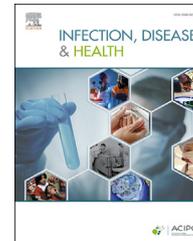




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Review

Effectiveness of insertion and maintenance bundles in preventing peripheral intravenous catheter-related complications and bloodstream infection in hospital patients: A systematic review

Gillian Ray-Barruel ^{a,b,c,d,e,*}, Hui Xu ^{a,f}, Nicole Marsh ^{a,b,d}, Marie Cooke ^{a,b},
Claire M. Rickard ^{a,b,d,e}

^a Alliance for Vascular Access Teaching and Research (AVATAR), Menzies Health Institute Queensland, Griffith University, Nathan, Australia

^b School of Nursing and Midwifery, Griffith University, Nathan, 4111, Australia

^c QEII Jubilee Hospital, Coopers Plains, Queensland, 4108, Australia

^d Royal Brisbane and Women's Hospital, Herston, Queensland, 4029, Australia

^e Princess Alexandra Hospital, Woolloongabba, Queensland, 4102, Australia

^f Logan Hospital, Meadowbrook, Queensland, 4131, Australia

Received 14 February 2019; received in revised form 22 March 2019; accepted 25 March 2019

Available online 18 April 2019

KEYWORDS

Catheterization;
Peripheral;
Intravenous;
Bundle;
Assessment

Abstract *Background:* Evidence-based bundles have reduced central line bloodstream infection rates in adult intensive care units. To tackle peripheral intravenous catheter (PIVC) bloodstream infection, many hospitals have implemented PIVC insertion and maintenance bundles. However, the efficacy of PIVC bundles in preventing PIVC complications and infection in hospital patients is uncertain. The aim of this paper is to synthesize evidence on the effectiveness of PIVC insertion and maintenance bundles on preventing adverse events.

Methods: In this systematic review, we searched multiple electronic databases, trial registries, and grey literature for eligible studies published in English (January 2000–December 2018) to identify intervention studies evaluating PIVC insertion or maintenance bundles with two or more components. Search terms: peripheral intravenous catheter/cannula, insertion, maintenance, bundle, infection, infiltration, extravasation, dislodgement, thrombosis, occlusion, and phlebitis. Two reviewers independently conducted data extraction and quality assessments using the Downs and Black checklist.

Results: Of 14,456 records screened, 13 studies (6 interrupted time-series, 7 before-and-after) were included. Insertion and maintenance bundles included multiple components (2–7 items per bundle). Despite testing different bundles, 12 studies reported reductions in phlebitis and bloodstream infection, and one study reported no change in bloodstream infection and an

* Corresponding author. Griffith University N48_0.09, 170 Kessels Rd, Nathan, QLD 4111, Australia.

E-mail address: g.ray-barruel@griffith.edu.au (G. Ray-Barruel).

increase in phlebitis rate. Methodological quality of all studies ranked between 'low' and 'fair'.

Conclusions: The effect of PIVC bundles on PIVC complications and bloodstream infection rates remains uncertain. Standardisation of bundle components and more rigorous studies are needed. PROSPERO registration number: CRD42017075142.

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Highlights

- Many hospitals are implementing peripheral intravenous catheter (PIVC) insertion and maintenance bundles with the goal of preventing PIVC-related complications and infection.
 - The effectiveness of implementing peripheral intravenous catheter insertion and maintenance bundles is unclear.
 - This is the first systematic review of PIVC insertion and maintenance bundles
 - A lack of standardization of bundle components precludes meaningful comparison of reported outcomes
 - Further research is needed to identify which bundle components are effective in reducing PIVC-related complications and infection.
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Introduction

Peripheral intravenous catheters (PIVC) are essential for the delivery of medical treatments in over one billion patients annually [1]. Yet PIVC complications (infiltration and extravasation, blockage, dislodgement, and phlebitis) result in premature access failure in up to 69% of hospital patients [2], requiring the insertion of a new device, with delays in treatment and increased costs. Furthermore, catheter-associated bloodstream infection (BSI) is a threat to healthcare outcomes worldwide [3].

Despite evidence-based guidelines, the uptake of recommendations into clinical practice can be difficult. The introduction of care bundles that simplify lengthy guidelines into point-of-care reminders has improved staff compliance with best practice [4]. By definition, care bundles comprise a small set of up to five evidence-based practices implemented in their entirety [4]. Bundles for central venous access device (CVAD) insertion and maintenance demonstrate reductions in BSI when implemented with compliance monitoring [5–7]. Infection prevention measures in CVAD bundles include hand hygiene, optimal insertion site selection, maximal sterile barriers for line insertion, chlorhexidine skin disinfection, and daily review of device necessity with prompt removal of unneeded lines [5]. With the reported success of CVAD bundles, PIVC insertion and maintenance bundles are being implemented in many hospitals [8,9]. While compliance with CVAD bundles has resulted in BSI reductions in adult intensive care units (ICU), the impact of PIVC insertion and maintenance bundles is unclear.

This systematic review aimed to: (i) systematically critique (and meta-analyse, if possible) evidence for the effectiveness of PIVC insertion and maintenance bundles to prevent BSI and catheter-related complications in hospital

patients of all ages, and (ii) describe components of bundles, implementation strategies, and reported compliance.

Methods

Protocol

The systematic review was conducted in accordance with the Cochrane EPOC guidelines [10]. The protocol was registered on PROSPERO (registration: CRD42017075142). Findings were reported in accordance with the PRISMA guidelines [11].

Search strategy

The search strategy was developed by two researchers (GRB, HX) with help from a university research librarian. Comprehensive searches were undertaken of electronic biomedical databases: MEDLINE, PubMed, CINAHL, EMBASE, Cochrane CENTRAL, and ISI Web of Science. Grey literature was searched via Google Scholar; www.opengrey.eu/; <http://www.greylit.org/>; www.ahrq.gov/; www.joannabriggs.edu.au/Search.aspx; and www.nice.org.uk/. Clinical trials registries searched: <http://www.who.int/ictrp/en/>; <https://clinicaltrials.gov/>; and <http://www.anzctr.org.au/>. The full search strategy and search terms are listed in [Supplementary file 1](#).

Selection criteria

Prospective intervention studies reporting multimodal strategies or bundles with two or more components for PIVC insertion or management in hospital patients of all ages to reduce BSI or catheter-related complications published in English (January 2000–December 2018) were included.

Eligible study designs included randomised controlled trials, interrupted time series (ITS), before-and-after studies (BA), and cohort studies only. Studies that reported implementing a single intervention were excluded. Articles that did not define the strategy or bundle components or report outcome measures were excluded. Conference abstracts, letters, and articles unable to be accessed in full-text were excluded.

