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Implementing best practice for peripheral intravenous cannula use in Australian emergency departments: a stepped-wedge cluster-controlled trial and health economic analysis protocol

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ABSTRACT

Introduction Over one billion adults attend emergency departments (EDs) internationally every year, including 6.6 million in Australia. Up to half of these patients have a peripheral intravenous catheter (PIVC) inserted. Although healthcare workers believe that placing a cannula is helpful ('just in case'), PIVCs often remain idle. PIVC insertion is painful for patients, takes clinicians' attention away from other care, has adverse outcomes and causes major economic and environmental burden. Our aim is to codesign an implementation toolkit to reduce unnecessary PIVC insertions and improve other national quality indicators using an implementation science framework.

Methods and analysis A stepped-wedge cluster-controlled trial will be conducted in nine ED sites (clusters) across Australia. The interventions will be codesigned with and adapted to sites based on local context. The interventions are evidence-based multimodal intervention (MMI) and aligned to the 2021 Australian Commission for Safety and Quality in Health Care National PIVC Clinical Care Standard. The Consolidated Framework for Implementation Research and Learning Health System will be used to guide implementation. Interventions will be phased across three steps (three sites per step), and each site will collect control and postintervention data using mainly routinely collected clinical data. Each site will be allocated to receive the intervention at one of three study steps. Implementation strategies will tailor broad clinician and consumer engagement, policy changes, education, audit and feedback and clinical champions, along with environment and equipment changes, to each site. The primary objective is to reduce the proportion of adult patients who have a PIVC inserted by 10%. We will evaluate the clinical, implementation and cost-effectiveness of the intervention.
Study findings will be used to conduct a health economic analysis, develop an implementation toolkit and inform a sustainable roadmap for national roll-out. This will meet the needs of a diverse range of EDs nationally and internationally.

Ethics and dissemination The protocol was approved by the Monash Health Human Research Ethics Committee (HREC Reference Number: HREC/100808/MonH-2023-390692(v3)). The outcomes of this trial will be disseminated through peer-reviewed publications, conference presentations and communication with study partners and stakeholders including professional colleges and the Australian Commission for Safety and Quality in Health Care.

Trial registration number Australian New Zealand Clinical Trials Registry registration number: ACTRN12623001248651. Date of registration: 1 December 2023. https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=386256&showOriginal=true&isReview=true

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The stepped-wedge cluster-controlled design provides strong methodological rigour for assessing intervention effects over time.
⇒ Validated implementation frameworks will guide stakeholder engagement and support codesign of the intervention.
⇒ Use of routinely collected clinical data in a real-world setting may result in variability in data quality and pose challenges with data access and sharing.
⇒ Analyses of a large dataset enable comprehensive evaluation; however, contextual variability, resource limitations and unidentified confounders may affect outcome measures.

INTRODUCTION

Each year, more than one billion adults attend emergency departments (EDs)

internationally, and in Australia this exceeds 6.6 million.[1] Up to half of these patients have a peripheral intravenous catheter (PIVC) inserted during their visit,[2–5] equating to over 3 million PIVCs inserted in Australian EDs annually.

PIVCs are painful to have inserted and have associated complications and cost.[6] One of the most serious complications is healthcare-associated *Staphylococcus aureus* bacteraemia (HA-SAB). It is reported that almost a quarter of HA-SAB infections are associated with PIVCs, and 60% of these cases occur when the PIVC was inserted in either the ED or prehospital setting.[7]

Research suggests that between 32% and 52% of PIVCs inserted in the ED remain unused and are inserted 'just in case'.[2 4 5 8] For a limited number of patients with high-risk conditions (eg, acute coronary syndromes), an unused PIVC can be appropriate to insert.[9] However, a PIVC that remains unused offers no (or little) advantage to the patient, the healthcare system and/or the environment. Unused PIVCs are a major economic burden, with the total estimated cost of unused cannulas around A$305.9 million per year in Australia.[10] A PIVC, once placed, may drive low value care and can provide an intervention bias towards intravenous therapy when alternative approaches may have been appropriate.

