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Peripheral intravenous catheters: A review of guidelines and research

Prof Samantha Keogh and Dr Saira Mathew from the Queensland University of Technology have prepared this report on behalf of the Australian Commission on Safety and Quality in Health Care.

Support was also provided by the following authors in preparing this report:

Dr Evan Alexandrou, A/Prof Andrew C. Bulmer, Prof Marie Cooke, Dr Linda Coventry, Alexandra Hawthorn, Tricia Kleidon, Emily Larsen, Nicole Marsh, Anthony Marshall, Dr Gillian Ray-Barruel, Stephen Sinclair, Eugene Slaughter, Alana St John, Kerry Taliaferro, A/Prof Amanda Ullman, and Prof Claire M. Rickard from the Australian Vascular Access Society (AVAS).



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Level 5, 255 Elizabeth Street, Sydney NSW 2000

Phone: (02) 9126 3600

Fax: (02) 9126 3613

Email: mail@safetyandquality.gov.au

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Preface

The insertion of a peripheral intravenous catheter (PIVC) is one of the most common clinical procedures performed. About 30 million are used in Australia each year, with up to 70% of hospitalised patients requiring a PIVC at some point during their hospital stay. However studies estimate that 4% to 28% of PIVCs inserted are not actually needed, placing the patient unnecessarily at risk of infection.

Despite frequency in PIVC use, complications are reported to be as high as 70%. They can be prone to blockage and dislodgment, cause inflammation of the vein and infection. Nearly half of all first insertion attempts also fail, causing undue pain and anxiety for patients as a result of multiple failed attempts.

To reduce rates of PIVC-related complications, a number of evidence-based strategies have been suggested. Best practice guidelines recommend a range of strategies to reduce risk of complications and increase chances of PIVC success. Despite this, data from Australia and internationally suggest that a significant proportion of patients do not receive care as recommended to optimise use of PIVCs.

A clinical care standard on peripheral intravenous access will aim to support national consistency of best practice for the insertion and management of PIVCs. To inform development of this clinical care standard two literature reviews were undertaken.

The Commission engaged Professor Samantha Keogh and Dr Saira Mathew from the Queensland University of Technology (QUT) to conduct a literature review to better understand the current clinical environment of the techniques used for preventing and managing adverse events associated with the insertion and use of PIVCs.

Key findings

This report provides a broad summary of the quality of current guidelines and recommendations regarding the insertion, management and removal of PIVCs in paediatric and adult patients.

The report highlights a number of similarities between guidelines including adherence to basic infection control measures through maintenance of hand hygiene and aseptic technique; skin decontamination prior to insertion; ongoing assessment for vascular access needed and removal when no longer required. Differences between guidelines were related to escalation pathways for patients with difficult vascular access; needless decontamination; flushing frequency, and device replacement schedule.

Gaps in evidence were reported in relation to the potential merits of having vascular access specialists (such as a service or team of clinicians), innovative catheter designs, optimal dressings and securement, and port or hub decontaminations. Other areas that require further research were noted, which included clinical monitoring of the device and the patient experience.

Recommendations of the report

The authors of the report have made a number of recommendations in relation to the findings from this review. These include:

- I. Development of a national clinical care standard aimed at reducing PIVC related complications and failure.

- II. Education and training of nursing and medical staff that focus on contemporary and evidence based PIVC insertion and maintenance care.
- III. Evidence based assessment of patient's need for vascular access and device type.
- IV. Early referral to vascular access specialist and use of ultrasound to minimise insertion trauma in patients identified as having difficult vascular access.
- V. Routine use of analgesic agents or strategies to minimise pain associated with PIVC insertion.
- VI. Evidence based clinical assessment of PIVC site and function
- VII. Ongoing monitoring and reporting of PIVC use and outcomes to facilitate benchmarking and drive quality improvement
- VIII. Inclusion of patients' views in all future research in to the optimal PIVC insertion and maintenance practices and products.

Next steps for the Commission

The Commission will consider the report's recommendations in the development of the Peripheral Intravenous Access Clinical Care Standard.

Executive summary

Peripheral intravenous catheters are the most commonly used medical device nationally and globally. Up to 80% of patients require a PIVC to provide essential medical treatment. Rates of failed insertion and post insertion complications are high, with nearly half of all first insertion attempts and average of 40% of devices failing. Such failure rates for an essential device are unacceptable, especially as most failure is preventable with good insertion and maintenance practice. Therefore the Australian Commission on Safety and Quality in Health Care commissioned this review to appraise guidelines currently influencing clinical practice locally and internationally, analyse and synthesise recent trial research, and to better understand the current clinical environment for preventing PIVC associated complications and failure.

Eighteen guidelines from professional colleges, membership associations and guideline agencies, as well as state health authorities were identified via systematic search strategy and appraised on their scope, quality and rigour using the appraisal of Guidelines for Research and Evaluation II (AGREE) tool. Most of the jurisdictional guidelines were ranked low against the tool, particularly in the area of rigour of development. There were a number of similarities between guidelines including adherence to basic infection control measures through maintenance of hand hygiene and aseptic technique; skin decontamination prior to insertion; ongoing assessment for vascular access needed and removal when no longer required. The main differences were related to escalation pathway for patients with difficult vascular access; needless decontamination; flushing frequency, and device replacement schedule.

In total, 40 trials were identified, appraised, data extracted, meta analysed where possible or summarised narratively. The majority of trials evaluated different insertion practices and products, predominately focusing on the merits of visual aids (e.g, ultrasound or near infrared), and analgesia to minimise pain on insertion. Studies addressing post insertion care evaluated the impact of different dressing and securement products, flushing techniques and solutions, and device replacement schedules had on PIVC complications and failure. Gaps in evidence were identified in relation to the potential merits of vascular access specialist (service or team), innovative catheter designs, optimal dressing and securement, and port or hub decontaminations. Other areas of research that require further research included clinical monitoring of the device and patient experience.

A number of recommendations are made in relation to the findings from this review. These include:

- I. Development of a national clinical care standard aimed at reducing PIVC related complications and failure.
- II. Education and training of nursing and medical staff that focus on contemporary and evidence based PIVC insertion and maintenance care.
- III. Evidence based assessment of patient's need for vascular access and device type.
- IV. Early referral to vascular access specialist and use of ultrasound to minimise insertion trauma in patents identified as having difficult vascular access.
- V. Routine use of analgesic agents or strategies to minimise pain associated with PIVC insertion.
- VI. Evidence based clinical assessment of PIVC site and function
- VII. Ongoing monitoring and reporting of PIVC use and outcomes to facilitate benchmarking and drive quality improvement
- VIII. Inclusion of patients' views in all future research in to the optimal PIVC insertion and maintenance practices and products.

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Abbreviations

APTT	Activated Prothrombin Time
AUD	Australian dollar
AGREE II	Appraisal of Guidelines Research and Evaluation, Second Edition
BPD	Bordered Polyurethane Dressing
CRBSI	Catheter-Related Blood Stream Infection
CRT	Cluster-Randomised Trial
CVC	Central Venous Catheter
EMLA	Eutectic Mixture of Local Anaesthetics
EMLA	Eutectic mixture of two local analgesics (lignocaine & prilocaine)
FLACC	The Face, Legs, Activity, Cry, Consolability scale
HR	Hazard Ratio
IQR	Interquartile range
ISD	Integrated Securement Device
IV	Intravenous
MeSH	Medical subject headings
PIVC	Peripheral Intravenous Catheter
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PT	Prothrombin
PVC	Peripheral Venous Catheter
RCT	Randomised Controlled Trial
SD	Standard Deviation
VAS	Visual analogue scale

1. Introduction and background

The majority of patients presenting to hospitals require at least one peripheral intravenous catheter (PIVC) for the delivery of intravenous fluids and medications or blood sampling. Despite the ubiquity of peripheral catheters in hospital care (~80%), the rate of complications associated with the insertion and use of these devices is reported to be unacceptably high. Nearly half of all first insertion attempts fail in adults and children¹⁻³. Device failure due to other complications (dislodgement, infiltration, occlusion, local inflammation) can be up to 69%⁴⁻⁷. The rate of PIVC CRBSI is relatively low compared to that of central vascular access devices (from <0.01% to 0.18%⁸⁻¹¹), however the far greater number of PIVCs in use means that the absolute infection rates for PIVCs increase the overall absolute infection rates¹². This underscores the need for greater investment in PIVC research to reduce associated patient discomfort, delays in vital medical treatments, and waste of healthcare resources.

The aim of this overall review is to identify and review current guidelines for PIVC insertion and maintenance as well as appraise evidence of interventions that prevent PIVC failure and make recommendations for policy and practice. Understanding the different PIVC related complications and possible risk factors associated with difficult insertion and post insertion failure is the first step in the development of practice and products that may mitigate this risk.

PIVC complications and failure

The rates for PIVC failure were derived from published research. Currently there is no regular surveillance or monitoring PIVC outcomes. Challenges with gaining successful and patent peripheral vascular access start at the moment of insertion. First attempt PIVC insertion failure rates can be up to 35-40% for adults^{1,2} and between 50–65% for children^{1,3}; with a concerning 10% of adults and a quarter of all children experiencing more than four attempts at insertion¹.

The most frequently cited reasons for PIVC failure before the completion of prescribed treatment are dislodgement, occlusion, infiltration and phlebitis⁵⁻⁷. These may occur in isolation or in combination, indeed existence of one may be precursor to another complication.

Dislodgement of the PIVC out of the vein, partial or complete, occurs when there is poor securement of the catheter to the skin, or with patient or operator (staff) interference^{13,14}. Dislodgement or accidental removal reportedly accounts for between 6% and 20% of catheter failures^{11,15,16}. This may be a contributing factor to localised irritation and inflammation (phlebitis) through micro motion (pistoning) of the device in the vein, further heightening the risk of failure. A poorly secured catheter often causes the patient discomfort and result in catheter failure, delaying intravenous (IV) therapy and requiring insertion of a new IV device.

Occlusion, either partial or complete blockage, results in the inability to infuse or inject fluids or medications through the lumen of the PIVC^{5,17}. Occlusion can be mechanical (e.g kinking), thrombotic or medication related in origin. Occlusion can also occur from irritation or trauma to the cannulated vein wall, leading to a release of thromboplastic substances and platelets¹⁸. This process promotes the clotting of blood and can result in narrowing or complete occlusion of the cannulated vein. Occlusion of the catheter lumen can be a precursor to infiltration as the IV fluid or medications leak into the surrounding tissue¹⁹.

Infiltration is defined as the leakage of a non-vesicant solution into surrounding tissues²⁰. This may be related to dislodgement of the device from the vein or occlusion of the lumen. Signs and symptoms of infiltration can include oedema, stretched or blanched skin, localised

cool skin, or visible leakage of IV fluids around the site¹⁹. This may or may not be accompanied with discomfort or pain. Although injury due to infiltration is often considered minor and usually resolves without any intervention, there is a risk of significant morbidity related to localised compression or even tissue damage²¹. Extravasation is traditionally distinct from infiltration as it specifically refers to the leakage of *vesicant* fluids or drugs (including contrast media or cytotoxic agents)^{19,20}. The incidence of infiltration and extravasation is hard to determine because of limited reporting; however, extravasation injury from cancer chemotherapy is reported to be 11% in children and 22% in adults¹⁹. One study found that, of all the complications associated with peripheral cannulas, 34% occurred as a result of infiltration²¹. Given the root cause (vesicant substance) and related tissue damage, the presenting signs and symptoms of extravasation are similar to infiltration, but accompanied with more visible tissue damage and pain²². In recognition of the risk associated with their treatment Imaging and Cancer Care specialities usually have specific policies and procedure for dealing with extravasation to minimise damage^{23,24}.

Phlebitis is defined as localised irritation or inflammation of the vein wall has been the focus of much discussion and research in relation to PIVC complications^{25,26}. It can have either a mechanical, chemical, or bacterial origin, and it can occur in isolation or in combination with any of the other known PIVC complications^{25,26}. Reported phlebitis rates vary widely between studies (between 2% and 80%)^{11,27-29}. However this may be reflective of the variation in the tools used to measure phlebitis rather than the prevalence of the condition itself²⁵. Generally, phlebitis is characterised by a combination of tenderness/pain, erythema, oedema, purulent discharge, or a palpable cord, and results in failure and removal of the device³⁰. However, even one sign, (e.g. erythema) can be an indication of underlying phlebitis^{26,30}.

PIVC associated infections are a relative rare but serious complication and occur when micro-organisms track along the insertion site and into the cannulated vein, irritating the vessel wall, contaminating the catheter and then the bloodstream^{12,31}. These microbes may be from the patient's skin, contaminated disinfectant or healthcare workers' hands. The process may happen on insertion if the catheter is contaminated and then introduced into the patient or via microbial migration at any time while the catheter is in situ¹². This may give rise to biofilm formation, proliferation of bacteria, and lead to blood stream infection^{32,33}. The most common signs and symptoms of a local PVC-related infection are pain, erythema, pus, and palpable venous cord, whereas the more serious catheter related blood stream infection presents with fever, chills, headache, tachycardia, and nausea/vomiting^{20,31}. Infection rates associated with PIVCs are much lower than those reported for central venous catheters (CVC), (0.2–0.7 episodes per 1000 calendar days)^{8,34}.

Whatever the root cause of failure of the PIVC it has significant implications for the patient's treatment, hospital experience and healthcare budget. Failed PIVCs need to be removed and replaced, which means repeated painful needlesticks for the patient and interruptions to vital therapy. The mean cost of PIVC replacement has been costed at \$70.00 AUD per episode of IV treatment³⁵. At the current rate of failure, this costs the Australian healthcare system approximately \$700 million each year. Repeated PIVC replacements can lead to venous access difficulties, increasing the need for more frequent replacements and the possibility of requiring a central venous access device

Risk factors for PIVC complications

To reduce the incidence of catheter failure and avoid preventable IV replacements, a clear understanding of why catheters fail is required. Previous research has identified that catheter gauge,^{7,27,36} insertion site,³⁷⁻³⁹ and inserter skill,^{7,40} have an impact on PIV failure. Limitations of existing research are small study sizes, retrospective design, or secondary analysis of an existing data set; all potentially introducing sampling or reporting bias^{41,42}. However, a large prospective study with rigorous analysis was recently published⁶. The

study identified that one in three PIVCs failed before the completion of prescribed therapy. This mirrored results observed in trials in similar settings^{7,11,43}.

Phlebitis was the main complication observed at a rate of 17%, followed by occlusion and/or infiltration (14%) and dislodgement (10%)⁶. Factors that were associated with PIVC failure included the PIVC gauge, insertion site, poor securement, type of IV medication administered and number of IV accesses generally.

Specifically in Marsh and colleagues' study, 22-gauge catheters were more likely to fail from occlusion/infiltration than other sizes (Hazard Ratio (HR) 1.43). The PIVC gauge has been previously identified as a risk factor for catheter failure: in particular, small gauge catheters (≤ 22 gauge) and large gauge catheters (≥ 18 gauge)^{7,27,36}. The issue of PIVC gauge may also be related to the catheter to vein ratio which is rarely measured or reported on in relation to PIVC insertion. Further, risk may not be because related to gauge alone. The level of *intravascular purchase* (degree to which catheter sits in the vein) associated with a shorter length may also influence PIVC performance⁶. These considerations challenge the recommendation to insert the smallest gauge peripheral catheter possible^{44,45}.

Marsh and colleagues' study demonstrated that insertion in the patient's dominant side was associated with phlebitis (HR 1.39)⁶. PIVCs inserted in the hand, anterior cubital fossa or over a joint have also been associated with an increased risk of catheter failure^{7,16,38,39}. The placement of a PIVC over an articulated joint increases the risk micro movement which in turn increases the risk of local irritation and dislodgement of the PIVC within the vein. Patients have reported significant discomfort and pain associated with this also⁴⁶.

Multiple different products are available to facilitate PIVC insertion site dressing and securement. A recent four-armed trial did not demonstrate superiority of any of the major product types in use. Overall failure was approximately 40% in all groups⁴³. However, the trial and cohort study did show that additional (secondary) securement was significantly associated with reduced risk of dislodgement (HR 0.44)⁶. However *ad hoc* use of non-sterile tape and joint immobilisation products (e.g. elasticised tubular bandage) may contaminate site or reduce visibility and assessment⁴⁴.

Multiple studies have reported certain IV medication and IV antibiotics as risk factors for PIVC failure^{7,27,47,48}. Marsh and colleague's study specifically identified IV Flucloxacillin with a 2-fold increase in occlusion/infiltration and phlebitis⁶. The overall osmolarity and pH of the final reconstituted drug is what determines the compatibility with peripheral access⁴⁸. Apart from the potentially vesicant nature of the drug, medication associated PIVC failure may be related to poor drug reconstitution, too rapid administration, or inadequate post drug administration flushing⁴⁹. The risk of device failure was augmented by the number of accesses per day. This and similar results from other trial work underscore the fragility of peripheral access when subjected to repeated injection and infusion⁵⁰. The association between PIVC use and failure may indicate that many of these patients were not suitable for a PIVC, and alternative devices and access needed to be considered (e.g. deep peripheral or central venous access devices)⁶.

