heterogeneity (also evidenced by high I^2), thus, random effects models were used. Using Grading of Recommendations, Assessment, Development and Evaluation, the certainty of evidence for non-randomised studies for both pressure injury prevalence and hospital-acquired pressure injury rate was very low. The certainty for incidence

Table 3
Risk of bias non-randomised studies (RoBANS).

Study	Selection of participants	Confounding variables	Measurement of exposure	Blinding of outcome assessments	Incomplete outcome data*	Selective outcome reporting	Overall judgement
Al-Otaibi et al. (2019)	High	High	Unclear	Unclear	Unclear	Low	High
Elliott (2010)	High	High	Low	Unclear	Low	Low	High
Keen and Fletcher (2013)	High	High	Unclear	Unclear	Unclear	Unclear	High
Martin et al. (2017)	High	High	Unclear	Unclear	Unclear	Low	High
Smith et al. (2018)	High	High	Unclear	Unclear	Unclear	Low	High
Stausberg et al. (2010)	High	High	High	Unclear	Low	Unclear	High
Young et al. (2015)	High	High	Low	Unclear	Unclear	Unclear	High

density in the two randomised studies was low (Supplementary File Tables 4–7).

3.5. Consumer involvement

Our health consumer author contributed throughout the review process from protocol development to manuscript preparation. Supplementary File Table 8 details their contribution and our learnings according to the Guidance for Reporting Involvement of Patients and the Public Short Form checklist (Staniszewska et al., 2017). Our health consumer played a key role in searching and screening and in data interpretation and writing the manuscript.

4. Discussion

4.1. Principal findings

This systematic review of nine studies assessed the effect of pressure injury prevention care bundles with four to eight components on pressure injury prevalence, hospital-acquired pressure injury rate and incidence of pressure injuries. Meta-analyses of the non-randomised studies, all of which used historical controls, identified a statistically significant reduction in hospital-acquired pressure injuries but a statistically non-significant reduction in pressure injury prevalence. However, prediction intervals were very wide and non-significant. All non-randomised studies were assessed as high risk of bias and the certainty of evidence for both outcomes was very low. Two non-randomised studies with historical controls that measured cumulative incidence of pressure injuries showed positive effects. In the two randomised trials that measured incidence density (number of patients with a pressure injury per 1000 person days), the care bundle showed no statistically significant risk reduction; the studies were at high risk of bias; and the certainty of evidence was low. Our pressure injury prevalence meta-analysis results are inconsistent with previous systematic review findings on care bundles targeting various other conditions (Lavallée et al., 2017; Martinez-Reviejo et al., 2023; Ospina et al., 2017; See et al., 2023; Tanner et al., 2015), where generally they have been found to be beneficial irrespective of study quality and the certainty of evidence. They are also inconsistent with the one meta-analysis of three pressure injury care bundle studies (Lavallée et al., 2017). This is possibly due to the intent of most bundles to prevent pressure injury (i.e., hospital-acquired pressure injury), as opposed to resolving injuries that are pre-existing (e.g., present on admission). However, our meta-analytic result that care bundles are associated with fewer hospital-acquired pressure injuries is consistent with benefits found in previous meta-analyses of care bundles in patients with other conditions.

The prediction intervals and I^2 showed high heterogeneity, which likely reflects variability in populations, study sample sizes, the number and types of bundle components and the strategies used to implement the bundle resulting in variable uptake of its components. This issue of heterogeneity has been previously described in a number of other reviews of care bundles both in general (Lavallée et al., 2017) and specifically pressure injury prevention care bundles (Niederhauser et al., 2012; Sullivan and Schoelles, 2013). High heterogeneity prevents drawing definitive conclusions regarding care bundle effectiveness but effectiveness across studies in the presence of heterogeneity may suggest that external validity is strong. In other words, care bundles may be effective in preventing hospital-acquired pressure injuries, despite variations in clinical contexts and components, suggesting the results may be more generalisable across different hospitals and bundles. It is to be expected that care bundles would have some minor differences given their implementation to address local evidence-practice gaps and the need for some interventions to be individualised. Calculating prediction intervals was particularly helpful because they quantify, in the same units of measurement, heterogeneity and predicted effects (IntHout et al., 2016). Future researchers may design more rigorous studies in the future based on an awareness of the study shortfalls and limitations uncovered in this review.