Previous studies have reported that a human factor multimodal intervention (MMI) can safely reduce PIVC insertion in EDs by approximately 10%.[4 5] These effects were sustained for 5 years and were associated with reduced PIVC-associated HA-SAB with no change in the rate of appropriately unused PIVCs.[5 11 12] Clinicians were encouraged to place fewer and cleaner PIVCs and only insert one in haemodynamically stable patients when they were 80% confident that it was needed. While this MMI was demonstrated to be effective at individual health services, an evidence gap exists regarding how it can be adapted and scaled.

In 2021, the Australian Commission for Safety and Quality in Health Care (ACSQHC) released the Management of Peripheral Intravenous Catheters Clinical Care Standard.[13] It recommends 10 quality indicators for monitoring within health services. The first of these is the rate of PIVCs not used for therapeutic purposes. The feasibility and implementation methodology for health services to collect and monitor these indicators and whether they will achieve the safety and quality outcomes they intend to drive have not been studied. This is an opportunity to combine elements of our MMI with the ACSQHC PIVC Standards and introduce them into clinical practice.

Our overarching implementation approach will be guided by the Consolidated Framework for Implementation Research (CFIR).[14] This will be complemented and enhanced by the Learning Health System (LHS),[15–17] behaviour change wheel[18] and the RE-AIM framework.[19] The purpose of this paper is to report the methodology for the stepped-wedge cluster-controlled trial.

METHODS AND ANALYSIS

Trial funding and administering institution

This study is supported by the Medical Research Future Fund (MRFF)—Clinical Trials Activity Initiative—2021: Clinical Trials Activity Grant Opportunity—Stream 5 (MRF2023389). The funding body has no role in the design of the study or collection, analysis or interpretation of the data and will not be involved in reporting the results. The administering institution of this trial is Monash University, Australia. Monash University ensures that each research activity is carried out in an ethical, responsible, diligent and competent manner and in accordance with the approved MRFF application.

Study aims and hypotheses

Study aims

Our overall study aim is to reduce unnecessary PIVC insertions using a codesigned MMI. We also aim to investigate the feasibility of implementing select ACSQHC PIVC standard indicators.

To meet these aims, we will have determined the following study objectives:

1. Codesign a study site-specific MMI aimed at reducing unnecessary PIVC insertions and select quality standards.
2. Implement the codesigned MMI and evaluate the clinical and cost effectiveness and implementation pathways.
3. Develop a roadmap for national scale-up including implementation toolkits.

Hypotheses

Our primary hypothesis is that our codesigned MMI will safely reduce PIVC insertions by 10% of adult patients attending the study site EDs.

Secondary hypotheses are that the codesigned MMI will: (1) increase the proportion of inserted PIVCs that are used for therapeutic purposes; (2) reduce pathology ordering rates; (3) not adversely impact the safety of patients without a PIVC; (4) reduce the rate of PIVC-associated HA-SAB; (5) decrease the proportion of PIVCs inserted over an area of flexion (ACSQHC indicator 4b); (6) increase the proportion of PIVCs inserted on the first attempt (ACSQHC indicator 5); (7) improve healthcare professionals' competency in PIVC insertion, monitoring and removal (ACSQHC indicator 3); (8) improve the documentation for PIVC insertion, maintenance, removal and regular review in ED (ACSQHC indicator 7a); (9) increase the proportion of consumers who understand the reason for PIVC insertion (ACSQHC indicator 2 and 3); (10) increase the level of consumer satisfaction with PIVC insertion and care; and (11) increase the level of healthcare professionals' satisfaction and confidence with PIVC insertion and maintenance.

Trial design and setting

The study plan is (a) stepped-wedge cluster-controlled trial across nine participating Australian ED sites

