

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

Gillian Ray-Barruel,^{1,2,3} Marie Cooke,^{1,4} Marion Mitchell,^{1,3,4,5} Vineet Chopra,⁶ Claire M Rickard^{1,2,3,4}

To cite: Ray-Barruel G, Cooke M, Mitchell M, *et al*. Implementing the I-DECIDED clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: protocol for an interrupted time-series study. *BMJ Open* 2018;**8**:e021290. doi:10.1136/bmjopen-2017-021290

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2017-021290>).

Received 21 December 2017
Revised 23 April 2018
Accepted 11 May 2018

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,



For numbered affiliations see end of article.

Correspondence to

Dr Gillian Ray-Barruel;
g.ray-barruel@griffith.edu.au

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 clinicometric 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			
	Month	Baseline			Implementation		Evaluation			
	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: _____

Family Name: _____

Given Names: _____

Address: _____

Date of Birth: _____ Sex: M F

I-DECIDED™ IV ASSESSMENT & DECISION TOOL

If the IV is not needed, not working, or has any complications, it should be removed as soon as possible.

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

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:	
IV Removal:	
Date:	
Reason:	
Removed by:	

IV Assessment and Decision Record <small>Tick when completed</small>	Date	Insertion day			Day 1			Day 2			Day 3			Day 4			
		AM	PM	ND	AM	PM	ND	AM	PM	ND	AM	PM	ND	AM	PM	ND	
		I IDENTIFY if an IV is in situ <small>If an IV has been removed in past 48 hrs, observe site for post-infusion phlebitis.</small>															
D OES patient need the IV? <small>If not used in past 24 hrs, or unlikely to be used in next 24 hrs, consider removal. Consider change to oral medications.</small>																	
E FECTIVE function? <small>Does the IV infuse and/or flush well? Follow local policy for flushing and locking.</small>																	
C OMPPLICATIONS at IV site? <small>Pain ≥ 2/10, redness > 1cm, swelling > 1cm, discharge, infiltration, extravasation, hardness, palpable cord or purulence.</small>																	
I NFECTION prevention <small>Hand hygiene, ANTT, scrub the hub & allow to dry before each IV access.</small>																	
D RESSING & securement <small>Goal = Clean, dry, and intact. Change if moist, soiled or loose. Secure IV & tubing.</small>																	
E VALUATE & EDUCATE <small>Evaluate concerns. Educate as needed. Discuss IV plan with patient & family.</small>																	
D OCU MENT your decision, based on this assessment (<i>choose one</i>)																	
Continue to monitor																	
Dressing/securement change																	
Remove IV and document above																	
<i>Initials</i>																	

DOCUMENT ANY CONCERNS IN THE PATIENT MEDICAL RECORD.

VASCULAR ACCESS DEVICE ASSESSMENT FORM

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 clinicometric 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.

Author affiliations

¹Alliance for Vascular Access Teaching and Research (AVATAR), Menzies Health Institute Queensland, Griffith University, Brisbane, Queensland, Australia

²Centre for Clinical Nursing, Royal Brisbane and Women's Hospital, Brisbane, Queensland, Australia

³Nursing Practice Development Unit, Princess Alexandra Hospital, Brisbane, Queensland, Australia

⁴School of Nursing and Midwifery, Griffith University, Brisbane, Queensland, Australia

⁵Intensive Care Unit, Princess Alexandra Hospital, Brisbane, Queensland, Australia

⁶Division of Hospital Medicine, Patient Safety Enhancement Program, Michigan Medicine and VA Ann Arbor Health System, Ann Arbor, Michigan, USA

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.

Funding GR-B is supported by a Griffith University postdoctoral fellowship, Menzies Health Institute Queensland New Researcher Grant, Menzies Health Institute Queensland Incentive Quality Development Scheme and Australian College for Infection Prevention and Control 2017 Early Career Research Grant.

Disclaimer No commercial entity had any role in the conception, design or funding of this study, or in the preparation of this manuscript.