4.2. Clinical and research implications

Pressure injury prevention care bundles generally include some form of risk assessment, review or updating of equipment and other resources such as skin care products, ensuring better access to these supplies such as support surfaces and education or training of staff (Lovegrove et al., 2021; Soban et al., 2011; Sullivan and Schoelles, 2013). Each of these components has either a strong theoretical or empirical rationale, or both, thus they should form part of any institution-wide pressure injury prevention programme. Additionally, in recent years good quality evidence has emerged for the use of prophylactic dressing (Beeckman et al., 2021; Hahnel et al., 2020). Further, the use of sub-epidermal moisture scanners has also been recommended as an adjunct to pressure injury risk assessment (European Pressure Ulcer Advisory Panel et al., 2019) and these devices are being used in clinical practice in several countries (McLaren-Kennedy et al., 2023).

Table 4
Risk of bias randomised studies (ROB-2).

Author	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Overall risk
Chaboyer et al. (2016)	Some concerns	Low	Low	Low	Low	Some concerns
Jafary et al. (2018)	Some concerns	Low	Some concerns	Low	Low	Some concerns

Domain 1: Bias arising from the randomisation process.
Domain 2: Bias arising from the timing of identification and recruitment of individuals in relation to timing of randomisation.
Domain 3: Bias due to deviations from intended interventions.
Domain 4: Bias due to missing outcome data.
Domain 5: Bias in measurement of the outcome.

Table 5
Care bundles, implementation strategies, and outcomes.

Author (year) Country	Care bundle components	Bundle foundation	Implementation strategies	Intervention fidelity	Loss-to-follow-up; ITT analysis	PI prevalence and/or incidence
Al-Otaibi et al. (2019) Saudi Arabia	n = 6 Core 1. Adoption of PIP guidelines 2. Daily PI risk assessment interventions 3. Repositioning regime 4. Use of specialised mattresses 5. Prophylactic dressings over bony prominences 6. Nurse and physician training Discretionary None	Foundation: • Institute for Healthcare Improvement resources • Local evidence • Research evidence Delivered by: • Nurses • Physicians Anatomical location: Not reported	Prior to bundle use • Cycle 1 Plan-do-study-act review • PI risk assessment and repositioning audits • Multidisciplinary wound team and reinforcement of their role • Weekly HAPI prevalence audits During bundle implementation • Cycle 2 and 3 Plan-do-study-act reviews • Weekly audits of PI risk assessment, repositioning, support surface and prophylactic dressings • Procure additional support surfaces • Clinical form redesign into single page, colour coded tool with a supplementary guide • Multidisciplinary wound team role reinforcement • Wound care team support and coaching for some units Activities to embed: Not reported	PI risk assessment, repositioning support surfaces and prophylactic dressing audits but results not reported	LTFU not applicable Complete case analysis	Hospital-acquired PI [a]Control: 29/368 (7.8 %) [a]Intervention: 12/1537 (0.78 %) Reduction of HAPI by 84 % (RR 0.16; 95 % CI 0.07 to 0.3; p value 0.0001) Incidence not reported
Chaboyer et al. (2016) Australia	n = 4 Core 1. Keep moving 2. Skin care 3. Good nutrition 4. Staff education (Patient participation, mobility, skin care, nutrition) Discretionary None	Foundation: • Research evidence • Theory (patient participation and PUP Clinical Practice Guidelines) • Previous research (× 5 Systematic reviews) • Consumer engagement Delivered by: Intervention RA (nurse or dietitian) Anatomical location: All	Prior to bundle use: Nurse education on the bundle (intervention wards) During bundle implementation • Patient education using DVD, brochure and poster • Education by Intervention RA • Nurse education on the bundle (intervention wards) Activities to embed: Not reported	n = 31 (3.9 %) did not receive intervention	LTFU 50/1598 ITT and complete case analysis	PI prevalence not reported HAPI incidence density Control: 20.1 per 1000 person days Intervention: 9.6 per 1000 person days Incidence rate ratio: Unadjusted 0.48 (0.33–0.69, p < 0.0001) Hazard ratio: Unadjusted 0.48 (0.20–1.21) Adjusted (age, baseline PI, BMI, type of admission, aged care resident, co-morbidity on admission) 0.58 (0.25 = 1.33)
Elliott (2010) United Kingdom	n = 6 Core 1. Risk assessment 2. Support surfaces 3. Repositioning 4. Skin evaluation 5. Education/awareness campaign Discretionary 6. Heel offloading	Foundation: Local evidence Delivered by: • Tissue Viability support workers (Equipment) • Tissue viability nurses Anatomical location: All	Prior to bundle use: • Education/Awareness campaign During bundle implementation: • Risk assessment in Emergency Department • Equipment redeployment • Revised documentation/care plans • Heel offloading protocol Activities to embed: Not reported	Change in percentage compliance reported, ranging from 9 % improvement to 5 % decrease in compliance	LTFU not applicable Complete case analysis	PI prevalence Control: 151/976 (15.5 %) Intervention: 125/930 (13.4 %)