Insertion skill and training have been associated with rates of PIVC insertion success and performance⁵¹⁻⁵⁴. However, there are limitations to these studies based on date, size, and design of study that make it hard to draw firm conclusions or apply findings to contemporary practice. Wallis and colleagues' (2014) retrospective cohort study showed a reduced risk of dislodgement associated with cannulas inserted by an IV service (HR 1.69)⁷. The study also showed an increased risk of failure associated with second and subsequent PIVCs, underscoring the need to optimise first insertion success and maintenance practice for the duration of treatment. There is a need for good-quality randomised controlled trials (RCTs) to evaluate the efficacy of a vascular access specialist team approach for vascular access device insertion and care for the prevention of failure⁵⁵.

PIVC failure has also been associated with insertion setting (emergency or community). Analysis in a cohort study identified an increased risk of dislodgement (HR 1.78) with PIVCs inserted by paramedics⁶. A prospective study conducted in two tertiary hospitals found a 20% higher rate of PIVC-associated *Staphylococcus aureus* infections with PIVCs inserted in the emergency department compared to those inserted in the wards⁵⁶. So, the quality of the conditions of insertion need to be considered when assessing need for removal and replacement of the device.

There are also a number of other important, albeit non-modifiable risk factors that clinicians need to consider prior to PIVC insertion. Other risk factors for PIVC insertion and maintenance include age (the very young and elderly)^{57,58}, gender (female)^{7,50}, obesity^{59,60}, some medications (anticoagulants and corticosteroids) and patients with chronic diseases such as cancer, diabetes, or cardiovascular disease^{61,62}. Knowledge of these risk factors can assist clinicians in their assessment of vascular access insertion and device choices.

In summary, PIVCs are important devices in modern medicine. They are the most commonly used medical device with approximately 1.8 billion used globally each year and 25 million in Australia^{63,64}. Despite their essential widespread use, multiple international and national guidelines, PIVC associated complications rates persist at an unacceptably high rate. Given the recent spotlight on PIVC complications the Australian Vascular Access Society and the Australian Commission for Safety and Quality in Healthcare sought a structured, evidence-based literature review to better understand the current clinical environment for preventing and managing PIVC related complications. Well-designed and executed randomised controlled trials (RCTs) provide reliable evidence with minimal bias compared to other study designs and are therefore considered the “gold standard” for evaluating the effectiveness of interventions^{65,66}. Systematic reviews evaluate the combined results of RCTs, analyse for bias, and provide an even higher level of evidence⁶⁷.

Clinical guideline developers and health care staff rely on quality RCTs and systematic reviews to guide decision-making in clinical practice, however the guideline development and updating process can be so unwieldy that the timely inclusion of evidence in contemporary practice is hindered⁶⁸.

1.1 Research questions

1. What guidelines, standards for practice, policies and procedures relevant to the PIVC insertion and maintenance are available in Australia and internationally?
2. What do current guidelines recommend for management of PIVC insertion and maintenance?
3. What evidence is there regarding current clinical practice in Australia for the prevention of PIVC related complications?
4. What indicators are currently used to measure or report adverse outcomes (e.g routine monitoring, audits or quality improvement activities)?
5. What contributes to variations in complication rates and other adverse outcomes associated with PIVCs, including patient groups with higher risk? What are the evidence gaps?
6. What is the literature on interventions to reduce PIVC related complications? What is the effectiveness of those interventions? What are the evidence gaps?

Information on the monitoring of PIVCs, the prevalence of PIVC complications, failure and associated risk factors have been covered in the introduction and background. The remainder of this document focuses on systematic reviews of PIVC guidelines and trial research.

2. Method

This review addresses two main areas: (1) a review of national and international guidelines; and (2) a review of the published literature. We have included publications that have been published in English in the previous five years (2013-2018) and focused on relevant guidelines, and standards of practice, policy and procedure documents (Australian and international) available from the internet, and in addition randomised clinical trials available through recognised electronic databases and relevant grey literature. This systematic reviews followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines⁶⁹. Each review protocol was registered at PROSPERO (CRD42019120013 and CRD42019120011).

2.1 Systematic Review of Guidelines

2.1.1. Search methods

The literature was searched using MeSH terms and combinations of key terms in four databases: CINAHL, PubMed, Medline and google advanced search. The search was limited to English language publications from 2013 to 18 December 2018. The last five years were included to focus on the most recent national and international guidelines and standards of practice on peripheral intravenous device insertion, management and removal. The search syntax for each database are presented in the Appendix A. The search strategies were developed with the assistance of a health librarian using subject headings or text words relevant to peripheral intravenous catheters, peripheral intravenous devices, clinical practice guidelines, management guidelines, standards of practice with associated Boolean logic (and, or). Reference lists of all retrieved and relevant publications identified by these strategies were hand-searched.

The selection of articles consisted of three stages of screening (titles, abstracts, and full text). Two reviewers (SK, SM) independently screened titles and abstracts, excluding studies that did not meet the inclusion criteria. Two authors also did full-text screening (SK, SM), with a third author (CMR) arbitrating any disagreement arising at any stage of the screening process. Results were imported, and duplicates removed with the help of reference management software (EndNote).

2.1.2 Inclusion and exclusion criteria

2.1.2.1 Types of studies

Guidelines and practice standards specifically aimed at guiding and assisting healthcare professionals and patients in making decisions about insertion, management and removal of PIVCs were included in the review. Individual hospital guidelines, expert consensus (with process), and discussion papers on guidelines were excluded from the review. If the guidelines had been updated, only the most recent version was assessed.

2.1.2.2 Types of participants

Adults or children requiring insertion, maintenance and removal of a PIVC in any acute or community healthcare setting.

2.1.2.3 Outcomes

The primary outcome of this review was to identify the national and international guidelines on the insertion and maintenance of PIVCs appraise the scope quality and rigour of these and synthesise findings.

2.1.3 Quality appraisal

The AGREE II tool was used to assess methodological quality of the guidelines⁷⁰. The tool examines rigour and transparency of reporting. It was also used to determine whether the guidelines were evidence-based and whether they reported search strategies, and data extraction, to classify/grade the strength of their recommendations. The AGREE II consists of 23 items categorised into six domains and two overall assessment items. The first domain (Scope and purpose) addresses the objective, target population and health question addressed by the guideline. The second domain (Stakeholder involvement) assesses the involvement of stakeholders' and consumers' views and preferences on the development of the guideline. The third domain (Rigour of development) evaluates the process of collecting and synthesizing evidence, formulating recommendations, and developing methods to update the guidelines in future. The fourth domain (Clarity of presentation) covers the language, structure and presentation of the guideline. The fifth domain (Applicability) evaluates the potential barriers and facilitators to implementation and strategies to improve the application of the guidelines. The sixth domain (Editorial independence) assesses whether the guideline reported any conflict of interest and funding for the development of the guideline. The two additional assessment items (Overall Guideline Assessment) rate the overall quality of the guideline and whether the guideline is recommended for use in practice with or without any modifications, or should not be used at all. Each AGREE item is rated on a 7-point Likert scale ranging from 'strongly disagree' to 'strongly agree'.

Four appraisers (initials LC, SK, SK, AU) assessed each guideline to increase the reliability of the assessment according to AGREE II. The scores of the four appraisers were used to calculate an average for each domain and total scores were presented as percentages. Scores were checked and, where appropriate, moderated if there was a delta of three or more between scores.

Once scores were finalised, a quality score was calculated for each domain as per the AGREE II tool recommended formula⁷⁰. This comprised of calculating the maximum and minimum score possible for each domain, calculated as a composite of the maximum or minimum score multiplied by the number of items in the domain and the number of appraisers. These values were then used in the final formula that generated a percentage reflecting the overall domain score. Cohen's Kappa coefficient was used to evaluate the agreement among authors on the overall recommendation for use in practice.

2.1.4 Data extraction

The authors extracted data from all the included guidelines and standards using an Excel® (Microsoft)-based data extraction form designed for this review. The following data was extracted: clinical practice guideline, title, year, country and scope as defined by authors.

2.1.5 Data synthesis

Due to the nature of this review, a structured narrative synthesis was undertaken. Characteristics of the guidelines and standards are summarised and presented in the results.

2.2 Systematic Review of trials

2.2.1 Search methods

The literature was searched using MeSH terms and combinations of key terms in four databases: CINAHL (Cumulative Index to Nursing and Allied Health Literature), PubMed, Medline and Cochrane library. The search was limited to English language publications from 2013 to current. The last five years were included to focus on the most recent publications on peripheral intravenous device insertion, management and removal to ensure relevance to current clinical practice. The search syntax for each database is presented in the Appendix B. The search strategy was developed with the assistance of a health librarian using subject headings, Mesh terms or text words relevant to peripheral intravenous catheter, peripheral intravenous devices, insertion site, securement, dressings, occlusive dressings, flushing, antiseptics, removal strategies, connectors, regimen, risk factors, infection, phlebitis, morbidity, mortality, dwell time, device failure, device malfunction, occlusion, blockage, infiltration, extravasation, dislodgement, removal, leakage, inserter skill, inserter characteristics, multiple insertion attempts, multiple cannulation, attempts, insertion difficulty, difficult vascular access, difficult intravenous access, cumulative, impact of multiple insertion attempts, escalation, with associated Boolean logic (and, or). Reference lists of all retrieved and relevant publications identified by these strategies were hand searched.

2.2.2 Inclusion criteria

2.2.2.1 Types of studies

This review only included randomised controlled trials (RCTs) and cluster-randomised trials (CRTs).

2.2.2.2 Types of participants

All age groups, including neonates, requiring insertion, maintenance or removal of a PIVC within a healthcare setting.

2.2.2.3 Outcomes

The primary outcomes for insertion trials were first insertion success and time to insertion. Secondary outcomes included PIVC failure, local and primary infection, dwell time, level of patient reported pain relief, patient satisfaction and cost. The primary outcomes for maintenance trials were PIVC failure as a composite measure of occlusion; infiltration; dislodgement, and phlebitis. Secondary outcomes included local infections, bloodstream infections (primary), as well as dwell time, patient satisfaction and cost.

2.2.3 Study selection

The selection of studies consisted of three stages of screening (titles, abstracts, and full text). Two teams of paired reviewers (SK and SM plus AH and ES) independently screened titles and abstracts and excluded those studies that did not meet the inclusion criteria. Two authors then did full text screening (SM and AH) and a third author (SK) arbitrated any disagreement arising at any stage of the screening process. Results were imported, and

duplicates removed with the help of reference management software (EndNote, Clarivate Analytics).

2.2.4 Data extraction

The results and characteristics of each study were extracted by the following authors (EA, AB, MC, SK, TK, EL, NM, SM, GRB, ES, AStJ, KT) and a second experienced researcher checked for accuracy and completeness (SK and SM). The authors extracted data from all the included studies using a data extraction form designed for this review. The data was extracted for the following items: author, date (year), study design, country, setting, participants and sample size, plus intervention and primary outcomes. When the information presented in the studies were unclear or incomplete, an attempt was made to contact the study author for further data or clarification.

2.2.5 Data synthesis

Clinical (sample or intervention characteristics), methodological and statistical heterogeneity was considered. Where appropriate, data was pooled using meta-analysis with Review Manager (RevMan) version 5.3. A random effects model was considered due to the clinical and statistical heterogeneity present in the studies. A structured narrative summary of all the studies included in the review was also conducted. Heterogeneity measures the variability among the combined studies; if there is considerable variation in the combined or pooled results, it may be misleading to report a combined summary measure. The chi-square test and I^2 statistic were used to assess heterogeneity. The chi-square statistic was used to test the null hypothesis that there is no heterogeneity, with a P value < .05 indicating heterogeneity. The I^2 statistic describes the variability in effect measurements that is due to heterogeneity rather than sampling error. The I^2 value was interpreted as follows: Less than 40% might not be important, 30% to 60% may represent moderate heterogeneity, 50% to 90% may represent substantial heterogeneity, and 75% to 100% represents considerable heterogeneity. The pooled result was considered heterogeneous if the I^2 statistic was >40% and the P value was <0.05.

Data from cluster trials were transformed to effective sample size by calculating the design effect using the Rao and Scott (1992) calculation to avoid unit-of-analysis error with data⁷¹. The average cluster size and the intraclass coefficient (ICC) was calculated (using either the ICC from the actual study or a reliable estimate from previous publications). The design effect for the study as a whole was calculated and number of participants and the number experiencing the event were adjusted for the categorical data meta-analysis. For continuous data, only the sample size was reduced; means and standard deviations remained unchanged.

2.2.6 Quality appraisal

Two independent reviewers (SM and ES) applied the Cochrane Risk of Bias (RoB2) for RCTs to assess the methodological quality of the studies included in this review⁷². Each study was assessed on the five bias domains (selection, performance, detection, attrition and reporting bias). The risk of bias was assessed as low risk, high risk or unclear risk. A third reviewer (SK) arbitrated discrepancies at any stage of the quality assessment.

3. Results

3.1 Systematic review of guidelines

A total of 584 citations and abstracts were identified through the database search and grey literature. Duplicates were deleted. Eighteen were excluded from 36 full-text guidelines as they did not meet the inclusion criteria (see Appendix C). Eighteen guidelines and standards ultimately met the inclusion criteria and were eligible for appraisal. The selection process is summarised in the PRISMA flow diagram in Figure 1. Notable and potentially eligible guidelines were not available for appraisal because they were either out of date range or currently under review (see Table of guidelines unavailable for review in Appendix D).

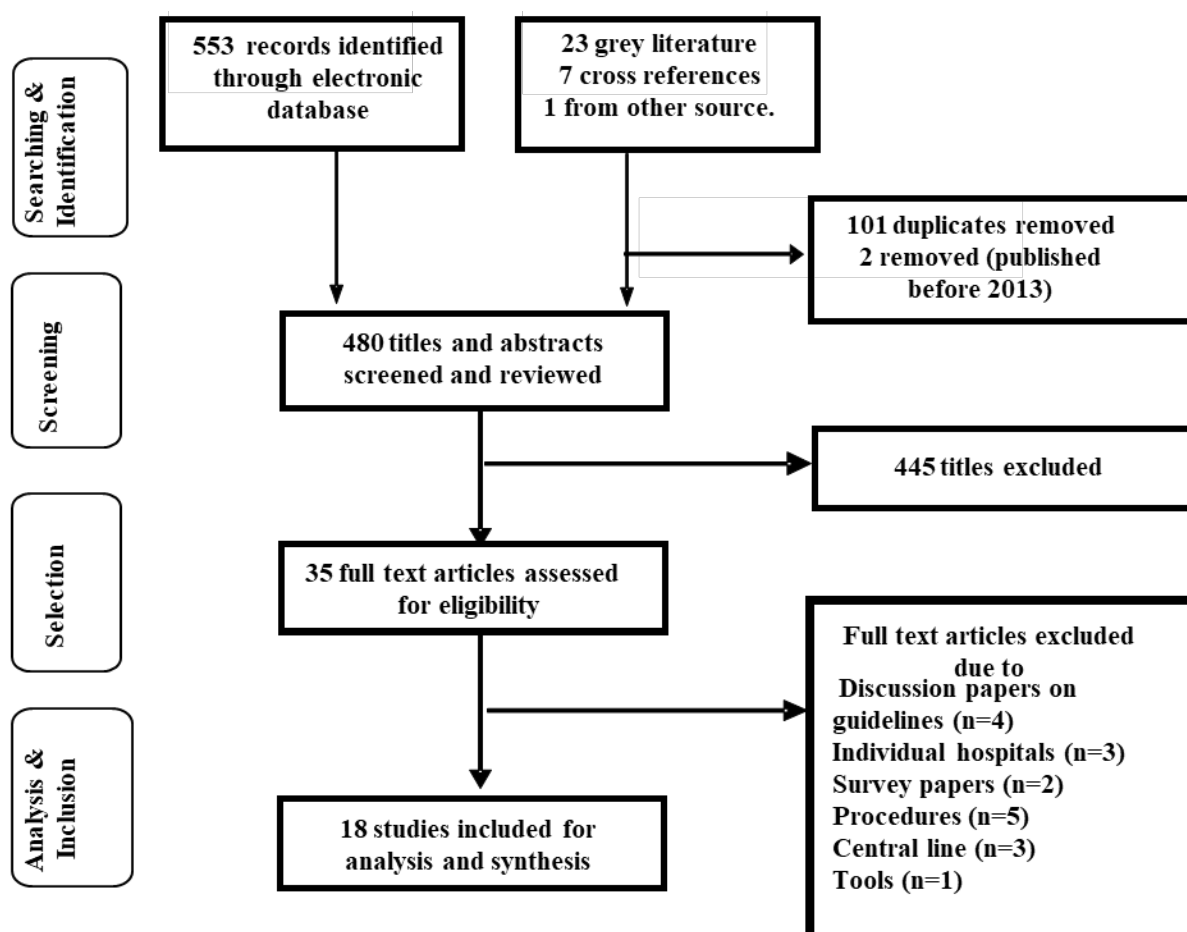


Figure 1: PRISMA flow diagram

3.1.1 Characteristics of guidelines

The characteristics of the selected national and international guidelines are presented in Table 1 and Table 2. Of the 18 included guidelines none were developed by an international body or group; however, two guidelines had international representation on their guideline development committee^{73,74}. Guidelines were representative of either national professional organisations⁷⁵⁻⁷⁹ or national health departments⁸⁰⁻⁸², or state health departments⁸³⁻⁸⁹. Specifically, there were seven (state-based) guidelines from Australia, three each from the UK and USA and two from Spain, one each Ireland, France and Korea.