Competing interests Griffith University has received on GR-B's behalf unrestricted investigator-initiated research grants (3M, BD, Smiths Medical) and consultancy payments (3M, BD, Medline, ResQDevices). MC: Griffith University has received on her behalf unrestricted investigator-initiated research or educational grants (3M, Baxter, BD, Entrotech). CMR: Griffith University has received on her behalf unrestricted investigator-initiated research or educational grants (3M, Adhezion, Angiodynamics, Bard, Baxter, BBraun, BD, Centurion Medical Products, Cook Medical, Entrotech, Flomedical, ICU Medical, Medical Australia, Medtronic, Smiths Medical, Teleflex) and consultancy payments (3M, Bard, BBraun, BD, ResQDevices, Smiths Medical). VC: VC is supported by a career development award from the Agency for Healthcare Research and Quality (1-K08- HS022835- 01).

Patient consent Not required.

Ethics approval Hospital and University Human Research Ethics Committee (HREC) approval has been obtained 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).

Provenance and peer review This study has been peer reviewed by Griffith University internal competitive grant funding schemes.

Open Access This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>

© Article author(s) (or their employer(s) unless otherwise stated in the text of the article) 2018. All rights reserved. No commercial use is permitted unless otherwise expressly granted.

REFERENCES

- Zingg W, Pittet D. Peripheral venous catheters: an under-evaluated problem. *Int J Antimicrob Agents* 2009;34(Suppl 4):S38–42.
- Austin ED, Sullivan SB, Whittier S, et al. Peripheral intravenous catheter placement is an underrecognized source of staphylococcus aureus bloodstream infection. *Open Forum Infect Dis* 2016;3:ofw072.
- Marsh N, Webster J, Larson E, et al. Observational study of peripheral intravenous catheter outcomes in adult hospitalized patients: a multivariable analysis of peripheral intravenous catheter failure. *J Hosp Med* 2018;13:E1–7.
- Wallis MC, McGrail M, Webster J, et al. Risk factors for peripheral intravenous catheter failure: a multivariate analysis of data from a randomized controlled trial. *Infect Control Hosp Epidemiol* 2014;35:63–8.
- Murayama R, Uchida M, Oe M, et al. Removal of peripheral intravenous catheters due to catheter failures among adult patients. *J Infus Nurs* 2017;40:224–31.
- Hadaway L. Short peripheral intravenous catheters and infections. *J Infus Nurs* 2012;35:230–40.
- Helm RE, Klausner JD, Klempner JD, et al. Accepted but unacceptable: peripheral IV catheter failure. *J Infus Nurs* 2015;38:189–203.
- Alexandrou E, Ray-Barruel G, Carr PJ, et al. International prevalence of the use of peripheral intravenous catheters. *J Hosp Med* 2015;10:530–3.
- McGuire R. Assessing standards of vascular access device care. *Br J Nurs* 2015;24:S29–35.
- New KA, Webster J, Marsh NM, et al. Intravascular device use, management, documentation and complications: a point prevalence survey. *Aust Health Rev* 2014;38:345–9.
- Russell E, Chan RJ, Marsh N, et al. A point prevalence study of cancer nursing practices for managing intravascular devices in an Australian tertiary cancer center. *Eur J Oncol Nurs* 2014;18:231–5.
- Wong K, Cooper A, Brown J, et al. The prevalence of peripheral intravenous cannulae and pattern of use: A point prevalence in a private hospital setting. *J Clin Nurs* 2018;27(1-2):e363–7.
- Webster J, Osborne S, Rickard CM, et al. Clinically-indicated replacement versus routine replacement of peripheral venous catheters. *Cochrane Database Syst Rev* 2015;8:CD007798.
- Johansson ME, Pilhammar E, Khalaf A, et al. Registered nurses' adherence to clinical guidelines regarding peripheral venous catheters: a structured observational study. *Worldviews Evid Based Nurs* 2008;5:148–59.
- Johansson ME, Pilhammar E, Willman A. Nurses' clinical reasoning concerning management of peripheral venous cannulae. *J Clin Nurs* 2009;18:3366–75.