An insertion bundle was defined *a priori* as at least two evidence-based practices for insertion, including but not limited to: hand hygiene [12–16], personal protective equipment [13,16], vein visualisation technology [12,16], site selection [12–14,16], skin antisepsis [12–14,16], sterile occlusive dressing [12–14,16], aseptic insertion technique [12–14,16], and pain relief [12]. A maintenance bundle was defined *a priori* as at least two evidence-based practices for maintenance, including but not limited to: daily evaluation of need [15,17], patency assessment [12,13,15,16], assessment of complications [12–16], and infection prevention (hand hygiene, scrub the hub, aseptic non-touch technique, dressing and securement changes, patient education, documentation, prompt removal) [12–14,16].

Primary outcome measures, also determined *a priori*, included BSI [18,19] or PIVC-related complication (pain, infiltration, extravasation, blockage, premature dislodgement, thrombosis, phlebitis) [1,2]. Secondary outcome measures included first-time insertion success [20], compliance rates with individual bundle components and total bundle [9], improved functional dwell time of PIVC [2], sustainability of the intervention (e.g. long-term compliance at 6 or 12 months), and cost effectiveness [21].

Data extraction

Searches were imported into EndNote X9 (Clarivate Analytics, Philadelphia) to screen for relevance and identify duplicates. Two reviewers (GRB, HX) independently screened all titles and abstracts to select potentially relevant articles for the review. Full text papers of relevant citations were reviewed and independently assessed for eligibility for inclusion. Reference lists of retrieved articles were examined, and relevant articles were sourced and reviewed. Data from included studies were extracted into a pre-defined data extraction spreadsheet by two reviewers independently, summarised into an evidence table, and cross-checked for accuracy. Minor disagreements were resolved with discussion between reviewers; arbitration via a third reviewer was not required.

Data extracted included: title, author, year, country of study, aims and objectives, study design, number of data collection time-points, duration, setting, population (adult/paediatric/neonate), sample size, unit of measurement (PIVC or participant), person collecting data, frequency of data collection, bundle users, guidelines used for bundle development, insertion bundle components, maintenance bundle components, implementation strategies, primary outcomes, secondary outcomes, outcome assessor, blinding of outcome assessor, definitions (CLABSI, phlebitis,

complications, compliance, insertion success), use of phlebitis/infiltration scale, reported findings (CLABSI, phlebitis, complications, compliance, insertion success, cost), sustainability, trial registration, ethics approval, and funding source.

Risk of bias assessment

Two reviewers independently completed the quality assessment of each study and compared results. Discrepancies were resolved with discussion. The Downs and Black checklist was used to assess study methodology risk of bias [22]. The checklist has 27 questions which evaluate study quality of reporting, external validity, internal validity (bias), internal validity–confounding (selection bias) and power. Quality assessment of studies is determined by the following cut-points: excellent (26–28), good (20–25), fair (15–19), and poor (≤ 14) [23]. An overall quality score was assigned to individual studies.

Synthesis of results

A narrative synthesis of the characteristics and reported outcomes of the included studies was undertaken. Where possible, outcome measures of ITS and BA studies were reported as relative risk, confidence intervals (95% CI), per cent change relative to baseline and probability (*p*-values). We planned to pool results across studies for meta-analysis where possible; however, we prespecified that the expected number and heterogeneity of care bundle components and implementation strategies could make this unfeasible. Given the predicted heterogeneity of the study populations, the following subgroup analyses were planned: (1) Bundle components that increase or reduce the intervention effect; (2) Electronic medical records vs paper-based bundles; and (3) Adult vs paediatric vs neonate bundle components and implementation strategies.

Results

Database and grey literature searches identified 14,456 records; from this, 4161 duplicates were removed, and 10,295 records were screened by title or abstract. Of 45 full-text articles assessed for eligibility, 32 were excluded and 13 studies were included in the final review. A PRISMA flow diagram [11] depicts the number of articles obtained in the searches, subsequent exclusions and final numbers included in the review to maximise transparency and clarity (See Fig. 1).

Study characteristics

The characteristics and outcomes of the 13 included studies are provided in Table 1. Excluded studies are displayed in Table 2. We identified six interrupted time-series studies [30,32–36] and seven before-and-after studies [24–29,31]. All included studies reported implementing a PIVC care bundle for insertion ($n = 9$) or maintenance ($n = 10$), or

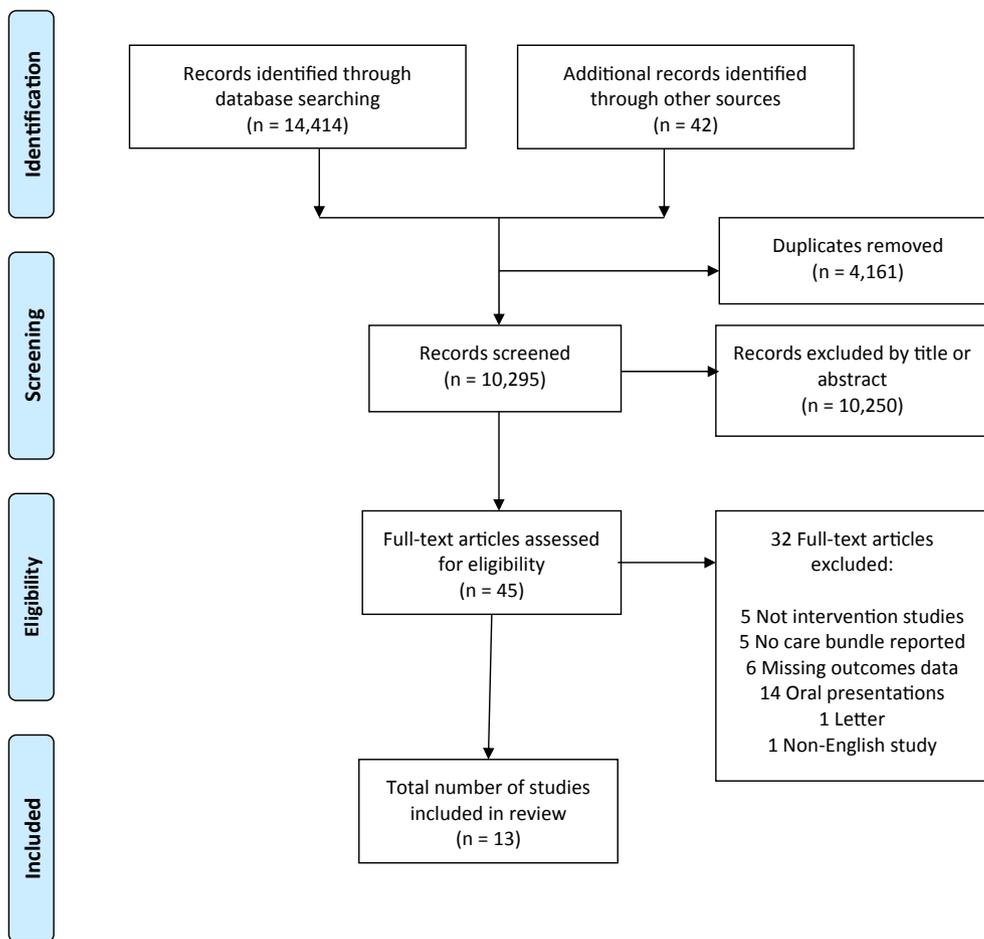


Figure 1 PRISMA diagram.

both (n = 8) in an acute care hospital inpatient setting. Studies were conducted in a range of countries, including Australia [32,36], USA [25,26,29], UK [27], Spain [30,33], Germany [34], Taiwan [24], South Korea [31], and Thailand [35]. Bundles were implemented for the adult (n = 10), paediatric (n = 2), and neonate (n = 1) populations.