Table 1: Characteristics of state/hospital guidelines

Author	Clinical practice guideline	Organisation	Country	Year	Population (adults/ paed)	Scope
Clinical Excellence Commission	Peripheral Intravenous Cannula (PIVC) Insertion and Post Insertion Care in Adult Patients	NSW Government Health	Australia	2013	Adults	Insertion, maintenance and removal
CSS-Infection Prevention	Peripheral Intravenous Cannula, Adults and Children (Not neonates)	ACT Government	Australia	2015	Both	Insertion, maintenance and removal
Gaylard et al	Peripheral Intravascular Catheters (PIVC) Insertion and Management (Adult) NT Health Services Procedure	Northern Territory Government	Australia	2015	Adults	Insertion, maintenance and removal
Edwards et al	Peripheral Intravenous Cannula (PIVC) Insertion, Care and Maintenance Protocol	Tasmanian Government	Australia	2016	Adults	Insertion, maintenance and removal
Communicable Disease Control Directorate	Insertion and Management of Peripheral Intravenous Cannulae in Western Australian Healthcare Facilities policy	Government of Western Australia	Australia	2017	Both	Insertion, maintenance and removal
Caroll et al	Peripheral intravenous catheter (PIVC) Guideline	Queensland Health	Australia	2018	Both	Insertion, maintenance and removal
Thomas et al	Peripheral Intravenous device management	The Royal Children's Hospital	Australia	2018	Paeds	Insertion, maintenance and removal

Table 2: Characteristics of international guidelines

Author	Clinical practice guideline	Organisation	Country	Year	Population (adults/ paed)	Scope
Alonso-Ortiz-del-Rio et al	Clinical Practice Guideline on Intravenous Therapy with Temporary Devices in Adults	Ministry of Health, Social Services and Equality-Spanish NHS	Spain	2014	Adults	Insertion, maintenance and removal
Loveday et al	Epic3: national evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England	Department of Health (Accredited by NICE)	UK	2014	Both	Infection control
Valdez et al	Clinical Practice Guideline: Difficult Intravenous Access	Emergency Nurses Association	USA	2015	Both	Insertion and device selection
Chopra et al	The Michigan Appropriateness Guide for Intravenous Catheters (MAGIC): Results From a Multispecialty Panel Using the RAND/UCLA Appropriateness Method	Multiple institutions (hospitals & universities)	USA	2015	Adults	Device selection
Bouaziz et al	Guidelines on the use of ultrasound guidance for vascular access	Society of French anaesthetics and resuscitation (Societe francaise d'anesthesie et de reanimation)	France	2015	Both	Insertion
Denton et al	Standard for Infusion Therapy	Royal College of Nursing	UK	2016	Adults	Insertion, maintenance and removal
Hallam et al	Development of the UK Vessel Health and Preservation (VHP)	Multiple institutions (hospitals & universities)	UK	2016	Both	Insertion and device selection

	framework: a multi-organisational collaborative					
Gorski et al	Infusion Therapy Standards of Practice	Infusion Nurses Society	USA	2016	Both	Insertion, maintenance and removal
Capdevila et al	2016 Expert consensus document on prevention, diagnosis and treatment of short-term peripheral venous catheter-related infections in adults	Spanish Society of Cardiovascular Infections	Spain	2016	Adults	Infection control
O'Shea et al	Guiding Framework for the Education, Training and Competence Validation in Venepuncture and Peripheral Intravenous Cannulation for Nurses and Midwives (2017)	Office of the Nursing & Midwifery services	Ireland	2017	Both	Insertion
Kim et al	Development of Evidence-based Nursing Practice Guidelines for Peripheral Intravenous Catheter Management in Hospitalized Children and Adult	Multiple institutions (hospitals & universities)	Korea	2018	Both	Insertion, maintenance and removal

There was variation in scoring in the scope and aims of the different documents. For example, MAGIC⁷³ aimed to provide health professionals with evidence-based appropriateness criteria to guide vascular access device selection; epic3⁷⁴ aimed to describe clinically effective measures to be used by health professionals in hospital infection prevention; where as others gave more comprehensive recommendations about PIVC insertion, maintenance and removal^{73,75-79,81-89}. The majority of reviewed guidelines (10) made recommendations for both adult and paediatric populations^{74,77,78,80-83,88-90}. Seven guidelines^{73,75,76,79,84,86,87} were dedicated to adult populations and one guideline focused on children⁸⁵.

3.1.2 Appraiser agreement

The overall agreement was moderate ($K = 0.58$; 95% CI 0.36–0.79), with a substantial intra-category concordance ($K = 0.66$) for guidelines classified “Yes, recommended for use without modification”. The evaluators also demonstrated substantial agreement ($K = 0.68$) on those guidelines that were not recommended to be used in clinical practice. A moderate level of agreement ($K = 0.41$) was demonstrated among appraisers on the guidelines that required modification in its use.

3.1.2.1 Overall scores

Domain scores and the overall assessment of the appraised guidelines are summarised in Appendix E. Highly skewed scores are acknowledged; however, both mean (SD) and median (range) are reported due to multiple scores of ‘zero’ across domains and across guidelines⁹¹.

Overall scores ranged from 25% to 96% (median 58%), with a mean (SD) of 56% (21). Only four guidelines^{73,74,76,78} were accepted without modifications and had high overall scores. Seven guidelines^{75,79-82,85,90} were ranked moderately (50%–80%) and would be accepted with modifications. The remaining seven guidelines^{77,83,84,86-89} were not accepted and scored poorly overall (< 50%).

3.1.2.2 Domain scores

Domain 1 (Scope and purpose)

The mean (SD) overall score for the scope and purpose domain was 78% (22), (median: 86%; range: 8%-99%). Six guidelines received scores greater than 90%^{74-76,81,82,86} and one received a score below 50%⁸⁷. The high scores were due to good reporting of objective and intent of guideline.

Domain 2 (Stakeholder involvement)

For this domain, the mean (SD) overall score was 45% (21), (median: 37%; range: 22%–89%). Two guidelines scored highly at 89%^{73,74} and 10 guidelines received scores below 50%^{75,77,80,81,83,84,86,88-90}. The low scores were given mainly due to the guidelines’ lack of focus on the views and preferences of the target audience.

Domain 3 (Rigour of development)

The mean (SD) score for this domain was 43% (31) (median: 42%; range: 7%–97%). Two guidelines received very high scores (> 90%)^{74,78}, and nine received scores below 50%^{79,82-89}, with three scoring less than 10%^{83,84,89}. The low scores in this domain were largely due to the lack of reported systematic searching of the literature, selection and appraisal of evidence. The recommendations provided lacked any supporting evidence and external appraisal.

Domain 4 (Clarity of presentation)

The mean (SD) score for the clarity of presentation domain was 67% (16) (median: 68%; range 36%–90%). One guideline scored over 90%⁷⁴ with two guidelines scoring less than 50%^{77,79}. This domain was relatively well addressed, as most made clear and specific recommendations for practice.

Domain 5 (Applicability)

The mean (SD) score for the applicability domain was 30% (26) (median: 25, range: 0%–84%). Two guidelines received a high score (> 85%)^{74,76}. Most guidelines scored below 50%, while six scored 10% or lower^{77,84-86,88,90}. These low scores were due to the lack of

provision of tools or advice, and/or a lack of demonstrated understanding of the facilitators, barriers or resource implications of their recommendations.

Domain 6 (Editorial independence)

The mean (SD) score for this domain was 37% (42) (median: 15%; range: 0%–100%). Three guidelines received the highest possible score (100%)^{73,74,80}, and nine guidelines received scores of less than 5%^{77,83-88,90}. These low scores were due to lack of reporting.

3.2 Systematic review of trials

Out of 606 studies identified through the search strategy 273 titles and abstracts were screened (after removal of duplicates) and 71 studies were assessed at full text level. Ultimately, 40 studies were eligible for review. See PRISMA flow diagram in Figure 2.

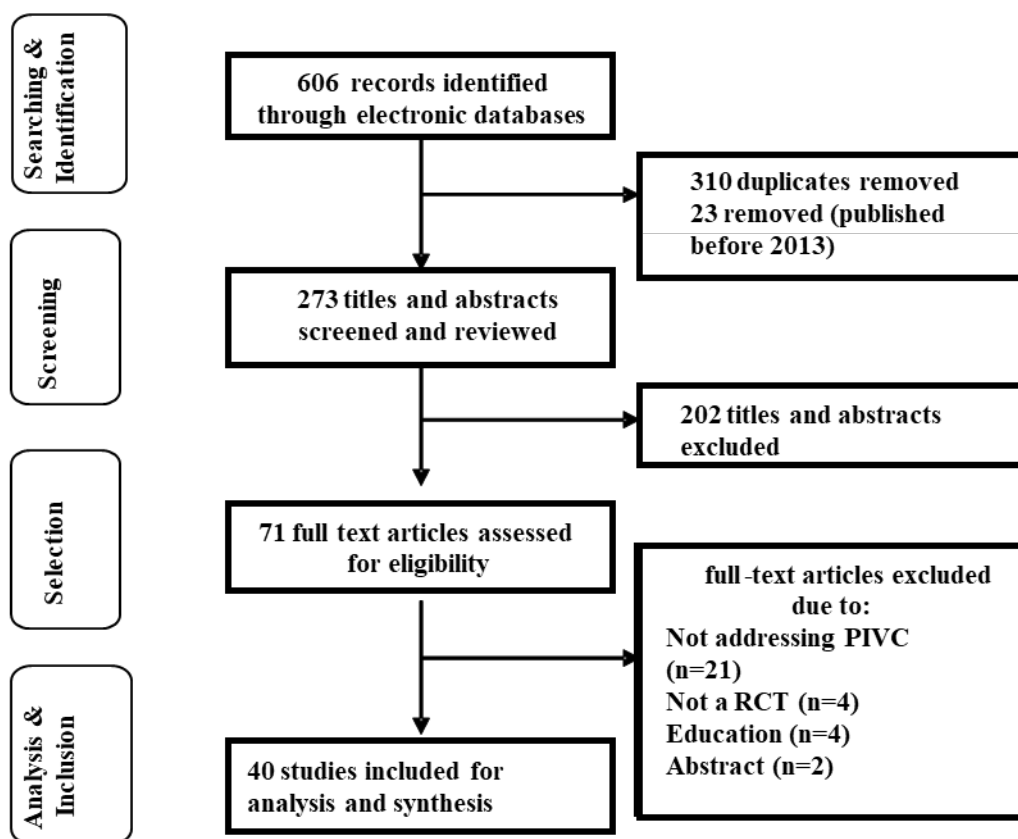


Figure 2: PRISMA flow chart

3.2.1 Characteristics of studies

The 40 studies eligible for review can be grouped under two broad categories: Insertion (n = 27) and Maintenance (n = 13) and see Appendix F. Within these categories, there are further subcategories of Insertion expertise (n = 1)⁹², Catheter design (n = 1)⁹³, Ultrasound guided insertion (n = 6)⁹⁴⁻⁹⁹; Near infrared devices (n = 6)¹⁰⁰⁻¹⁰⁵, Guidewire insertion (n = 3)¹⁰⁶⁻¹⁰⁸, Insertion site (n = 1)¹⁰⁹, and Pain reduction on insertion (n = 9)¹¹⁰⁻¹¹⁸. Within Maintenance subcategories included, Dressing and securement (n = 5)^{10,119-122}, Flushing technique (n = 2)^{123,124}, Flush and/or lock solution (n = 3)¹²⁵⁻¹²⁷, and Removal (n = 3)¹²⁸⁻¹³⁰. Three CRTs were included in reviewed studies^{101,102,130}. Van der Woude et al's title stated it was a CRT,

however examination of method and results indicated that the trial was conducted like a traditional RCT randomising at individual level¹⁰⁵.

The 40 studies reviewed had a total of 15,335 participants (range 40 - 1807), and an age range from neonate to 90 years of age (10,789 adults, 4,273 paediatrics, 273 neonates). Studies were conducted in following settings: General medical and surgical n= 13^{10,92,93,98,107,112,117,121-124,128,130}, Emergency Department n = 9^{95,97,99,100,104,105,113,115,119}, Intensive Care Unit n = 5^{96,111,120,125,129}, Surgical unit, n= 3^{94,114,127}, Anaesthetic and Operating Room n = 4^{101-103,118}, Medical unit n= 2^{116,126}, and 1 study each from Medical Imaging¹¹⁰, Obstetrics¹⁰⁹, Out-patients¹⁰⁶ and healthy volunteers in simulation unit¹⁰⁸. However, this population was spread across the 12 sub categories (Insertion (n = 7), Maintenance (n = 4). Detailed information on the populations within individualised studies is presented in Table 1. Most of the studies were conducted in the USA (n = 11) and Australia (n = 7). Other countries represented included France (n = 3), Netherlands (n = 4), Italy and China (n = 3 each), Brazil and India (n = 2 each) and 1 each from Canada, Denmark, Malaysia, Spain and Turkey.

3.2.2 Quality appraisal

We analysed seven domains of potential risk of bias in the included studies (see Appendix G). Most studies avoided selection bias by using computerised randomisation methods. Allocation concealment was poorly reported across most studies. We rated the performance risk of bias as high for four studies^{95,108,127,128} and unclear for 9 studies^{93,96-98,104,106,112,118,119} with the remaining 27 studies at a low risk of bias. The main reason for performance bias was lack of blinding of both participants and personnel to intervention. This is not surprising given the challenge of blinding study participants and staff to study products and/or practice in the clinical setting. However, many studies did employ blinding of outcome assessors to minimise detection bias, though not all. There was minimal attrition and reporting bias. However, discrepancies between tabulated and textual data were noted in some studies thereby introducing other possible sources of bias^{93,108,114,125,128}.

3.2.3 Outcomes

The findings of the review are listed under their relevant outcomes. Meta-analysis could not be undertaken for all outcomes due to variable intervention or outcome reporting. A narrative summary of these studies is presented.

3.2.3.1 Primary insertion outcomes:

First insertion success

Ultrasound guided insertion

Six studies evaluated the impact of ultrasound-guided insertion on first insertion success⁹⁴⁻⁹⁹. Analysis of pooled data (n = 2181, Figure 3) demonstrated that using ultrasound made no significant difference to first insertion success rates (RR 1.06, 95% CI 0.96, 1.16). However, this result has to be interpreted with caution due to the high heterogeneity demonstrated through the I² statistic of 70%. Studies were mostly conducted in general paediatric or adult patients. Only one study⁹⁹ evaluated impact of ultrasound guided insertion of patients with difficult IV access. Operators included a mixture of nurses, technicians and anaesthetists, most with no ultrasound experience or training prior to studies.

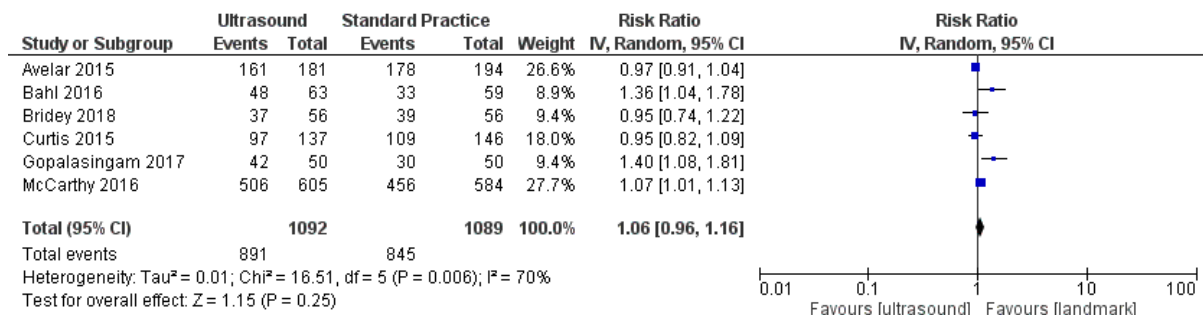


Figure 3: Forest plot of studies comparing ultrasound versus standard practice for first insertion success rate

Near infrared

Six studies evaluated the impact of near infrared viewing devices on first insertion success^{94-99,131}. Six of these studies could be pooled for meta-analysis¹⁰⁰⁻¹⁰⁵ (n=1410, see Figure 4). This included results from two CRTs¹⁰¹. The overall results (using transformed CRT data) showed no difference in primary outcome between groups (RR 1.03, 95% CI 0.97, 1.10). Heterogeneity was moderate (I² 44%). Patient population were mostly neonatal or paediatric, with the exception of one adult study. Operators comprised of mixture of nursing and anaesthesiologists new to infrared use.

