

Development and validation of a care bundle for PICC and midline catheter management: a literature-based approach and clinical usability evaluation

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ABSTRACT

Introduction: Standardizing the maintenance of peripherally inserted central catheters (PICC) and midline catheters is essential to reducing preventable complications. Care bundles have proven effective in promoting adherence to evidence-based practices, but no specific maintenance bundle for these devices currently exists.

Methods: A targeted literature search (2000-2026) was conducted in MEDLINE/PubMed to identify primary studies on maintenance interventions for PICC and midline catheters, including securement, dressing, disinfection, flushing, and education. Based on the evidence extracted, an eight-step maintenance bundle was developed. A focus group validated the content, and 80 nurses evaluated its clarity and applicability through a structured questionnaire.

The study was designed as a practice development initiative, focusing on the translation of available evidence into a standardized maintenance tool and on the evaluation of its clinical usability in routine nursing practice.

Results: The literature review identified 14 relevant studies, most of which described reductions in infectious and mechanical complications following the implementation of structured catheter maintenance interventions. In the usability evaluation, nurses consistently rated the bundle as clear and applicable in daily clinical practice. The bundle was perceived as a useful tool for standardizing PICC and midline maintenance procedures.

Conclusions: The proposed PICC–Midline bundle, built on current evidence and validated by clinical users, offers a practical tool for improving standardization and patient safety in vascular access management. Its implementation could help reduce variability, enhance adherence to best practices, and support hospital decision-making on equipment procurement. Future studies should explore its clinical and organizational impact.

Keywords: Care bundle, Central venous catheter, Management, Midline Catheter, PICC

Introduction

The concept of the bundle emerged in the early 2000s within the Institute for Healthcare Improvement (IHI) as a practical tool to enhance patient safety through the consistent and standardized application of a few essential, evidence-based recommendations (1). A bundle is not a mini guideline or a checklist: it is a small, well-defined group of interventions that must all be applied to every patient, every time, following an “all-or-nothing” logic. It is precisely this

complete and systematic implementation that determines its impact on clinical risk.

The first demonstration of the bundle’s effectiveness came from intensive care units, through the seminal work of Pronovost and colleagues, who reported a marked reduction in central line–associated bloodstream infections (CLABSI) after introducing a dedicated bundle (2). Since then, bundles have been adopted in many clinical areas as quality improvement tools, as they make guideline recommendations operational.

The bundle approach aligns with the patient safety goals promoted by the “targeting zero” philosophy—an approach that, while recognizing the theoretical impossibility of eliminating all risk, aims to reduce preventable complications until they become statistically negligible. This philosophy underpins both IHI programs and the Centers for Disease Control and Prevention (CDC) recommendations, which emphasize the importance of completely preventing avoidable infections (3). The Italian GAVeCeLT movement has also contributed to spreading

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the bundle concept in vascular safety, promoting structured initiatives such as *Targeting Zero*, with the goal of minimizing complications related to central venous devices (4).

In recent years, focus has shifted from the insertion phase to catheter maintenance, especially for peripherally inserted central catheters (PICCs) and midlines, with indications for dressing type, use of securement devices, site care, disinfection, adherence to protocols, and periodic audits—all of which are just as important as the insertion procedure in preventing infectious and mechanical complications (6,8,9).

At the same time, organizational and process standardization have emerged as key factors. Expert consensus statements, such as those from GAVeCeLT, highlight the importance of structured pathways for managing central venous devices in critical care settings (7). Experiences during the COVID-19 pandemic further confirmed the value of rigorous, standardized, and safe vascular access management to reduce risks for both patients and healthcare workers (5). Recent data also reinforce the role of daily management in outcomes such as catheter dwell time and infection risk (10,11).

Altogether, this evidence makes it clear that complication prevention cannot rely on isolated actions but requires an integrated, reproducible, and shared strategy. From this awareness arises the need to develop a maintenance bundle for PICCs and midlines, based on the best available evidence and designed to standardize often heterogeneous clinical practices, in order to reduce care variability, enhance safety, improve clinical effectiveness, and support the “targeting zero” objective for preventable complications.

The main aim of this study was to develop an easy-to-use, practical, and intuitive eight-step care bundle for central venous catheter (CVc) dressings. It combines simple but strong evidence-based recommendations—easy to remember and apply—effective only when consistently and consciously implemented by all healthcare professionals for every patient.