- Palese A, Cassone A, Kulla A, et al. Factors influencing nurses' decision-making process on leaving in the peripheral intravascular catheter after 96 hours: a longitudinal study. *J Infus Nurs* 2011;34:319–26.
- Bolton D. Clinically indicated replacement of peripheral cannulas. *Br J Nurs* 2015;24:S4–12.
- DeVries M, Valentine M, Mancos P. Protected clinical indication of peripheral intravenous lines: successful implementation. *Journal of the Association for Vascular Access* 2016;21:89–92.
- Helton J, Hines A, Best J. Peripheral IV site rotation based on clinical assessment vs. length of time since insertion. *Medsurg Nurs* 2016;25:44–9.
- Morrison K, Holt KE. The effectiveness of clinically indicated replacement of peripheral intravenous catheters: an evidence review with implications for clinical practice. *Worldviews Evid Based Nurs* 2015;12:187–98.
- Tan YH, Tai WL, Sim C, et al. Optimising peripheral venous catheter usage in the general inpatient ward: a prospective observational study. *J Clin Nurs* 2017;26:133–9.
- Tuffaha HW, Rickard CM, Webster J, et al. Cost-effectiveness analysis of clinically indicated versus routine replacement of peripheral intravenous catheters. *Appl Health Econ Health Policy* 2014;12:51–8.
- Becerra MB, Shirley D, Safdar N. Prevalence, risk factors, and outcomes of idle intravenous catheters: An integrative review. *Am J Infect Control* 2016;44:e167–72.
- Castro-Sánchez E, Charani E, Drumright LN, et al. Fragmentation of care threatens patient safety in peripheral vascular catheter management in acute care--a qualitative study. *PLoS One* 2014;9:e86167.
- Gledstone-Brown L, McHugh D. Review article: Idle 'just-in-case' peripheral intravenous cannulas in the emergency department: Is something wrong? *Emerg Med Australas* 2017.
- Limm EI, Fang X, Dendle C, et al. Half of all peripheral intravenous lines in an Australian tertiary emergency department are unused: pain with no gain? *Ann Emerg Med* 2013;62:521–5.
- Rickard CM, Ray-Barruel G. Peripheral intravenous catheter assessment: beyond phlebitis. *Lancet Haematol* 2017;4:e402–3.
- Göransson K, Förberg U, Johansson E, et al. Measurement of peripheral venous catheter-related phlebitis: a cross-sectional study. *Lancet Haematol* 2017;4:e424–30.
- Marsh N, Mihala G, Ray-Barruel G, et al. Inter-rater agreement on PIVC-associated phlebitis signs, symptoms and scales. *J Eval Clin Pract* 2015;21:893–9.
- Ray-Barruel G, Polit DF, Murfield JE, et al. Infusion phlebitis assessment measures: a systematic review. *J Eval Clin Pract* 2014;20:191–202.
- Infusion Nurses Society. Infusion therapy standards of practice. *J Infus Nurs* 2016;39.
- Loveday HP, Wilson JA, Pratt RJ, et al. epic3: national evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England. *J Hosp Infect* 2014;86(Suppl 1):S1–70.
- Miliani K, Taravella R, Thillard D, et al. Peripheral venous catheter-related adverse events: evaluation from a multicentre epidemiological study in France (the CATHEVAL Project). *PLoS One* 2017;12:e0168637.
- Royal College of Nursing. *Standards for infusion therapy*. London, UK: Royal College of Nursing, 2016.
- Keogh S, Flynn J, Marsh N, et al. Nursing and midwifery practice for maintenance of vascular access device patency. A cross-sectional survey. *Int J Nurs Stud* 2015;52:1678–85.
- Keogh S, Flynn J, Marsh N, et al. Varied flushing frequency and volume to prevent peripheral intravenous catheter failure: a pilot, factorial randomised controlled trial in adult medical-surgical hospital patients. *Trials* 2016;17:348.
- Goossens GA. Flushing and locking of venous catheters: available evidence and evidence deficit. *Nurs Res Pract* 2015;1–12.
- Yagnik L, Graves A, Thong K. Plastic in patient study: prospective audit of adherence to peripheral intravenous cannula monitoring and documentation guidelines, with the aim of reducing future rates of intravenous cannula-related complications. *Am J Infect Control* 2017;45:34–8.
- McHugh SM, Corrigan MA, Dimitrov BD, et al. Role of patient awareness in prevention of peripheral vascular catheter-related bloodstream infection. *Infect Control Hosp Epidemiol* 2011;32:95–6.