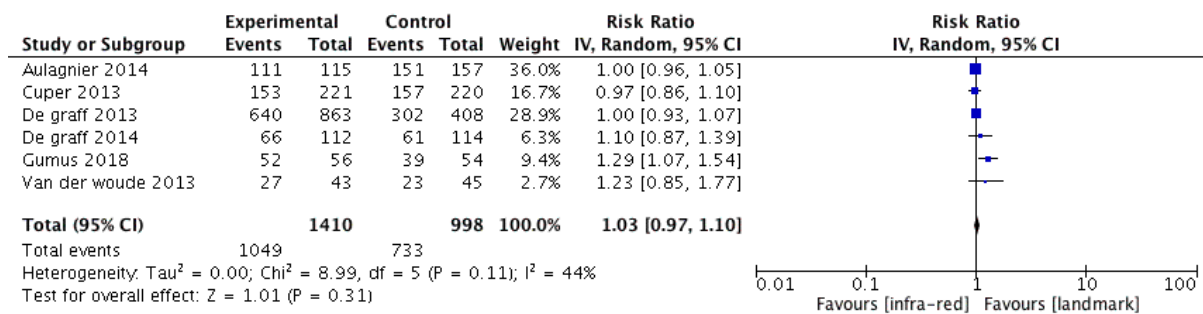


Figure 4: Forest plot of studies comparing infrared versus standard practice for first insertion success rate

Guidewire

Three studies evaluated the impact of using a guidewire during PIVC insertion compared to a standard catheter¹⁰⁶⁻¹⁰⁸. All of the studies were pooled into a meta-analysis (n = 652, see Figure 5). Results demonstrated that there was no significant difference in first insertion success between groups (RR 1.38, 95% CI 0.86, 2.21). However, very high heterogeneity was observed, reflected by the I² statistic (94%). Patient population studied was adults and operators were nurses or combat medics.

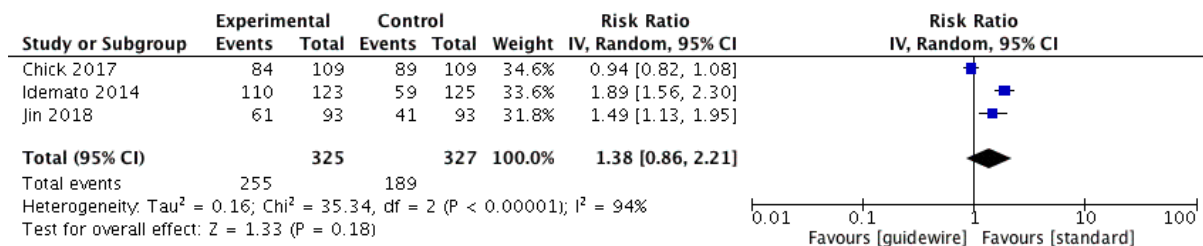


Figure 5: Forest plot of studies comparing guidewire versus standard practice for first insertion success rate

Catheter design

There was only one trial that evaluated the impact of catheter design on outcomes of interest. Lopez and colleagues⁹³ compared a closed (integrated extension set) versus open (non integrated) PIVC system (n=1131). Successful insertion was higher in the open system at 98% compared to closed at 94% (p .004).

Insertion site

One study evaluated first insertion success when the PIVC sited in the hand compared to forearm¹⁰⁹. Initial cannulation success was higher for the hand compared to the forearm (hand 93.5% versus 86.9% p =.05, 95% CI 1, 1.2).

Insertion model

The main clinical outcome for Marsh et al 's study⁹² was PIVC failure. However, they also evaluated impact of expert versus generalist model on overall insertion success. Overall PIVC insertion success was higher in the expert group compared to the generalists (100% versus 78%). The average number of insertion attempts was also slightly reduced but not significantly (Experiment 1.22 and Control 1.74).

Time to insertion

Two studies evaluated impact of ultrasound on time to insertion^{95,97}. There was no significance difference reported between groups. Meta-analysis was not possible due to incomplete outcome reporting. Five studies evaluated the impact of infrared and time to insertion. Four studies could pooled for meta-analysis^{100,101,104,105} (See figure 6). This demonstrated that infrared had no significant impact on time to insertion (SMD 7.07, 95% CI -9.79, 23.93). Data from De Graff et al's study¹⁰³ was excluded due to highly skewed values that distorted the already high statistical heterogeneity (I^2 94%).

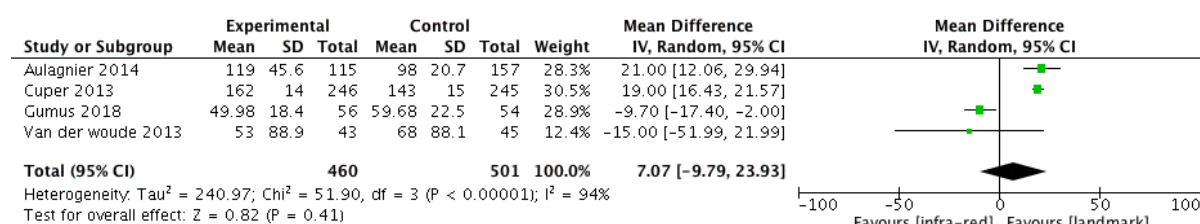


Figure 6: Forest plot of studies comparing guidewire versus standard practice for time to insertion

The three guidewire studies measured impact on time to insertion between groups. Idemoto et al¹⁰⁷ demonstrated a 2.1 minute reduction in time. No time difference was reported between groups in Chick et al's study¹⁰⁶. Conversely time to insertion using a guidewire increased by 41.7 second in Jin et al study¹⁰⁸. Insufficient and highly skewed data meant it could not be pooled for meta-analysis.

3.2.3.2 Secondary insertion outcomes:

PIVC failure

Six studies examined the impact of different insertion products or practices on PIVC failure^{92-94,99,107,109}. None were amenable to meta-analysis due to variation in intervention. Insertion model⁹² and site choice¹⁰⁹ had no impact on rate of PIV failure. Catheter design, use of ultrasound, and guidewire did have impact on PIV failure outcome. In the study of catheter design, composite measure of failure was not reported however the rate of phlebitis per 1000 catheter hours was less in the closed system at 1.29 versus 2.01 in the open system, (p =.004, IRR 0.64, 95% CI 0.47, 0.88) with 20% relative risk reduction in catheter related

infection⁹³. In McCarthy et al's study infiltration was lower in difficult access group (USG 2.1% versus Landmark 3.2%)⁹⁹. In Avelar et al's study the proportion of patient's experiencing infiltration was higher in the experimental group than the control (USG 34 (74%) versus landmark 23 (51%) $p=.025$). In Idemoto et al's study¹⁰⁷, use of guidewire was also associated with reduced PIV failure (PIVC failure Guidewire 44% versus Standard 12% $p < .001$). Additionally, infiltration and phlebitis were higher in the control group (Infiltration: Experiment 3(2%) versus Control 33(26%); Phlebitis: Experiment 1(<1%) versus Control 11 (9%)).

Infection (local or primary)

Idemoto and colleagues and Gonzalez et al^{93,107} were the only two insertion studies that reported infection outcome. This was negligible, (i.e. 0 in the experimental group and 1 case in the control group) in the Idemoto study. The results were also negligible in Gonzalez study 13/529 in closed integrated system and 11/574 in the open PIVC system ($p = .635$)

Dwell time

Two studies evaluated the impact of insertion practice or product on dwell time. Use of integrated catheter design was associated with longer dwell time at 137.1 hours compared to open at 96 hours ($p < .001$)⁹³. In Idemoto et al's guidewire insertion study dwell time was higher for patients in the experimental group (mean time and (SD), guidewire 105 hours (61) versus control 35hours (25))¹⁰⁷.

Patient reported pain

Nine studies evaluated various forms of analgesia for PIVC insertion¹¹⁰⁻¹¹⁸. Only two studies^{113,115} were amenable to meta-analysis due to similar interventions and outcomes, however reported outcome values (median and range), therefore, data could not be pooled¹³². These two studies evaluated the effect of vapocoolant compared to placebo on pain upon PIVC insertion in an emergency department. Patient perception of pain was no different in Edwards and colleagues study¹¹³ (Median pain score (range): Vapocoolant 2 (0-9) versus Placebo 2.5 (0-10, $p = .33$)). However, a statistically significant difference of 2 points, where the median pain on the Numeric Pain Scale (NRS) pain scale was less for vapocoolant group was observed between groups in Mace and colleagues' ($p < .001$).

A number of studies evaluated Eutectic Mixture of Local Anaesthetics (EMLA) as an intervention and control^{110,112,114,118}. Balanyuk and colleagues'¹¹⁰ study showed a significant improvement with distraction compared to EMLA. Mean pain score Distraction 0.69 (SD1.26) versus EMLA 1.86 (173), $p < .001$ with respect to the local anaesthetic in reducing pain perception. Cozzi and colleagues¹¹² evaluated EMLA versus warm lidocaine and tetracaine patch on pain during insertion. No significant difference in first insertion success or pain score (Self-reported Wong Baker pain score $>4/10$, Lidocaine 18/172 (11%) compared to EMLA 15/167 (9%) $p = .65$)). Stolz and colleagues¹¹⁸ evaluated J-tip needleless delivered lidocaine intradermal versus EMLA on children's pain scores for PIVC insertion. Results showed EMLA had lower procedural pain compared to intervention (Mean pain score J-tip lidocaine 2.99 (SD 2.58) versus EMLA 1.63 (SD1.65), $p < .001$). Gupta and colleagues¹¹⁴ conducted a four-arm RCT evaluating EMLA and Capsaicin (chilli pepper extract with analgesic properties) alone and in combination versus plain lubricant cream (placebo) on pain scores. The authors reported that the incidence of *no pain* was higher in the EMLA group compared to all others. However, statistical reporting was poor for this study and this conclusion could not be verified. One final study using *active* analgesia compared topical powdered lidocaine to sham placebo in a paediatric population¹¹⁷. The substance was well tolerated and the Wong-Baker FACES Pain scores were significantly reduced in the powdered lidocaine group (Mean pain score Lidocaine 1.28 (SD 0.09) versus Sham placebo 1.67 (SD 0.9), $p = .002$).

The final study reviewed on analgesia for pain on PIVC insertion compared oral sucrose with placebo in the neonatal population¹¹¹. Results showed that mean pain scores were reduced on insertion in the sucrose group compared to placebo (6.5 (SD 3.7) vs 8.0 (SD 3.8), $p < .05$). Time to return to baseline comfort/pain scores was similar between groups¹¹¹.

A study by Redfern et al examined the effect of thermomechanical simulation (buzzy) on procedural pain and reported that there was no significant difference on the pain scores between the groups (2.52 (0.37) in buzzy group and 2.43 (0.36) in standard group $p = .86$)¹¹⁶.

Patient satisfaction

Patient satisfaction was measured in five studies. Patient satisfaction scores did not differ between groups in Bridey et al's ultrasound study⁹⁶. Patients satisfaction was reported as higher in the control group of Chick et al's study¹⁰⁶ evaluating effect of Guidewire on insertion (4.5/5 versus 3.9/5 $p < .001$). Conversely, patients in Idemoto's et al study¹⁰⁷ universally reported higher satisfaction scores for insertion, dwell time and removal for guidewire inserted PIVCs. Patients in Marsh et al's study⁹² reported higher satisfaction scores using a numerical rating scale (NRS). Median NRS for insertion, Expert 9 (8,10) versus Generalist 7 (3.5,9); and overall Expert 7 (6,9) versus Generalist 4.5 (1.5,6). Patients in Redfern et al's study¹¹⁶ on management of pain on PIVC insertion reported lower satisfaction scores in the experimental group using thermomechanical stimulation.

Cost

Only one insertion focused study evaluated cost effectiveness. Lopez and colleagues⁹³ determined that the reduced level of phlebitis and risk of infection reported in the trial using closed PIVC design was equated to a saving of 0.09 Euro per day. The closed PIVCs extended dwell time (up to 144 hours) compared to open PIVCs (96 hours) equated to a saving of 786.257 Euro per thousand beds per year.

3.2.3.3 Primary maintenance outcomes:

PIVC failure (dislodgement, occlusion, infiltration, phlebitis)

Dressing and securement

Five trials evaluated the impact of different dressing and securement products on PIVC failure^{43,119-122}. The results of two studies lent themselves to the generation of two meta-analyses^{43,122}. Pooled analysis compared data from two studies across three interventions; bordered polyurethane (BPU, $n = 886$), sutureless securement device (SSD, $n = 891$) and standard polyurethane with tissue adhesive (SPU +TA, $n = 891$) (Figure 8). No significant difference across groups (overall RR 0.92 95% CI 0.84, 1.01). There was no heterogeneity present across analyses.

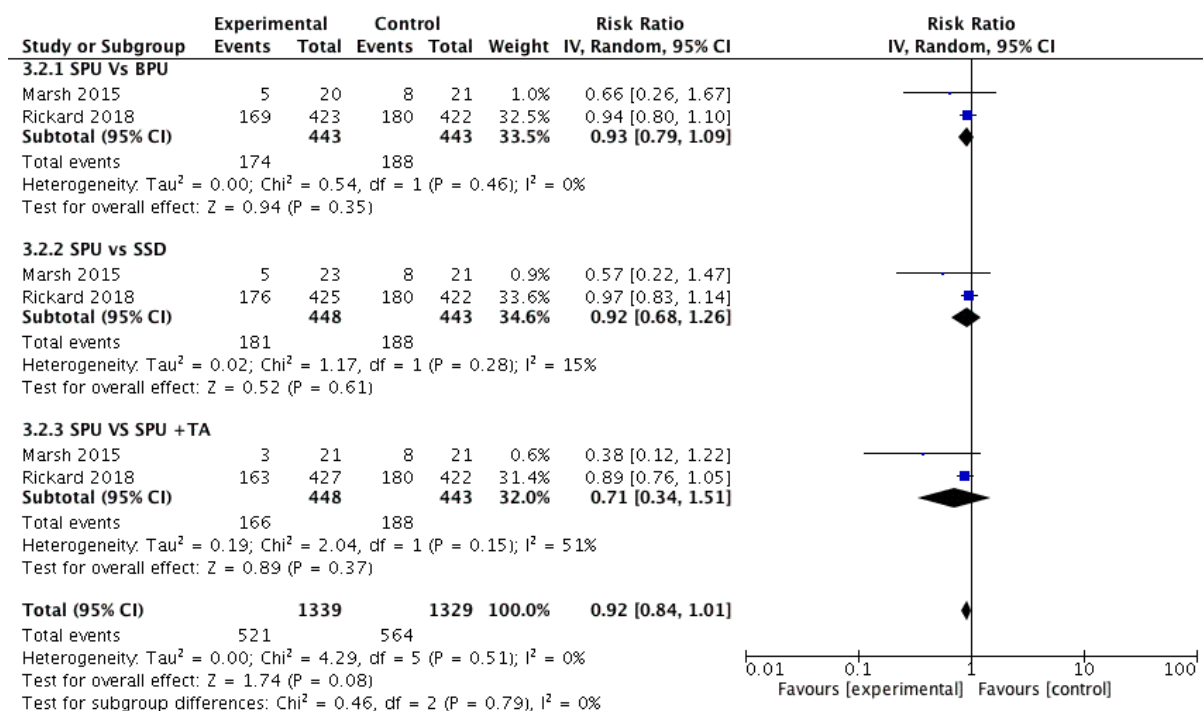


Figure 7: Forest plot of studies on impact of different dressings (SPU, SSD + SPU, TA+SPU, BPU+SPU) and PIVC failure

Three other studies evaluated securement and dressing products. Bugden and colleagues¹¹⁹ compared their BPU dressing against BPU + TA (n = 369). PIVC was lower in the BPU +TA group (31 (17%) versus BPU only 52(27%) p = .04).

Gunter and colleagues¹²⁰ trialled an advanced dressing compared to the standard dressing at the respective study site for a range of vascular access devices (peripheral and central). The features of, and differences between study products were not well described. The study evaluated outcomes of 873 PIVCs. Complication rates were similar between groups demonstrating the equivalence in performance between the three dressing types. Overall complications in PIVCs occurred at a rate of 41.9 % or 25.5/1000 catheter-days. The most frequent complication leading to early catheter removal was dysfunction (or occlusion), with an incidence rate of 16/1000 catheter-days. Dislodgement occurred in 55 cases, 6 % of all PVCs, and at a rate of 5.2/1000 catheter-days. No cases of CRBSI were reported in the PIVC group of the study.

The other study was a pilot trial comparing the effect of a dressing with an integrated securement device to a standard bordered polyurethane dressing on PIVC failure (n = 300)¹³³. Failure was proportionally similar between groups, occurring in 43/150 (29%) bordered polyurethane dressing and 40/150 (27%) integrated securement device patients with an overall failure rate of 28%. Overall proportion of phlebitis was 6% and there were no laboratory-confirmed local venous or primary bloodstream infections.

