

BMJ Open Implementing the I-DECIDED clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: protocol for an interrupted time-series study

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ABSTRACT

Introduction Millions of acute care hospital patients need a peripheral intravenous catheter (PIVC) each year. However, up to half of PIVCs remain in situ when not being used, and 30%–50% of intravenous (IV) catheters develop complications or stop working before treatment is finished, requiring the insertion of a new device. Improved assessment could prompt timely removal of redundant catheters and prevent IV complications. This study aims to validate an evidence-based PIVC assessment and decision-making tool called I-DECIDED and evaluate the effect of implementing this tool into acute hospital clinical practice.

Methods and analysis The protocol outlines a prospective, multicentre, mixed-methods study using an interrupted time-series (multiple measures preintervention and postintervention) implementation at three Australian hospitals between August 2017 and July 2018. The study will examine the effectiveness of the I-DECIDED assessment and decision-making tool in clinical practice on prompting timely PIVC removal and early detection of complications. Primary outcomes are prevalence of redundant PIVCs (defined as device in situ without a clear purpose), IV complications (occlusion, dislodgement, infiltration, extravasation and phlebitis) and substandard dressings (loose, lifting, moist or soiled); device utilisation ratios; and primary bloodstream infection rates. Secondary outcomes including staff barriers and enablers to PIVC assessment and removal, patient participation, documentation of PIVC assessment and decisions taken to continue or remove the PIVC will be recorded. Using the Promoting Action on Research Implementation in Health Services framework, we will undertake staff focus groups, bedside patient interviews and PIVC assessments and chart audits. Patients aged 18 years or more with a PIVC will be eligible for inclusion.

Ethics and dissemination Ethical approval from Queensland Health (HREC/17/QPCH/47), Griffith University (Ref No. 2017/152) and St Vincent's Health and Aged Care Human Research and Ethics Committee (Ref No. 17/28). Results will be published.

Trial registration number ANZCTR: 12617000067370; Pre-results.

Strengths and limitations of this study

- This interrupted time-series study in three hospitals will test the clinical effectiveness of a novel peripheral intravenous catheter assessment and decision-making tool on prompting timely removal of redundant catheters and early detection of complications.
- Interrupted time-series is a robust quasi-experimental design used to assess the effect of an intervention when randomisation is not feasible. Incorporating substantial data from multiple time-points before and after the intervention enables consideration of underlying trends in the clinical practice environment.
- Clinicometric properties of the I-DECIDED tool will be evaluated, including validity, reliability, feasibility and acceptability.
- Qualitative evaluation, including staff focus groups and patient interviews, will explore experiences regarding peripheral intravenous catheter assessment, preimplementation and postimplementation of the I-DECIDED tool.
- A limitation of interrupted time-series studies is that there is no way to assess the impact of concurrent events on the outcomes of interest; therefore, we cannot confirm that measured outcomes truly result from the implementation of the tool.

INTRODUCTION

Peripheral intravenous catheters (PIVCs) are required in almost 70% of patients hospitalised in acute care settings for vital medical therapies such as intravenous (IV) fluids and electrolytes, antibiotics, pain relief, chemotherapy, blood transfusions and nutrition.¹ Despite the high prevalence of PIVCs, their significance historically has been overlooked.^{1 2} These devices are not risk-free, and up to 69% of cannulations experience premature failure due to complications (eg,

occlusion, dislodgement, infiltration, extravasation and phlebitis)^{3–5} which can result in future vascular compromise, treatment delays, extended hospital stay and financial burden, and local and bloodstream infections (BSI).^{1 6 7}

Recent vascular access device (VAD) prevalence audits demonstrate substantial concerns with everyday clinical practice, particularly regarding redundant devices, insertion site complications, substandard dressings and documentation of site assessment and flushing practices.^{8–12} Clinical decision-making depends on a complex mixture of prior education, evidence-based guidelines, hospital policy, the individual patient situation and previous experience. Although much controversy has focused on PIVC dwell time, a 2015 Cochrane systematic review found no difference in phlebitis rates or BSI when PIVCs were subject to clinically indicated or routine replacement.¹³ In hospitals that continue with a policy of 72–96-hour PIVC replacement, experienced nurses often remove a PIVC earlier if they judge it is no longer needed or a potential risk to the patient^{14 15} or leave a functioning PIVC in situ beyond this time if they decide it is clinically appropriate: for instance, if the patient is shortly to complete treatment or has poor vasculature.^{14–16} With a rigorous process that supports clinical decision-making and PIVC assessment education for staff, clinically indicated replacement has proven to be safe and cost-effective.^{17–22}