Sample sizes ranged from small, single-centre studies with fewer than 200 patients [36] to large multicentre studies with over 2 million patient days [28]. Duration of the interventions ranged from 4 months [36] to 14 years [33], with data collection time-points ranging from every PIVC [29] to annual surveillance audits [30,33].

Outcome assessors were most often infection control professionals [25,26,30,32,33], nurse researchers [29,31], nurse anaesthetists [24], study coordinating centre staff [28], or not stated [27,34–36]. Blinding of outcome assessors was not reported in any studies.

Insertion bundle components

Twenty-one different insertion bundle components were detailed in 10 studies [24,25,27–29,31–34,36]. Each insertion bundle comprised two to seven items, with some overlap among bundles. The most often reported items were 2% chlorhexidine gluconate (CHG) skin prep

[25,27,28,33], hand hygiene [24,28,34], vessel assessment/site selection [28,29,31], aseptic technique [24,33,36], integrated closed catheter [25,27,33], and transparent film dressing [24,28,33]. Sterile gloves [25,33], nurse self-assessment of PIVC insertion ability [29,31] and documentation of insertion [31,36] featured in two insertion bundles apiece. Other components each featured in one insertion bundle included: dedicated PIVC insertion trolley [32], cannula size (20–22 G) [24], skin prep (not specified) [34], CHG sponge/dressing [25], catheter securement [25], needleless connectors [27], extension tubing [33], alcohol caps [25], cannula alert stickers [32], patient activity assessment [31], patient comfort plan [29], and nurse decision to stop PIVC insertion [29] (See Fig. 2).

Maintenance bundle components

Twenty-two different maintenance bundle components were identified in 11 studies [24,26–28,30–36]. Each maintenance bundle comprised two to seven items, again with occasional overlap among bundles. The most prevalent maintenance bundle items included daily review of need for PIVC (7 studies) [24,27,28,30,34–36] and poster reminders of the bundle intervention (7 studies) [28,31–36].

Table 1 Characteristics and outcomes of included studies.

First author, year, country (ref)	Study design, duration, frequency of data collection; Population: sample size	Insertion bundle components	Maintenance bundle components	Implementation strategies	Reported outcomes	Reported compliance	D&B Score ^a
Chiu, 2015, Taiwan [24]	BA, 10 months, NR Adult surgical inpatients: pre 1340; post 13,342; total 14,682 patients	<ul style="list-style-type: none"> • hand hygiene • aseptic technique • cannula size (20–22G) • transparent dressing 	<ul style="list-style-type: none"> • PIVC checklist (patency, date, site complications, securement, rate, line setup); • flowchart/algorithm for PIVC use • consider PIVC need • routine resite 3 days 	<ul style="list-style-type: none"> • quality assurance meetings every 2 weeks • feedback 	<ul style="list-style-type: none"> • Reduction in PIVC adverse events (line obstruction, disconnection, line mismanagement, phlebitis): pre 0.75%; post 0.13% (p < .01) 	NR	14
DeVries, 2016, USA [25]	BA, 18 months, NR Inpatients: post 364 patients. No total denominator given.	<ul style="list-style-type: none"> • 2% CHG skin prep • sterile gloves • integrated catheter • CHG sponge/dressing • securement • alcohol caps 	NA	<ul style="list-style-type: none"> • policy & literature review • education (staff huddles, bedside training, patient care champions, PIVC insertion & site selection classes) • audits 	<ul style="list-style-type: none"> • 19% relative reduction PIVC-BSI per 100 patient-days: pre 0.0150; post 0.0121 	<ul style="list-style-type: none"> • 48% relative reduction in IV start kit usage. • 35% dwell time \geq5 days 	10
Duncan, 2018, USA [26]	BA, 7 months, NR Adult inpatients: pre 167; post 1977; total 2144 PIVC	NA	<ul style="list-style-type: none"> • PIVC site assessment • dressing integrity checks • alcohol caps • alcohol tip protectors • minimize tubing disconnects 	<ul style="list-style-type: none"> • education (online module, nursing huddles, in-service) • audits 	<ul style="list-style-type: none"> • 81% relative reduction PIVC-BSI per 1000 patient-days: pre 0.57; post 0.11 (p < .001). • Reduction in phlebitis: pre 8%; post 2% (p < .0001) 	<ul style="list-style-type: none"> • Use of alcohol caps on peripheral lines: pre 36%; post 89%. • Use of alcohol tips on administration sets: pre 0%; post 84%. 	12
Easterlow, 2010, UK [27]	BA, 13 months, 4 timepoints Inpatients: pre 238; post 269; total 507 PIVC	<ul style="list-style-type: none"> • 2% CHG skin prep • integrated catheter • needleless connector 	<ul style="list-style-type: none"> • drug chart with PIVC insertion and removal details and phlebitis scale • nursing care plan • review PIVC need 	<ul style="list-style-type: none"> • new cannulation policy • education (use of integrated catheter) • audits 	<ul style="list-style-type: none"> • 39% relative reduction PIVC-BSI: pre 9/238, post 4–6/260 	<ul style="list-style-type: none"> • 84% of patients had integrated catheter • 90% of patients had needleless connector • Daily PIVC site assessment: pre 30%; post 60% 	14