Flushing technique

There were two studies that evaluated the impact of different flushing techniques on PIVC failure^{123,124}. The data comparing different flushing frequencies was pooled into a meta-analysis (n = 557, Figure 8). Analysis of high (Q6h or Q12h) versus low frequency (Q24h) showed no difference in PIVC failure (RR 1.40 95% CI 0.90, 2.19). There was low heterogeneity (I² 0%). Keogh and colleagues¹²³ factorial trial also evaluated the impact of different flushing volumes (10mL versus 3mL). Results showed that the proportion of PIVC failure rates per 1000 hours was increased in the 10 mL (versus 3 mL) group (44% vs 29%

respectively), but this was not statistically different (10mL 7.44/1000 hours, (95% CI 5.54, 10) versus 3mL 4.84/1000 hours, (95% CI 3.36, 6.96), $p = .063$).

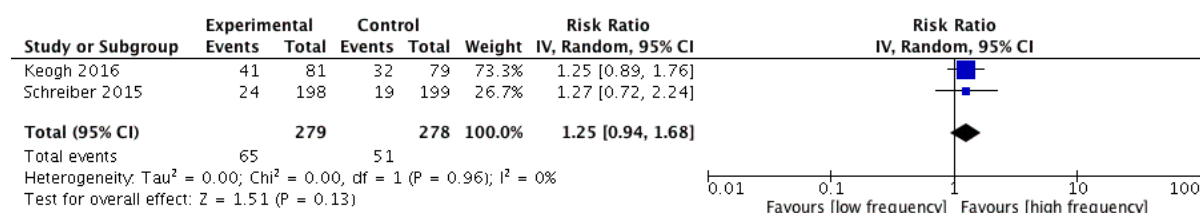


Figure 8: Forest plot of studies on flushing frequency (high frequency Q12h/Q6h vs low frequency Q24h) and PIVC failure

Flushing solution

Three studies examined the impact of heparin as a flush or lock solution on the functional duration of catheter devices. We were unable to conduct meta-analysis due to heterogeneity with the intervention. Upadhyay and colleagues¹²⁵ conducted a trial in neonates evaluating the effect of intermittent heparinised saline flush (1.0ml 10U/ml) compared to flushing with 1mL of 0.9% Sodium Chloride. Between the two groups, mean difference (95% CI) in functional duration of catheters was 13.9 hours (4.7–23.1) in favour of the heparinised saline group ($p < 0.005$). Nil adverse events were recorded.

Wang and colleagues¹²⁶ evaluated impact of a 5mL heparinised saline flush (50U/mL) compared to a 5mL flush of 0.9% Sodium Chloride in an adult population ($n = 68$). The proportion of PIVCs removed for abnormal reasons were 30.7% and 22.4% in the heparinised and normal saline groups, respectively (OR 0.65, 95% CI 0.33–1.27, $p = .208$), with an absolute risk increase of 8.3% in the heparinised group. Haematological screening demonstrated that heparinised saline tended to mildly impair the prothrombin (PT) and activated prothrombin time (APTT) levels in patients with liver cirrhosis.

Xu and colleagues¹²⁷ also evaluated impact of heparinised saline flushes (3mL of 50U/mL) compared to 3mL of 0.9 Sodium Chloride in an adult population with liver dysfunction ($n = 286$). There was no significant difference between the two groups in the rate of catheter obstruction; 15.1% (44/292) for the heparinised group and 18.6% (59/317) for the normal saline group. Likewise, there were no significant differences in the median duration time and rates of phlebitis, infiltration and accidental catheter removal or dwell time between the two groups. No serious adverse events including infection occurred during the study.

One trial evaluated the impact of replacing PIVCs electively (i.e. routinely at 72-96 hours) as opposed to the standard practice of removing when clinically indicated, with the extravasation rates as a primary outcome, in a neonatal population ($n = 113$ patients and $n = 274$ PIVCs)¹²⁸. Results showed a reduction in the proportion of patients experiencing extravasation (routine 72-96 hours 28/58, 48.3% versus clinically indicated 33/55, 60%), with a reported 20% reduction in risk (RR 0.8, 95% CI 0.57 to 1.13, $p = .21$), however this did not factor in dwell time. It is uncertain whether data were reported per patient or per catheter, which hindered comprehensive data extraction for this trial.

Two studies evaluated the impact of different removal schedules on phlebitis^{129,130}. We pooled these for meta-analyses ($n = 1622$, see Figure 10). This included one CRT. Using an assumed ICC of 0.05 to transform CRT data there was meta-analysis demonstrated comparable risk between groups (RR 0.89, 95% CI 0.66, 1.20). Heterogeneity was low $I^2 = 0\%$. (See figure 9).

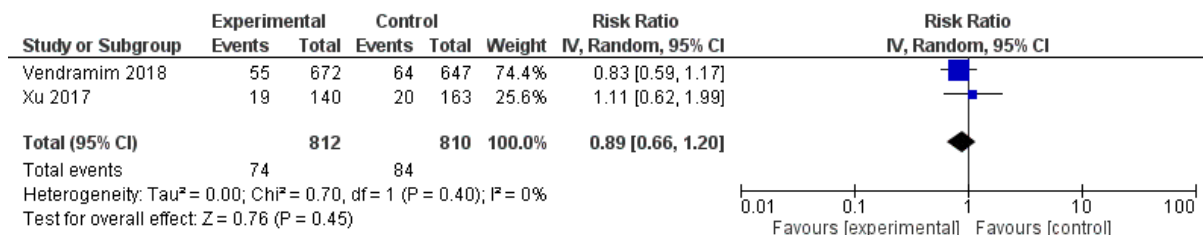


Figure 9: Forest plot of studies on different removal schedules (routine vs clinically indicated) on phlebitis.

3.2.3.4 Secondary maintenance outcomes:

Infection (local and primary)

Eleven studies evaluated the impact of different maintenance practices and products on infection (local and primary). Catheter-related, laboratory confirmed or primary bloodstream infection rates were nil or negligible in all studies, hence meta-analysis could not be conducted^{10,119-123,126-130}.

Dwell time

Four studies reported on the impact of different maintenance practice or products on device dwell time. None were amenable to meta-analysis. In Marsh et al's study (2018) of advanced dressing and securement, dwell time in hours was slightly longer in intervention group but not significantly 68.8 (50.7) versus control 57.9 (40.5), $p = .699$ ¹²¹. In Rickard et al's 4 arm RCT of different dressing and securement product¹⁰, dwell time was comparable across all groups at an average of 54 hours. Keogh et al's flushing trial also reported comparable dwell times across all groups flush volume at an average of 60 hrs¹²³. Xu and colleague's study of clinically indicted removal, demonstrated significantly increased dwell time in the intervention group commensurate with the protocol 96h (2-491), versus control 48h (2-216) $p < .0001$ ¹³⁰.

Patient satisfaction

Two studies evaluated patient satisfaction in relation to study intervention. A higher patient satisfaction scores were observed in the Marsh and colleagues 4-arm pilot trial of different dressing and securement products; BPU (median, range: 9 (8, 10) TA 10(9-10)) compared to the control 8 (5-9) and SSD 8.5 (7-10). However, patient satisfaction scores were similar across the groups in Rickard and colleagues larger 4-armed trial of same products^{10,122}. There was no notable difference in the patient satisfaction scores between the groups in the Marsh and colleagues (2018) trial of BPU and Integrated Securement Device¹²¹.

Cost

Only one study measured and reported cost effectiveness. Total cost included initial dressing and securement products, staff costs, costs associated with initial PIVC, replacement PIVC and treatment of infections highlighted significant rang of cost across the groups as follows: Mean cost (SD), SSD: \$9.76 (0.96), SPU: \$17.23 (308.84), TA: \$17.78 (2.67), and BPU: \$35.52 (435.72)¹⁰.

4. Discussion

4.1 Guidelines

The aim of this systematic review was to appraise the scope, quality and rigour of contemporary clinical guidelines and practice standards for insertion, maintenance and removal of peripheral intravenous catheters in adult and paediatric hospital populations. We analysed the guidelines and standards published since 2013 using the AGREE II tool. Variability in the methodological quality of the retrieved guidelines and standards was high. Only one guideline (the UK's epic3¹³⁴) scored consistently high (> 80%) across all domains, except for a score of 72% in Domain 5 (Applicability). Three other guidelines scored consistently over 50%,^{73,76,78} with variation in quality in Domain 5 (applicability). The remaining guidelines were highly variable or rate consistently poor against the AGREE II tool categories.

Most guidelines performed adequately or well in Scope and Clarity of presentation; however, the most poorly adhered to domain was rigour of development. The development of evidence-based guidelines requires a well-resourced and representative committee, who have the skills and knowledge to search and appraise relevant research and make recommendations for clinical practice¹³⁵.

A number of large international and national bodies are resourced to generate and maintain quality guidelines, and this was reflected in their AGREE scoring (e.g. MAGIC, epic3, INS). The Centers for Disease Control (CDC) Guidelines for Prevention of Intravascular Catheter-Related Infections (2011) did not meet search criteria because of date limitations³¹. The CDC is a well-resourced independent body that convened a large and representative healthcare team to generate these guidelines based on the best available evidence sourced through systematic search and appraisal. Thereby demonstrating many of the key desirable characteristics of quality guidelines. Since the original publication date of these in 2011 the CDC has stated that they will only make updates when significant new evidence becomes available¹³⁶. An example of this is the recommendation to use chlorhexidine impregnated dressings for short term non tunnelled central venous catheters in 2017.

Guidelines were found from all major states in Australia. National guidelines for the prevention and control of infection in healthcare from 2010 were outside the date limits and unavailable as currently under review¹³⁷. The guidelines generated by local bodies reviewed did not perform well against the AGREE II scoring categories. It is unclear as to whether the issue is with quality of reporting of these documents or the development process itself, but the reviewer and indeed the user has only the content published to appraise.

Similarities and differences between guidelines

Much of the content of the guidelines are similar especially in regards to standard and transmission based precautions, hand hygiene and aseptic technique. These are largely based on the CDC and epic3 Guidelines.

Other commonalities include:

- Assessment (at basic level) of need and type of IV device, and catheter site selection
- Skin decontamination with 2% Chlorohexidine in 70% alcohol solution (unless contraindicated)
- Limiting of insertion attempts to two (2) per practitioner
- Use of a transparent, semi permeable dressing to cover IV insertion site and secure catheter
- Decontamination of any ports or hubs prior to access
- Use of 0.9% sodium chloride flushes pre and post drug administration

- Removal and replacement of IV device if (a) no longer device no longer working (i.e. occluded) or (b) patient shows signs of local or systemic infection (i.e. local redness, pain or swelling or fever and malaise).
- Removal of device when no longer required

There are a number of differences between and unresolved issues in the guidelines. These include:

- Quality and detail of patient assessment determining the type of and site location for the PIVC. For example, MAGIC guidelines, INS and epic3 give detailed instructions on device selection or site choice based patient and treatment factors and harm minimisation.
- Detailed assessment of quality of patient's vessel integrity. The UK's Vessel Health Preservation framework and the US's Emergency Nurse's Clinical Practice Guidelines are only documents to provide decision matrix to guide and strategies for patients with difficult vascular access
- Escalation of insertion process if first insertion attempts unsuccessful. Most guidelines limited each individual to two attempts but few offered a formal pathway to optimise insertion thereafter (other than more *blind* attempts)
- If and when to use ultrasound guided vessel location and insertion (as above)
- Use of analgesia agents or pain relieving strategies. Few recommended routine pain relief pre insertion despite significant evidence and patient reports in favour of this
- Specific type of dressing and securement device(s). Generic desirable characteristics of dressing and securement device listed but no specific product types named.
- Type of needleless connector. No specific product characteristic or type recommended.
- Type and technique of port or hub decontamination. There were varied recommendations for decontamination solution (70% alcohol versus 2% Chlorhexidine in alcohol), decontamination timing (times of 5, 15 and 30 second cited), as well as technique (active scrubbing versus passive cap).
- Frequency and technique for IV flushing. Varied frequencies cited for flushing of PIVCs not in continuous use (e.g. Q24h, Q8h, Q6h and PRN).
- Frequency of IV administration set changes. Disagreement between key guidelines on frequency of IV administration set changes (for solutions not containing blood or lipid). CDC recommend change every seven days and epic3 recommend change every four days.
- Criteria for ongoing assessment of PIVC site and function. There was a general recommendation for management of dressing and patency of PIVC and removal if showing site or patient exhibiting signs of infection, but no comprehensive criteria for assessment or recommendation of frequency of assessment.
- Criteria for replacement of PIVCs. Disagreement between key national and international reviews. The UK, Spanish and Irish guidelines all recommend replacement of PIVCs as clinically indicated. The CDC (2011) recommend removal of PIVCs no more frequently than 72-96 hours and regard clinically indicated as unresolved (except in children). All local (Australian) guidelines recommend PIVC replacement at 72 hours.

In summary, many of the national and international guidelines exhibited consensus on the key recommendations regarding PIVC insertion and maintenance. Several guidelines focused on optimising device selection and insertion, reflecting the growing research and commentary around vessel health preservation. Most cited the level and source of evidence that supported these recommendations. Areas of practice that remained unresolved were largely due to lack of high quality evidence (e.g. needless decontamination). There was significant variation in reporting and quality of guidelines at a local level, which invites the question of whether state and local bodies would do better to endorse relevant national and international guideline and then provide staff with local work statements to implement these.

Clinicians rely on guidelines and standards to create hospital policies designed to aid decision-making at the bedside and drive quality practice. If the guidelines themselves are of poor or variable quality, this raises concerns for patient outcomes.

4.2 Intervention trials

Forty trials assessing PIVC-related interventions in the last five years were identified. These differed in quality, size and scope. The aim was to identify high-level evidence to guide PIVC insertion and maintenance practice.

Insertion

The majority of trials identified in this review focused on insertion products and practice. This is commensurate with the results of a Scoping Review in 2014¹³⁸. Most of the studies focused on evaluation of visual aids to optimise first insertion success and time to insertion. Findings from the meta-analysis of eligible studies did not demonstrate a significant difference in this review. However, these results should be viewed with caution due to the high statistical heterogeneity observed across studies as well as the significant clinical variation with population, settings and operators. Most studies only offered new operators a short course (theory and practice) as a requirement for training before they entered the study. Therefore, aids like ultrasound may not have demonstrated superiority due to the complexity of the procedure and training required, versus the usual landmark technique. Operator experience does have an impact on the rate and quality of PIVC cannulation¹³⁹. So standardising and optimising education related to PIVC insertion (with and without ultrasound) is important for patient outcomes.

Previously published systematic reviews and meta-analysis of studies found that in patients with difficult IV access the use of ultrasound-guidance for peripheral venous access improved first time success rates compared to traditional technique¹⁴⁰⁻¹⁴³. The studies did not demonstrate that ultrasound guided insertion had an impact on time to successful cannulation or the number of skin punctures though. However, two paediatric studies found that time to successful cannulation was reduced and fewer attempts were required to achieve success for patients randomised to ultrasound guided insertion compared with the traditional method^{144,145}. Further, a systematic review and meta-analysis found that ultrasound guided peripheral IV cannulation significantly reduces number of attempts and procedure time in paediatric patients¹⁴⁶. Based on systematic reviews of the literature, routine use of ultrasound-guided peripheral venous cannulation is not recommended, however, for patients with known or suspected difficult venous access ultrasound-guided techniques improve success rates in a timely manner with improved patient satisfaction.

Research for peripheral catheter insertion has also focused on pre insertion analgesia. Analgesia for catheter insertion featured in 32% of PIVC trials identified in a scoping review of RCTs in peripheral vascular access devices¹³⁸. No meta-analysis of studies was possible in this review due to variation in interventions. However, individual studies did demonstrate reduced patient reported pain scores with analgesia intervention^{115,118}. Three systematic reviews of studies that pre dated this review demonstrated the impact of some sort of analgesia over no treatment¹⁴⁷⁻¹⁴⁹. Meta-analysis of studies did not demonstrate which anaesthetic was superior to another¹⁴⁷, and Vapocoolant was not found to be as effective in children¹⁴⁸. However overall, pain is less is using any local anaesthetic or numbing agent than when unattenuated during cannulation and some sort of pain relief should be routinely offered to patients prior to PIVC insertion.

Other studies on inserter model and catheter design were limited, but considering the increased acuity and comorbidities of patients requiring vascular access demand further investment in quality research to inform future practice and product use.

Maintenance

Given the challenges of acquiring successful peripheral vascular access it is vital to maintain the integrity and performance of the device. Although many RCTs examined catheter insertion strategies there were significantly less studies focused on post insertion care and maintenance of peripheral catheters. This mirrors the findings of a prior scoping review in this area¹³⁸. Just one third of studies reviewed evaluated different interventions related to post PIVC insertion care and maintenance. The largest subcategory was evaluation of dressing and securement products on PIVC complications and failure (n=5 trials). Only one small study in the Emergency Department yielded a significant result favouring the intervention (Bordered dressing plus tissue adhesive)¹¹⁹. Just two studies were amenable to meta-analysis and neither this nor the remaining studies demonstrated a superior product for dressing and securement. Guidelines are currently unable to make firm recommendations for dressing and securement practice and products due to the lack of evidence. The extensive use of PIVCs, high rates of failure, and substantial costs to healthcare for dressing and securement products highlights the need for further investment and innovation to develop effective products⁴³.