Jafary et al. (2018) Iran	n = 7 Core 1. Patient education (pamphlets, posters) 2. Staff training 3. Bedside card (high risk sign) 4. Regular repositioning 5. Daily visits by wound care nurse Discretionary 6. Pressure-relieving beds 7. Regular ulcer dressings	Foundation: Local evidence (lack of patient programmes in the hospital) Delivered by: 'nursing staff' Anatomical location: All	Prior to bundle use: Training to nurses and carers During bundle implementation: Not reported Activities to embed: Not reported	70 % of pts. got 100 % of the intervention; 30 % of pts got 90 % of the intervention	LTFU not reported ITT analysis stated in report but per protocol analysis confirmed by author	PI prevalence not reported HAPI incidence density Control: 5.49/1000 pt-days (n = 1855) Intervention: 4.62/1000 pt-days (n = 1657) Incidence rate ratio: Adjusted 2 levels (pt and unit) 0.78 (0.60–1.0)
Keen and Fletcher (2013)	n = 8 Core 1. Pre-education 2. Staff PI knowledge audit 3. Bedside chart (SKIN Bundle Chart) 4. Surface (assess) 5. Skin inspection 6. Keep moving (reposition) 7. Nutrition Discretionary 8. Incontinence care	Foundation: • Local feedback (Transforming Care Initiative) and reflections. • SKIN bundle concept • International and national guidelines Delivered by: Trained Nurses in the SKIN bundle Anatomical location: All	Prior to bundle use • Planning workshops • Development of relevant education for nurses During bundle implementation • Facilitated workshops • Audit and feedback • Nursing education • Stakeholder involvement • SKIN bundle improvements • Additional staff resources: support staff, tissue viability link nurse Activities to embed • Facilitated workshops • Checklist developed • Documentation • Staff leadership: Tissue viability link nurse • Health board facilitated the implementation of the Transforming Care initiative	Not reported	LTFU not applicable Complete case analysis	PI prevalence Control: 11/35 (28.6 %) Intervention × 1: 6/33 (18.2 %) Intervention × 2: 0/13 (0.0 %) Hospital-acquired PI Control: 5/35 (14.3 %) Intervention × 1: 3/33 (9.1 %) Intervention × 2: 0/13 (0.0 %) PI incidence not reported
Martin et al. (2017) Canada	n = 4 Core 1. PI screening tool 2. Malnutrition screening tool 3. Mattresses 4. Staff education Discretionary 5. Therapeutic sleep surfaces (n = 12) 6. Sliders 7. Heel lift boots 8. Incontinence care products	Foundation: • Local evidence • Theory (Iowa Model of Evidence-Based Practice to Promote Quality Care; Diffusion of Innovation Model) Delivered by: • Nurses (RN, LPN), • Healthcare aides • Allied health (physiotherapists, occupational therapists, dieticians) Anatomical location: All	Prior to bundle use • Steering committee • Multidisciplinary Subcommittees • Staff awareness campaign During bundle implementation • Education by allied health professionals (slider use), and dietitians (nutrition screening) Activities to embed: Not reported	Not reported	LTFU not applicable Complete case analysis	PI prevalence Control: 83/242 (34.3 %) Intervention: 18/239 (7.5 %) p < 0.0001 PI cumulative incidence Control: 16.5 % (19/115) Intervention: 5.1 % (8/156) p < 0.002
Smith et al. (2018) Australia	n = 7 Unclear which were core and discretionary 1. E-learning course (health professionals)	Foundation: • Local evidence • Theory (Theory of Planned Behaviour, modified) • International and national guidelines	Prior to bundle use: Not reported During bundle implementation: Not reported Activities to embed: 'Communication' to facilitate improvements	Risk assessment 2008: n1110 (78.9 %) 2010: n = 1073 (80.6 %) 2014: n = 938 (84.3 %)	LTFU not applicable Complete case analysis	PI prevalence Control (2008): 399/1407 (28.4 %) Intervention (2010): 173/1331 (13.0 %) Intervention (2014): 130/1199 (10.8 %)

