TITLE

The I-DECIDED Study: An interrupted time-series study to test the effectiveness of a device assessment and removal tool in supporting clinical decision-making to improve intravenous catheter care and reduce redundancy of intravenous catheters in hospital patients

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SIMPLIFIED DESCRIPTION

Up to 70% of acute care hospital patients need an intravenous (IV) catheter for fluids or medicines during admission. However, 30–50% of IV catheters have painful complications or stop working before treatment is finished, requiring the insertion of a new device. There are numerous reasons for IV catheter failure, some of which may be preventable with appropriate intervention. Improved assessment could help prevention and early detection of IV complications, but **no comprehensive and validated IV assessment tool exists**. An evidence-based IV education and assessment tool called I-DECIDED has been created to improve assessment and care of IV devices and to prompt IV device removal in hospital patients. This study will evaluate the effect of introducing this tool into clinical practice at several Queensland hospitals.

RESEARCH AIMS AND SIGNIFICANCE

AIM:

Aim: To test the effectiveness of a decision-making tool (I-DECIDED) in improving IV catheter assessment and care, and prompting IV catheter removal in hospital patients.

SIGNIFICANCE:

Each year in Australia, almost 10 million patients are admitted to hospital.[1] Over 70% of hospital patients need an IV catheter for vital medical therapies, such as fluids and electrolytes, antibiotics, pain relief, chemotherapy, blood transfusions and nutrition,[2] therefore in Australia, up to 7 million hospital patients need at least one IV catheter each year. Up to 50% of peripheral IV catheters are left in place when not in use,[3] putting patients at risk of bloodstream infection. Overall, 30–50% of IVs have painful complications or stop working before treatment is finished.[4, 5] Complications leading to failure include infiltration, extravasation, occlusion, accidental removal, nerve damage, or symptoms of phlebitis (pain, redness, swelling, palpable cord, hardness of the vein, and/or purulence).[2] The failure of an IV catheter before treatment is completed requires the re-siting of a new device, leading to discomfort for the patient and often delays in treatment. A recent economic analysis of data from a multi-site Queensland randomised controlled trial showed the mean cost of catheter replacement was approximately $70 when staff time and equipment was calculated.[6]

Improved assessment could help prevention and early detection of IV complications, and prompt removal of IV catheters when no longer needed, but **no comprehensive and validated IV assessment tool exists**. The I-DECIDED tool is unique because it has been designed as an evidence-based education, assessment, and audit tool that encourages patient

participation. A structured and comprehensive approach to IV assessment and care would promote early detection of complications, and prompt removal of IV catheters when no longer needed. This would reduce unnecessary pain and suffering for patients, decrease the risk of potentially deadly bloodstream infection, and reduce treatment delays and hospital costs. This could benefit millions of Australians annually.

DETAILED BACKGROUND

Despite the high prevalence of IV catheters in acute hospital patients, IV therapy is not risk-free. Currently, 30–50% of peripheral intravenous catheters (PIVC) stop working before treatment is completed,[5] and many patients undergo repeated and painful needle sticks to continue treatment. As well as being painful, IV catheter failure is frustrating and time-consuming for patients and staff, leads to treatment delays, and creates a financial burden for the health system. Furthermore, up to 50% of PIVCs are inserted and remain idle in the patient without any orders for IV medications, fluids, blood products, or planned procedures, in case they *might* be needed.[3] In one study, half of all PIVCs inserted in the emergency department were still not used 72 hours later,[7] which suggests they were not needed or that no one noticed them. PIVCs are often left in, in the belief that this will reduce workload if the patient might need a PIVC later.[8] PIVCs are a potential source of infection and should not be left in, 'just in case'.[2] The practice of not removing redundant PIVCs increases the patient's risk of serious and potentially fatal bloodstream infection (BSI).[2] In 2013–14, 1621 Australian public hospital patients acquired a healthcare-associated BSI with *S. aureus*,[9] a potentially deadly infection often caused by PIVCs.[10] In addition, 25% of IV catheter dressings are wet, soiled or falling off, despite guidelines mandating that dressings should be 'clean, dry and intact'[11, 12]; assessment for complications is often poor or non-existent[4]; and poor hand hygiene for IV catheters carries an infection risk.[13, 14] Practice change is not automatic once evidence is provided to clinicians; disruption of convention and cultural change is also required.[15]