Other studies within Maintenance tested the impact of different flushing techniques and solutions. Meta-analysis of two small studies of different flushing frequency demonstrated that less frequent flushing was not associated with increased risk of PIVC failure and could therefore be considered as a safe alternative to high frequency flushing regimens prescribed in many guidelines. However, the mechanisms of how IV flushing, medication and fluid administration impact on the cannula, vessel endothelium and blood components are poorly understood and require further explication. We need to explore how syringe and infusion technology and method of administration can make a difference to PIVC outcomes^{18,50}.

Three studies compared heparinised saline versus saline flush alone on PIVC function and dwell time. Meta-analysis was not possible due to clinical variation in the intervention (i.e. heparin concentration). One study reported a statistical difference of 14 hours duration. Previous trials and systematic reviews have failed to demonstrate a benefit of heparin over saline as flush or lock solution in peripheral or central IV devices in adults¹⁵⁰⁻¹⁵⁴. The use of anticoagulant (usually heparin) to prevent occlusion of IVs has been traditionally used in the past, based on a not unreasonable suspicion of effectiveness. However, the process of *in vivo* catheter occlusion is complex and multi factorial, not simply based on blood clotting or deposit of blood proteins or cells¹⁵⁵. Thrombotic occlusion only accounts for only 58% of occlusions. Intraluminal occlusion can also be secondary to mechanical (e.g. kinks, pinches) and chemical causes (e.g. drug precipitate, lipid build up)¹⁵⁶. Leading guideline bodies do not recommend the routine use of anticoagulant lock or flush solutions, with the exception for central IVs in paediatrics^{44,134,157}. Although this recommendation lacks a firm evidence base. Moving forward, researchers should consider rigorous evaluation of other lock solutions (e.g. tetrasodium citrate, thrombin inhibitors, plasmin activators).

The impact of different PIVC replacement schedules was the focus of three trials evaluated in this review. They all evaluated the impact of routine compared to clinically indicated removal of PIVCs. Meta-analysis of two of the studies demonstrated equivalent risk of phlebitis between groups. Cases of catheter related bloodstream infection across groups and overall was nil or negligible. The result aligns with that of a current systematic review of seven trials¹⁵⁸. The authors concluded that there was moderate certainty evidence of no clear difference in rates of CRBSI, thrombophlebitis, all-cause blood stream infection, mortality or pain between clinically indicated or routine replacement of PIVC (ibid). Adopting the practice of replacement of PIVCs as clinically indicated would provide significant cost savings³⁵, spare patients the unnecessary pain of routine re-sites in the absence of clinical indications and would reduce time spent by busy clinicians on this intervention. Replacement of PIVCs as clinically indicated in children is standard recommended practice in all

guidelines. As noted earlier in this review a number of leading national guidelines no longer recommend routine removal of PIVCs^{44,76,134,159}. The CDC regards the issue of clinically indicated removal as unresolved, However, this statement predates the publication a major trial and systematic reviews addressing this issue¹³⁶. To minimise PIVC related complications, clinical staff should regularly assess the insertion site and remove the catheter if signs of pain, inflammation, infiltration, occlusion, or infection are present, or if the catheter is no longer needed for therapy. This underscores the need for pragmatic and evidence based tools to guide clinical assessment.

Just seven studies (17%) evaluated patient satisfaction or feedback on practice or product under evaluation. These were in relation to ultrasound guided insertion, catheter design, distraction therapy (for pain relief) and type of dressing or securement. The role of the consumer was placed front and centre in the recently updated in the Australian National Quality Healthcare Standards¹⁶⁰. Partnering with consumers was described as a broad concept that could involve consumer engagement and participation in care decision as well as consumer centred care itself (ibid). This can extend to research groups and guideline development bodies. *“The purpose of these partnerships is to improve the outcomes, experiences and the delivery of care by drawing on the knowledge, skills and experiences of people who are using, have used or may use the health service.”(NSQHC Standard 2: Partnering with consumers)*

In summary, of the 40 trials identified in the five years only one large, high quality PIVC trial was conducted and reported in the last five years. Billions of devices are used in healthcare settings globally, with billions of dollars spent on related products and staff resources. Yet there is such little investment in quality research to inform product and practice choices. Clinicians and policy makers largely operate in an evidence vacuum. This clearly contributes to practice inconsistency, inefficiency and ineffectiveness of some practice and products. Note though, that where there is evidence, there is poor uptake. (For example, use of ultrasound and analgesia for insertion, flushing solution, and device removal). There is an onus on government and the healthcare industry to invest in vascular access research; a further onus on vascular access researchers to conduct and report on quality and meaningful research. Finally, there is an onus on clinicians as health professionals to value and implement findings to improve patient outcomes and reduce waste of healthcare resources.

4.3 Gaps in identified literature

This literature review identified several gaps in the evidence base, which need to be met to facilitate development of strong evidence-based recommendations. In particular, there is a need for adequately powered and efficiently designed randomised control trials to assess:

- Impact of vascular access specialist (team or service) on patient and PIVC outcomes
- Clinical and cost effectiveness of innovative catheter design on insertion and function
- Optimal dressing and securement product(s) to reduce PIVC failure
- Needleless connector type on PIVC function and infection outcomes
- Needleless connector denomination solution, timing and technique and infection outcomes
- Impact of infusion and flushing regimens on maintaining PIVC function

Other areas where more research is needed include:

- Criteria for clinical assessment to monitor PIVCs
- Patient experience of PIVC insertion and different maintenance practices

4.4 Limitations

The review of national and international guidelines and local policies was limited by access to the materials online. It is possible that many hospitals in Australia (if not all) have a policy on PIVC insertion and maintenance, however these will often be behind institutional firewalls and therefore we were unable to access. However the guidelines reviewed appeared to be representative of key local, national and international agencies.

Limitations with the systematic review of PIVC intervention trials are related to the quality and heterogeneity of the trials. The risk of bias analysis demonstrated that the most of the trials (two thirds) had a low risk of bias. However, the process of data extraction revealed small sample sized and inconsistencies and variation in reporting that meant meta-analysis was not possible. The review was also limited to the last five years. However, the aim was to capture trial research that reflected contemporary practice and products. Other significant trials and systematic reviews were referenced in the discussion and inform the final recommendation

5. Implications and recommendations

This review highlighted a number of inconsistencies between Australian guidelines and leading international bodies. Universally, there are areas of PIVC practice that do not reflect the most recent or highest level of evidence available. (For example, use of ultrasound and analgesia for insertion, flushing solution, and device removal.) The review highlighted gaps in evidence that make it challenging for guidelines developers to construct definitive recommendations about specific practice or products to optimise PIVC outcome and the patient's IV experience. Many PIVC complications are avoidable and investment in quality evidence generation and implementation is urgently warranted. Given the enormous number of PIVCs used, even small differences in clinical and cost-effectiveness of different practices and products could generate significant improvement in patient outcomes and cost savings for hospital budgets.

A number of recommendations are made in relation to the findings from this review. These include:

- I. Development of a national clinical care standard aimed at reducing PIVC related complications and failure.
- II. Education and training of nursing and medical staff that focus on contemporary and evidence based PIVC insertion and maintenance care.
- III. Evidence based assessment of patient's need for vascular access and device type.
- IV. Early referral to vascular access specialist and use of ultrasound to minimise insertion trauma in patients identified as having difficult vascular access.
- V. Routine use of analgesic agents or strategies to minimise PIVC insertion associated pain.
- VI. Evidence based clinical assessment of PIVC site and function
- VII. Ongoing monitoring and reporting of PIVC use and outcomes to facilitate benchmarking and drive quality improvement
- VIII. Inclusion of patients' views in all future research in to the optimal PIVC insertion and maintenance practices and products.

6. Conclusion

This structured evidence-based literature review was undertaken to better understand the current clinical environment for peripheral intravenous catheter insertion and care, and to identify issues or gaps that may be addressed by clinical experts at a clinical roundtable.

The review includes an analysis of international, national and state guidelines as well as a review of 40 randomised clinical trials. There was a high degree of variation in guideline quality and recommendations. This may be contributing to inconsistency in practice and the unacceptable rates of PIVC failure reported in studies.

The development of a national clinical care standard should assist in bringing clinicians and health services together to agree upon the way forward to improve outcomes for all patients who rely on safe and patent vascular access for the delivery of vital medical treatment.

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8. Appendices

Appendix A: Detailed search strategy for guideline review

Search syntaxes customised for each database

Database	Search syntax
CINAHL	((MH "Catheterization, Peripheral+") OR "peripheral intravenous catheters" OR "peripheral venous cannula" OR "peripheral venous device" OR "pivc" OR "piv" OR (MH "Vascular Access Devices+")) AND ((MH "Practice Guidelines") OR (MH "Nursing Practice, Evidence-Based+") OR "clinical practice guidelines in nursing" OR "clinical practice guideline*" OR guideline OR "standard of practice")
PubMed	("Practice Guidelines as Topic"[Mesh] OR "Guidelines as Topic"[Mesh] OR "Guideline Adherence"[Mesh] OR "Evidence-Based Nursing"[Mesh] OR "Evidence-Based Practice"[Mesh] OR "clinical practice guidelines in nursing" OR "clinical practice guideline*" OR guideline OR "standard of practice") AND ("Catheterization, Peripheral"[Mesh] OR "Vascular Access Devices"[Mesh] OR "Peripheral Venous Catheterization"[Text Word] OR "peripheral intravenous catheter" OR "peripheral venous cannula" OR "peripheral venous device" OR pivc OR piv)
MEDLINE	("Practice Guidelines as Topic"[Mesh] OR "Guidelines as Topic"[Mesh] OR "Guideline Adherence"[Mesh] OR "Evidence-Based Nursing"[Mesh] OR "Evidence-Based Practice"[Mesh] OR "clinical practice guidelines in nursing" OR "clinical practice guideline*" OR guideline OR "standard of practice") AND ("Catheterization, Peripheral"[Mesh] OR "Vascular Access Devices"[Mesh] OR "Peripheral Venous Catheterization"[Text Word] OR "peripheral intravenous catheter" OR "peripheral venous cannula" OR "peripheral venous device" OR pivc OR piv)
Google advanced search	clinical practice guidelines AND peripheral intravenous catheter insertion (OR maintenance)

Appendix B: Detailed search strategy for intervention review

Search syntaxes customised for each database

Database	Search syntax
CINAHL	<p>Insertion ((MH "Catheterization, Peripheral+") OR "peripheral intravenous catheter" OR "peripheral venous cannula" OR "peripheral venous device" OR (MH "Vascular Access Devices+") OR "pivc" OR "piv") AND (insert* OR placement OR ultrasound OR infrared OR expert OR (failure OR success)) AND ("randomised controlled trial" OR "randomized controlled trial" OR "clinical trial")</p> <p>Maintenance ((MH "Catheterization, Peripheral+") OR peripheral intravenous catheter OR "peripheral intravenous catheter" OR "peripheral venous device" OR (MH "Vascular Access Devices+") OR "pivc" OR "piv") AND (maintenance OR care OR "extention sets" OR "connectors" OR "antiseptic caps" OR "wipes" OR "securement" OR flushing OR dressing OR "dwell time") AND ((MH "Catheter Occlusion +") OR "occlusion" OR (MH "phlebitis+") OR phlebitis OR "dislodgement" OR failure OR "device failure" OR "device malfunction" OR (MH "Catheter-Related Bloodstream Infections") OR (MH "Catheter-Related Infections") OR infection OR "infiltration" OR "extravasation" OR "blockage" OR "leakage" OR "insertion attempts" OR "multiple cannulation attempts" OR "insertion difficulty" OR "difficult vascular access" OR "difficult intravenous access" OR "cumulative impact of multiple insertion attempts" OR "escalation") AND ("randomised controlled trial" OR "randomized controlled trial" OR "clinical trial")</p> <p>Removal ((MH "Catheterization, Peripheral+") OR "peripheral intravenous catheter" OR "peripheral intravenous catheter" OR "peripheral venous device" OR (MH "Vascular Access Devices+") OR "pivc" OR "piv") AND removal AND ((MH "phlebitis+") OR phlebitis OR (MH "Catheter-Related Bloodstream Infections") OR (MH "Catheter-Related Infections") OR infection) AND ("randomised controlled trial" OR "randomized controlled trial" OR "clinical trial")</p>
MEDLINE	<p>Insertion ((MH "Catheterization, Peripheral+") OR "peripheral intravenous catheter" OR "peripheral venous cannula" OR "peripheral venous device" OR (MH "Vascular Access Devices+") OR "pivc" OR "piv") AND (insert* OR placement OR ultrasound OR infrared OR expert OR (failure OR success)) AND ("randomised controlled trial" OR "randomized controlled trial" OR "clinical trial")</p> <p>Maintenance ((MH "Catheterization, Peripheral+") OR "peripheral intravenous catheter" OR "peripheral intravenous catheter" OR "peripheral venous device" OR (MH "Vascular Access Devices+") OR "pivc" OR "piv") AND (maintenance OR care OR "extention sets" OR "connectors" OR "antiseptic caps" OR "wipes" OR "securement" OR flushing OR dressing OR "dwell time") AND ((MH "Catheter Occlusion +") OR "occlusion" OR (MH "phlebitis+") OR phlebitis OR "dislodgement" OR failure OR "device failure" OR "device malfunction" OR (MH "Catheter-Related Bloodstream Infections") OR (MH "Catheter-Related Infections") OR infection OR "infiltration" OR "extravasation" OR "blockage" OR "leakage" OR "insertion attempts" OR "multiple cannulation attempts" OR "insertion difficulty" OR "difficult vascular access" OR "difficult intravenous</p>

access" OR "cumulative impact of multiple insertion attempts" OR "escalation") AND ("randomised controlled trial" OR "randomized controlled trial" OR "clinical trial")

Removal

((MH "Catheterization, Peripheral+") OR "peripheral intravenous catheter" OR "peripheral intravenous catheter" OR "peripheral venous device" OR (MH "Vascular Access Devices+") OR "pivc" OR "piv") AND removal AND ((MH "phlebitis+") OR phlebitis OR (MH "Catheter-Related Bloodstream Infections") OR (MH "Catheter-Related Infections") OR infection) AND ("randomised controlled trial" OR "randomized controlled trial" OR "clinical trial")

MEDLINE

Insertion

("Catheterization, Peripheral"[Mesh] AND "Vascular Access Devices"[Mesh] OR "Peripheral Venous Catheterization"[Text Word]) OR ("peripheral intravenous catheter" OR "peripheral venous cannula" OR "peripheral venous device" OR pivc OR piv) AND (insertion OR placement OR ultrasound OR infrared OR expert OR (failure OR success)) AND ("randomised controlled trial" OR "randomized controlled trial" OR "clinical trial")

Maintenance

("Catheterization, Peripheral"[Mesh] AND "Vascular Access Devices"[Mesh] OR "Peripheral Venous Catheterization"[Text Word]) OR ("peripheral intravenous catheter" OR "peripheral venous cannula" OR "peripheral venous device" OR pivc OR piv) AND AND (maintenance OR care OR "extention sets" OR "connectors" OR "antiseptic caps" OR "wipes" OR "securement" OR flushing OR dressing OR "dwell time") AND (occlusion OR phlebitis OR "dislodgement" OR failure OR "device failure" OR "device malfunction" OR infection OR infiltration OR "extravasation" OR "blockage" OR "leakage" OR "insertion attempts" OR "multiple cannulation attempts" OR "insertion difficulty" OR "difficult vascular access" OR "difficult intravenous access" OR "cumulative impact of multiple insertion attempts" OR "escalation" OR "Catheter-Related Infections"[Mesh]) AND ("randomised controlled trial" OR "randomized controlled trial" OR "clinical trial")

Removal

("Catheterization, Peripheral"[Mesh] AND "Vascular Access Devices"[Mesh] OR "Peripheral Venous Catheterization"[Text Word]) OR ("peripheral intravenous catheter" OR "peripheral venous cannula" OR "peripheral venous device" OR pivc OR piv) AND (removal) AND (phlebitis OR "Catheter-Related Infections"[Mesh]) AND ("randomised controlled trial" OR "randomized controlled trial" OR "clinical trial")