(continued on next page)

Table 5 (*continued*)

Author (year) Country	Care bundle components	Bundle foundation	Implementation strategies	Intervention fidelity	Loss-to-follow-up; ITT analysis	PI prevalence and/or incidence
	2. Changes in policy 3. Surveillance of PIP strategies 4. Equipment for PIP and management 5. Documentation of standardised PIP assessments 6. Wound management 7. Standardised PIP assessments	Delivered by: • Health professional • Staff practitioners Anatomical location: All		Risk Assessment completed on admission: 2008: n = 281 (68 %) 2010: n = 301 (23 %) 2014: n = 379 (71 %) Documentation of repositioning 2008 = 290 (20.6 %) 2010 = 415 (31.2 %) 2014 = 583 (74.0 %) Pressure relieving devices 2008 = 843 (59.9 %) 2010 = 520 (39.1 %) 2014 = 530 (44.0 %)		Hospital-acquired PI Control (2008): 329/1407 (23.4 %) Intervention (2010): 106/1331 (8.0 %) Intervention (2014): 83/1149 (6.9 %) PI incidence not reported
Stausberg et al. (2010) Germany	n = 6 Core 1. PI prevention guideline 2. Risk assessment 3. Nurse training 4. Mattresses Discretionary 5. Alternating pressure mattresses 6. Wound management service	Foundation: No information provided Delivered by: No information provided. Anatomical locations: All	Prior to bundle use: Not reported During bundle implementation: Not reported Activities to embed: Not reported	Not reported	LTFU not applicable Complete case analysis	PI prevalence Control: n = 700/49,904 (1.4 %) Intervention: n = 762/43,143 (1.8 %) p < 0.001 PI cumulative incidence Control: n = 280/49,904 (0.6 %) Intervention: n = 282/43,143 (0.7 %) p = 0.069
Young et al. (2015) USA	n = 6 Core 1. Skin assessment protocol 2. Skincare 3. Advanced support surfaces 4. Turning regime Discretionary 5. Incontinence care 6. Optimise nutrition and hydration	Foundation: • Local evidence • Financial impact of PI fines • Previous research Delivered by: • Nurses • WOCN • DWC • Dietician • Multidisciplinary team Anatomical locations: Not reported	Prior to bundle use • New Director for Wound Care (DWC) position • New Wound ostomy continence nurse (WOCN) position • Hospital-wide multidisciplinary wound team • Mandatory training for all nurses • WOCN delivered 1 h PI lecture to the graduate nurses During bundle implementation • Bedside discussions between DWC and WOCN • WOCN screened all patients for PI risk Activities to embed • Hospital-wide multidisciplinary wound team Ongoing leadership support	Not reported	LTFU not applicable Complete case analysis	Hospital-acquired PI [a]Control: 41/135 (30.4 %) [a]Intervention: 1/119 (0.84 %) PI incidence not reported

Note. PI, pressure injury; ITT, intention to treat; LTFU, loss-to-follow-up.