The practice of not removing idle or redundant devices increases the risk of BSI.^{1 23} Up to 50% of PIVCs remain in situ without any orders for intravenous medications, fluids, blood products or planned procedures.²³ They are often left in, despite a lack of indication, in the belief that this will reduce workload if the patient later needs a PIVC.^{23–25} In one study, half of all PIVCs inserted in the emergency department remained unused 72 hours later,²⁶ suggesting they were either unnecessary or unnoticed by providers. A recent prevalence audit reported that nurses would not replace one-third of PIVCs in the event of failure.¹²

Comprehensive routine assessment is important for the early detection and management of PIVC complications and prompt removal of redundant PIVCs. Yet complications and catheter redundancy persist *despite* policies for routine assessment, possibly because, to date, IV assessment tools have focused largely on phlebitis,²⁷ but many fail to consider factors for failure, such as infiltration, blockage or dislodgement, even though such complications are prevalent and affect one-third of patients with a PIVC.⁴ Despite the popularity of phlebitis tools in clinical practice, the utility is questionable because many use complex scales and none has been rigorously evaluated.^{27–30} Phlebitis scales rely on subjective assessment of symptoms, and inter-rater reliability is poor.²⁹ In addition, the risk of catheter failure increases with poor dressing and securement practices.²⁹ Despite guidelines stressing that catheter dressings should be clean, dry and intact,^{31 32} a significant proportion are in substandard condition in clinical practice,^{11 33} risking catheter

dislodgement, infection and micromotion (facilitating phlebitis and occlusion).

While nursing standards highlight the need to routinely assess catheter patency,^{31 34} nursing practice discrepancies in this area abound. In many institutions, actual flushing practices remain a mystery, with evidence of a diverse range of flushing practices and a lack of documentation of the procedure.^{11 35 36} The effect of intermittent flushing of PIVCs requires further research, and the ideal amount and frequency of flushing has not adequately been confirmed.³⁷ Professional practice standards expect nurses to document assessment and action taken, but recent studies report that documentation of IV assessment and management is inadequate or missing in 14%–68% of patient charts.^{10 11 38}

Patient education and engagement in PIVC assessment is another area that needs attention. A prevalence study in Ireland found a significant association between patients unaware of the reason for their PIVC and the PIVC being redundant, predisposing them to avoidable infection.³⁹ While not all patients with a PIVC will want to be involved in the decision process,⁴⁰ they should, at a minimum, be reminded to alert the nurse for any signs and symptoms of catheter dysfunction.

The current high incidence of PIVC redundancy and complications may be attributed, in part, to the lack of a comprehensive and valid assessment and decision tool. Development and validation of such a tool could have a significant positive impact on patient outcomes.^{27 41} Structured assessment and decision frameworks have shown improvements in clinician performance of patient assessment in general, but it is not yet known if such frameworks have a positive impact on patient outcomes.⁴² This manuscript outlines the protocol for such a study.

The *aims of this study* are to: (1) test the clinimetric properties of the I-DECIDED tool, including validity, reliability, feasibility and acceptability; (2) examine the effectiveness of the I-DECIDED tool on PIVC assessment and documentation, timely removal of redundant devices, dressing and securement, and patient participation in PIVC assessment and (3) analyse the barriers and facilitators of implementing the I-DECIDED tool in preparation for further studies of effectiveness of the tool with other VADs, as well as use of the I-DECIDED tool for education and audit purposes.

METHODS AND ANALYSIS

This prospective, multicentre, mixed-methods study using an interrupted time-series (repeated measures preintervention and postintervention) intervention will include consultation with key stakeholders, staff focus groups, bedside interviews, PIVC assessments and clinical chart audits, BSI surveillance data and field notes. Focus groups and bedside interviews will be audio-recorded and transcribed, and data analysed for themes. Field notes related to the positive or negative aspects of study processes will be documented and included in the thematic analysis.