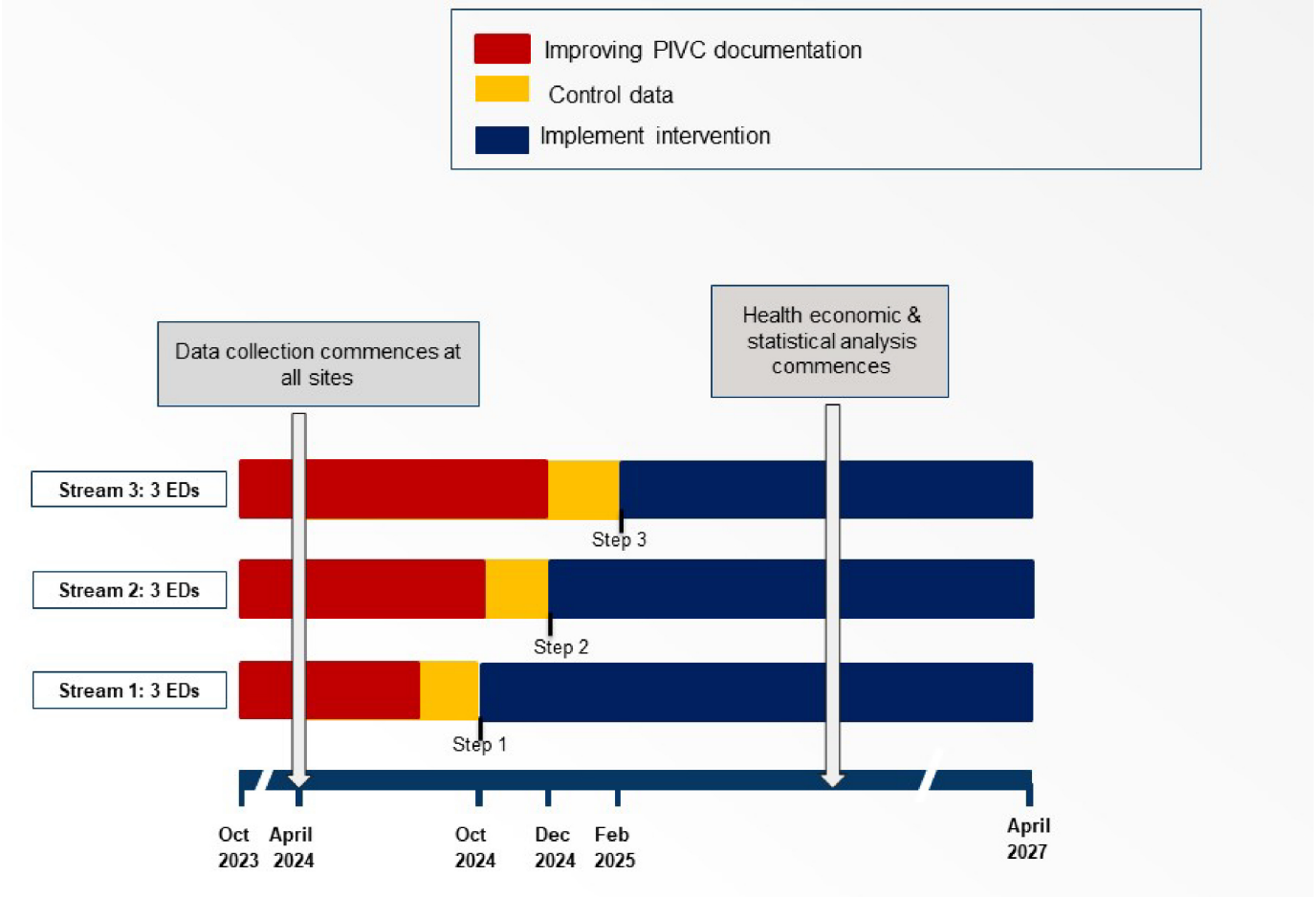

Figure 1 A stepped-wedge cluster-controlled design. Each site is a cluster, and we have nine clusters (three in each stream). Stream 1 clusters receive the intervention in step 1. Stream 2 clusters receive the intervention in step 2. Stream 3 clusters receive the intervention in step 3. Data collection periods are 2 months in duration. ED, emergency department; PIVC, peripheral intravenous catheter.

(clusters) to test an adaptive codesigned intervention, (b) undertake an implementation evaluation, (c) conduct a health economic analysis of the intervention. Codesigned adaptation of the interventions will be guided by the LHS framework.[16 17] The results will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement for stepped-wedge trial designs[20 21] and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 statement.[22] A completed SPIRIT 2013 checklist for this study protocol is provided in the online supplemental material.

This trial involves nine diverse Australian EDs across three states that treat adult patients aged 18 years and over. Five health services of different classifications, with regional and rural representation, bring diversity that will inform the translation and scalability of the trial intervention.

