Implementing an evidence-based, standardized care bundle to enhance patient safety and quality of Safe Intravascular Access Device care management - (Safe-IVAD - project)

Safe Intravascular Access Device (Safe-IVAD) - Bridging the gap to enhance patient safety

Research Plan

Implementing an evidence based, standardized care bundle to improve the patient safety and quality of care for Intravascular Access Devices (IVADs) Management: A mixed-methods implementation intervention embedded within a process evaluation framework.

Summary

This larger project aims to develop, test and implement evidence-based practices to improve the quality of IVAD care to prevent complications such as, thrombophlebitis, dislodgement and extravasation/infiltration, at Sahlgrenska University Hospital/Mölndal. These complications can delay or interrupt treatment, prolong length of hospital stay, increase costs and patients suffering, and in the worst case, mortality. In a previous study conducted by our Safe Hands research group, we found varied success in IVADs best practices. In 44-88% of cases, the nurses or anesthesiologists contaminated the IVAD or the insertion site, prior to insertion and hand disinfection before IVAD insertion varied between 21-64% of cases. Further findings from our quality improvement monitoring showed multiple unnecessary peripheral intravascular catheters (PIVCs), multiple insertion attempts, thrombophlebitis, dislodgment, and infiltration/extravasation. These findings will be the foundation of co-designed standardized best practices and e-learning activities (care bundles), to be implemented to prevent IVAD-related complications. This also involves validating a difficult vein access assessment tool, which serves as a critical step to avoid multiple insertion attempts and to ensure timely insertion of appropriate type of IVAD. A multidisciplinary team consisting of researchers, nurses, anesthesiologists, safety and care-developers, and development leaders will participate in this implementation project. Two hospitals will participate, one intervention hospital (I-hospital) and one control (C-hospital). The outcomes include evaluating changes in the quality of IVADs care and staff knowledge. It also includes a process evaluation which will contribute to new knowledge on barriers and enablers to improve safe IVAD-care for patients. This knowledge can guide decision- and policymakers when promoting safer care.

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Background

Patients in the hospital rely on the safe and timely insertion of Intravascular Access Devices (IVADs) to obtain access to the bloodstream for the administration of medications, blood sampling, dialysis, interventional procedures, and continuous monitoring. The most used IVAD are peripheral intravenous catheters (PIVC). More than 70% of patients have at least one PIVCs during hospital stay. Other commonly used catheters are central vein catheters (CVC), midline and arterial catheters. Although IVADs are essential for patient care, they are associated with various complications, such as dislodgment, infiltration/extravasation, thrombophlebitis (vascular inflammation and/or thrombosis), bacteremia, and sepsis (1-5). These complications can delay or interrupt treatment, increase patient suffering, morbidity, mortality, length of hospital stay and costs. However, a systematic registration of these complications is lacking, so the extent of the problems remains unknown (6, 7).

The recommendations to prevent these complications include for example: education, indication, hand disinfection and aseptic techniques for insertion and management, prompt removal and skill assessment (6, 8, 9). Findings from one of our previous study at the intervention-hospital (I-hospital), showed low and varied adherence to hand disinfection before IVADs insertion (21-64%) and frequent failure in aseptic techniques (44-88%) (10). Pre-monitoring of the quality of IVADs showed high incidence of thrombophlebitis, dislocated catheters, infiltration and extravasation, contaminated dressings, unnecessary PIVCs, and inadequate documentation This non–evidence-based practice is of significant concern, as it can increase the risk of skin pathogens, such as Staphylococcus aureus, entering the bloodstream via the catheter or insertion site (11). In particular, sepsis is associated with increased mortality (11) and substantially higher healthcare costs (12). However, sepsis is a relatively rare event compared with thrombophlebitis and infiltration or extravasation of medications (2, 3).