The clinical need for an IV catheter should be reassessed each shift.[12] Assessment should first identify the presence of an IV catheter and prompt clinicians to consider if there is a clinical indication for the device or if it could be safely removed. Next, the effectiveness of device function, presence of complications, and the integrity of the dressing and securement should be considered. Assessment enables early detection of complications leading to IV failure, including infection. Comprehensive routine IV assessment and prompt removal of IV catheters that are not in use or not needed would reduce complications and BSI rates. However, **no validated tool for comprehensive IV assessment currently exists** in the peer-reviewed literature. To date, IV assessment tools have focused largely on the complication of phlebitis (inflammation of the vein), but fail to consider other factors for failure, such as infiltration, blockage or dislodgement, despite these complications being more prevalent and affecting one third of patients with a PIVC in Australian hospitals.[5] These outcomes can be attributed, at least in part, to the lack of a comprehensive and valid IV assessment and action tool. In the Australian context, PIVC insertion is often a medical responsibility, while nurses are responsible for the bulk of PIVC assessment and care.[16] Nurses are expected to identify when complications arise and take appropriate action. However, many nurses do not receive training in PIVC assessment other than in the undergraduate nursing curriculum. Competency assessment and training varies widely between hospitals, and not all clinicians have good PIVC assessment skills.

Strategies to involve patients to influence clinician's behaviour could be an untapped resource to promote appropriate use and timely removal of unnecessary/malfunctioning devices.[17] Patients and carers can be an effective tool to improve healthcare outcomes. In one

US study, high participation patients were half as likely to experience an adverse event compared to those with low participation in their care.[18] Patient participation in IV catheter bundles is likely cost-effective, but has not been adequately tested. A study in Ireland found that 38% of patients were unaware of the reason for their IV catheter, and this was significantly associated (seven-fold) with the presence of a redundant device.[19] A quality improvement initiative in New Zealand reported a reduction in unnecessary PIVC dwell time with the implementation of a daily distribution of an education pamphlet to patients, in addition to a daily chart sticker prompting the consideration to remove unneeded devices.[20] A year later, the authors reported they had modified the intervention to a size A4 laminated poster in each patient's room, rather than a daily pamphlet, and the improvements were not sustained, likely because over 40% of posters were not visible from the bedside.[21]

The current study draws on the evidence surrounding clinical decision-making tools.

Clinical decision making tools

Clinical assessment tools are widely used to guide nursing practice. Existing IV assessment tools are limited mostly to detection of phlebitis. While phlebitis is an important consideration, IV catheter failure is more often caused by occlusion, infiltration, or accidental removal. Phlebitis assessment tools do not assess other important factors, such as the continued need for the device, dressing and securement integrity, adherence to infection prevention standards, patient preference and education needs, or documentation of IV catheter assessment and care provided. Furthermore, the utility of current phlebitis assessment tools is limited, as many use complex scoring scales or do not define phlebitis 'cut-offs', and none has been rigorously evaluated.[22] Only the Visual Infusion Phlebitis (VIP) score specifies actions to accompany the score, and even then, PIVC removal is only advised once moderate inflammation of the vein has already occurred.[23] Interrater reliability of phlebitis scales is poor and no scale can be recommended.[24] The Infusion Nurses Society (INS) recommends an 'acceptable' phlebitis rate of 5%,[25] but estimates in published studies range widely from 0% to 91%; this reflects discrepancies in phlebitis tools.[22] The INS has a phlebitis scoring tool and an infiltration scoring tool, but neither has been adequately validated. Furthermore, neither tool provides recommendations for action, which means these tools lack accountability. Without recommendations for action, staff use inconsistent and potentially fallible judgement rather than objective assessment parameters.[26] Assessment tools should include recommendations for action to promote accountability; otherwise they increase paperwork, not patient safety.