Appendix C: Table of excluded guidelines

Guideline	Country	Reason
1 Clinical Practice procedures: Access/peripheral intravenous cannulation	Queensland Health (Queensland Ambulance service)	Procedure
2 Peripheral intravenous (IV) catheter insertion for neonates (insertion)	Victorian Agency for Health Information	Procedure
3 Infection prevention in the operating room anesthesia work area	The society for Healthcare Epidemiology of America (SHEA)	Procedure/decontamination
4 Adoption and application in Italy of the principal guidelines and international recommendations on venous access	Italy	Not original review (Review of other guidelines)
5 Prevention of Intravascular Catheter-related Infection in Ireland	Ireland	Not original review (Review of other guidelines)
6 Safe vascular access	Association of Anaesthetists of Great Britain and Ireland*	Central venous catheters
7 Guideline for clinical staff on intravenous cannulation	Our Lady's Children's Hospital, Ireland	Individual hospital
8 Changing Blood Transfusion Policy and Practice	American Journal of Nursing	Individual hospital
9 Peripheral IV Catheter	Covenant Health	Individual hospital
10 Vascular access device management	South Australia	Central venous catheters
11 Ultrasound-guided vascular access: a comprehensive review	Journal of Cardiothoracic and Vascular Anesthesia	Not original review (Review of other guidelines)
12 A snapshot of guideline compliance reveals room for improvement: A survey of peripheral arterial catheter practices in Australian operating theatres	Australia	Survey on guideline compliance
13 Neonatal extravasation injury: prevention and management in Australia and New Zealand-a survey of current practice	Neonatal units in Australia and New Zealand	Survey on guideline compliance
14 Quality improvement guidelines for vascular access and closure	Division of Vascular Imaging	Tool

	device use	and Intervention, Department of Radiology, USA	
15	US-guided peripheral vascular interventions, comments on the EFSUMB guidelines	Review paper	Not original review (Review of other guidelines)
16	Decision guide on venous access devices issued	Cancer Nursing Practice	Central venous catheters
17	Intravenous access - Peripheral guideline	The Royal Children's Hospital Melbourne	Procedure
18	Peripheral Intravenous Initiation	Fraser Health	Procedure

Appendix D: Table of unavailable guidelines

Guideline			
1	NHMRC	Australia	Under review expected release date mid 2019
2	CVAA	Canada	In development expected release date 2019
3	RNAO (2004 & 2008)	Canada	Out of date
4	SA Health	Australia	In development expected release date 2019
5	CDC (2011)	USA	Next update unknown

Appendix E: Table of guideline quality assessment scores

Author	Clinical practice guideline	Domain 1 Scope and purpose (%)	Domain 2 Stakeholder development (%)	Domain 3 Rigour of development (%)	Domain 4 Clarity of presentation (%)	Domain 5 Applicability (%)	Domain 6 Editorial Independence (%)	Overall score (%)	Recommendation
Denton et al	Standards for Infusion Therapy	89	50	25	43	46	38	58	Yes with modification
Caroll et al	Peripheral intravenous catheter (PIVC) Guideline	57	29	9	53	18	2	38	No
O'Shea et al	Guiding Framework for the Education, Training and Competence Validation in Venepuncture and Peripheral Intravenous Cannulation for Nurses and Midwives (2017)	93	60	33	74	55	27	63	Yes with modification
Clinical Excellence Commission	Peripheral Intravenous Cannula (PIVC) Insertion and Post Insertion Care in Adult	94	35	14	54	6	2	38	No

Patients									
Alonso-Ortiz-del-Rio et al	Clinical Practice Guideline on Intravenous Therapy with Temporary Devices in Adults	99	67	81	89	84	75	83	Yes
Loveday et al	Epic3: national evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England	94	89	97	90	72	100	96	Yes
Kim et al	Development of Evidence-based Nursing Practice Guidelines for Peripheral Intravenous Catheter Management in Hospitalized Children and Adult	86	26	59	36	10	2	38	No
Hallam et al	Development of the UK Vessel Health and Preservation (VHP) framework: a multi-organisational collaborative	61	29	51	68	28	100	54	Yes with modification

Communicable Disease Control Directorate	Insertion and Management of Peripheral Intravenous Cannulae in Western Australian Healthcare Facilities policy	57	38	7	69	23	2	29	No
CSS-Infection Prevention	Peripheral Intravenous Cannula, Adults and Children (Not neonates)	83	31	11	53	2	0	29	No
Gorski et al	Infusion Therapy Standards of Practice	81	57	91	88	66	69	83	Yes
Valdez et al	Clinical Practice Guideline: Difficult Intravenous Access	79	35	62	79	0	0	67	Yes with modification
Chopra et al	The Michigan Appropriateness Guide for Intravenous Catheters (MAGIC): Results From a Multispecialty Panel Using the RAND/UCLA Appropriateness Method	88	89	79	88	52	100	79	Yes

Bouaziz et al	Guidelines on the use of ultrasound guidance for vascular access	96	22	54	64	11	52	67	Yes with modification
Capdevila et al	2016 Expert consensus document on prevention, diagnosis and treatment of short-term peripheral venous catheter-related infections in adults	90	22	63	71	26	96	67	Yes with modification
Gaylard et al	Peripheral Intravascular Catheters (PIVC) Insertion and Management (Adult) NT Health Services Procedure	67	28	7	53	4	0	25	No
Edwards et al	Peripheral Intravenous Cannula (PIVC) Insertion, Care and Maintenance Protocol	8	53	19	63	30	0	38	No
Thomas et al	Peripheral Intravenous device management	86	51	19	67	6	0	58	Yes with modification

Appendix F: Table of included intervention studies

Author & year	Study design	Country	Setting	Participants and sample size	Age (Mean / Median (SD/IQR))	Scope	Primary outcome Dichotomous (number of events/ number measured) Continuous (mean, standard deviation and sample number)	Additional outcomes
Auglagnier et al. ¹⁰⁰ 2014	Single center, open study, randomised clinical trial	France	Emergency department	Adults ≥ 18 years (n=266) Accuvein: n=115 Standard: n=157	Accuvein: 57 (53.5-60.9) Standard: 57 (53.8-60.1)	Insertion-Infrared	First insertion success was similar between groups AccuVein 111/115 (96.2%) and Standard 151/157(96.5%) Time to successful placement of catheters success was also similar between groups, 119 seconds (92.7-154.3) in Accuvein group	Visual analogue pain scores was 2.9 (2.51-3.24) in the standard group and 3.3(2.89-3.83) in Accuvein group (p =.11).

								and 98 seconds (85.3-113.3) in standard group ($p = .24$)
Avelar et al. ⁹⁴ 2015	A prospective, randomised controlled trial	Brazil	Paediatric surgical unit	Paediatrics (12-18) years (n=382) Ultrasound: n=188 Standard: n=194	Ultrasound: 8.2 (4.8 – 12.5) Standard: 7.2 (3.9 – 10.6)	Insertion: Ultrasound	No significant difference between groups on the first success insertion using ultrasound 161/181 (88%) or standard 78/194 (91%) ($p = .059$)	Rate of infiltration was 34/161 (21%) in ultrasound group and 23/178 (13%) ($p = .025$). Rate of phlebitis was 2/161 (<1%) in ultrasound group and 7/178 (<1%) ($p = .09$).
Bahl et al. ⁹⁵ 2016	Randomised, prospective single-site study	United States	Emergency Department	Adults \geq 18 years (n=122) Ultrasound: n=63 Standard: n=59	Ultrasound: 61 Standard: 62	Insertion: Ultrasound	Successful IV insertion was 48/63 (76%) in ultrasound guided arm and 33/59 (56%) in standard group ($p = .02$). The mean time to intravenous catheter placement was 15.8 minutes in the ultrasound guided arm and 20.7 minutes in the standard group ($p = .75$).	

Balanyuk et al. ¹¹⁰ 2018	Monocentric, randomised, open-label, clinical trial	Italy	The Radiology Division of the Hospital	Adults ≥ 18 years (n=72) Distraction: n=36 EMLA: n=36	Distraction: 61.9 (16.2) EMLA: 63 (13.25)	Insertion: pain	The average pain (numerical rating scale) in distraction group was 0.69 (1.26) and 1.86 (1.73) in EMLA group ($p < .001$).	
Bridey et al. ⁹⁶ 2018	Randomised, controlled, prospective, open-label, single centre study	France	Intensive Care Unit	Adults ≥ 18 years (n=114) Ultrasound: n= 57 Standard: n=57	Ultrasound: 65.5 (52 – 75.8) Standard: 64 (49 – 72)	Insertion: Ultrasound	Successful IV insertion was 37/56 (66%) in ultrasound group and 39/56 (70%) in the standard group	The rate of extravasation was 18/53 (34%) in the ultrasound group and 9/51 (18%) in the standard group. Patient satisfaction did not differ between groups, 8 (7-9) in ultrasound group and 8 (7-9.5) ($p = .543$).
Bugden et al. ¹¹⁹ 2016	Non-blinded, single-centre, two-armed, Superiority RCT	Australia	Emergency Department	Adults ≥ 18 years (n=369) Skin glue: n=179 Standard care: n=190	Glue: 60 Standard: 57	Securement : Glue	PIVC failure was lower in skin glue group 31/179 (17%) when compared to those in standard group 52/190 (27%) ($p = .04$).	The rate of phlebitis was 6/60 (3%) in skin glue group and 9/57(5%) in standard group.
Chick et al. ¹⁰⁶ 2017	Prospective randomised trial	USA	Outpatients requiring IR procedure	Adults (18-89) years (n=218) Guidewire:	Guidewire: 55.14 (14.5) Standard: 56.89 (15.3)	Guidewire	Success at first attempt was 84/109 (77%) in guidewire group and 89/109	Patient satisfaction was higher in standard group than guidewire group (4.5/5 and 3.9/5, $p < .001$)

				n=109 Standard: n=109			(82%) in standard group (p = .82). Time to successful cannulation was 2.9 (5.7) minutes in guidewire group compared to 2.7 (7.1) minutes in standard group (p=0.82).	
Chin et al. ¹²⁸ 2018	Randomised, non-blinded, control trial	Australia	Neonatal unit	Neonates (> 32 weeks) (n=113) Elective replacement: n = 58 Standard: n =55	Elective replacement: 36 (33-39) Standard: 35 (33-39)	Removal	Extravasation was 28/58 (48%) in elective replacement group and 33/55 (60%) in the standard group.	The rate of phlebitis was 1.3 in standard group and 2.2 in the elective replacement group.
Cook et al. ¹¹¹ 2017	Double-blind, randomized, placebo-controlled trial	USA	Level III NICU	Neonates (gestation age 28-36 weeks) (n=40) Sucrose: n=20 Placebo: n=20	Sucrose: 34.5 (3.9) Placebo: 35.7 (3.8)	Insertion: pain	Pain scores were higher in placebo group 8 (3.8) than sucrose group 6.5 (3.7). The scores 8 minutes after insertion and were similar between groups 2.7 (2.8) in sucrose group	

							and 1.7 (1.7) in placebo group ($p = .05$).	
Cozzi et al. ¹¹² 2017	Multicentre randomised controlled trial	Italy	Paediatric unit	Children (3 - 10) years (n=172) Warm lidocaine: n=172 EMLA cream: n=167	Warm lidocaine patch: 6 (4.3-9.0) EMLA cream: 6 (4.0-8.0)	Insertion: pain	First insertion success was 158/172 (92.4%) using warm lidocaine + tetracaine patch and 142/167 (85.0%) for those who used EMLA cream ($p=0.03$).	Self-reported pain scores (Wang Baker scale) >4 was 18/172 (10.5%) in warm lidocaine and 15/167 (9%) in EMLA group.
Cuper et al. ¹⁰¹ 2013	Pragmatic cluster randomised clinical trial	Netherlands	Operating room complex	Children (neonates–18) years (n=494) Near infrared: n=248 Standard: n=246	Near Infrared: 5.0 (1.8-9.8) Standard: 4.9(1.2-9.4)	Insertion-Infrared	Success at first attempt was 171/246 (70 %) in near infrared group and 175/245 (71%) in standard group. Time to successful placement of catheters was 162 (14) seconds in the near infrared group and 143 (15) seconds in standard group ($p = .26$).	

Curtis et al. ⁹⁷ 2015	Stratified, parallel-group, randomized controlled trial	Canada	Emergency Department	Children (3-16) years (n=283) Ultrasound: n=137 Standard: n=146	Ultrasound: 7.81 (5.71) Standard: 6.76 (5.41)	Insertion: Ultrasound	Successful IV insertion on first attempt between groups was 97/137 (70%) in ultrasound and 109/146 (74%) in standard group ($p = .3$).	
Degraff et al. ¹⁰² 2013	Four-armed, single-centre, pragmatic cluster randomised clinical trial	Netherlands	Operating room complex	Children (neonates–18) years (n=1383) Veinviewer: n=357 Accuvein: n=292 VascuLuminator: n=290 Standard: n=444	Veinviewer: 5 (2-10) AccuVein: 6 (2-10) VascuLuminator: or: 5 (2-10) Standard: 5 (1-10)	Insertion: Infrared	Success at first attempt were similar among groups 267/357 (74.8%) in veinviewer group, 218/292 (74.7%) in Accuvein group, 211/290 (72.8%) in VascuLuminator group and 328/444 (73.9%) in control group ($p = .94$). Mean time to successful catheterisation did not differ across study arms. It was 8.3 (15.9) for ultrasound group and 6.5 (10.3) in the	The average number of insertion attempts was 1.40 with the use of ultrasound and 1.43 using standard practice.

							standard group.	
Degraff et al. ¹⁰³ 2014	Two-armed, single-centre, pragmatic cluster randomised clinical trial	Netherlands	Department of Anaesthesia	Children (neonates–18) years (n=226) VascuLuminator: n=112 Standard: n=114	VascuLuminator: 7 (1-12) Standard: 6 (1-11)	Insertion: Infrared	Success at first attempt were similar between the two groups in VascuLuminator group 66/112 (59%) and 61/114 (54%) in standard group ($p = .41$). Time to successful placement of catheters: was 246 (120-600) seconds in VascuLuminator group and 300 (120-600) seconds in standard ($p = .54$).	Pain (FLACC/VAS) scores was similar between groups, 5 (3-8) in vasculuminator group and 6 (3-8) in standard group.
Edwards et al. ¹¹³ 2017	Randomised, double-blinded, placebo-controlled, single-centre trial	USA	Emergency Department	Adults ≥ 18 years (n=72) Vapocoolant: n=38 Placebo spray: n=34	Vapocoolant: N/A Placebo spray: N/A	Insertion: pain	Pain perception did not vary between groups 2 (0-9) in vapocoolant and 2.5 (0-10) in placebo spray ($p = .33$).	

Gonzalez et al. ⁹³ 2014	Prospective, randomised controlled trial	Spain	Medical and Surgical Wards	Adults ≥ 18 years (n=1131) Open: n=574 Closed: n=529	All study groups: 71.5 years	Maintenance Open vs closed system	Successful Insertion was higher in open system 563/574 (98%) than closed system 529/557 (94%).	Dwell time was 137.1 hours for closed PIV than open PIV (96 hours) ($p = .001$). The rate of phlebitis was 70/529 (12%) in closed PIVC system and 101/574(16.9%) in open PIVC system ($p = 0.017$).
Gopalasingam et al. ⁹⁸ 2017	Randomised controlled cross-over study	Denmark	Paediatric unit	Children < 4 years (n=50) Ultrasound: n= 25 Standard: n= 25	Total study group: 15 months (Range: 4-47 months)	Insertion: Ultrasound	<u>First attempt success rate</u> was 42/50 (84%) in ultrasound group and 30/50 (60%) in the standard group.	
Gumus et al. ¹⁰⁴ 2018	Prospective randomised controlled clinical study	Turkey	Emergency department	Children (1–10) years (n=110) Veinlite: n=56 Standard: n=54	Veinlite: 4.60 (2.74) Standard: 4.35 (2.53)	Insertion: infrared	Success at first attempt was higher in Veinlite group 52/56 (92.9%) than standard group 39/54 (72.2%) ($p<0.004$). Shorter total time of attempts per patient seen in Veinlite (49.98 ± 18.4	

							seconds) group compared with the standard group (59.68 ± 22.5 seconds) (p = 0.01).	
Gunther et al. ¹²⁰ 2016	Non-blinded, two-armed, single-centre, superiority RCT	France	Intensive Care Unit	Adults ≥ 18 years (n=2214) 3M IV advanced: n=1142 Standard care: n=1072	Experiment: N/A Control: N/A	Securement : Dressing	Post-insertion complications were similar between both dressings 330/638 (52%) in the advanced group and 307/638 (47%).	The rate of extravasation was 26(28.1%) in advanced group and 19(21.2%) in standard group.
Gupta et al. ¹¹⁴ 2013	Single-center, prospective, randomized, double-blind, placebo-controlled study	India	Surgical unit	Patients (15–60) years (n=120) EMLA: n=30 Capsaicin: n=30 EMLA+ capsaicin: n=30 Control: n=30	Experiment: EMLA: 42.6 (15.8) Capsaicin: 39.7 (13.3) EMLA+ Capsaicin 48.5 (14.3) Control: 44.5 (14.4)	Insertion: pain	Incidence of pain was lower in EMLA 9/28 (32%) compared to capsaicin 9/30 (30%) and capsaicin +EMLA 14/30 (47%).	
Idemoto et al. ¹⁰⁷ 2014	Prospective randomised clinical trial	United States	Inpatient Unit	Adult (18-89) years (n=248) Guidewire: n=123 Standard: n=	Guidewire: 62.8 (15.5) Standard: 62.2 (14.5)	Guidewire	First attempt success rate was higher using guidewire 110/123, (89%) than standard 59/125, (47%)	The rate of dislodgement was 3/123 (2%) in the guidewire group and 6/125 (5%) in standard group. The rate of phlebitis was 1/123

				125			(p<0.01). Time for successful cannulation was 4.7 minutes using guidewire and 6.8 using standard catheter. Catheter failure was 12 % in guidewire group compared to 44% in standard group.	(<1%) in the guidewire group and 11/125 (9%) in standard group. Patient satisfaction was 4.6 (0.69) in the experimental group and 3 (1.27) in the standard group (p = < .001).
Jin et al. ¹⁰⁸ 2018	Prospective randomised trial with cross-over design	United States	U.S. Army Medical Simulation Training Classroom	Combat medics (18 - 45) years (n=186) Guidewire: n=93 Standard: n=93	Guidewire: N/A Standard: N/A	Guidewire	First attempt success rate was 41/93 (44.1%) in guidewire group compared to 61/93 (66.7%) in standard group. Time taken to complete cannulation was 56.7 ± 14.8 seconds using the standard catheter and 98.4 ± 37.4 seconds using guidewire cannulation.	