The total study duration is 3 years and consists of three steps (figure 1). Routinely collected clinical and health service data will be collected from participating EDs for the duration of the trial. The nine participating ED sites are divided across three streams, with three sites in each stream (figure 1). Each stream will be allocated to receive the intervention at one of three study steps. This means that one stream will receive the intervention at step 1, another stream cluster will receive the intervention at step 2 and the final stream will receive the intervention at step 3.

Our initial audits demonstrated that PIVC insertion documentation across the nine ED clusters was much lower than previously reported (average of 49.3%). We are currently improving PIVC documentation in electronic medical record (EMR) to >80% to ensure that data collected are accurate prior to the implementation phase of each stream. Poor EMR documentation can result in negative consequences including prolonged PIVC dwell time and higher complication rates.[23]

Following the trial commencement and our baseline data collection, the governance committee was approached by our stakeholder health services and jurisdiction partners. Several sites experienced an increase in PIVC-associated HA-SAB, prompting the organisations to prioritise the implementation of PIVC best practices. After consulting with the data committee, we decided to shorten the implementation timeline from 6 months to 2 months. This adjustment, backed by our strong statistical

evidence, allows us to expedite the rollout of the intervention to the next group of clusters, in alignment with organisations' safety and quality priorities. The trial committee approved this revised timeline, confirming that necessary resources are available to support the accelerated delivery of the intervention across multiple sites. See figure 1 for the trial timeline.

Sample size estimation

Feedback from our stakeholders determined that site diversity both geographically and for types of ED was needed for the implementation evaluation 'power' and to provide the external validity required to drive the national scale up. Greater numbers of patients and staff included in the trial will result in more different scenarios being encountered, and therefore, better plans developed for national scale-up.

The primary objective of this study is to reduce the PIVC cannulation rate in adults by a minimum of an absolute proportion of 10%. This figure was chosen based on our previous research. Currently, the nine participating EDs represent more than 400 000 adult presentations per year. The PIVC cannulation rate in adults is approximately 40% or 160 000 per annum (or 3000, for every 2-month period, at each of the nine participating EDs). In a sample of nine clusters, with each cluster having 3000 adult patients in each of the four, 2-month time periods (see figure 1), we have ample power (0.99) to detect a difference of 10% (ie, a cannulation reduction from 40% to 30%), assuming an alpha of 0.001, intraclass correlation coefficient within cluster sites of 0.03, number of steps (3) and patient data collected cross-sectionally at four time points (baseline, step 1, step 2 and step 3).

The total sample size required is 108 000 adult ED presentations over 2 years, representing a minimum of 3000 adults at each ED at four time points (baseline, step 1, step 2 and step 3). The sample size was calculated using Stata software's stepped-wedge cluster-controlled command 24.

Data collection and management

Data collection

A data dictionary was developed by the study team that was informed by previous research and the Metadata Online Registry.[24] Most data will be prospectively collected as routine clinical and administrative data in health services from their EMR systems or equivalent. Demographic and clinical data will be extracted from existing databases. Additional secondary and exploratory outcomes will be determined by a feasibility analysis of sites and collected using convenient sampling and survey development. Site level outcomes, consumer and staff satisfaction will be surveyed using validated tools.

Data management

Deidentified patient information will be collected from participating EDs. Data will be managed using REDCap (Research Electronic Data Capture, Vanderbilt, Tennessee, USA) services hosted and managed by Helix (Monash University). Data will be kept in locked premises, in locked filing cabinets or password protected digital files according to data type.

Routine audits will be conducted to validate data collection for the study's primary outcome. The audits will determine the completeness of PIVC documentation on the EMR or other systems used for documentation for adult patients within participating EDs. Monitoring of primary outcome data will occur via audits and the documentation rate recorded monthly. When a site achieves two consecutive months of an EMR PIVC documentation rate at 80% or above, this will be taken as evidence that the primary outcome is being recorded as required. The data from these months may also become control data in the main stepped-wedge cluster-controlled trial.[25]

Data quality and integrity will be monitored throughout the trial by the project and data manager. The data management committee will meet quarterly, and the site research nurses will meet monthly to address any missing data and ensure completeness and compliance.