Clinical practice guidelines became popular in the 1990s with the demand for evidence-based practice. International guidelines list key parameters for IV catheter care, including regular assessment, timely removal, infection prevention, dressing care, and documentation.[23, 25] No Australian-wide IV guidelines exist; each State/Territory has developed their own. Guidelines promote, but cannot enforce, standardised care. Hospitals adapt guidelines to their local context, but staff disregard guidelines that do not take into account individual patient needs and professional clinical judgement based on education and previous experience.[8, 27] For instance, some international guidelines recommend PIVC removal only when clinically indicated.[12, 25] Despite a Cochrane review to support this practice,[28] some hospitals continue routine 72–96 hour PIVC removal policies. In reality, staff often leave functioning PIVCs in place beyond this time if they decide it is clinically appropriate, such as an elderly patient or patient with poor veins.[29] An IV assessment tool is needed that takes both guidelines and clinicians' informed decisions into consideration, and promotes accountability for actions taken based on the assessment.

Algorithms are designed to prompt clinical decision making by outlining an ordered sequence

of steps for a specific circumstance. Algorithms are popular in many health settings because they are process and outcomes-focused tools, engineered to deliver efficient, cost-effective and standardised care. The Australian Guidelines for the Prevention and Control of Infection in Healthcare[30] stress the importance of decision-making in IV catheter management. Decision-making algorithms are popular in healthcare; e.g., the Michigan Appropriateness Guide for Intravenous Catheters (MAGIC) is a clinical decision framework for choosing the most appropriate IV device.[31] MAGIC includes evidence-based, patient-focused criteria for the appropriate insertion and care of IV devices. Another decision tool is the Vessel Health and Preservation (VHP) Protocol[32] that has been adapted and promoted in the UK. Both MAGIC and VHP focus on informed choice of IV device type and best insertion site. These complex tools require substantial education for staff, and it is not yet known if they are effective, feasible or acceptable to patients and staff. Neither contains a user-friendly IV daily assessment and action strategy.

Bundles are the most recent approach to IV catheter practice. In 2006, the Keystone project authors reported success in lowering CLABSI rates in intensive care units (ICUs) following the introduction of a defined set of core practices for central line insertion.[33] Consequently, the Institute of Healthcare Improvement (IHI) and NHMRC recommend a bundled approach to IV catheter management to standardise care and improve patient outcomes.[30, 34] A 'bundle' is a "small set of evidence-based interventions for a defined patient segment/population and care setting that, when implemented together, will result in significantly better outcomes than when implemented individually" (p. 2).[34] Bundles are designed to be used in their entirety. Queensland Health advocates the "I-Care intervention bundle for the management of intravascular devices".[35] In addition to a 26-page guideline, I-Care provides point-of-care tools for PIVC insertion and management. The 2-page daily management tool contains some reminders for PIVC assessment, dressing and securement, access, and replacement of IV fluids,[35] but it lacks prompts for patient education or documentation of actions taken, and its effectiveness has not been reported. It could also be challenging for staff to remember all the necessary steps. Other PIVC bundles are reported in the literature, but most are complex and do not use a mnemonic to prompt decisions and action, making it difficult for busy staff to memorise all bundle elements. Simple mnemonic tools have much better uptake in clinical practice than complex guidelines and decision algorithms. For example, FASTHUGS[36] is a bundle of key considerations when caring for the critically ill patient, used by critical care clinicians around the world. Similarly, SBAR has become widely used and accepted as a clinical handover tool for facilitating interdisciplinary communication and increasing patient safety.[37] Using a structured assessment tool for decision-making, documentation, and clinical handover facilitates transdisciplinary communication and increases patient safety.[36, 37]

A NEW APPROACH TO IV ASSESSMENT

Based on previous work[16, 22, 24, 38] and the evidence of clinical assessment tools, guidelines, algorithms, and bundles, the **I-DECIDED device assessment and safe removal tool** has been developed. This evidence-based, mnemonic tool prompts staff to conduct a thorough IV assessment, identify complications, and take action as needed. I-DECIDED is a user-friendly, clinical decision-making tool with action prompts for IV site assessment, infection prevention, flushing, dressing and securement, patient and carer education, and documentation. Every component of the tool is based on evidence. Although recommendations for individual components may change as research findings are updated, the principles of comprehensive assessment and action will remain consistent.