Freixas, 2013, Spain [28]	BA, 2 years, 4 timepoints 11 hospitals, adult inpatients: pre 1,191,843; post 1,173,672; total 2,365,515 patient days	<ul style="list-style-type: none"> • hand hygiene • 2% CHG skin prep 	<ul style="list-style-type: none"> • disinfect needleless connectors • dressing integrity checks • daily review PIVC need • 72 h & prn replacement (or 48 h for ED-inserted) 	<ul style="list-style-type: none"> • education (pocket leaflets, posters, staff training sessions) • audits • feedback 	<ul style="list-style-type: none"> • No change in PIVC-BSI: pre and post 0.05/1000 patient days (pre 95% CI 0.03–0.06; post 95% CI 0.04–0.07; p = .52) • Increase in phlebitis rate: pre 2.5%; post 3% (p = .33) 	<ul style="list-style-type: none"> • 54.5% compliance 	bundle 15
Hartmann, 2018, USA [29]	BA, NR, every PIVC Inpatients (0–27 years): pre 419; post 302; total 721 PIVC insertion attempts	<ul style="list-style-type: none"> • patient comfort plan • vessel assessment/site selection tool • nurse self-assessment of IV access capability • nurse decision to stop insertion 	NA	NR	<ul style="list-style-type: none"> • No change in first attempt PIVC success rate: pre 51.3%; post 52.0% (p = .86) • Relative reduction in overall attempts: pre 98.6%; post 92.4% post (p = .002) 	NR	15
Mestre, 2013, Spain [30]	ITS, 8 years, multiple 1631 inpatients with 2325 PIVC	NA	<ul style="list-style-type: none"> • phlebitis scale • review PIVC need • 96 h routine resite (July 2005–June 2008) • 120 h routine resite (July 2008–December 2011) 	<ul style="list-style-type: none"> • education (theoretical and practical sessions in small groups of nurses) • annual PIVC audits 	<ul style="list-style-type: none"> • 48% relative reduction in phlebitis: pre 23.3%; 95% CI 16.4–30.1; post 12.1%; 95% CI 10.7–13.2; (p < .05) • 59 CRBSI over 8 years (11 were PIVC-BSI); none detected during surveillance audits 	<ul style="list-style-type: none"> • Routine adherence improved when policy changed from 96 h to 120 h: pre 30.8%; post 68.2% (p < .05) 	resite 14
Park, 2016, South Korea [31]	BA, 7 months, daily Inpatients (0–18 years): pre 2894; post 3651; total 6545 PIVC	<ul style="list-style-type: none"> • vessel assessment/site selection (nurse self-assessment of insertion ability) • patient observation • document insertion 	<ul style="list-style-type: none"> • shift assessment and documentation • infiltration grading tool 	<ul style="list-style-type: none"> • education (posters, leaflets, “IV filtration management program”) • parent education • inter-rater reliability of infiltration grading tool 	<ul style="list-style-type: none"> • Relative reduction in infiltration rate: pre 4.4%; post 0.9% (p < .001) 	NR	14

(continued on next page)

Table 1 (continued)

First author, year, country (ref)	Study design, duration, frequency of data collection; Population: sample size	Insertion bundle components	Maintenance bundle components	Implementation strategies	Reported outcomes	Reported compliance	D&B Score ^a
Rhodes, 2016, Australia [32]	ITS, 4 years, multiple Inpatients: pre 273; post 279; total 552	<ul style="list-style-type: none"> standardized PIVC insertion trolleys cannula alert stickers to prompt 24 h removal for out-of-hospital and sub-optimal insertion 	<ul style="list-style-type: none"> PIVC observation chart with phlebitis scale Hand hygiene 	<ul style="list-style-type: none"> education (posters) new documentation updated PIVC training program audits 	<ul style="list-style-type: none"> 63% relative reduction PIVC-BSI per 10,000 occupied bed days (RR 0.36; 95% CI 0.17–0.76; $p = .018$) Relative reduction in phlebitis rate: pre 23.4%; post 7.9% ($p < .05$) Estimated cost savings AU\$105,000 over 12 months 	<ul style="list-style-type: none"> Reduction in PIVC dwell time ≥ 4 days: pre 6.9%; post 2.6% ($p < .05$) 	15
Saliba, 2018, Spain [33]	ITS, 14 years, multiple Inpatients: 227 patients with BSI. No denominator given.	<p>2003–2005:</p> <ul style="list-style-type: none"> 2% CHG skin prep sterile gloves transparent dressing extension tubing <p>2010–2016:</p> <ul style="list-style-type: none"> integrated closed catheters 	<p>2003–2005:</p> <ul style="list-style-type: none"> dressing integrity checks extension tubing routine replacement 72 h & prn replacement <p>2006–2009:</p> <ul style="list-style-type: none"> 48 h replacement for ED-insertion <p>2010–2016:</p> <ul style="list-style-type: none"> pre-filled syringes unscheduled replacement 	<ul style="list-style-type: none"> daily microbiology meetings prospective PIVC-BSI surveillance PIVC training review hospital guidelines pocket card guidelines for all staff wall charts compliance audits feedback to staff after every PIVC-BSI 	<ul style="list-style-type: none"> Relative reduction in PIVC-BSI per 10,000 patient days: pre 1.17; post 0.36 (RR 0.92; 95% CI 0.90–0.96) Relative reduction in phlebitis rate: pre 0.7%; post 0.5% Relative reduction in extravasation rate: pre 0.7%; post 0% Relative reduction in 30-day mortality rate per 10,000 patient days: pre 0.27; post 0.00 (RR 0.82; 95% CI 0.74–0.91) 	<ul style="list-style-type: none"> 2011–2016: Compliance data reported for 3119 PIVCs (dressing, PIVC site, extension tubing, replacement as per policy): pre 95.8%; post 98.7% 	16

Salm, 2016, Germany [34]	ITS, 4 years, multiple 32 neonatal ICUs (neonates < 1500 g): pre 3028; post 3194; total 6222 patients	<ul style="list-style-type: none"> • hand hygiene • skin disinfectant (not specified) 	<ul style="list-style-type: none"> • hand hygiene • PIVC checklist • daily PIVC site assessment • daily review PIVC need • IV medication management 	<ul style="list-style-type: none"> • education (lectures, scripts, case discussions, posters) 	<ul style="list-style-type: none"> • 24.7% relative reduction PIVC-BSI per 1000 patient days: pre 3.04; post 2.58 (RR 0.75; 95% CI 0.61–0.92) 	NR	15
Sriupayo, 2014, Thailand [35]	ITS, 11 months, multiple Paediatric inpatients: pre 2252; post 2456; total 4708 PIVC	NA	<ul style="list-style-type: none"> • daily review PIVC need • remove PIVC for infiltration or extravasation • dressing integrity checks • hand hygiene 	<ul style="list-style-type: none"> • education (training, posters, booklets, slogan contest) • audits • weekly feedback and reminders 	<ul style="list-style-type: none"> • Relative reduction in infiltration rate: pre 5.6%; post 0.8% (RR 0.14; 95% CI 0.29–0.23; p < .001) • Relative reduction in phlebitis rate: pre 0.6%; post 0.2% (RR 0.33; 95% CI 0.12–0.91; p = .02) 	<ul style="list-style-type: none"> • Overall bundle compliance among nurses: pre 58.6%; post 77.3% (p < .001) 	16
Yagnik, 2017, Australia [36]	ITS, 4 months, multiple Adult medical inpatients: pre 102 (162 PIVC); post 68 (114 PIVC); total 170 (276 PIVC)	<ul style="list-style-type: none"> • posters on PIVC trolleys to prompt removal of un-needed PIVCs • use aseptic non-touch technique during insertion • document insertion 	<ul style="list-style-type: none"> • daily review PIVC need • posters on PIVC trolleys • PIVC column on journey board • PIVC row on medical proforma 	<ul style="list-style-type: none"> • education • team meetings • audit 	<ul style="list-style-type: none"> • Relative reduction in phlebitis: pre 3.7%; post 0% (p = .08) 	<ul style="list-style-type: none"> • Documentation on PIVC dressing label improved: pre 36.4%; post 50% (p = .025) • Documentation in progress notes did not improve: pre 37%; post 31.6% (p = .35) • Documentation in nursing care plan improved: pre 86.4%; post 89.5% (p = .44) • Relative reduction in PIVC dwell time \geq 4 days: pre 11.2%; post 2.9% (p = .018) 	14

BA = before-and-after study; ITS = interrupted time-series study; PIVC = peripheral intravenous catheter; CHG = chlorhexidine gluconate; BSI = blood stream infection; ICU = intensive care unit; NA = not applicable; NR = not reported.