Participating clusters

The participating study clusters are ED sites. Eligible EDs have consented to participate in the trial by providing a letter of support and signing the multi-institutional agreement. This indicates the clinical leadership and the health service executive teams support the development of the quality improvement interventions and the study team using routinely collected clinical and health service data.

Inclusion criteria

Each participating ED is required to meet all the following criteria to be enrolled in the study: (a) has more than 50 adult presentations daily; (b) uses an EMR platform that allows data collection; (c) the overarching health service consents to participation; (d) be an Australasian College for Emergency Medicine (ACEM) accredited ED, defined as an ED that meets ACEM's criteria to provide core ED training for the Fellowship ACEM Training Programme.

Exclusion criteria

EDs meeting the following criterion will be excluded from the trial: has had an active PIVC quality improvement intervention programme within the last 12 months.

Waiver of consent

A waiver of consent was approved by the Monash Health Human Research Ethics Committee, for access to patient health information within the study clusters. This was on the basis that this research is low risk and has benefits for the patient that justify any risks associated with absence of consent, as we had met the criteria of the National Statement on Ethical Conduct in Human Research.[26]

Interventions

Implementation frameworks and approaches

The CFIR will be used as an overarching framework to map stakeholders, contextualise codesigning intervention with clinicians (medical and nursing), consumers, local stakeholders and the implementation within participating ED sites.[14 27] The study will be guided by the core CFIR domains: (a) the outer settings which are national research funding bodies MRFF, policy, partner organisations and stakeholders including ACSQHC; (b) the inner settings are the participating health services and research institutions; (c) the individuals who are the researchers, clinicians and consumers; (d) the evidence-based interventions to be implemented across the participating EDs and (e) the implementation process.[14]

While the CFIR framework maps stakeholders and contextualises co-designing interventions,[14] it is primarily a static determinant framework and lacks detail on the processes needed for change in complex systems. Therefore, the LHS framework, an evidence-based approach to health system change, will be used to support the implementation process.[15 28–31] The LHS incorporates four essential sources of evidence including from stakeholders, research, practice and data and implementation. Each source is essential to capture and address stakeholder priorities, contextual factors and emergent challenges to codesign and implement the systems level intervention needed for this initiative to deliver sustainable health impact.[28 31 32]

The site-specific adapted interventions will be based on design thinking methodology that incorporates human factors; discovered through focus groups and ethnography with clinicians (medical and nursing), consumers and local stakeholders. The interventions will be built on and informed by our previous MMI[33] and the ACSQHC Standards.[13]

The study team led by emergency medical and nursing champions will work alongside ED clinicians, local stakeholders, consumers and researchers to codesign sustainable interventions. These will include contextualisation of the guideline and education package, facilitation of the environmental modifications, establishment of the audit-feedback process and appointment of clinical champions.[34 35] Safe alternatives to intravenous therapy such as oral hydration and medication administration will be explored for use, depending on patients' treatment needs, using evidence and codesign.

To understand the context of each participating ED setting and the adaptations required for the intervention. Each ED site will conduct a mapping exercise of local practices and barriers/enablers analysis. Mapping and contextualisation will ensure the necessary opportunity for efficient implementation, learning about appropriate adaptation at each site and providing a set of context-sensitive strategies and processes required for future sites. Table 1 outlines the codesign implementation strategies which include intervention components.

The evaluation of the implementation intervention at each site will be structured using the RE-AIM framework.[19] This framework evaluates the Reach, Effectiveness, Adoption, Implementation and Maintenance of an intervention and together determines the impact of the interventions. This will be conducted for each cluster (site) and stream (group of three clusters).

Trial outcomes

The primary outcome is the proportion of PIVC inserted per month in adults attending a participating ED. Rates of PIVC insertion, use, safety and PIVC-related infections will be measured by routinely collected clinical and administrative data in health services from EMR. The validity and reliability will be tested by the audit plan. Table 2 outlines the primary and secondary outcome measures of this trial.

Governance structure

The executive leadership team oversees the strategy, governance, risk, delivery and sustainability of the project. This group includes representatives from the chief and associate investigators. The data and intervention codesign subgroup oversees financial reporting, internal controls, management of the risk register and implementation framework, made up of investigator leads who are health economists, statisticians and implementation scientists. The trial steering committee oversees the trial and ensures that the hospital sites are on track. The site working groups are responsible for local governance, implementation, data collection and risk reporting. This group includes chief site investigators, research nurses and local study champions. The emergency adult care consumer group provides input, advice and codesign interventions. All layers of governance include multidisciplinary clinicians led by nursing and medical professionals.