This simple tool empowers the clinician to make a decision based on assessment, in discussion with the patient and the transdisciplinary team, to provide optimum care for the

hospital patient with an IV catheter. The tool prompts staff to evaluate patient knowledge about their IV catheter and therapy, educate where needed, and encourage patients to verbalise any questions or concerns. It is anticipated that staff would come to remember the mnemonic I-DECIDED as a memory aid for device assessment. I-DECIDED is also an IV education tool, guiding staff to learn the essential components of IV care. Audit measures will also be facilitated, based on the I-DECIDED tool.

The predicted outcomes of implementing this tool include: fewer IV catheters left in place when not being used; early detection of complications; improved documentation; and an improved patient experience. A structured and comprehensive approach to IV therapy would reduce unnecessary pain and suffering for patients, decrease the risk of potentially deadly BSI, and reduce treatment delays and subsequent hospital costs.

I-DECIDED DEVICE ASSESSMENT AND SAFE REMOVAL TOOL

1. IDENTIFY if the patient has a device

If the PIVC is not documented in the patient's chart, the nurse should ask the patient if they have a PIVC. Anecdotal evidence shows that some patients have been discharged home with an unused PIVC because no one was aware the patient had a PIVC.[39] This puts the patient at risk of BSI[2] and the hospital at risk of medical malpractice for negligence.

I-DECIDED prompts nurses to check if the patient has a PIVC.

2. DOES the patient need this device?

Many PIVCs are not promptly removed when no longer needed, with a recent review reporting up to 50% of PIVCs are left in place without any orders for IV medications, fluids or tests.[3] One study found that patients often had more than one PIVC, but in the majority of cases (82%), only one PIVC was needed.[4] In another study, half of all PIVCs inserted in the emergency department were still not used 72 hours later,[7] which suggests they were not needed or that no one noticed them. PIVCs are often left in, in the belief that this will reduce workload if the patient might need a PIVC later.[8] PIVCs can be a source of infection and should not be left in, 'in case'.[2] The clinical need for a PIVC should be reassessed each shift.[12] If the PIVC is not needed, it should be removed.

I-DECIDED prompts nurses to take action and remove redundant PIVCs.

3. EFFECTIVE flow and flush?

When a PIVC is inserted, a flashback of blood in the chamber confirms location in the vein. Following initial confirmation, the location of the PIVC is estimated by flow of IV fluids (either by infusion pump or gravity) and/or IV flushes (manual injection). Flushing the PIVC with 0.9% saline before and after the administration of IV medications reduces admixture of medicines and decreases the risk of IV blockage.[40] Flushing practices vary greatly and are often poorly documented.[41] The I-DECIDED tool prompts the nurse to assess IV function with 2 simple questions: "Does the IV flush easily?" "Does the IV fluid flow easily?" Resistance or failure to flush or flow indicates that the PIVC might be kinked or blocked, or could have migrated out of the vessel.[25, 40]

I-DECIDED prompts checking and charting of flow and flush.