I-DECIDED™

IV ASSESSMENT & DECISION TOOL

IDENTIFY if an IV is in situ

If an IV has been removed in past 48 hrs, observe site for post-infusion phlebitis.

DOES patient need the IV?

If not used in past 24 hrs, or unlikely to be used in next 24 hrs, consider removal. Consider change to oral medications.

EFFECTIVE function?

Does the IV infuse and/or flush well? Follow local policy for flushing and locking.

COMPLICATIONS at IV site?

Pain $\geq$ 2/10, redness $>$ 1cm, swelling $>$ 1cm, discharge, infiltration, extravasation, hardness, palpable cord or purulence.

INFECTION prevention

Hand hygiene, scrub the hub & allow to dry before each IV access. Careful use of administration sets.

DRESSING & securement

Clean, dry, and intact. IV and lines secure.

EVALUATE & EDUCATE

Evaluate concerns. Educate as needed. Discuss IV plan with patient & family.

DOCUMENT your decision

Continue to monitor, change dressing/securement or remove IV.

*Always consider local policy,
and consult with team & patient as required.*

Figure 1 I-DECIDED IV assessment and decision tool.

I-DECIDED is an acronym for an evidence-based, clinical decision-making tool for intravenous device assessment and removal. The tool was developed by the lead author, based on prior work on PIVC assessment^{8 29 30 43–45} and synthesis of evidence including best practice clinical guidelines,^{31 32 34 46 47} phlebitis assessment tools,^{29–31 34} decision algorithms,^{48–51} checklists^{52 53} and PIVC maintenance bundles.^{18 54–61} Taking a step-by-step approach, the tool guides clinicians to assess each aspect of device management and to facilitate decision-making related to device necessity, in consultation with the treating team and the patient (see [figure 1](#)).

The Promoting Action on Research Implementation in Health Services framework^{62 63} will guide the processes used for implementing evidence into practice. Practice change is not automatic once evidence is provided to clinicians; disruption of convention and cultural change are also required.⁶⁴ Therefore, the information provided by key stakeholders and focus group participants is crucial in determining how organisational context, culture and resources at each site shape the local implementation of the intervention and development of associated educational resources.

Study setting

The study will take place in a total of seven medical/surgical wards in three Australian (Queensland) hospitals (two public, one private) between August 2017 and July 2018. Senior hospital nurses have been approached by the lead author, informed of the study and invited to participate. Nurses from the research, infection control and education departments of three hospitals have expressed interest; discussed the study at local nursing and medical executive meetings; and invited nurse unit managers to enrol their ward in the study. Each hospital has nominated a research nurse to assist with local participant enrolment and data collection, 1 day per fortnight.

Outcomes

Primary outcomes

- ▶ Device utilisation ratios (number of PIVCs per total number of patients per ward, and number of PIVCs per patient).
- ▶ Prevalence of redundant PIVCs, defined as device in situ without a clear purpose; that is, not used for intravenous fluids, blood products, parenteral nutrition or medications for the past 24 hours and not anticipated to be used in the next 24 hours (eg, no current intravenous fluid or intravenous medication orders, no planned procedure, no cardiac monitoring, no history of seizures, unstable medical condition or recent rapid response call), determined by chart audit and in consultation with the bedside nurse and treating team, if required. The tool is not intended to prescribe the direction of medical care. It is designed as a prompt to help staff make an informed decision regarding PIVC management. If staff consider a patient to be possibly unstable or unwell, the decision to leave the PIVC in situ would be justified.
- ▶ Prevalence of loose, moist or soiled IV dressings, as a percentage of all dressings assessed.
- ▶ Prevalence of IV complications as a percentage of all PIVCs assessed, defined as any of the following: patient-reported pain $\geq 2/10$, redness >1 cm from insertion site, swelling >1 cm from insertion site, infiltration (defined as permeation of intravenous fluid into the interstitial compartment, causing swelling of the tissue around the catheter site), discharge, hardness, palpable cord or purulence.
- ▶ Presence of primary BSI: laboratory confirmed, collected from monthly routine infection control surveillance data at each hospital. Primary BSI is defined as (1) isolation of one or more recognised bacterial or fungal pathogens from one or more blood cultures (eg, *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Escherichia coli*, *Klebsiella*, *Proteus*, *Candida albicans*, etc) or (2) the patient has at least one of the following signs and symptoms within 24 hours of positive blood culture being collected: fever ($>38^{\circ}\text{C}$), chills or hypotension AND any of the following:

- ▶ Isolation of the same potential contaminant from two or more blood cultures drawn on separate occasions within a 48-hour period.
- ▶ Isolation of a potential contaminant from a single blood culture drawn from a patient with an intravascular line (within 48 hours of the episode) and appropriate antimicrobial therapy is commenced.⁶⁵
- ▶ Presence of PIVC-related *S. aureus* BSI (SAB), defined as a healthcare-associated SAB in a patient with:
 - ▶ A PIVC in situ or removed within 7 days before the positive blood culture; and
 - ▶ No other source of SAB identified and either a physician or a nurse documenting the PIVC as the source of the SAB in the medical record; and/or
 - ▶ Physical findings at the insertion site suggesting a PIVC as the source (tenderness, redness, induration, phlebitis).⁶⁶

Secondary outcomes

- ▶ Staff focus group feedback on acceptability of I-DECIDED tool and the barriers and facilitators to PIVC assessment and prompt removal.
- ▶ Proportion of patients verbally reporting that they have been informed by the staff about reasons for the PIVC or plans for intravenous treatment.
- ▶ Proportion of nursing shifts where (a) the I-DECIDED tool was completed in full and (b) the appropriate action to continue or remove the PIVC was carried out.

Research procedure

Prior to the study commencement, content and face validity assessments were undertaken with vascular access experts and clinicians experienced in PIVC assessment. Following validation of the tool, three study phases are planned: *Baseline* (T1) (4 months), *Intervention* (T2) (2 months) and *Evaluation* (T3) (4 months) (see figure 2).

Baseline phase (T1)

Baseline observations will include usual clinical practice of PIVC assessment and documentation; device utilisation ratios; prevalence of redundant PIVCs; IV complications; loose, moist or soiled dressings; primary BSI and PIVC-SAB data. Consultation with key stakeholders, staff focus groups, bedside interviews, PIVC assessments and chart audits will be conducted, as below:

- ▶ *Consultation with key stakeholders* (nursing and medical directors, nurse unit managers, nurse educators, vascular access experts, infection prevention team): conducted by the lead author to determine current PIVC policy including education, PIVC assessment tools in use and required documentation for VAD surveillance in each participating site.
- ▶ *Inter-rater reliability*: assessed between the lead author and three research nurses using the I-DECIDED tool for a total of 12 patients.

Activity	T1				T2		T3			
	Baseline				Implementation		Evaluation			
Month	1	2	3	4	5	6	7	8	9	10
Meet with key stakeholders	✓			✓			✓			✓
PIVC assessments, chart audits	✓	✓	✓	✓			✓	✓	✓	✓
BSI data	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Staff focus groups			✓						✓	
Bedside interviews			✓						✓	
Education sessions					✓	✓				
Use of the tool in clinical practice					✓	✓	✓	✓	✓	✓

PIVC, peripheral intravenous catheter; BSI, bloodstream infection

Figure 2 Timeline of the I-DECIDED study interrupted time-series analysis.

- *Device utilisation ratios*: calculated at each time-point (number of PIVCs per total number of patients per ward and number of PIVCs per patient).
- *Primary BSI and PIVC-SAB data per ward per month*: requested from each hospital infection prevention service.
- *PIVC assessment and chart audits* ($n=480$): over 4 months (eight time-points), research nurses will complete a screening log for each ward, detailing number of occupied beds, number of registered nurses that shift and number of patients with one or more PIVCs. Presence of another type of VAD in addition to a PIVC will be recorded. Using the I-DECIDED tool, the research nurse will assess PIVCs for redundancy, complications, dressing integrity and documentation. The research nurse will ask the patient's nurse about the functional status of the PIVC. Patients will be asked if the PIVC has been assessed or attended to in the past 8 hours, and any concerns will be directed to the patient's nurse. Data will be entered via hand-held electronic devices directly into an electronic data platform supported by Research Electronic Data Capture (REDCap).⁶⁷ The research nurse will then check the patient's chart for evidence of recent PIVC assessment. During T1, ward nurses will not yet be using the I-DECIDED tool, therefore this comparison will examine what nurses in the focus groups reportedly assess and the assessment documented in the patient's chart as per usual practice. Each PIVC will be assessed once, and no follow-up will be undertaken.
- *Focus groups with staff nurses* ($n=7$ groups, 30 min): conducted by the lead author during the shift change-over period, using semistructured questions from a prepared script. This will assess current practice of PIVC assessment, documentation and decision-making, and determine the level of support for the introduction of the I-DECIDED tool, as well as potential barriers and facilitators to implementation. Nurses will be asked to share their views on eliciting patient participation in PIVC assessment.
- *Short bedside interviews with patients* ($n=24$, <5 min): conducted by the lead author, using semistructured questions from a prepared script. Consenting patients will