Adverse event monitoring and reporting

This is a minimal-risk, standard-of-care implementation trial. Adverse events, including catheter-associated bloodstream infections, are related to routine PIVC insertion and maintenance. Specific indicators to track adverse events or patient safety outcomes include the rate of PIVC-related complications, such as infections and phlebitis. Unsuccessful cannulation incidents, indicated by the number of failed insertion attempts per patient, will also be monitored. Additionally, delayed treatment due to PIVC reduction will be closely monitored, particularly in instances when reduced PIVC use results in delays in administering critical medications or fluids. Adverse reactions, including pain, swelling or allergic reactions related to PIVC use, will be recorded, along with cases requiring escalation of care due to complications from PIVC use, such as extended hospital stays. All adverse events will be reviewed by site investigators, with a summary submitted to Monash Health HREC within 30 days of occurrence.

Table 1 Codesign implementation strategies

Intervention components	Subcomponents	Change principles underpinning each component
Codesigned, adapted, site-specific intervention	a. Detailed study manual b. Interviews and observations c. Implementation workshops with clinicians, consumers, researchers, industry partners and designers d. Electronic medical record prompts e. Clinician-led and designed equipment and environmental changes f. Develop plans for access to resources and self-education opportunity	► Engages stakeholders (ED clinicians* and consumers) at each site in codesign and adaptation process. ► Provides a clear rationale for change in clinical heuristics and practice. ► Develops agreement regarding concrete and specific change goals including study objectives and priorities. ► Contextualisation of the guideline and education package. ► Provides an educational framework to support staff delivering the intervention. ► Uses credible and experienced trainers (chief investigators). ► Promotes access to resources and provides opportunities for practice.
Implementation strategies	a. Identification of implementation strategies b. Development of local audit and feedback processes c. Process evaluation	► Addresses systems, operations, structures and workforce issues that may impact the intervention being delivered as planned. ► Engages sites in implementing the intervention. ► Monitors and provides feedback about the implementation and change process.
Organisational support for study	a. Local clinical champions and researchers at each site b. Risk register c. Resources for improving sites' use of research d. Annual progress reports to stakeholders and the Medical Research Future Fund	► Engages sites in study timeline and proceedings. ► Uses champions and researchers to model and promote the use of the intervention. ► Promotes ongoing interaction of the sites with the study.

*Clinicians are healthcare professionals who have direct contact with patients, including doctors and nurses.
ED, emergency department.

Health economic analysis

A 'within trial' return-on-investment will be conducted to calculate the net present value of the quality improvement intervention. This will be done from hospital, health sector and societal perspectives. The cost of delivering the quality improvement intervention, cost of PIVC insertion and relevant health service use will be considered for the intervention and control periods and will be determined from trial data. Healthcare service use per ED will consider the cost of PIVC insertion (staff time and equipment), as well as relevant health service use of patients' PIVCs during their 'hospital episode' (defined as the time from presentation to the ED until discharge home). The background health service utilisation data will be determined through data linkage to routinely collected ED and admitted patient data collection records and health service costing unit records for patients at each participating site during the intervention and control periods. The costing unit records will be used to assign a cost to each patient's episode of care, and the Independent Hospital Pricing Authority pricing reports will be used to assign a cost to public hospital funders for each episode of care. Generalised linear models will be used to compare the cost difference between the two groups (quality improvement intervention and control), adjusting for any unbalanced confounders in patient characteristics. Bootstrapping will be used to estimate the distribution around costs. One-way and multiway sensitivity analyses will be conducted around key variables. The net present value of the quality improvement intervention will be the benefits of its provision (difference in cost between the quality improvement intervention and control groups), minus the cost of providing it. Broader community and carbon costs will also be explored if possible. Carbon impact will be estimated by obtaining the carbon footprint of a catheter (manufacturing, transportation, storage and disposal) and multiplying it by the reduction in catheter insertion between intervention and non-intervention periods. A shadow price will be used and tested in the sensitivity analysis.