^a Downs and Black scores: Excellent (26–28); Good (20–25); Fair (15–19); and Poor (\leq 14).

Table 2 Excluded studies.

First author, Year, Country	Exclusion Reason
Ahlqvist, 2000, Sweden [37]	Not an intervention study; evaluation of properties of a PVC assessment tool
Al-Seoud, 2012, Saudi Arabia [38]	Oral abstract presentation.
Andersen, 2005, Australia [39]	Missing outcomes data; PIVC outcomes were not separated from the overall outcomes data.
Anderson, 2013, Ireland [40]	Oral abstract presentation.
Aziz, 2009, UK [41]	Missing outcomes data; no complications or PIVC related infection data provided.
Bertoglio, 2017, Italy [8]	Review paper; not an intervention study.
Boyd, 2011, UK [9]	Missing outcomes data; no patient outcomes data provided.
Bruno, 2011, Ireland [42]	Letter.
Butenko, 2014, Australia [43]	Oral abstract presentation.
Caguoia, 2012, UK [44]	Missing outcomes data; no patient outcomes data provided.
Caguoia, 2014, UK [45]	Oral abstract presentation.
Crowell, 2017, USA [46]	Missing outcomes data; minimal patient outcomes data provided.
Duncan, 2017, USA [47]	Oral abstract presentation.
Egerton-Warburton, 2015, Australia [48]	Oral abstract presentation.
Fakih, 2012, USA [49]	No care bundle reported.
Finan, 2010, Ireland [50]	Oral abstract presentation.
Förberg, 2016, Sweden [51]	No care bundle reported; intervention tested a reminder system.
Frimpong, 2015, UK [52]	Not an intervention study; description of a PIVC bundle only.
Garcia-Rodriguez, 2012, Spain [53]	Oral abstract presentation.
Kampf, 2013, Germany [54]	Oral abstract presentation.
Martires, 2016, <i>no data</i> [55]	Oral abstract presentation.
Morris, 2008, UK [56]	Not an intervention study; discussion paper.
Orsman, 2011, UK [57]	Oral abstract presentation.
Penney-Timmons, 2005, USA [58]	No care bundle reported; intervention is an insertion kit only.
Platt, 2018, USA [59]	No care bundle reported; intervention is a closed catheter only.
Samethadka, 2015, India [60]	Oral abstract presentation.
Talento, 2011, Ireland [61]	Oral abstract presentation.
Tartari, 2013, Malta [62]	Oral abstract presentation.
Taylor, 2015, USA [63]	No care bundle reported; education intervention only.
Upadhyaya, 2018, UK [64]	Missing outcomes data. Did not match criteria of primary or secondary outcomes in the search protocol. The study measured compliance with documentation only.
Vergara, 2017, Chile [65]	Study not written in English.
Vizcarra, 2014, USA [66]	Not an intervention study; discussion paper.

Five studies included PIVC site assessment [26,30,31,33,34]. Dressing integrity checks, and documentation of insertion and removal each appeared in four studies [26,28,33,35]. Hand hygiene appeared in three studies [32,34,35], as did the use of a phlebitis scale (3 different scales were used) [27,30,32]. Four studies [24,28,30,33] reported a 72-h routine replacement policy, but one study [33] changed the replacement policy during the data collection period to unscheduled (clinically indicated) replacement. Two studies [28,33] also included 48-h replacement for emergency department-inserted PIVCs. Two studies reported implementing a checklist as part of the maintenance bundle [24,34] or alcohol caps [25,26]. Each of the following items appeared in one maintenance bundle: routine re-site >4 days [30], infiltration scale [31], disinfection of needleless connectors [28], alcohol tip protectors [26], pre-filled syringes [33], intravenous medication management [34], extension tubing [33], minimize tubing disconnections [26], and PIVC column on the patient journey board [36] (See Fig. 3).

Implementation strategies

All except one study [29] reported the strategies used to implement the bundles, which included education, audits, and feedback. Education strategies included a mix of: PIVC site selection and insertion training, in-service sessions, nursing huddles, bedside training, lectures, online modules, PowerPoint, posters, booklets/leaflets, and case studies. One study [25] encouraged patient care champions, and another [35] featured a slogan contest. Five studies reported implementing new PIVC documentation: revised drug chart [27], nursing care plan [27], PIVC observation chart [32], checklist [24,34], revised medical proforma [36], and alert stickers [32]. Only one study [25] reported developing the bundle based on a literature review of published evidence, while another [35] reported adapting the Health Protection of Scotland PIVC bundle. Three studies reported updating the PIVC policy [25,27,33] to reflect the bundle implementation.