40. Larsen E, Keogh S, Marsh N, *et al.* Experiences of peripheral IV insertion in hospital: a qualitative study. *Br J Nurs* 2017;26:S18–S25.
41. Alexander M. A Search for tools to support decision-making for PIVC use. *J Hosp Med* 2017;12:859–60.
42. Munroe B, Curtis K, Considine J, *et al.* The impact structured patient assessment frameworks have on patient care: an integrative review. *J Clin Nurs* 2013;22:2991–3005.
43. Takashima M, Ray-Barruel G, Keogh S, *et al.* Randomised controlled trials in peripheral vascular access catheters: a scoping review. *Vascular Access* 2015;1.
44. Webster J, McGrail M, Marsh N, *et al.* Postinfusion phlebitis: incidence and risk factors. *Nurs Res Pract* 2015.
45. Zhang L, Cao S, Marsh N, *et al.* Infection risks associated with peripheral vascular catheters. *J Infect Prev* 2016;17:207–13.
46. O'Grady NP, Alexander M, Burns LA, *et al.* Guidelines for the prevention of intravascular catheter-related infections. *Clinical Infectious Diseases* 2011;52:e162–e193.
47. HSE Health Protection Surveillance Centre. Prevention of intravascular catheter-related infection in Ireland update of 2009 national guidelines. 2014. <http://www.hpsc.ie/a-z/hepatitis/guidance/forenalunits/File,4115,en.pdf>
48. Chopra V, Flanders SA, Saint S, *et al.* The Michigan Appropriateness Guide for Intravenous Catheters (MAGIC). *Ann Intern Med* 2015;163:S1–40.
49. Moureau NL, Trick N, Nifong T, *et al.* Vessel Health and Preservation (Part 1): a new evidence-based approach to vascular access selection and management. *J Vasc Access* 2012;13:351–6.
50. Hallam C, Weston V, Denton A, *et al.* Development of the UK Vessel Health and Preservation (VHP) framework: a multi-organisational collaborative. *J Infect Prev* 2016;17:65–72.
51. Brier J, Carolyn M, Haverly M, *et al.* Knowing 'something is not right' is beyond intuition: development of a clinical algorithm to enhance surveillance and assist nurses to organise and communicate clinical findings. *J Clin Nurs* 2015;24:832–43.
52. Hales B, Terblanche M, Fowler R, *et al.* Development of medical checklists for improved quality of patient care. *International Journal for Quality in Health Care* 2008;20:22–30.
53. Winters BD, Gurses AP, Lehmann H, *et al.* Clinical review: Checklists - translating evidence into practice. *Critical Care* 2009;13:210.
54. Boyd S, Aggarwal I, Davey P, *et al.* Peripheral intravenous catheters: the road to quality improvement and safer patient care. *J Hosp Infect* 2011;77:37–41.
55. Caguioa J, Pilpil F, Greensitt C, *et al.* Hands: standardised intravascular practice based on evidence. *Br J Nurs* 2012;21(14 Suppl):S4–11.
56. Crowell J, O'Neil K, Drager L. Project HANDS: A bundled approach to increase short peripheral catheter dwell time. *J Infus Nurs* 2017;40:274–80.
57. Freixas N, Bella F, Limón E, *et al.* Impact of a multimodal intervention to reduce bloodstream infections related to vascular catheters in non-ICU wards: a multicentre study. *Clinical Microbiology and Infection* 2013;19:838–44.
58. Mestre G, Berbel C, Tortajada P, *et al.* Successful multifaceted intervention aimed to reduce short peripheral venous catheter-related adverse events: a quasiexperimental cohort study. *Am J Infect Control* 2013;41:520–6.