The bundle was developed drawing inspiration from the Institute for Healthcare Improvement (IHI) Model for Improvement (2001), created by Associates in Process Improvement.

The model consists of two key components (Fig. 1):

1. Three fundamental questions that can be addressed in any order.
2. The Plan–Do–Study–Act (PDSA) cycle, used to test changes in real working environments.

The PDSA cycle guides the testing of a modification to determine whether it represents an actual improvement.

Setting the measures

The protocol recommends using quantitative measures to verify whether a specific change leads to measurable improvement. Alongside the bundle, a short questionnaire was distributed to collect feedback on its ease of application in clinical practice.

Selecting the changes

Ideas for change often emerge from professionals working directly within the system. The concept for this bundle

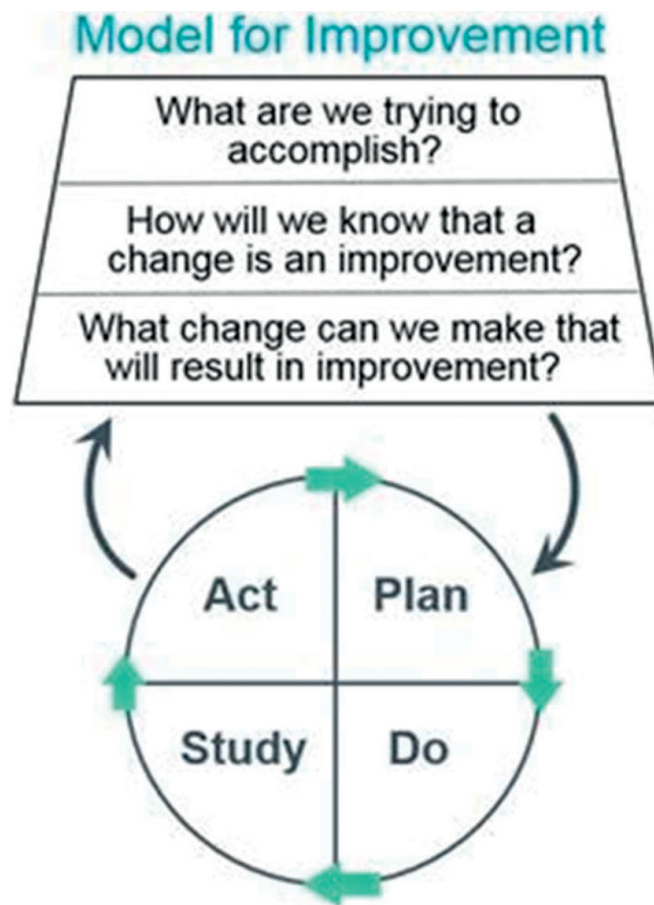


FIGURE 1 - The PDSA cycle used as a framework for the development and testing of the PICC–Midline maintenance bundle (IHI).

arose precisely from daily clinical experience, with the aim of promoting consistency in care processes.

Testing the changes

The PDSA cycle was applied to test modifications in real clinical settings—by planning, implementing, observing the results, and acting based on what was learned. This method represents the scientific approach adapted for action-oriented learning and continuous improvement.

Materials and methods

Literature review

A structured targeted literature review was conducted to identify the best available evidence on the maintenance of PICCs and midline catheters, with particular focus on interventions relevant to the development of a care bundle, including securement, dressing, disinfection, flushing, auditing, and training.

The search was performed in the MEDLINE database (via PubMed) without initial time restrictions to ensure maximum sensitivity. The final selection included studies published between 2000 and 2025.

Relevant MeSH terms and keywords were combined using Boolean operators, including: “Peripherally Inserted Central Catheter” and “PICC”; “Midline catheter”; “Central Venous Access Devices”; “Maintenance bundle” and “care bundle”; “Dressing”, “securement device”, “tissue adhesive”, and “CHG dressing”; “Catheter-related bloodstream infection”, “CLABSI”, and “CRBSI”. The complete search strategy is reported in Table 1.

To ensure completeness, manual citation chaining was performed on included articles and their reference lists. Additional academic sources were reviewed to identify relevant primary studies. All retrieved articles were verified using DOI and PubMed identifiers.

Based on the evidence extracted from the literature, key recommendations were synthesized to develop the maintenance bundle. Focus groups were subsequently conducted in several hospitals within a local health authority to support bundle refinement. Once finalized, the bundle was presented to 80 nurses working in medical and surgical wards to evaluate its clarity and applicability in daily clinical practice.