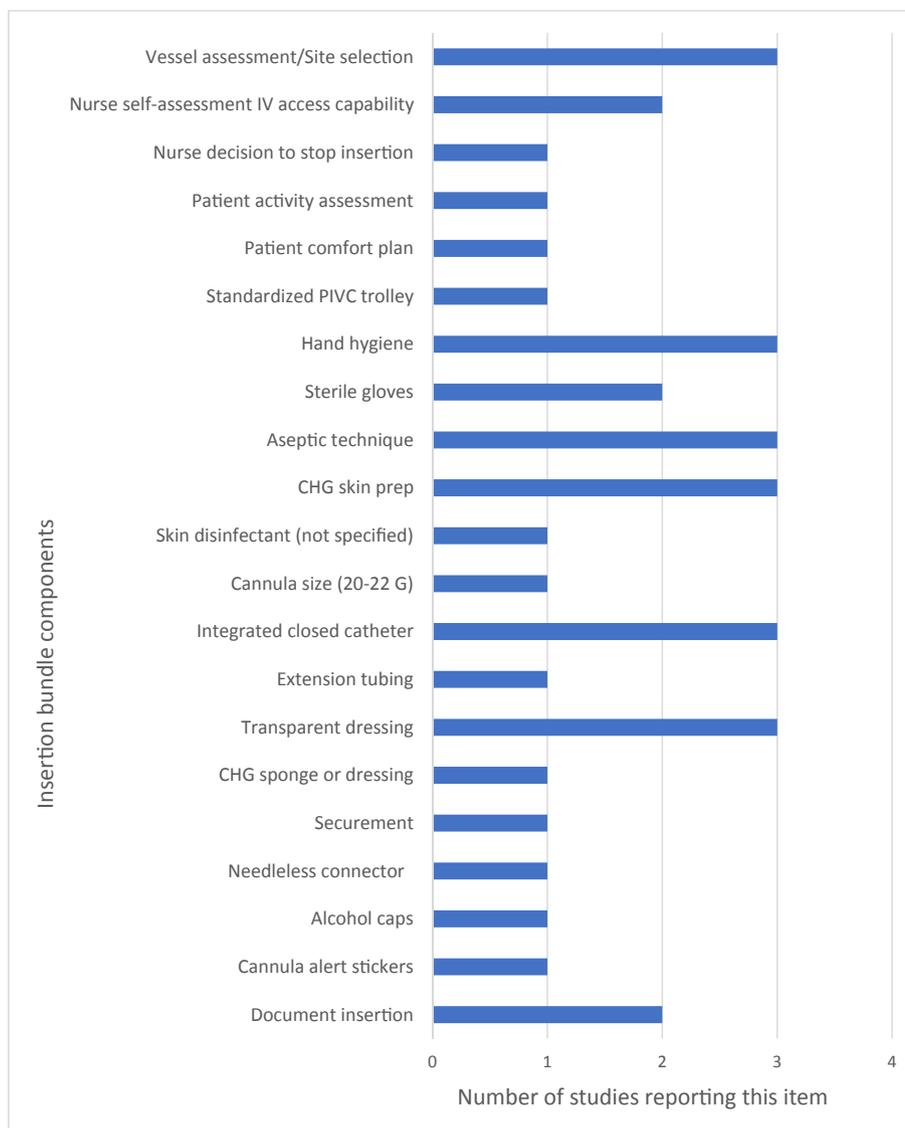


Figure 2 PIVC Insertion bundle components and frequency.

Reported outcomes

Reported outcomes were predominantly infection-related. Most authors reported BSI outcomes used the CDC NHSN definition [67]. Seven studies [25–27,30,32–34] reported a relative reduction in PIVC-related BSI rates, ranging from 19% to 81%, although one study [28] reported no change in PIVC-BSI rates after implementing a bundle. All studies reporting PIVC-BSI provided *Staphylococcus aureus* data, and one study [28] reported all organisms linked to PIVC-BSI. Only one study [33] reported 30-day mortality rates, which showed a significant decrease following introduction of the PIVC bundle. Phlebitis reporting entailed a variety of phlebitis scales and definitions; six studies [24,26,30,32,35,36] reported a reduction in phlebitis rates, while one study [28] reported an increase in phlebitis.

Two studies [31,35] reported a reduction in infiltration rates in paediatric patients, despite implementing very different strategies. One study [31] reported a 3.5% relative

reduction in PIVC infiltration rates with the introduction of an infiltration-focused insertion and maintenance bundle (with site assessment and infiltration grading tool) for paediatric patients. Another study [35] reported a 4.8% decrease in infiltration rates in paediatric patients post-implementation of a maintenance bundle (daily review of PIVC need, hand hygiene, site assessment and dressing checks). One study [24] reported a 0.62% relative reduction in all PIVC adverse events (including line obstruction, dislodgment, line mismanagement, and phlebitis). Only one study [29] reported insertion success rates (number of attempts), and in that study, implementation of an insertion bundle (comfort plan, venous assessment grading tool, and nurse self-assessed insertion skill and self-assessment to continue or stop) did not improve first attempt PIVC success or overall success rates; indeed, successful insertion after two attempts tended to decrease. However, after an unsuccessful first attempt, numbers of overall attempts decreased, which the authors attributed to the success of empowering nurses to stop-the-line [29].

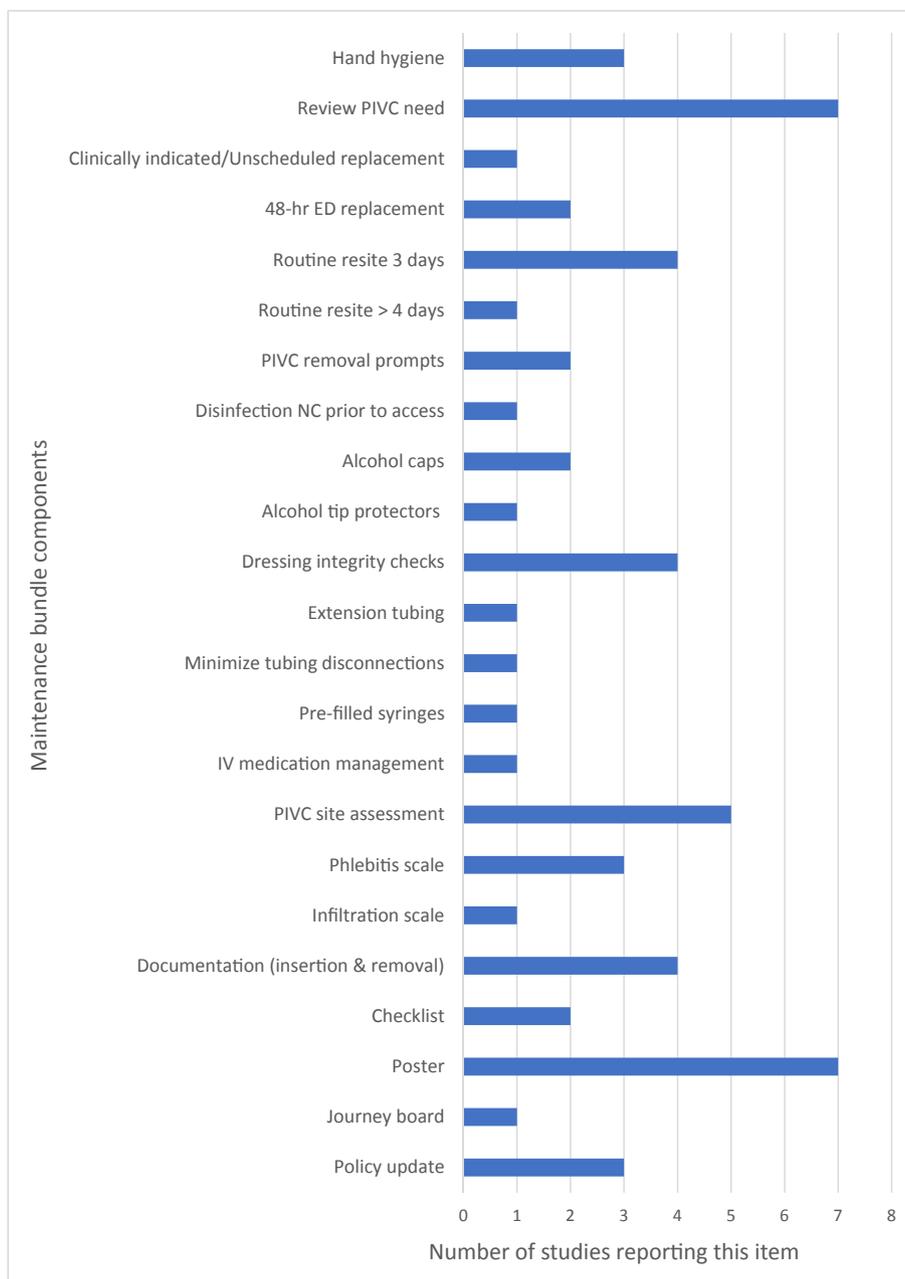


Figure 3 Maintenance bundle components.