Statistical methods

Methods of analysis

The main analysis will use all available eligible study data in an intention-to-treat approach. The examination of secondary and other data will be for exploratory analyses and hypothesis generation. The primary and secondary outcome data collected over 3 years will be reported for each of the nine ED sites (clusters) and overall, as mean, SD, median and IQRs as appropriate. Dichotomous

Table 2 Trial outcome measures

Outcomes	Information	Data source
Primary		
Number of PIVC inserted	The proportion of PIVC cannulation per month in adults attending participating EDs.	Routinely collected clinical and administrative data in health services from EMR
Secondary		
(1) PIVCs used for therapeutic purposes	The proportion of PIVCs used for therapeutic purposes per adult patient attending participating EDs. Therapeutic purposes have previously been defined in Lim *et al*, 2020[5]	Routinely collected clinical and administrative data in health services from EMR and/or audit data.
(2) Number of pathology ordered	The absolute number of pathology ordering per adult patient attending participating EDs.	Routinely collected clinical and administrative data in health services from EMR and/or audit data.
(3) Number of adverse events caused by not initiating PIVC cannulation in ED	An adverse event caused by not initiating PIVC cannulation would be a delay in the provision of medical treatment, for example, a delay in the administration of intravenous antibiotics.	► Health service adverse events monitoring system, for example, RiskMan (by RiskMan International). ► Reported by site research nurse within 30 days of the event.
(4) Bloodstream infection from PIVC cannulation	The proportion of PIVC HA-SAB per 10 000 patient days of care under surveillance in participating EDs	► Health service adverse events monitoring system for example, RiskMan (by RiskMan International).
(5) Locally approved PIVC policy that aligns with ACSQHC	The existence of locally approved policy that ensures healthcare professionals are competent in PIVC insertion, monitoring and removal. Mapping tool to ensure ACSQHC alignment.	Audit data[25]
(6) Local arrangements that provide systematic support for PIVC device selection decisions	The existence of local arrangements that provide systematic support for decisions related to the selection of an appropriate PIVC device in ED	Audit data[25]
(7) Locally approved policy that ensures ED healthcare professionals are inserting patients' PIVCs using standard precautions	Evidence of a locally approved policy that ensures ED healthcare professionals are inserting patients' PIVCs using standard precautions, including aseptic technique and sterile, transparent, semipermeable dressing unless contraindicated.	Audit data[25]
(8) Locally approved policy that defines the PIVC documentation	Evidence of a locally approved policy that defines the documentation for PIVC insertion, maintenance, removal and regular review in ED.	Audit data[25]
(9) Site-based audit and feedback process	Rates of PIVC insertion, use, safety and PIVC-related infections during, preintervention and postintervention.	Audit data,[25] focus groups and survey
(10) Patients can identify the reason for PIVC insertion	The proportion of patients with a PIVC in situ who can identify the reason for their device insertion in participating EDs.	Audit data[25]
(11) Number of PIVCs inserted on the first attempt	The proportion of PIVCs inserted on the first attempt per adult patient attending participating EDs.	Routinely collected clinical and administrative data in health services from EMR and/or audit data.[25]
(12) Number of PIVC documentation performed by clinicians	The proportion of PIVC documentation performed by clinicians for adult patients in participating EDs.	Audit data[25]
(13) Clinicians apply a clean, dry, secure PIVC dressing.	Proportion of ED clinicians inserting a PIVC with a clean, dry and secure PIVC dressing.	Audit data[25]
(14) Number of PIVCs inserted over an area of flexion	The proportion of PIVCs inserted over an area of flexion per adult patient attending participating EDs.	Routinely collected clinical and administrative data in health services from EMR and/or audit data.[25]

ACSQHC, Australian Commission for Safety and Quality in Health Care; ED, emergency department; EMR, electronic medical record; HA-SAB, healthcare-associated *Staphylococcus aureus* bacteraemia; PIVC, peripheral intravenous catheter.

secondary outcomes will be reported as counts and proportions. Next, the primary and other outcomes data collected over 3 years from all ED sites will be analysed using generalised mixed models to account for clustering within ED sites, to determine if non-intervention periods have higher rates of PIVC cannulation compared with postintervention periods. The random effect will be the ED site (cluster) to account for clustering. Fixed effects will be the step period, intervention received status of the cluster, urban/rurality location, baseline PIVC rate

and other important factors that the chief investigator and executive teams deem as influential on the primary outcome rates. These results will be presented as adjusted mean rates with SEs and ORs with 95% CIs. Results will be reported according to the CONSORT statement for stepped-wedge cluster-controlled designs. The details of the statistical analysis plan are discussed separately.[36]

Ethics

Research ethics and waiver of consent to access to patient health information is approved by Monash Health Human Research Ethics Committee (HREC Reference Number: HREC/100808/MonH-2023-390692(v3)).