Inclusion and exclusion criteria

Studies were eligible for inclusion if they met the following criteria: primary studies, including randomized controlled trials, prospective or retrospective observational studies, comparative studies, and quality improvement projects; adult populations with PICC or midline catheters; maintenance-related interventions applicable to a bundle approach (securement, dressing, tissue adhesive, CHG, flushing, or auditing); reported infectious outcomes (CLABSI/CRBSI) and/or mechanical complications (dislodgement, occlusion, or catheter failure); and publication in English or Italian.

Studies were excluded if they focused on centrally inserted CVCTs or dialysis catheters; addressed insertion procedures only; involved exclusively pediatric populations; consisted of reviews, editorials, or consensus documents without primary data; or were available only as conference abstracts or without accessible full texts.

Screening and data extraction

Two independent reviewers removed duplicates, screened titles and abstracts, assessed full texts for eligibility, and extracted data using a standardized data collection form. Discrepancies were resolved through discussion and consensus with a third reviewer. The study selection process is summarized in the PRISMA flow diagram (Fig. 2).

Data synthesis

Given the heterogeneity of study designs, interventions, and reported outcomes, a meta-analysis was not performed. Evidence was synthesized descriptively to inform the development of the maintenance bundle.

Usability evaluation

In addition to the literature review, a custom-designed questionnaire (Annex 1) was administered to 80 nurses from different Italian hospitals. Before completing the questionnaire,

participants were presented with a prototype of the maintenance bundle developed based on the evidence identified in the literature. The questionnaire was used to explore clarity, applicability, and perceived usefulness of the bundle in routine clinical practice.

TABLE 1 - Search strategies and number of records retrieved from MEDLINE (PubMed)

Search strategy	Database	Items found
“Peripherally Inserted Central Catheter”[MeSH] OR “PICC” AND “maintenance” AND “bundle”	PubMed	124
“Midline catheter” AND “care bundle” OR “maintenance bundle”	PubMed	56
“Central Venous Access Devices” AND “maintenance” AND (“dressing” OR “securement” OR “tissue adhesive”)	PubMed	83
“Catheter-related bloodstream infection” AND “prevention” AND “bundle”	PubMed	100

Results

The flow chart summarizes the process of study identification and selection. A total of 363 records were retrieved through the MEDLINE database search. After duplicate removal, titles and abstracts were screened, followed by full-text assessment. Data were extracted using standardized tables.

Of the retrieved records, 60 articles were excluded as duplicates and 254 were excluded after title and abstract screening because they were not relevant. Thirty-five articles were excluded after full-text review due to one or more of the following reasons: pediatric population, language other than English or Italian, interventions not related to PICC or midline maintenance, non-primary publications (editorials, protocols, conference abstracts), or non-relevant outcomes. In total, 14 studies were included in the final analysis.

Most of the included studies were conducted in the United States, followed by Canada, Australia, the United Kingdom, and Italy, as shown in the table of included studies. The selected literature mainly addressed structured catheter maintenance interventions and reported reductions in infectious and mechanical complications associated with standardized practices.

All participants completed the questionnaire, resulting in a response rate of 100%. Respondents consistently rated the bundle as clear, practical, and applicable in routine clinical settings. The bundle was described as useful for standardizing CVCT dressing procedures and as a supportive tool for daily practice, including for newly hired staff. Participants also reported that the bundle helped summarize essential steps required for correct dressing performance. The complete bundle is presented in Annex 2.

The questionnaire results identified several organizational and knowledge-related issues in current catheter maintenance practices. Limited familiarity with the bundle concept was reported by 55% of participants, while 25% reported not being aware of all the recommended supplies. In addition,

32.5% of nurses reported that not all materials described in the bundle were consistently available in their unit.

Despite these limitations, all respondents stated that the bundle was applicable in practice and perceived it as a useful guide for vascular access management. The absence of a dedicated central line dressing trolley was reported by 57.5% of participants, although 92.5% confirmed the presence of patients with central venous access devices in their unit. Detailed questionnaire results are presented in Table 2.

Overall, these results describe current maintenance practices, perceived usability of the proposed bundle, and organizational constraints related to PICC and midline catheter management.

Discussion and conclusions

This project combined evidence synthesis and clinical usability evaluation to support the development of a standardized maintenance bundle for PICC and midline catheters. Rather than assessing clinical outcomes, the study focused on translating available evidence into a practical tool and on exploring its applicability, perceived usefulness, and organizational impact in daily nursing practice.