4. COMPLICATIONS or CONCERNS?

Complications cause 34% of PIVC to stop working before treatment is complete, resulting in painful and time-consuming additional IV insertion procedures, which also increases costs.[5] Complications include any of the following: warmth, pain/tenderness, redness, swelling,

hardness or palpable cord (indicating thrombosis/clot), nerve damage, discharge or pus from the site.[23, 25] Pain is an early indicator of failure (Rickard, unpublished data), so if the patient reports pain greater than 2 out of 10 (analogue scale 0–10), the PIVC should be removed. Complications indicate that the PIVC is not functioning properly, prompting early identification and correction of issues, and if necessary, removal and insertion of a new PIVC. The nurse should continue to assess the site for 48 hours because post-infusion phlebitis can occur after the PIVC has been removed.[38]

I-DECIDED prompts nurses to address PIVC complications or concerns.

5. INFECTION prevention and awareness

Nurses often perceive PIVCs as a low infection risk and may not always take stringent infection prevention measures when handling them.[8] Hand hygiene and aseptic non-touch technique are essential to prevent infection.[25] PIVC bundles include strategies such as 'scrub the (injection) hub' with antiseptic, but compliance is as low as 10%.[42] If the patient has signs of systemic inflammatory response syndrome (low or high temperature, elevated heart rate, elevated respiratory rate, low or high white blood cell count), any invasive device is a possible cause,[43] and insertion sites should be examined for inflammation or purulence. If no obvious source of infection is detected, removal of the device should be considered and diagnostic investigations undertaken.[43]

I-DECIDED prompts awareness of infection.

6. DRESSING and securement?

Current recommendations support transparent polyurethane or sterile gauze and tape IV dressings.[44] Polyurethane dressings allow visibility of the insertion site and can remain in place up to 7 days. Gauze and tape dressings should be changed every 2 days. Regardless of type, dressings must be clean, dry and intact to prevent microbial contamination of the site. The dressing should be changed if damp, loose or visibly soiled, and infusion tubing firmly secured with tape or bandage, leaving the site visible.[25] Yet hospital audits show 25% of PIVC dressings are not clean, dry and intact at any given time[4]; this increases infection risk, and risk of PIVC dislodging from the vein. A poorly secured PIVC encourages infection, as PIVC movement in the vein can allow migration of organisms along the catheter and into the bloodstream.[44]

I-DECIDED prompts the nurse to assess dressing and securement, and take action, if needed.

7. EVALUATE and EDUCATE

The nurse should evaluate the patient/family's understanding of treatment and the reason for the PIVC, and provide explanations and education, as needed. A prevalence study in Ireland found that the patient's lack of awareness of the reason for the PIVC was significantly associated with the PIVC being redundant, predisposing them to avoidable infection.[19] Involving the patient and family has a beneficial effect on PIVC care by empowering the patient and family to voice their concerns, and prompts nursing action to address problems and remove unused PIVCs.

I-DECIDED encourages patient/staff collaboration in IV care decisions.

8. DOCUMENTATION

Professional standards of practice expect nurses to document assessment and action taken in the patient's chart, but standards are not always maintained; nursing documentation of PIVCs is inadequate or missing in 25% of patient charts.[4, 16] Documentation should include, at a minimum: PIVC insertion date and time; assessment and action each nursing shift; PIVC

removal date and time. If the PIVC is not documented, this increases the likelihood that it will be forgotten and not removed, increasing the risk of complications and BSI.[2] Infusion-related lawsuits are among the fastest growing litigation brought against nurses, with poor documentation apparent in most cases.[45]

I-DECIDED makes documentation a priority.

9. ACTION

Based on the nurse's assessment and consultation with the patient and the transdisciplinary health team, *I-DECIDED directs action*. Four options are offered:

- Continue (no change);
- Continue but change dressing;
- Remove PIVC and do not replace;
- Remove PIVC and arrange for a new device.

This simple evidence-based tool empowers the nurse to make a decision based on his/her assessment, in discussion with medical staff, to provide optimum care for the hospital patient with a PIVC. Using a structured assessment tool for decision-making and clinical handover facilitates multidisciplinary communication and increases patient safety.[36, 37]

RESEARCH PLAN

Research Problem

The research problems are the large numbers of redundant IV catheters being left in place, the high complication and failure rate of IV catheters, and the associated costs (personal for the patient and economic for the organisation).