IVADs insertion, management and removal are carried out by both anesthesiologists and nurses, although the management and removal are primarily part of the nurse's caregiving responsibilities. Insertion failures are a major concern for PIVCs, with approximately 35-50% failing on the first try (2, 13). PIVC insertion failures can be patient-related when veins are not visual, palpable or small, and/or staff related, i.e. limited clinical skills, insufficient use of appropriate technical equipment, and a lack of evidence-based knowledge. Ultrasound-guided insertion and prediction tools for difficult vein access can facilitate a successful first attempt (13-15). Specialized IVADs teams can also aid when first attempts failure is expected and the team can provide training, standardization of practices and offer expert consultation (13, 16, 17). However, robust evidence to support their widespread use remains limited and Sweden lacks a validated difficult vein access tool. Despite the existence of guidelines for IVADs best practices, for insertion, management and removal, the implementation remains inconsistent across healthcare settings (2, 18-21). This compromise patient safety and undermines efforts to deliver sustainable, high-quality hospital care. The WHO identifies safe, effective, and affordable healthcare as central to Sustainable Development Goal (SDG) 3, yet this

sustainability perspective is largely absent in IVAD research, with few nursing studies addressing SDGs (22). Most studies focus on dwell time or complications without linking these outcomes to resource use, environmental impact, or equitable access. Applying a sustainability lens shows that each preventable IVAD-related complication not only harms patients but also consumes unnecessary financial and material resources, weakening cost-effectiveness and long-term healthcare sustainability.

Our research group has recently conducted a theory-driven implementation of evidence-based practices to prevent urinary tract infections and bladder distension (23). The result was an associated significant reduction in the incidence of these adverse events in patients with hip fractures, 19%-4% and 41%-9%, respectively (24, 25), and found to be cost-effective (26). Building on these findings, we aim to further test our implementation methods and strategies inspired by theories on organizational culture and leadership and dialogue (27, 28), on the prevention of IVADs complications. We aim to promote changes in staff (nurses and anesthesiologist) specific cultures related to IVADs best practices, using an integrated knowledge translation approach (29). The collaboration is grounded in the expertise of researchers, healthcare professionals, clinical experiences, and scientific evidence to improve safe IVAD practices. The implementation process is guided by the new medical research council (MRC) guidance for process evaluation of complex intervention (30). The intervention will be conducted at a smaller hospital located at a different site within the university hospital organization, while the control hospital is a county hospital.

Aims

This larger research project aims to evaluate the effectiveness of implementing a co-designed, standardized care bundle on IVADs quality and staff knowledge (nurses and anesthesiologists) before and after the intervention at the I-hospital, compared with the C-hospital. Additional aims are to: (a) translate and validate a tool for identifying patients with difficult vein access within the Swedish healthcare context; and (b) to evaluate the implementation related to its feasibility, acceptability, fidelity, and cost-effectiveness.

Research questions

- Does the implementation of standardized, evidence-based practices improve the quality of IVADs care and increase nurses' and anesthesiologists´ knowledge, including reductions in complications such as thrombophlebitis?
- Does the intervention bridge barriers to successful implementation and support routinization of evidence-based IVADs practices?
- Which factors influence the implementation in terms of feasibility, acceptability, cost-effectiveness and compatibility with professionals' existing values and clinical workflows?

Table 1.

PICOT framework for the study

Population/Setting/Problem	*Population and Settings:* The I-hospital is part of a university hospital, and the C-hospital is a county hospital. The implementation program targets all nurses and anesthesiologists working at the I-hospital involved in IVADs practices. Local champions (defined as clinically active staff members with specific training and responsibility for supporting practice change) will be selected in each unit to function as experts, to monitor the intravascular catheter quality and to ensure maintenance of the intervention. *Problem:* Patients with intravascular access devices (IVADs) experience preventable complications due to suboptimal adherence to evidence-based practices among healthcare professionals.
Intervention	I-hospital: The implementation program will be led by six facilitators. The implementation objects are co-designed standardized best practices (care bundles) to prevent IVADs-related complications.
Comparison	Compared with care as usual at the C-hospital.
Outcomes	*Primary outcome:* changes in quality of IVAD care and nurses' and anesthesiologists' knowledge of IVADs best practices. before and after the intervention at the I-hospital, compared with the C-hospital. *Secondary outcomes:* (a) translate and validate a tool for identifying patients with difficult vein access within the Swedish healthcare context; and (b) to evaluate the implementation related to its feasibility, acceptability, fidelity, cost-effectiveness and compatibility with existing values.
Type of study and time	A longitudinal implementation study design with an embedded process evaluation conducted over three years, integrating mixed methods.

Abbreviation: C-hospital=control hospital, I-hospital=intervention hospital, IVAD= Intravascular Access Device.