[a] After correspondence with author, data calculated from figures and text.

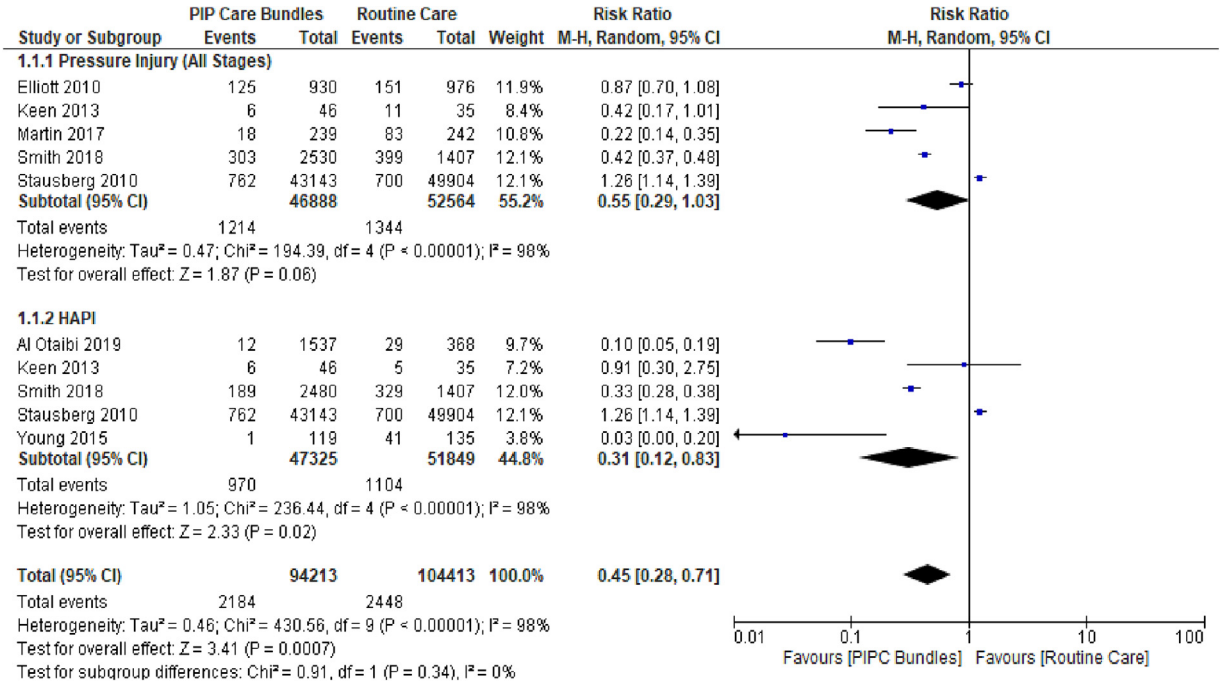

Fig. 2. Pooled pressure injury prevalence and hospital-acquired pressure injury (random effects meta-analysis).

Thus, future bundles may evolve to include these and other emerging evidence-based interventions as core or discretionary components.

There was a wide range of implementation strategies reported, with some authors not mentioning this at all and others giving it little consideration. Given care bundles are meant to change clinicians' behaviours and improve practice (Institute for Healthcare Improvement, 2023), this oversight may be one reason that explains why the randomised studies did not show beneficial bundle effects. Understanding the barriers and facilitators to practice change such as care bundle uptake and then implementing strategies that address the barriers and capitalise on the facilitators supports successful implementation of intervention (Graham et al., 2006; Lynch et al., 2018; Michie et al., 2005). Practice surveys, interviews and observations can be used to collect data on barriers and facilitators. Our review identified limited evidence on how researchers had considered how the bundle could be embedded into routine practice beyond the study period. This was surprising given that the science of implementation has advanced over recent decades with many theory-based frameworks and resources now available (Flottorp et al., 2013; Michie et al., 2005; Nilsen, 2015) to support comprehensive implementation plans that include strategies for spread and sustainability.