The usability evaluation highlighted relevant gaps in both knowledge and organization. More than half of participating nurses reported limited familiarity with the bundle concept, and a substantial proportion were not fully aware of all recommended materials. These findings may reflect the disruption of educational activities during the COVID-19 pandemic, which reduced opportunities for training and limited the dissemination of guideline-based practices, including those related to vascular access management. In this context, structured tools such as care bundles may help support consistency of practice, particularly in settings characterized by staff turnover or limited access to formal education.

Organizational constraints also emerged as a key issue. The inconsistent availability of recommended supplies and the absence of dedicated dressing trolleys in several units represent potential barriers to adherence to best practices. These

findings suggest that variability in catheter maintenance is influenced not only by professional knowledge, but also by systemic and logistical factors. By clearly defining essential materials and steps, the proposed bundle may serve as a reference tool to support alignment between clinical practice and organizational processes, including procurement policies.

Despite these educational and organizational limitations, the bundle was unanimously perceived as clear, applicable, and useful in routine practice. Participants described it as a practical support for standardizing dressing procedures and reducing uncertainty during catheter maintenance, including for newly hired staff. This perception indicates that the strength of the bundle lies in its ability to consolidate existing recommendations into a concise, accessible format that can be readily adopted across different clinical settings.

If implemented within an appropriate organizational framework, the proposed bundle could contribute to reducing variability in PICC and midline maintenance practices and to promoting a shared approach among healthcare professionals involved in vascular access management. Multidisciplinary collaboration, supported by ongoing education, would be essential to sustain its implementation and ensure consistency with evolving evidence and guidelines.

Standardizing professionals' behaviors through the use of the bundle is necessary to achieve performance objectives that include zero targeting for catheter-related infections. Indeed, a recent literature review with meta-analysis shows that the mortality odds ratios for CLABSI and CRBSI, compared to uninfected patients, are 3.19 (95% CI: 2.44, 4.16; $I^2 = 49\%$) and 2.47 (95% CI: 1.51, 4.02; $I^2 = 82\%$), respectively. Catheter-related infections also lead to increased mean length of stay compared to uninfected patients (17).

The implementation of our bundle, which aims to reduce catheter-related infections, certainly finds application also in the nephrology and dialysis contexts, considering that the tunneled CVCt represents, after the arteriovenous fistula, the most frequently used vascular access in hemodialysis patients. The latest official data report a prevalence of 18.4% of the population (18).

TABLE 2 - Results of the questionnaire assessing nurses' familiarity with bundle concepts, availability of materials, and perceived usefulness of the PICC–Midline maintenance bundle

Request	Question regarding the vascular access management bundle	YES	NO	Response rate	% Response Yes
1	Are there patients with central venous access in your unit?	74	6	100%	92.5%
2	Do you have a dedicated trolley for CVCt dressings?	34	46	100%	42.5%
3	Were you already familiar with the concept of bundles?	36	44	100%	45.0%
4	Were you already familiar with all the supplies recommended in the bundle for central line dressing?	60	20	100%	75.0%
5	Were you already familiar with all the steps and procedures described in the bundle for central line dressing?	74	6	100%	92.5%
6	Are all the required supplies available in your unit?	54	26	100%	67.5%
7	Do you find it useful to have a descriptive bundle outlining all the dressing steps, to simplify the procedure and avoid uncertainty?	80	0	100%	100.0%
8	Do you believe the bundle can be an effective tool for managing central venous devices and preventing incorrect practices?	80	0	100%	100.0%