Redundant IV catheter is defined as device in situ without a clear purpose; i.e., 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 (e.g., planned procedure, cardiac monitoring in situ, history of seizures, unstable medical condition or recent rapid response call).

IV complications are defined as any of the following: pain ≥ 2/10, redness, swelling, infiltration, extravasation, discharge, hardness, palpable cord, or purulence.

Research Questions

- Can use of the I-DECIDED tool reduce the number of redundant IV catheters?
- Can use of the I-DECIDED tool reduce the number and severity of IV complications?
- Can an increased focus on IV dressing and securement reduce the incidence of loose, lifting, soiled dressings and accidental IV catheter dislodgement?
- Is it feasible to undertake an efficacy trial of IV decision-making algorithms?
- Will the I-DECIDED tool prompt health worker engagement in IV assessment?
- Will the I-DECIDED tool prompt patient engagement in IV assessment?
- Can use of the I-DECIDED tool improve documentation of IV management?

Primary outcomes

- Clinicometric properties (reliability, validity, acceptability, feasibility) of a comprehensive IV assessment and decision-making tool.
    - Reliability is defined as the stability or consistency of measures between assessors (inter-rater) and across time for the same assessor (intra-rater).
    - Validity is defined as the degree to which the instrument measures what it is

supposed to measure. This includes construct validity (objective assessment that the tool actually measures what it is designed to measure) and content validity (whether the instrument covers all the important points of the area being measured).
    - Acceptability is the perception of clinical useability of the tool.
    - Feasibility is an assessment of the amount of time it takes to complete the tool, ease of completion, and clarity of the items and instructions for use.
- Device utilisation ratios (number of PIVCs per total number of patients per ward, and number of PIVCs per patient) in T3 (evaluation phase), compared to T1 (baseline).
- Prevalence of redundant/idle PIVCs, defined as device in situ without a clear purpose; i.e., not used for IV fluids, blood products, parenteral nutrition, or medications for the past 24 hours and not anticipated to be used in the next 24 hours (e.g., planned procedure, cardiac monitoring in situ, history of seizures, unstable medical condition or recent rapid response call) in T3, compared to T1.
- Prevalence of IV complications, defined as any of the following: patient-reported pain ≥ 2/10, redness, swelling, infiltration, extravasation, discharge, hardness, palpable cord, or purulence in T3, compared to T1.
- Prevalence of loose, moist or soiled IV dressings in T3, compared to T1.
- Presence of confirmed or suspected Catheter-related blood stream infection (CRBSI) (defined as a positive blood culture from a peripheral vein; clinical signs of infection; no other apparent source for the bloodstream infection except the intravenous catheter; and colonised intravenous catheter tip culture with the same organism as identified in the blood)
- Primary BSI rates/1,000 catheter days, including prevalence of *Staphylococcus aureus* bacteraemia bloodstream infection in T3, compared to T1.

Secondary outcomes

- Large trial feasibility (composite of recruitment > 80% of eligible patients recruited per month; protocol adherence > 70%; missing data (I-DECIDED tool not fully completed each shift in T3) < 10%)
- Staff focus group feedback on usability of I-DECIDED tool and the barriers and enablers to PIVC assessment and prompt removal
- Proportion of patients verbally reporting that they have been informed by the staff about the reasons for the IV device or plans for IV 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 IV was carried out.

Research design/methods

To achieve the objective of improving IV assessment and care, we will conduct a **prospective, interrupted time-series study**. This is a robust method to measure the effect of an intervention as a trend over time. The interrupted time-series study is a powerful and effective way to overcome bias of simple before-and-after studies.[46] Repeated measures build rigour into the study design and enable the researchers to rule out the effects of extraneous circumstances that may otherwise impact the findings.[47] Multiple observations will be collected over several evenly-spaced time-points during the baseline and following implementation of the I-DECIDED tool.