In the studies we reviewed, implementation fidelity was poorly reported. Clear reporting of implementation fidelity, or the extent to which programmes are implemented as intended, is needed because this integrity can influence intervention outcomes (Carroll et al., 2007). Over 15 years ago, Carroll et al. (2007) developed a conceptual framework to systematically consider implementation fidelity. They identify three main elements, including adherence, moderators, and essential components. Given the implementation strategies in the studies we reviewed ranged from very few or none (Smith et al., 2018; Stausberg et al., 2010) to many (Al-Otaibi et al., 2019; Keen and Fletcher, 2013; Young et al., 2015), our meta-analyses of non-randomised studies, and reporting of the results of the two randomised studies may reflect issues with implementation fidelity and not just intervention effectiveness. Whilst study authors did not report on the fidelity of their implementation strategies, it seems logical that if they were effective, then intervention fidelity might be supported. However, in four of the nine studies in this review, there was no mention of intervention fidelity.

One widely used framework that could support implementation, spread and sustainability of pressure injury care bundles is May's Normalisation Process Theory (May and Finch, 2009; May et al., 2014; Papoutsi et al., 2024). Normalisation Process Theory focusses on the individual and collective behaviours required to normalise a new intervention such as care bundles in practice. According to this theory, the resources required (termed capacity) and those available (termed potential) along with the ability to integrate a new intervention (termed capability) need to be considered in any implementation plan. In their review of how nurses implemented clinical practice guidelines, May et al. (2014) determined that the guidelines had to have the potential to be easily integrated into routine practice, and they had to be seen to be differentiated from and legitimised by nurses. They also had to be supported by an emerging community of practice and collective knowledge improvement (May et al., 2014). This theory could be used when developing implementation plans for the uptake of pressure injury prevention care bundles, although this is just one of many examples of how theory can be used to guide implementation.

Leeman et al. (2017) provide a classification of implementation strategies, which may be useful when planning care bundle implementation. They describe five domains of strategies including dissemination, implementation process, integration, capacity building, and scaleup. A comprehensive pressure injury prevention care bundle implementation plan could be developed with specific activities targeting each of these domains. For example, a dissemination strategy might be to widely advertise the bundle and its components through various hospital communication infrastructure, and an implementation process could include using group meetings to gain stakeholders' advice on how and when the bundle should be enacted. Integration strategies could be as simple as automated computerised reminders. Education and access to technical experts and facilitators are commonly used for capacity building. Finally, scaleup strategies include activities that support ongoing bundle use such as implementation toolkits and social structures such as quality improvement collaboratives and recognition programmes. Ultimately, our effectiveness results may be partially explained by implementation fidelity and not just intervention fidelity.

To understand how the care bundle components might work (i.e., pathway complexity) we undertook an a priori assessment of

pathway complexity that was informed by empirical evidence and theory. The bundle components we identified within included studies were aligned with our proposed pathway complexity. As envisioned, we found that most bundles include risk assessment. Current practices related to support surfaces, heel offloading devices, skin care products and repositioning routines were all common care bundle components as we anticipated, reflecting attention to load and tolerance. We anticipated that some components such as the use of nutrition support and incontinence products would be used to mitigate risk in some individuals, and we did find some evidence that these components were used; generally discretionary. The use of tailoring bundle components with clear criteria for this tailoring may provide additional guidance to clinicians. Education was often part of the bundle, which we thought was aimed at improving staff competence, capability, and commitment to pressure injury prevention. Finally, we anticipated that access to and use of pressure injury prevention resources might be improved as part of the care bundles, and this improved access was evident in many of the studies we reviewed.