be asked about their experience with the current PIVC, including their experience of staff education, communication and responsiveness to any concerns. Questions or concerns will be directed to the patient's nurse. In addition, patients will be asked about types of education or support they would like to see implemented, if any, to assist in their participation in PIVC care.⁶⁸

Intervention phase (T2)

The I-DECIDED tool will be implemented in seven wards across three hospitals. Regular meetings with key local opinion leaders will continue. Ward staff champions will be identified and trained to facilitate implementation and support staff in the use of the tool.

- *Education sessions for ward staff* regarding use of the I-DECIDED tool: provided by the lead author, in collaboration with hospital educators. Educational materials (posters, lanyard cards, bedside folder inserts) will be developed and provided.⁶⁹
- A dedicated VAD care plan with I-DECIDED tool (see figure 3) has been developed in consultation with key stakeholders and approved by the forms committee at each participating hospital. This care plan will be used in the trial wards instead of the usual PIVC assessment documentation to track assessment and decisions made to continue current care, change the dressing and securement, or remove the PIVC. Completed care plans will be filed in the patient care record.
- Nurses will use the I-DECIDED tool to perform PIVC assessment and document decision taken each shift. Any concerns will be documented in the medical record, as per usual practice.
- *Inter-rater and intrarater reliability*: assessed with four staff nurses in each hospital (total 12 nurses) by the lead author.
- *Think aloud assessments*: five staff nurses experienced in PIVC assessment will participate in an activity to track decision-making with the I-DECIDED tool.
- Ward in-service updates and informal discussions with staff will be conducted by the lead author and actual barriers and facilitators encountered during the implementation period will be noted.
- Data collection will not occur during this phase.

VASCULAR ACCESS DEVICE ASSESSMENT FORM Hospital: Ward:		(Affix patient identification label here)																																																							
		URN:																																																							
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		Given Names:																																																							
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I-DECIDED™ IV ASSESSMENT & DECISION TOOL <i>If the IV is not needed, not working, or has any complications, it should be removed as soon as possible.</i> <i>Always consider local policy and consult with team & patient as required.</i>																																																									
 Mark IV position with an X	IV Insertion Date: Time: Size/Gauge: Site/Location: Indication for IV: Number of insertion attempts: Inserted by (person or department): Comments about IV access:																																																								
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DRESSING & securement Goal = Clean, dry, and intact. Change if moist, soiled or loose. Secure IV & tubing.																																																									
EVALUATE & EDUCATE Evaluate concerns. Educate as needed. Discuss IV plan with patient & family.																																																									
DOCUMENT your decision, based on this assessment (choose one)																																																									
Continue to monitor																																																									
Dressing/securement change																																																									
Remove IV and document above																																																									
Initials																																																									

VASCULAR ACCESS DEVICE ASSESSMENT FORM

DOCUMENT ANY CONCERNS IN THE PATIENT MEDICAL RECORD.

Figure 3 Vascular access device assessment form.

Evaluation phase (T3)

The I-DECIDED tool will continue to be used in clinical practice, and PIVC assessments, chart audits, staff focus groups and patient bedside interviews will be repeated. Consultation with key stakeholders will continue, and ongoing education and feedback to staff will be provided at in-service sessions.⁷⁰

- *PIVC assessments and chart audits* (n=480) over 4 months (eight time-points) will examine device utilisation ratios, PIVC redundancy, complications, dressing

integrity, documentation and BSI data, and results will be compared with T1.