Only one study [32] estimated the economic costs and benefits of PIVC bundle implementation. In that study, the authors reported project costs of AU\$185,000 (nursing resources and standardized equipment) and estimated a reduction in 10 *S. aureus* bacteraemia events in 12 months (approximately AU\$290,000). Therefore, the authors estimated cost savings of AU\$105,000 over 12 months following the bundle implementation [32].

Of note, only six studies [28,30,32–35] reported relative risk and confidence intervals for the data, with most providing simple percentages and probability values but without numerators and denominators, therefore the calculations could not be checked. Furthermore, the variable time intervals reported in each study did not enable incidence risk ratios for BSI and phlebitis to be calculated.

Several subgroup analyses were originally planned but could not be undertaken due to the variability in bundle components and reporting, and therefore it was not possible to estimate which bundle items showed the most effect. No studies reported on electronic versus paper-based bundles, so the effect of electronic medical records on implementation of PIVC bundles is unknown.

Reported compliance

Auditing of bundle compliance (partial or total) was reported in nine studies; four studies [24,29,31,34] did not report compliance. Compliance data was reported as a percentage rather than numerators and denominators by most studies, making the completeness of the compliance

estimates unclear. Two studies reported total bundle compliance achieved of 54.5% [28] and 77.3% [35], respectively. Compliance with device interventions, such as integrated closed catheter [25,27,33], alcohol caps [25,26], and alcohol tip protectors [26], was reported as high (>80%). However, compliance with daily site assessment and documentation interventions was variable, with studies reporting only minimal-modest improvements [27,36]. Reduction in PIVC dwell time post bundle implementation was reported in a study [36] that included a daily review of PIVC need, and another study [32] that emphasised routine replacement within 3 days. One study [25] reported an increase in dwell time with no increase in complications or bloodstream infection, following implementation of the insertion bundle. One study [27] reported compliance with all hospital PIVC care policies for insertion site assessments, line labels, line changes, removal of 3-way taps, and phlebitis documentation, but only documentation was included in the reported implemented bundle. Sustainability of the bundle intervention was only reported in three studies: one study [25] reported sustainability six months after implementation, and two other studies [30,33] reported annual audits of the bundle components.

Risk of bias

All included studies had methodological limitations, and the reporting of the risk of bias variables was limited across studies. Studies with ITS and BA designs have inherent risk of bias which cannot be minimised (e.g., no randomisation, no blinding of outcome assessment, data collection at different time periods, possible indirect outcomes due to concurrent events), and therefore the Downs and Black quality scores were fair [27–29,32–35] or poor [24–26,30,31,36] (See [Supplementary file 2](#)). As no study scored highly on the quality assessment, a reporting bias is possible, considering that 12 out of 13 studies reported positive results.

None of the included studies reported trial registration. Ethics committee or institutional review board approval was reported by five studies [24,29,31,33,35], with three others [25,26,32] noting that approval was not required for quality improvement studies without collection of patient identification. Funding for the studies was provided by the product manufacturer in one study [26] and health department grants in two studies [28,31].

Discussion

This is the first systematic review to examine the effects of PIVC insertion and maintenance bundles on PIVC complications and PIVC-related BSI. Although all studies included in the review used similar study designs (ITS or before-after), it was difficult to compare findings due to diverse bundle components, different endpoints, time periods, and the use of a range of definitions and reporting measures. For instance, some before-after studies did not report the frequency or number of data collection points, some studies did not report the overall sample size, and while three studies reported using a phlebitis scale, all used different scales. Follow-up periods were generally brief,

and sustainability effects are unclear. The quality assessment of included studies ranged from low to fair, which is not unexpected for non-randomised studies [23]. While six studies each reported a reduction in BSI and phlebitis rates following the implementation of a PIVC bundle, all these bundles differed in components and outcome measurement, thus effects may not be generalisable outside the study setting. One study reported no change in BSI and an increase in phlebitis following PIVC bundle implementation. Therefore, the current evidence to support the introduction of a PIVC bundle to reduce adverse patient outcomes is promising but not robust.

CVAD bundles were initially introduced to improve adherence to best practice guidelines for catheter care [4]. Since Pronovost and colleagues [68] published their findings that CVAD insertion bundles significantly reduced CLABSI incidence in adult ICUs, implementation of bundles has become widespread in many healthcare settings. To date, several systematic reviews and meta-analyses have examined the effects of CVAD bundle interventions on patient outcomes and strategies to improve bundle compliance. Ista et al. [6] conducted a systematic review and meta-analysis confirming that CVAD insertion and maintenance bundles can reduce the incidence of CLABSI in ICU patients. Similarly, Blot et al. [5] conducted a systematic review and meta-analysis of quality improvement interventions to prevent CVAD-BSI and found infection rates decreased most in studies that implemented a bundle or checklist. The success of the CVAD bundle in ICU patients can be attributed to standardisation of the bundle components and consistency in their application.

Standardisation and consistency are less evident in PIVC bundle studies, which report a much greater variability in composition of bundle components. The number of items in PIVC insertion and maintenance bundles varies from two to seven, with little similarity between bundles. Standardisation of PIVC insertion and management is desirable to reduce variations in care and the potential for adverse outcomes; however, at present, the ideal components of a PIVC insertion and/or maintenance bundle are unclear. There are fewer published RCTs in PIVCs than CVADs, and while CVAD bundles are generally based on components supported by RCT evidence, this is not the case for PIVC bundles, which are rarely based on RCT evidence. The majority of papers in this review reported consulting evidence-based guidelines before compiling and implementing a PIVC bundle – presumably the remaining studies chose bundle items based on local opinion or need.

Bundles attempt to simplify lengthy guidelines into a short point-of-care reminder to improve staff compliance with best practice; therefore, bundle components should be based on high quality evidence [4]. Bundle items such as hand hygiene, chlorhexidine skin prep, disinfection of needleless connectors, PIVC site checks, PIVC dressing checks, daily review of PIVC need, and documentation of insertion and removal are all recommended in guidelines and clinical standards [12–14,16]. Other items included in bundles such as integrated closed catheters have demonstrated a relative risk reduction in BSI [69], but more research is underway [70], and these devices are not yet referenced in existing guidelines, so their inclusion in a bundle appears somewhat premature.