4.3. Strengths and limitations

Whilst a rigorous review that meets all 'AMSTAR 2:e A Measurement Tool to Assess systematic Reviews' criteria (Shea et al., 2017) was undertaken by a team of experts in both pressure injuries and the conduct of systematic reviews (including meta-analyses); this review also has several limitations. We only included studies published in English because of resource constraints and it is always possible that we did not identify some potential studies that should have been included in the review. Also, the studies included were conducted predominantly in Western countries, which has the potential to create a cultural bias, especially when identifying and selecting the bundle components and implementation strategies. Second, whilst two reviewers independently screened titles, abstracts and full-text articles and also undertook data extraction and risk of bias assessments adjudicated by another reviewer, we did not record the exact number of discrepancies and thus are unable to report on inter-rater agreement. Third, whilst we articulated how the care bundle might work including the pathway complexity, we did not assess the certainty of evidence for individual components of the care bundles. Fourth, we pooled studies that had some variation in components, but they all had six to eight components, at least three of which were common across studies, an approach is consistent to many other care bundle meta-analyses (Lavallée et al., 2017; Martinez-Reviejo et al., 2023; Ospina et al., 2017; See et al., 2023; Tanner et al., 2015). Whilst heterogeneity was high, it may not have arisen because of the types of care bundles; it could also be because of the differences in the sample sizes and results of the studies included in the actual meta-analyses. High heterogeneity in study populations may reflect the diversity of real-world conditions. Combining data from various studies with different participant characteristics, and settings, can result in a more generalised understanding of the intervention's effectiveness across a broader range of situations. This is especially important for informing clinical practice and public health decisions. Fifth, all studies in our meta-analyses were non-randomised intervention studies at high risk of bias but because of the number of studies in the meta-analyses we were unable to statistically investigate the risk of bias effect. We could not meta-analyse studies reporting on cumulative incidence because of differences in study design. Data were also not available for us to undertake planned subgroup analyses. Finally, a lack of studies and lack of reporting on our pre-defined outcomes meant that we were unable to undertake the planned subgroup analyses and assess publication bias.

5. Conclusions

This systematic review and meta-analysis critically appraised nine pressure injury prevention care bundle studies, seven of which were non-randomised studies with historical controls. There were a range of core and discretionary components in the bundles, with common components being risk assessment, repositioning, the use of appropriate support surfaces, skin care and staff or patient education. Reported implementation strategies ranged from comprehensive, theory and evidence informed activities to limited or no mention of any strategies. Whilst the care bundles showed a statistically significant risk reduction for hospital-acquired pressure injury rate, pressure injury prevalence and incidence density decreases were not statistically significant. The certainty of the body of evidence was low or very low for all outcomes. Given recent evidence for prophylactic dressings and other innovations such as using sub-epidermal moisture scanning technology, bundle developers should consider the potential benefits of adding emerging evidence-based components to pressure injury prevention care bundles. Future care bundle effectiveness studies should include contemporaneous controls and the development of a comprehensive, theory and evidence informed implementation plan.

Funding

The National Health and Medical Research Council (NHMRC) Application 1196436 provided some funding towards three review authors' salaries (SL, EH, JL, SJ). The NHMRC played no role in the systematic review.

CRediT authorship contribution statement

Wendy Chaboyer: Writing – review & editing, Writing – original draft, Visualization, Project administration, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Sharon Latimer:** Writing – review & editing, Methodology, Data curation. **Udeshika Priyadarshani:** Formal analysis, Methodology, Visualization, Writing – review & editing. **Emma Harbeck:** Data curation, Methodology, Writing – review & editing. **Declan Patton:** Formal analysis, Visualization, Writing – review & editing. **Jenny Sim:** Data curation, Methodology, Writing – review & editing. **Zena Moore:** Formal analysis, Methodology, Visualization, Writing – review & editing. **Jodie Deakin:** Data curation, Methodology, Writing – review & editing. **Joan Carlini:** Data curation, Methodology, Writing – review & editing. **Josephine Lovegrove:** Data curation, Writing – review & editing. **Sepideh Jahandideh:** Writing – review & editing, Data curation. **Brigid M. Gillespie:** Writing – review & editing, Methodology, Formal analysis, Data curation, Conceptualization.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Wendy Chaboyer and Brigid Gillespie were authors on one of the studies included in this systematic review. They had no role in data extraction or analysis of this study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnurstu.2024.104768.

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