Design and Method

The study adopts a longitudinal implementation design with an embedded process evaluation, guided by Medical Research Council guidance (MRC) framework: developing, feasibility, refinement, implementation and evaluation (30). The design integrates mixed methods to assess the effectiveness, implementation process, and contextual factors influencing the prevention of

IVAD-related complications across an intervention and a control hospital. A logic model of the intervention assumption will be developed (30, 31). The standards for reporting implementation studies checklists for reporting evaluation will be used (32). The study will be registered in clinical trials, ClinicalTrials.gov. A series of companion publications will be reported, see below. All statistical analysis plans will involve statisticians.

Setting, intervention and participants

The I-hospital is part of a university hospital with approximately 13,500 hospital stays per year, employing ~650 registered nurses and ~50 anesthesiologists of which all will participate in the intervention. The units involved are; emergency department and related emergency medical service, three operating room departments, one intensive care unit, three post-anesthesia care units, three medical wards, two ortho-geriatric wards, four orthopedic wards, one ophthalmology ward and one rheumatology ward, The C-hospital is a county hospital and will function as control for S. aureus-bacteremia, and a selection of similar units will function as controls units.

The intervention will be led by six main facilitators with experience of participating in change projects. They are researchers, quality and safety coordinators, development leaders, one anesthesiologist, and one physician specialist within infection prevention and control. They will ensure commitment to intervention, bridge barriers, establish effective communications channels, encouraging reflections about attitudes, assumptions to become receptive to change, and how current ways of working affect the gap. They will also facilitate safe places for learning and re-learning.

A specially educated IVAD team will be selected including four to five nurse anesthetists and one anesthesiologist. Each unit manager will select one or two nurses to be specially educated local champions. They will monitor the quality of IVADs care described below. The IVADs team and the local champions will co-design new innovations, see below. Timeline is presented in Table 2.

Theories and strategies

To enable the specific culture change, theories on organizational culture and leadership and dialogue will be used (27, 28). In line with our previous intervention (23) a multifaced implementation strategies will be used, i.e. collaboration and partnership between researchers and interest-holders, co-design of innovations, flexible facilitation, local champions, education and feedback on the quality of the IVADs.

Implementation object

The evidence-based recommendations consist of education, skill assessment, aseptic practices, chlorhexidine 5% cleansing before insertion and management, correct indications and removal plan, patients' information (indication and when to alert if the catheter causes pain, is red, swollen or leaking), use of ultrasound guidance for selected IVADs.

Intervention delivery

Step 1. Development - i) engaging interest-holders (managers, first and middle-liner leaders, controllers, development leaders, quality and safety coordinators, anesthesiologists and nurses), in collaboration with the main facilitators, ii) establishing the IVAD team, iii) validating a difficult vein access tool: iv) iterative co-design of innovations: a) standard practices for IVADs (peripheral, midline, central catheters and arterial catheter), b) co-design IVADs e-learning activities.

Step 2. Feasibility - testing the innovations in selected units.

Step 3. Refinement - in line with the findings from the feasibility test.

Step 4. Implementation - standard practices (care bundles) for the specific IVADs, education and learning activities including skill performance and assessment.

Step 5. Evaluation, if successful, adoption and routinization of the new practices. The process findings will be reported to all interest-holders including its cost-effectiveness, mechanism of impact and contextual factors affecting the intervention.

C-hospital, care as usual, which may or may not include local initiatives related to IVADs during the study period. The monitoring of the quality of IVADs care may or may not change behavior related to IVADs practices.

Table 2.

Timeline, activities and data collection

Time/ Activities	**Year 1 2025**	**Year 2026**	**Year 3 2027**	**Year 4 2028**
Pre-planning **I-H.** engaging interest-holders – creating a shared sense of urgency	x	x	(x)	
I-H. Implementation process - key uncertainties, barriers and enablers to change	x	x	x	x
I-H Co-design, learning activities, IVAD team and local champions. Translating and validating a difficult vein access tool.		x	x	
I-H. Feasibility, refinement and Implementation		x	x	
Both sites Survey - knowledge test[++]		x	x	x
I-H Implementing the IVAD e-learning activity (12 months)		x	x	
I-H. Feedback to interest-holders on the IVAD quality monitoring (monthly)[+]		x	x	x
C-H. Feedback to hospital management on bacteriemia (yearly) and IVAD quality monitoring (monthly).		x	x	x
Both sites. Collection of process data and costs.	x	x	x	x
Both sites. Monitoring quality of IVADs and thrombophlebitis[+]	(pre-tests)	x	x	x
I-H. Feedback on process outcomes – Ownership of new practices. If successful adoption of the innovations at **C-H**				x

[+] The quality monitoring protocol (33)

[++] Electronical knowledge test in line with The Handbook for Healthcare knowledge test (8)

Abbreviations: I-H= intervention hospital, C-H=control hospital, IVAD=Intravascular access devices.