- *Focus groups with staff* (n=7 groups) will explore the acceptability and feasibility of using the I-DECIDED tool in clinical practice.
- *Bedside interviews with patients* (n=24) will be conducted as per T1. The percentage of patients who report being asked about their PIVC will be calculated, and results will be compared with T1 to assess if there has been any evident change in patients' perceptions of

staff assessing their PIVC and engaging them in PIVC care.

Patient and public involvement

The research questions were developed from prior research work (online survey and interviews) from our group on patient experience of PIVC management.^{40 71} In prior work, patients expressed the need for more patient involvement in PIVC assessment and care, particularly expressing that staff were often not responding to their concerns. However, patients were not directly involved in the design of this study. The current study investigates the use of an assessment tool that prioritises evaluation of patient concerns and encourages patient education. Informed consent is being sought for all study activities, as described below. Patients and staff who participate in any study activities are provided with the lead author's contact details and offered the option of providing an email address so they may be contacted with the results of the study. Specific patient advisers were not consulted for this study.

Participants and recruitment

Patients over 18 years with a PIVC and able to provide informed consent may participate in PIVC assessments, chart audits and bedside interviews. The research nurse will approach patients with a PIVC and introduce the study. Patients will be provided with the opportunity to read the participant information sheet and ask any questions prior to deciding on participation. If a patient provides verbal consent, a sticker will be placed in the patient record, noting the chart has been audited for study purposes. During the PIVC assessment, patients who voluntarily express enthusiasm to speak about their own PIVC experience will be asked if they would consent to participate in a 5 min bedside interview about their current PIVC. Interviews will be conducted by the lead author.

Nurses working clinically on the medical and surgical wards where the project will take place will be invited by the research nurse to consent to participate in staff focus groups, conducted by the lead author. Focus groups will be held in a quiet room away from the clinical area during the staff in-service period, immediately following the afternoon shift handover. This time period has been chosen by nurse educators in each ward as likely to attract the most participants. Nurse educators and nurse unit managers will inform the staff about the focus groups in advance and encourage attendance. Demographics of clinical level and years of experience will be collected, but identifying personal details will not be collected.

Sample size estimate

Interrupted time-series studies require multiple observations preintervention and postintervention to identify trends over time. Penfold and Zhang recommend a minimum of eight time-points before and eight time-points after an intervention⁷²; therefore, a period of

4 months (eight time-points) each for phases 1 and 3 was chosen to account for seasonal variations in patient populations and enable statistical evaluations over time within the constraints of the study budget.

- PIVC assessments and chart audits: approximately 20 assessments/hospital x 3 hospitals x 8 time-points x 2 phases (T1, T3)=960, depending on the number of patients with a PIVC who consent to be included in the study on the day of data collection.
- Patient bedside interviews: 3–4 patients/ward x 7 wards x 2 phases (T1, T3)=approximately 48 patients, depending on the number of patients with a PIVC who consent to be interviewed about their PIVC experience on the day of data collection.

The sample size for PIVC assessments and chart audits is an estimate based on predicted participant availability, from data provided by the participating hospitals. The I-DECIDED tool encourages patient participation in PIVC assessment, and from our group's previous research in consumer experience of PIVCs,^{40 71} it is likely that the majority of patients will consent. The sample size of patient interviews is a projected estimate of the number of patients available and willing to discuss their PIVC experience in more depth.

- Staff focus groups: 4–6 staff/ward x 7 wards x 2 phases (T1, T3)=approximately 48–72 staff, depending on staff availability.

The sample size of staff focus groups was chosen to capture diverse nursing perspectives on PIVC assessment and decision-making from a variety of clinical settings (medical and surgical, public and private), rather than seek to recruit a representative sample.⁷³ Staff from each participating ward will be offered the opportunity to participate in a focus group to provide feedback and insights on the PIVC assessment process (T1, T3) and the I-DECIDED tool (T3). As the study has received support from nurse executives and nurse unit managers at each site, staff recruitment to participate in focus groups is not expected to be difficult.

Data analysis

The lead author and statistician will have access to the final dataset. Analysis and reporting will follow the Standards for QUality Improvement Reporting Excellence (SQUIRE) 2.0 guidelines.⁷⁴ The COSMIN guidelines (COnsensus-based Standards for the selection of health Measurement INstruments)⁷⁵ will guide analysis of the clinimetric properties of the I-DECIDED tool by the lead author and a research statistician. Statistical methods will include calculations of Cronbach's alpha (internal consistency), kappa calculations (inter-rater and intrarater reliability), intraclass correlation coefficient, face validity and content validity index.