Dissemination plans

The outcomes of this trial will be disseminated through a clinician toolkit, peer-reviewed articles, conference presentations and to study partners.

We have partnered with relevant peak bodies, academic institutions and workforce organisations. Our key study partners include: the ACSQHC, the ACEM, the College of Emergency Nursing Australasia (CENA), Safer Care Victoria, the New South Wales Agency for Clinical Innovation, Monash Centre for Health Research and Implementation, Monash Partners, Design Health Collab, Tasmanian and Victorian State Government Departments of Health and a number of Health Services in Victoria, Tasmania, Northern Territory and Queensland.

The new procedures, standards and the toolkit to be developed in this study will be disseminated and implemented with the assistance and support of CENA, ACEM and ACSQHC. The state-level government organisations such as our partner Victorian and Tasmanian health departments will drive jurisdictional implementation.

Patient and public involvement

The Interventions and clinical toolkit will be codesigned by researchers, clinicians and patients/consumers. The results of the study will be disseminated to the Emergency Adult Care Consumer Group.

Trial status

Trial commenced in April 2024.

DISCUSSION

The broad aims of this implementation effectiveness science trial are to reduce unnecessary PIVC insertion and improve quality usage, care and maintenance. The study will use routinely collected patient EMR data and intervene to improve ED PIVC use across nine EDs in Australia.

In 2013, Egerton-Warburton and colleagues implemented the intervention 'Just Say No to the Just in Case Cannula' at three EDs at a Victorian health service. The intervention reduced the number of cannulas inserted in adult patients by 13% and this reduction was sustained for 5 years.[33] In 2016, these results were reproduced in a second health service.[4] However, both studies lacked the rigour of a stepped approach and the external validity of a multisite trial. Two jurisdictions (Queensland and Victoria) have attempted local scale-up, but these have had limited success in size, scope and sustainability.[37]

The ACSQHC standard recommends 10 quality indicators that consumers, clinicians and healthcare services should use to ensure the safe and effective use of PIVCs.[13] These are voluntary standards, and indicators are not routinely collected or used to drive and inform healthcare improvement in Australian EDs. While the ACSQHC Standard exists, it lacks compelling evidence to drive implementation, and there is no current mechanism for adoption and scale-up into clinical practice.

This implementation study will provide immediate healthcare impacts using a stepped approach in participating health services. The implementation and cost-effectiveness evaluation, combined with implementation toolkits and strong clinician leadership and partnerships, will establish a robust policy framework for scalability and sustainability. A 10% reduction in PIVC insertions in EDs nationally could save an estimated A$60 million annually, excluding further savings from reduced complications and 'snowball' costs. This will allow ED clinicians to focus on value-added care while minimising healthcare waste and carbon impact.[10] This study will address the research and translation gap to adopt and enhance the new national standard.[13] Ultimately, we will deliver impact at the health services and jurisdictional levels with a roadmap for national scale-up.

ETHICS AND DISSEMINATION

Research ethics approval and waiver of consent to access patient health information

Research ethics and waiver of consent to access to patient health information is approved by Monash Health Human Research Ethics Committee (HREC Reference Number: HREC/100808/MonH-2023-390692(v3)).

Confidentiality

People with direct access to trial data will take all appropriate precautions to preserve confidentiality. All data collected during the study will be anonymised.

Dissemination policy

We will report the outcome of the trial in accordance with the CONSORT and SPIRIT 2013 Statement reporting guidelines. Findings will be published in an open-access peer-reviewed journal. We will also submit abstracts to disseminate the study results at relevant conferences. In addition, we will promote the study findings through professional networks. Due to the collection of sensitive, protected health information, data from this study cannot be made publicly available.

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