Keogh et al. ¹²³ 2016	Single-centre, pilot, non-masked, factorial randomised controlled trial	Australia	Medical and Surgical Wards	Adults ≥ 18 years (n=160) 3ml Flush volume: n=80 10ml Flush volume: n=80	Flush Volume: 3mL – 63 (22) 10mL – 64 (30) Flush Frequency: 24h – 63 (26) 6h – 64 (23)	Maintenance: Flushing	Device Failure Volume was higher in 10 ml group (44/80 (55%)) than 3 mL (29/80 (36%)). Frequency PIVC failure rates per 1000 hours were 32/79 (40%) for 24 hours and 41/81 (50%) for 6 hours.	Phlebitis was observed 7/80 (9) in 3ml group and 15/80 (19). Phlebitis was observed in 8(10) in 24-hour group and 14(17) in 6 h group. Device dwell time was 2.23 (1.46-4.32) in 3ml group and 2.73 (1.71-3.98). Phlebitis was observed in 2.83(1.65-4.25) in 24-hour group and 2.26 (1.67-3.58) in 6 h group
Mace et al. ¹¹⁵ 2017	Prospective, double blind, randomised, controlled trial	USA	Emergency Department	Adults (18–80) years (n=300) Vapocoolant: n=150 Placebo spray: n=150	Vapocoolant: 43(16.6) Placebo spray: 42.7 (16.6)	Insertion: pain	Pain during PIV insertion was 2 (0-4) using vapocoolant and 4 (2-7) using a placebo spray (p<0.001).	
Marsh et al. ¹²² 2015	Non-blinded, four-armed, single-centre, pilot RCT	Australia	General Medical and Surgical Wards	Adults ≥ 18 years (n=85) Standard polyurethane dressing: n=21 Tissue adhesive: n=21 Bordered polyurethane dressing: n=20	Tissue Adhesive: 60 (47-72) bordered polyurethane: 56 (42-70) sutureless securement device: 61 (44-74) standard polyurethane dressing: 65 (53-76)	Securement : Dressing, adhesive, devices	Catheter failure was lowest in tissue adhesive, 3/21 (14%) followed by Bordered polyurethane dressing 5/20 (25%) and suture-less securement device 5/23 (25%) and	Patient satisfaction was 8 (5-9) in standard polyurethane dressing group, 9 (8-10) in bordered polyurethane group, 8.5 (7-10) in sutureless securement device group and 10 (9-10) in tissue adhesive group.

				Suture-less Securement device: n= 23			highest in Standard polyurethane dressing 8/21 (38%).	
Marsh et al. ¹²¹ 2018	Non-blinded, two-armed, single-centre, pilot RCT	Australia	Medical and Surgical Wards	Adults ≥ 18 years (n=300) Bordered polyurethane dressing: n=150 Integrated securement device: n=150	Bordered polyurethane dressing: 62.3 (18.6) Integrated securement device: 60.4 (17.1)	Securement : Dressing	PIVC failure occurred in 40/150 (27%) patients who used bordered polyurethane dressing and 43/150 (29%) who used integrated securement device.	Dwell time was 57.9 (40.5) in the control group and 68.8 (50.7) in experimental group. The rate of phlebitis 9(6) in the control group and 6(5) in experimental group. Patient satisfaction was similar between two groups 9 (8-10).
Marsh et al. ⁹² 2018	Non-blinded, two-armed, single-centre, parallel-group pilot RCT	Australia	General medical and Surgical wards	Adults ≥ 18 years (n=119) Expert: n=69 Generalist: n= 50	Expert: 64.0 (47.0 – 73.0) Generalist: 62.0 (47.0 – 71.0)	Insertion: Inserter expertise	Successful insertion were similar between expert 33/69 (54%) and generalist 27/50 (48%) The average number of insertion attempts was 1.22 by expert and 1.74 by generalist.	The rate of phlebitis was 19/69 (28%) in the expert group and 10/50 (20%) in generalist group. The rate of infiltration was 13/69 (19%) in the expert group and 9/50 (18%) in generalist group. Patient satisfaction was 7 (6-9) in the expert group and 4.5 (1.5-6) in the generalist group.

McCarthy et al. ⁹⁹ 2016	Non-blinded, two-armed, single-centre, Parallel group RCT	United States	Emergency Department	Adults ≥ 18 years (n=1189) Ultrasound: n= 605 Standard: n= 584	Total study group: 45.4 mean years	Insertion: Ultrasound	First attempt success rate was higher using ultrasound for difficult (81.6% vs 31.5) and moderately difficult veins (81.2% vs 71.4%). However, landmark had a higher first attempt success rate for easier access veins (96.6% vs 85.9%)	The rate of infiltration was less than 5% across all groups.
Redfern et al. ¹¹⁶ 2018	Prospective randomised controlled trial	USA	Orthopaedic unit	Adults ≥ 18 years (n=105) Buzzy: n= 49 Standard: n=56	Buzzy: 63.86 (11.6) Standard: 62.82 (11)	Insertion	No difference in pain score between groups 2.52(0.37) in buzzy group and 2.43 (0.36) in standard group (p=0.86).	Patient satisfaction was strong in 30 (61.2) in the buzzy and 39 (69.6) in control group.
Rickard et al. ¹⁰ 2018	Non-blinded, four-armed, single-centre, parallel	Australia	Medical and Surgical Department	Adults ≥ 18 years (n=1807) Standard polyurethane	Tissue Adhesive: 59 (45-71) Bordered polyurethane:	Securement : Dressing, adhesive, devices	All-cause PIVC failure was 163/427 (38%) in tissue adhesive group	Phlebitis per 1000 was 108/427 (25%) in tissue adhesive group (p = .66), 94/423 (22%) in bordered polyurethane

	group, superiority RCT			<p>dressing: n=454</p> <p>Tissue adhesive: n=446</p> <p>Bordered polyurethane dressing: n=454</p> <p>Suture-less Securement device: n=453</p>	<p>61 (44-72)</p> <p>Securement device: 61 (44-74)</p> <p>Standard polyurethane dressing: 61 (48-72)</p>		<p>(p=0.19), 169/423 (40%) in bordered polyurethane group (p=0.44), 176/425 (41%) Securement device (p=0.73) and 180/422 (43%) in Standard polyurethane dressing group.</p>	<p>group (p = .33), 109/425 (26%), securement device (p = .42) and 112/422 (27%) in standard polyurethane dressing group. Patient satisfaction was 9 (8-10) in both tissue adhesive group, and bordered polyurethane groups, 8 (7-10) in both sutureless securement device and in standard polyurethane groups.</p>
Schmitz et al. ¹¹⁷ 2016	A Phase III, Randomised, double-blinded, placebo-controlled	USA	Paediatric unit	<p>Children (3 - 18) years (n=535)</p> <p>Active system: n=269</p> <p>Sham placebo: n=266</p>	<p>Active system: 11 (3-18)</p> <p>Sham placebo: 11 (3-18)</p>	Insertion – pain	<p>Pain FACES score was reduced in active system group 1.28 (0.09) than the Sham placebo group 1.67 (0.09) (p=0.002).</p>	
Schreiber et al. ¹²⁴ 2015	Non-blinded, two-armed, single-centre, non-inferiority RCT	Italy	Paediatric unit	<p>Children (1 – 17) years (n=400)</p> <p>Flushing (12hours): n=198</p> <p>Flushing (24hours): n=199</p>	<p>Flushing (12 hours): 7.8 (5.0)</p> <p>Flushing (24 hours): 7.8 (5.0)</p>	Maintenance: Flushing	<p>Device Failure was 19/199 (9.5%) for flushing every 12 hours group compared to 24/198 (12%) for flushing once a</p>	<p>Occlusion was observed in 15(7.6) for 2 hours group and 9 (4.5) for 24 hours group. Extravasation was observed in 6 (3.0) for 2 hours group and 4 (4.5) for 24 hours group.</p>

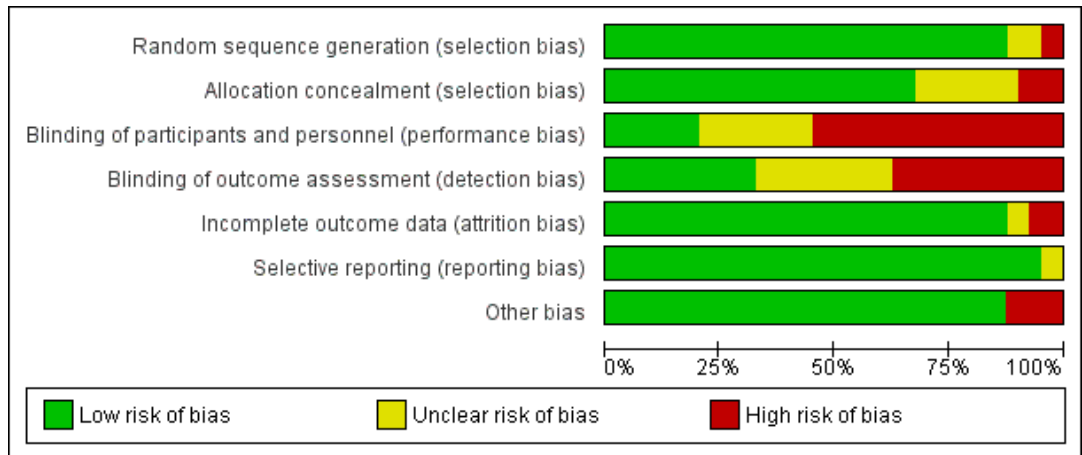
							day.	
Stoltz et al. ¹⁴² 2017	Prospective, randomized trial	USA	Peri-anesthesia care unit	Children (8 to 18) years (n=150) J Tip (needless lidocaine): n=75 EMLA: n=75	J Tip (needless lidocaine): 13.95 (1.59) EMLA cream: 13.77 (1.87)	Insertion: pain	Procedural pain scores were lower in EMLA group 1.63 (1.65) than J Tip 2.99(2.58) ($p < .001$).	
Tan et al. ¹⁰⁹ 2016	Non-blinded, randomised controlled trial	Malaysia	Obstetric Unit	Adults \geq 18 years (n=307) Hand dorsum: n=165 Forearm: n=142	Hand Dorsum: 29.8 (3.8) Forearm: 29.7 (3.8)	Insertion site	Successful first catheterisation was higher in the hand dorsum 144/154 (93.5%) compared to forearm: 133/153 (86.9%) ($p = .05$).	Mean pain VNRS (visual numerical rating score) was higher in the hand dorsum 4.4 (2.1) than the forearm 4.2 (2.1).
Upadhyay et al. ¹²⁵ 2015	Double-blinded, randomised controlled trial	India	Neonatal intensive care unit	Neonates(> 32 weeks) (n=120) Heparin: n=53 Normal saline: n=53	Heparin: 5.74 (2.5) Saline: 4.6 (3.1)	Maintenance-flushing	Mean functional duration was more in heparin group 71.68 (27.3) than normal saline group 57.7 (23.6).	The rate of occlusion was (77.3% versus 71.7%). The rate of phlebitis was (28% versus 22 %).
Van der woude et al. ¹⁰⁵ 2013	Pragmatic cluster randomized clinical trial	Netherlands	Emergency department	Children (neonates–15) years (n=88) Vasculuminat	Vasculuminat or: 2.7 (1.4-6.2) Standard: 2.9 (1.2-5.1)	Insertion: infrared	Success at first attempt was 27/43 (63%) in Vasculuminator group and 23/45	

				or: n=43 Standard: n=45			(51%) in standard group ($p = .27$). Time to successful placement of catheters was 53 (34-154) seconds in VascuLuminator group 68 (40-159) seconds in standard group ($p = .54$).	
Vendramim* et al. ¹²⁹ 2018 <i>Data from secondary source from Webster et al. 2018 review</i>	Multicentre, non-inferiority trial	Brazil	Intensive care units	Adults \geq 18 years (n=1319) Removal in 3 days: n = 672 Clinically indicated replacement: n=647	Experiment: 59.7 (20.9) Control: 59.9 (20.1)	Removal	Phlebitis: was 55/672 (8%) removal in 3 days group and 64/647 (9%) in the clinically indicated replacement group.	
Wang et al. ¹²⁶ 2017	Single blinded randomised controlled trial	China	Medical unit	Adults \geq 18 years (n=68) Heparin: n=36 Normal saline: n =32	Heparin: 47.4 (13.9) Saline: 51.1 (10.3)	Maintenance-flushing and locking	Mean maintenance duration for the Heparin group was 80.27 (26.47) and 84.19 (29.3) for saline group.	The rate of phlebitis was 1/36 (1.5) in heparin group and 2/32 (1.6) in normal saline solution. The rate of blood stream infection was 1 (1.5) in heparin group and 1 (0.8) in normal saline solution.

Xu et al. ¹²⁷ 2017	Open label randomised controlled trial	China	Surgical wards	Adults ≥ 18 years (n=286) Heparin: n=140 Normal saline: n = 146	Heparin: 52.3 (18.9) Saline: 55.6 (19.5)	Maintenanc e-flushing	Maintenance duration was 44/292 (15%) in heparin group and 59/317 (18%) in saline group.	The rate of phlebitis was 37(11.67) in the normal solution and 43 (14.73). The rate of infiltration was 94 (29.65) and 80 (27.40).
Xu et al. ¹³⁰ 2017	Non-blinded cluster- randomised trial	China	Internal medicine wards and surgery wards	Adults ≥ 18 years (n=1198) Removal in 3 days: n= 553 Clinically indicated replacement: n=645	Elective re: 58.67 (39.73) Control: 56.15 (27.14)	Removal	Phlebitis was 76/553 (13%) in the removal in 3 days group and 77/645 (12%) in the clinically indicated replacement.	The rate of occlusion was 82/477 (14.8%) and 81/645 (12.6%). In dwell time was 96 h (2- 491 hours) and 48 h (2- 216 hours).

Appendix G: Quality appraisal of intervention studies (Risk of bias graph and summary)

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Aulagnier 2014	+	+	+	+	+	+	+
Avelar 2015	+	+	?	?	+	+	+
Bahl 2016	+	+	+	+	+	+	+
Balanyuk 2018	+	+	+	+	+	+	+
Bridey 2018	+	?	+	+	+	+	+
Bugden 2016	+	?	+	+	?	+	+
Chick 2017	+	?	?	?	+	+	+
Chin 2018	+	+	+	+	+	+	+
Cook 2017	+	+	+	+	+	+	+
Cozzi 2017	+	?	?	?	+	+	+
Cuper 2013	+	+	?	?	+	+	+
Curtis 2015	+	+	+	+	+	+	+
De graff 2013	+	+	?	?	+	+	+
De graff 2014	+	+	?	?	+	+	+
Edwards 2017	?	+	+	+	+	+	+
Gonzalez 2014	+	?	+	+	+	+	+
Gopalasingam 2017	+	+	?	?	+	+	+
Gumus 2018	?	?	?	?	+	+	+
Gunther 2016	+	+	+	+	+	+	+
Gupta 2013	+	+	+	+	?	+	+
Idemato 2014	+	+	?	+	+	?	+
Jin 2018	+	?	+	+	+	?	+
Keogh 2016	+	+	+	+	+	+	+
Mace 2017	+	+	?	?	+	+	+
Marsh_pilot 2018	+	+	+	+	+	+	+
Marsh 2015	+	+	+	+	+	+	+
Marsh 2018	+	+	+	+	+	+	+
McCarthy 2016	+	+	+	+	+	+	+
Redfern 2018	+	+	+	+	+	+	+
Rickard 2018	+	+	+	+	+	+	+
Schmitz 2016	+	+	?	?	+	+	+
Schreiber 2015	?	+	+	+	+	+	+
Stoltz 2017	+	?	+	+	+	+	+
Tan 2016	+	+	+	+	+	+	+
Upadhy 2015	+	+	+	+	+	+	+
Van der woude 2013	+	+	?	?	+	+	+
Vendramim 2018	+	+	+	+	+	+	+
Wang 2015	+	+	+	+	+	+	+
Xu_ 2017	+	?	+	+	+	+	+
Xu 2017	+	?	?	?	+	+	+



AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Level 5, 255 Elizabeth Street, Sydney NSW 2000
GPO Box 5480, Sydney NSW 2001

Phone: (02) 9126 3600

Fax: (02) 9126 3613

Email: mail@safetyandquality.gov.au

Website: www.safetyandquality.gov.au