Clinical effectiveness of the I-DECIDED tool will be measured by statistical comparison of outcomes (PIVC utilisation, redundancy, all complications, BSI rates, substandard dressings and missing documentation) across time-points before (n=8) and after (n=8) the

intervention. Results from individual wards will be analysed using parametric testing (t-test) to identify differences in PIVC management between phases T1 and T3. CIs will be calculated to determine the statistical significance of the difference.⁷⁶

Statistical process control (SPC) analysis will be used to assess the effects of the intervention.⁷⁷ SPC charts will display data collected at the 16 time-points and indicate patterns of variation over the duration of the study, with built-in thresholds (upper and lower limits) to highlight significant variations in practice, such as seasonal bed occupancy. Bed occupancy data and staffing ratios will be collected on the study screening log at each time-point for this purpose.

Taped interviews with staff and patients will be transcribed and data analysed based on Norwood's framework⁷⁸ using an inductive content analysis process to allow themes to emerge from the data. Two researchers will independently conduct a simple thematic analysis of the audio transcripts and field notes of the focus groups and bedside interviews. Key themes and concepts will be categorised, and the researchers will meet to discuss and achieve consensus on the meaning of the data.

ETHICS AND DISSEMINATION

Clinical trial insurance is held by the Sponsor, Griffith University. Funding for the research nurses at each site is covered by the university postdoctoral fellowship scheme and competitive grant funding.

Informed verbal consent to participate in PIVC assessments and chart audits and written consent to participate in bedside interviews will be obtained. Patients will be given the opportunity to read the participant information sheet and ask any questions prior to deciding on participation. If the person consents, he/she will receive a copy of the participant information sheet and a sticker confirming participation will be placed in the medical record. Identifying details will not be collected. Each PIVC will be assigned an alphanumeric code.

Informed written consent to participate in staff focus groups will be sought. Staff will be given the opportunity to read the participant information sheet and ask any questions prior to deciding on participation. If the person consents, he/she will receive a copy of the signed and dated written consent form and the participant information sheet. Light refreshments will be provided at focus group sessions as a courtesy in exchange for the participants' time.

There is no foreseen risk of participation in any aspect of this study, and patients or staff who do not wish to attend will not experience any adverse consequences. Participants will be free to withdraw consent and discontinue participation at any time. They will be given the opportunity to revoke the researcher's rights to keep any data collected. This choice will not impact on their relationship with the hospital in any way.

Adverse events are not expected, but will be monitored and reported to the human research ethics committee (HREC). If protocol amendments are required (eg, changes to eligibility criteria), the lead author will update all investigators, HRECs, update patient information and consent forms, and update the trial registry. Before qualitative interviews and audio-recordings, participants will provide informed written consent. In the unlikely event that participants become distressed, they will receive initial support from the lead author and be referred to the relevant institutional contact.

The study results will be prepared for submission to peer-reviewed journals, consistent with International Committee of Medical Journal Editors Guidelines and authorship criteria. Results will be disseminated to participating sites, and presented at national and international conferences. A webinar will be prepared and posted online, and advertised via social media. Results will be disseminated on social media (Facebook, Twitter) and promoted to health groups and patient advocacy groups.

DISCUSSION

Too many PIVCs are left in place when no longer needed, and too many others fail before treatment completion, requiring the insertion of a new device. A structured and comprehensive approach to IV assessment and decision-making may promote early detection of complications and prompt removal of intravenous catheters when no longer needed. I-DECIDED is unique because it is an evidence-based IV assessment and decision tool that prompts patient education and participation. The predicted outcome of implementing this simple but comprehensive tool is an improved experience of intravenous therapy, early detection of complications, fewer idle PIVCs and improved documentation. This could reduce unnecessary pain and suffering for patients, decrease the risk of potentially deadly BSI, and reduce treatment delays and hospital costs. This interrupted time-series study will help to inform international policy and practice.

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Contributors GR-B conceived and developed the I-DECIDED tool. GR-B, MC, MM, VC and CMR conceived the study and designed the protocol. All authors prepared and approved the final version of the manuscript.

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