Ethics

The project will be performed after approval from the Swedish Ethical Review Authority, in line with Helsinki declaration (34), carefully considering how the benefits, risks, and burdens related to the project are distributed for involved participants at both study sites. The project is approved by hospital manager and the chief medical officer at both study sites.

Data management plan

We will develop a data management plan following the Swedish national data service checklist, ensuring compliance with Swedish regulations, FAIR principles, and Horizon Europe guidelines throughout data collection, storage, sharing, and preservation.

Clinical implications of the SIVAD study

The intervention targets key factors that can improve clinical practice and prevent complications related to IVADs. The study will generate new knowledge on IVADs related complications, previously not monitored in Sweden. If successful, both the tool to monitor IVAD complications and the e-learning activities can be used in a wider healthcare context, as regular measures of the quality of IVAD care and as continuous learning activities to promote safe care. The findings may also inform decision-makers and policymakers about barriers and enablers to change when bridging the gap between evidence and practice for safe IVADs care. Given the research group's expertise and the I-hospital's prior experience in routinizing new ways of working, the SIVAD study has strong potential to facilitate sustained, longitudinal changes in clinical practice.

Study 1. Aim to evaluate changes in the quality of IVADs care quality, healthcare professionals' knowledge and thrombophlebitis

Method

Data on IVAD care quality and healthcare professionals' knowledge will be collected longitudinally at both the intervention hospital (I-hospital) and the control hospital (C-hospital) over a three-year period. Multiple data sources will be used, including repeated bedside audits of IVADs and electronic knowledge questionnaires, to capture changes over time and between study sites.

Sample/ Data collection

In the present project, data collection will include Quality of IVADs care: All patients ≥18 years present at the wards at the time of monitoring with an IVAD in situ on the observation day. Patients without IVADs will be counted. Data will be collected once per month. From March 2026 to December 2028. Exclusion criteria: critical ill patients for example persons receiving end-of-life care. *Power calculation:* A conservative sample size calculation was

based on a simple before–after comparison of independent PIVCs (PIVC-miniQ, SD = 1.55), assuming 80% power, a two-sided $\alpha = 0.05$, and a detectable mean difference of 0.5 points, which requires approximately 150 PIVCs before and 150 after (≈300 total), inflated by 10–30% to account for clustering. Although the study includes all types of IVADs, this calculation provides a conservative estimate of the required sample size. In practice, PIVC-miniQ will be measured monthly over three years and analyzed using linear mixed-effects models that explicitly account for clustering and repeated measures over time, which is expected to yield at least comparable, and likely higher, statistical power.

Audit tool: Data on IVAD care quality will be collected by trained nurses, using a modified and validated audit tool (IVAD-miniQ) (33). The tool has been piloted at both sites and adapted to fit all IVAD commonly used at the study sites, IVAD-miniQ-Sweden. The final version is in electronic format. The instrument for monitoring IVADs, IVAD-miniQ-Sweden, is presented in additional file 1. The IVAD-miniQ-Sweden tool includes one part with information about age (years), sex (male/female), information brochure (yes/no) and unit. Other domains are type of intravenous device, insertion location, condition of dressing and equipment, documentation, and indication for use. Points are summarized, with an optimal score of zero indicating high quality in IVAD management, a summative score of ≤ 1, is assessed as high quality (4). Further assessment (6), thrombophlebitis, will be defined as redness, tenderness, swelling, pain, and a palpable cord along the affected vein, and classified using a severity grading scale from 0 to 4 grades, where higher grades indicate greater symptom severity (8, 35). The observer will notify nurses in charge if observing dislodgment, infiltration/extravasation or thrombophlebitis in line with hospital policy at the study sites.