59. Rhodes D, Cheng AC, McLellan S, *et al.* Reducing *Staphylococcus aureus* bloodstream infections associated with peripheral intravenous cannulae: successful implementation of a care bundle at a large Australian health service. *J Hosp Infect* 2016;94:86–91.
60. Sriupayo A, Inta N, Boonkongrat S, *et al.* Effectiveness of peripheral vascular catheter care bundle in the Pediatric Nursing Service, Chiang Mai University Hospital. *Thailand Chiang Mai Medical Journal* 2014;53:63.
61. Talento AF, Morris-Downes M, Thomas T, *et al.* Implementing peripheral vascular catheter care bundle in a tertiary care hospital: No room for complacency? *Clin Microbiol Infect* 2011;17(Suppl 4):S368.
62. Kitson AL, Rycroft-Malone J, Harvey G, *et al.* Evaluating the successful implementation of evidence into practice using the PARIHS framework: theoretical and practical challenges. *Implementation Science* 2008;3:1.
63. Rycroft-Malone J. The PARIHS framework—a framework for guiding the implementation of evidence-based practice. *J Nurs Care Qual* 2004;19:297–304.
64. Graham ID, Logan J, Harrison MB, *et al.* Lost in knowledge translation: time for a map? *J Contin Educ Health Prof* 2006;26:13–24.
65. Queensland Health. Signal infection surveillance manual: bloodstream infection. 2013. https://www.health.qld.gov.au/__data/assets/pdf_file/0036/374598/signal-manual.pdf
66. Stuart RL, Cameron DRM, Scott C, *et al.* Peripheral intravenous catheter-associated *Staphylococcus aureus* bacteraemia: more than 5 years of prospective data from two tertiary health services. *Med J Aust* 2013;198:551–3.
67. Harris PA, Taylor R, Thielke R, *et al.* Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
68. Coulter A, Locock L, Ziebland S, *et al.* Collecting data on patient experience is not enough: they must be used to improve care. *BMJ* 2014;348:g2225.
69. Giguère A, Légaré F, Grimshaw J, *et al.* Printed educational materials: effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev* 2012;11.
70. Fakhri MG, Jones K, Rey JE, *et al.* Sustained improvements in peripheral venous catheter care in non-intensive care units: a quasi-experimental controlled study of education and feedback. *Infection Control & Hospital Epidemiology* 2012;33:449–55.
71. Cooke M, Ullman AJ, Ray-Barruel G, *et al.* Not "just" an intravenous line: consumer perspectives on peripheral intravenous cannulation (PIVC). An international cross-sectional survey of 25 countries. *PLoS One* 2018;13:e0193436.
72. Penfold RB, Zhang F. Use of interrupted time series analysis in evaluating health care quality improvements. *Acad Pediatr* 2013;13(6 Suppl):S38–44.
73. Barbour R. *Doing focus groups*. London: SAGE Publications Ltd, 2007.
74. Ogrinc G, Davies L, Goodman D, *et al.* SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. *BMJ Qual Saf* 2016;25:986–92.
75. Mokkink LB, Terwee CB, Patrick DL, *et al.* The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol* 2010;63:737–45.
76. Polit DF, Beck CT. *Essentials of nursing research: appraising evidence for nursing practice*. 8th Edn. Philadelphia, PA: Wolters Kluwer, Lippincott Williams and Wilkins, 2014.
77. Polit DF, Chaboyer W. Statistical process control in nursing research. *Res Nurs Health* 2012;35:82–93.
78. Norwood SL. *Research essentials: foundations for evidence-based practice*. Upper Saddle River, NJ: Pearson Education, 2010.