A range of implementation strategies were reported in the included studies, including policy updates, documentation revisions, introduction of checklists, posters, bedside education, training workshops, regular meetings, PIVC audits, compliance audits, feedback, and reminders. In a 2015 systematic review of effective strategies for implementation and compliance for a variety of bundles for ICU patients, Borgert et al. [71] reported the heterogeneity of bundle elements and time periods for interventions made it impossible to identify the most effective implementation strategy. However, Ista et al. [6] demonstrated successful implementation of CVAD bundles required a combination of strong leadership, processes in place to support the bundle (protocol or checklist compliance), and empowerment of nurses to stop physicians if they observed a protocol violation. Green et al. [72] list four factors to support successful intervention of care bundles: availability of resources and training; perceived sustainability of the initiative by stakeholders; senior leadership support for the intervention; and practitioner incentives (such as financial incentives to attain quality targets). Understanding the contextual factors that affect the uptake of interventions and address the barriers and facilitators to implementation are integral facets of effectiveness and sustainable change [72]. Surprisingly, most studies in our review did not report contextual factors, such as leadership support for the project, which can greatly affect success of an intervention. None of the papers in this review discussed practitioner incentives, and only three papers reported on sustainability.

Notably, only the two paediatric studies reported considering the patients' comfort and activity needs prior to device selection and insertion. While cannulating a child can be both physically and psychologically challenging, recognition of the adult patient's needs should also receive priority, with patients reporting their personal needs and PIVC experiences are too often ignored by healthcare providers [73,74].

With scarcity of healthcare resources, implementation projects must measure compliance with new interventions, as well as cost-effectiveness [21]. In this review, compliance reporting was restricted to nine studies [25–28,30,32,33,35,36], and how compliance was achieved or measured was not always clear. Uneven compliance with bundles, guidelines and protocols is a recognised universal problem in health care [6] and has been reported by PIVC studies in nursing [75,76]. In addition, only one study [32] reported cost data.

Our findings have implications for clinical practice. While the beneficial effect of CVAD bundles is without doubt, particularly in ICU patients, PIVC bundles so far have not demonstrated similar success, primarily due to broad variability in bundle components. We hope the review findings provide useful guidance for policy makers and healthcare clinicians interested in implementing an evidence-based PIVC bundle. Firstly, healthcare settings considering implementing a PIVC bundle are recommended to consult the evidence-based guidelines before compiling the bundle. Each bundle item should be based on evidence. Secondly, engagement with relevant stakeholder groups (nurses, physicians, infection control and quality personnel, consumer advisory groups) is strongly

recommended, and strong leadership support is crucial to the success and sustainability of the intervention. Thirdly, an interrupted time-series study with multiple time-points pre- and post-intervention with a follow-up period after study completion is recommended to obtain reliable baseline data and evaluate the sustainability of the intervention. For instance, ongoing regular audits for PIVC complications are highly recommended [77], in addition to BSI monitoring. Next, when reporting the outcomes of bundle interventions, authors should provide details of the individual bundle components, process of implementation, and some description of context. Providing this level of information will assist other centres to replicate successful implementation of evidence-based practices. Finally, we found many conference abstract presentations reporting PIVC bundle success; however, most have not been published as full-text papers, so we could not examine those studies. Judging by the numbers of studies and conference abstracts reporting bundle implementation published in the past decade, motivation in this area of research is high and has potential for improving clinical practice and patient outcomes. We encourage nurses and other healthcare professionals to publish their research findings so that others may learn from their work.

Limitations

Several limitations are evident in this review. It is possible that we missed some relevant studies due to different terminology for care bundles. However, we did use a broad search strategy to search numerous databases and grey literature, as well as hand-searching of reference lists. We restricted our searching to English language papers, and therefore we could have missed relevant studies published in other languages. All studies included in this review were quasi-experimental designs and no randomised trials were found, therefore, reported improvements could have been caused by unstated factors or seasonal trends. A lack of reporting of context in the majority of studies precludes generalisation of the findings. Although we limited this review to studies that included two or more bundle components, the wide variability in bundle components, study duration, and reporting measures made meaningful comparisons between the PIVC bundles challenging. Meta-analysis was not feasible due to the variability between bundle components and implementation strategies. Meta-analysis might have been possible if we had limited the bundle components to a smaller group of evidence-based practices; however, we intentionally cast a wide net to identify the spread of bundles and components being implemented. We did not contact the primary authors for further information because it was agreed that the variability in bundles and study time periods prohibited direct comparison of outcomes.

Conclusion

Implementing an evidence-based bundle could lead to improved guideline adherence for PIVC care and better patient outcomes, but wide variation currently exists among PIVC bundles reported in the literature. Current

PIVC insertion and maintenance bundles include diverse components (not all evidence-based), and study quality is low to fair. The effect of PIVC care bundles on PIVC-related bloodstream infection rates appears promising but remains uncertain. Standardisation of evidence-based bundle components, and more rigorous studies with compliance, sustainability and cost reporting are needed.

Ethics

Ethics approval not required as this is a review paper.

Authorship statement

GR and HX conceived the study and drafted the research protocol. GR, NM, MC and CR provided critical review of and approved the study design. GR and HX conducted the database searches. GR and HX made the primary selection of eligible papers including data extraction. GR and NM checked the study selection process and data extraction. GR and HX analysed the data. All authors contributed to interpretation of the analysis. GR wrote the manuscript. All authors provided critical review and approved the final manuscript.

Conflict of interest

GRB: Griffith University has received on her behalf unrestricted investigator-initiated research grants (3M, BD, Smiths Medical) and consultancy payments (3M, BD, Medline, ResQDevices). HX: Nil. NM: Griffith University has received on her behalf: unrestricted research and educational grants from: 3M, Adhezion, Becton Dickinson, Centurion Medical Products, Cook Medical, Entrotech and Teleflex; and consultancy payments for educational lectures from Becton Dickinson. MC: Griffith University has received on her behalf unrestricted investigator-initiated research or educational grants (3M, Baxter, BD, Entrotech). CMR: Griffith University has received on her behalf unrestricted investigator-initiated research or educational grants (3M, Adhezion, Angiodynamics, Bard, Baxter, BBraun, BD, Centurion Medical Products, Cook Medical, Entrotech, Medtronic, Smiths Medical) and consultancy payments (3M, Bard, BBraun, BD, ResQDevices, Smiths Medical). No commercial entity had any role whatsoever in the conception, design or funding of this study, or in the preparation of this manuscript.

Funding

During the writing of this paper, GRB was supported by a Griffith University postdoctoral fellowship, Menzies Health Institute Queensland New Researcher Grant, Menzies Health Institute Queensland Incentive Quality Development Scheme, and Australian College for Infection Prevention and Control 2017 Early Career Research Grant.

No funding entities had any involvement whatsoever in the design or conduct of this review.

Provenance and peer review

Not commissioned; externally peer reviewed.

Acknowledgements

Nil.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.idh.2019.03.001>.

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