Knowledge assessment**:** Registered nurses and anesthesiologists involved in IVADs management at the study sites. Electronic knowledge questionnaire distributed before, during and after the care bundle implementation (mid-2026, mid-2027 and mid-2028). Based on the Swedish Handbook for Healthcare IVAD best-practice recommendations (8), see Additional file 2.

Statistical analysis

Descriptive statistics for patients with IVADs, healthcare staff, and IVAD characteristics. Linear mixed models will be used for longitudinal analysis of the repeated measurements of IVAD care quality and staff knowledge. With additional comparisons between the I-hospital and C-hospital. Different models will be used, the explanatory variables will be, nurses' and anesthesiologists' knowledge, care quality of IVAD and the hospital setting. Statistical significance set at $p < 0.05$; analyses conducted using standard statistical software packaging.

Study 2. Aim, to perform a translation and cross-cultural adaptation of an adult difficult vein access scale (A-DIVA) to Swedish context, resulting in the A-DIVA-Swe

Method

Translation and cross-cultural adaptation (36): The adult difficult vein access scale, Adult-DIVA scale (15) will be translated into Swedish and culturally adapted following internationally recommended guidelines. The process will include forward–backward translation, expert panel review, and cognitive debriefing with healthcare professionals to ensure conceptual, semantic, and operational equivalence.

Participants

To assess the validity and reliability among the Swedish registered nurse and anesthesiologists involved in difficult vein access management, a convenience sample (n=30) of general native Swedish speaking healthcare workers will be recruited from both I-hospital and C-hospital. After completing the cross-cultural adaptation, reliability and validity will be assessed within a larger sample (n=100) of healthcare workers involved with A-DIVA management.

Statistical analysis

Characteristics of the study participants are described using frequencies, percentages, mean and standard deviation.

Psychometric properties evaluation

Face validity (performed by the expert committee members through qualitative analysis of the participant's comments), reliability (test-retest intra class correlation coefficient, one week interval), construct validity (exploratory factor analysis (EFA)) will be performed. Factors will be extracted using the maximum likelihood method (MLE).

Study 3. Aim to evaluate the implementation process

Method

The implementation intervention will be guided by MRC framework (30). The design integrates quantitative and qualitative data to evaluate the implementation process, and contextual factors influencing the prevention of IVAD-related complications across an intervention and a control hospital.

Data collection

Quantitative process data: Attendance rate in meetings, completed IVAD certificates and staff turnover. Qualitative process data: Implementation logbook (notebook on processes, meetings, and reflections). Semi-structured interviews, with a strategic selection of participants on micro- and meso-level within the organization (variation from the involved units, type of profession, age, working years, and gender). The interviews will be performed by a researcher who is not involved in the intervention.

The questions will investigate the participants' experiences of:
-participating in the intervention, what worked? How and why?
-how the intervention interacted with different contextual features?
-how the intervention affected other care giving activities?
-how competing priorities affected the intervention and its activities?
-how different goals and prioritization such as limited resources in healthcare, affected the intervention?

Data analysis

The process data will be analyzed using a thematic analysis.

Quantitative data**:** Descriptive statistics.

Qualitative data: Thematic analysis according to Braun and Clarke (37, 38). Qualitative data will be analyzed thematically following Braun and Clarke's six-phase framework, which includes: (1) familiarization with the data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing the final report.

Study 4. Aim to evaluate the cost-effectiveness of the intervention

Method

A cost-effectiveness of the intervention will be performed using a before and after design (30).

Data collection

Implementation and intervention costs will be collected from logbooks and cost templates including mean salaries for different professions, including 50% social insurance and overhead costs. It includes activity-based costing methods based on time used and participants involved in different activities. Downstream costs will be estimated from administrative cost data provided by the hospital. Health outcomes will be patients with IVADs complications, i.e. thrombophlebitis and extravasation of intravenous medications, at baseline compared to post-intervention, using hospital data related to these complications. The implementation costs will be discounted at an annual rate of 3%, to account for the time value of money over a four-year period. The design and reporting of the cost-effectiveness evaluation follow the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) (39).

Statistical analysis

Cost-effectiveness analysis will be used to compare incremental costs from a health system perspective (implementation, intervention, and downstream) to the incremental health outcomes; the IVADs complications. The economic evaluation will include scenario analyses and sensitivity analyses according to state of the art, to account for uncertainty of parameters and underlying model uncertainty.

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