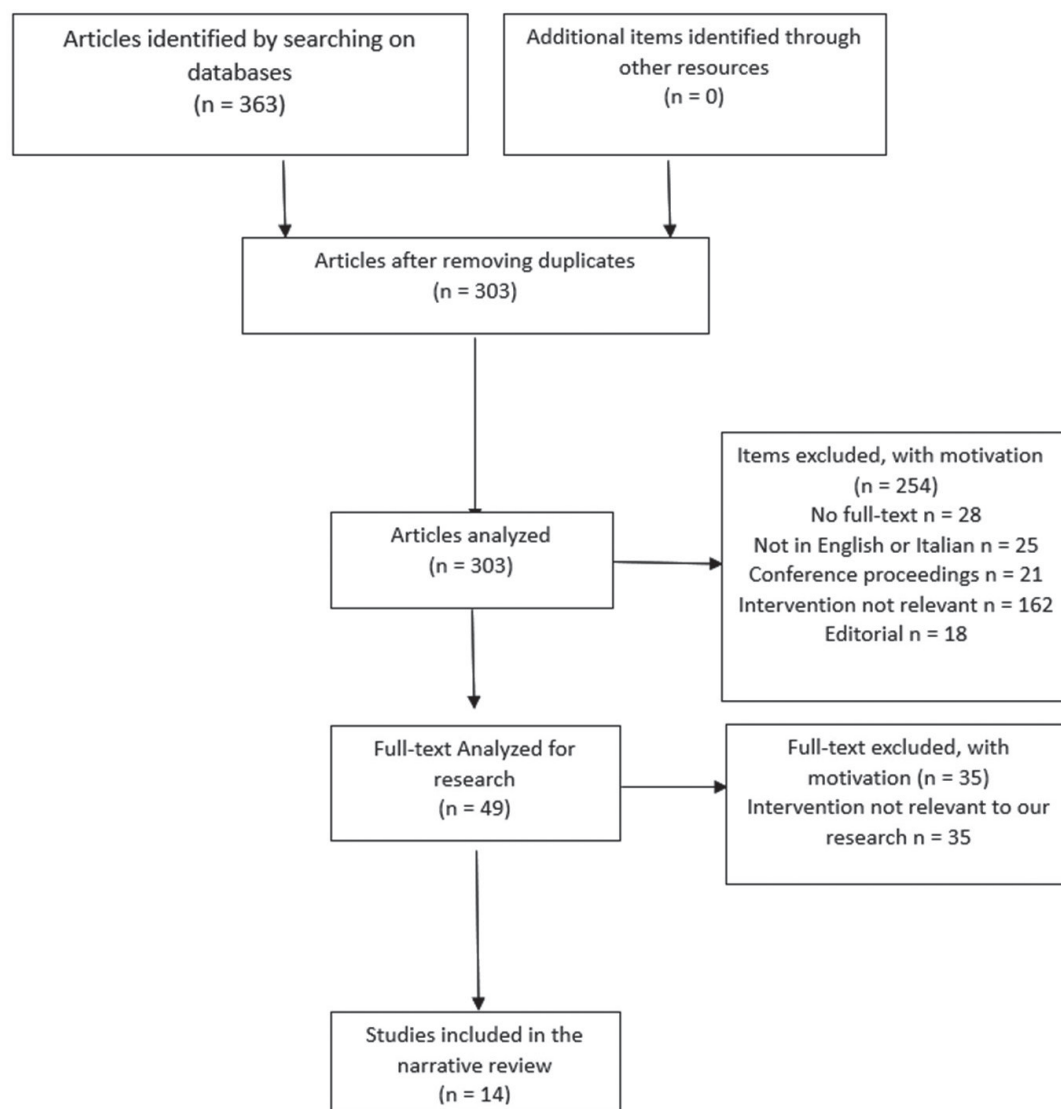


FIGURE 2 - Flow diagram of the literature search and study selection process.

The Vascular Access Project Group of the Italian Society of Nephrology also highlighted how the cost of a CRBSI in Italy ranges from €4,080 to €14,800, with an average cost of €5,575 (19), while other studies in other countries show even higher costs, which can fluctuate between \$17,000 to \$32,000 (20), with an average cost of a hospital stay for a CRBSI being \$23,451 (21).

In conclusion, this study highlights persistent gaps in resource availability and professional training related to CVCT care, while also demonstrating a high level of acceptance of the proposed bundle. The findings suggest that an evidence-informed, clinically usable maintenance bundle may represent a valuable practice development tool to support standardization, improve procedural consistency, and enhance patient safety. Further studies are needed to evaluate the organizational, economic, and clinical impact of bundle implementation over time, including assessments at 3, 6, and 12 months, with specific attention

to cost-effectiveness, workflow organization, and patient-related clinical outcomes directly related to catheter safety (catheter-related infections and mechanical complications, such as occlusion, thrombosis, dislodgement, catheter failure, or unplanned catheter removal).

Limitations of the study

The study has some methodological limitations, such as the single-center nature of the survey, potential peer courtesy bias, and selection bias resulting from using a single database for the initial review.

Disclosures

Conflict of interest: The authors declare no conflict of interest.

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