The I-DECIDED tool will be tested in 1 medical and 1 surgical ward in 3 Queensland hospitals (6 wards in total), as agreed by the Nurse Unit Managers. There will be four study phases, *Pre-baseline* (T0), *Baseline* (T1), *Intervention* (T2), and *Evaluation* (T3) (See Figure 1).

T0. Pre-baseline phase (July 2017)

Each step of the tool is based on clinical practice guidelines.[12, 23, 25, 35, 48-52] Prompts for each step have been developed from clinical expertise and consensus of the authors. Clinicometric testing of the I-DECIDED tool will be undertaken, as described below.

- *Content validity* of each item and corresponding prompts will be undertaken with 5-6 world-renowned vascular access experts and 5-6 clinicians with recent, weekly experience in PIVC assessment. Experts and clinicians experienced in vascular access (nurses and doctors) in the AVATAR group's clinical network will be informed of the study by CI Ray-Barruel and invited to participate by email. Experts and clinicians who agree to participate will be sent a link to an online survey (RedCAP: Research Electronic Data CAPture, Vanderbilt) to complete the CVI assessment questionnaire, and completion of the questionnaire will be accepted as consent. They will be asked to rate each item and prompt (*1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = highly relevant*)[53] and the content validity index (CVI) will be calculated. Comments will be encouraged, feedback will be analysed, and the tool will be amended to address this feedback where possible.
- To assess the *clinical utility and feasibility* of introducing a mnemonic decision algorithm for PIVC assessment in clinical practice, 'think aloud' assessments[54] with staff nurses will be undertaken. CI Ray-Barruel will train a convenience sample of 5 staff nurses experienced in PIVC assessment from a non-study ward in the use of the I-DECIDED tool, and they will then be asked to verbalise their assessment and decision processes while assessing a patient's PIVC using the tool. Informed written consent will be obtained from the nurses, and patients will receive an explanation of the process, particularly in regard to the constant talking by the nurse during the assessment. Patients will be given the option to stop the 'think aloud' assessment at any time, and CI Ray-Barruel will stop the assessment and data collection if there is any suggestion of patient distress. Concurrent field notes will be collected. Think aloud sessions will be audio-recorded and transcribed. Transcripts and field notes will be analysed by two authors to identify relevant information, which will then be organised into coded data elements. Further analysis of the coded data will be examined to allow investigators to make inferences about the nurses' reasoning processes while assessing the PIVC.
- *Inter-rater reliability* will be evaluated between CI Ray-Barruel and research nurse at each site. Both will independently assess the PIVC five minutes apart, and results will be compared and consensus reached. *Intra-rater reliability* for each research nurse will be assessed three times by CI Ray-Barruel.

T1. Baseline phase (August - mid-November 2017):

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 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) will be conducted by CI Ray-Barruel to determine current PIVC policy including education, PIVC assessment tools in use, and required documentation for vascular access surveillance at each hospital.

- *Device utilisation ratios* will be calculated at each time-point (number of PIVCs per total number of patients per ward, and number of PIVCs per patient).
- *Blood stream infection data* per ward per month will be requested from the hospital infection prevention service.
- *PIVC assessment and chart audits* (n = 480). Each fortnight (n = 8 time points), the research nurses will complete a screening log for each ward, detailing number of occupied beds, number of staff that shift, and number of patients with one or more PIVCs. Presence of another type of vascular access device in addition to a PIVC will be recorded. Using the I-DECIDED tool the research nurse will assess every PIVC 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 in the past 8 hours, and any concerns will be directed to the patient's nurse. Data will be entered using hand-held tablet devices and a REDCap database for contemporaneous data entry (Research Electronic Data CAPture, Vanderbilt). 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. Informed verbal consent will be sought from each eligible patient. All eligible patients will be provided with a Participant Information Sheet, and the study will be explained by the Research Nurse and any questions will be addressed. If the patient decides to consent to the project, a sticker confirming verbal consent will be placed in the patient's chart. No identifiable patient information will be collected.
- *Focus groups with staff* (n = 6 groups, 30 minutes) will be conducted by CI Ray-Barruel during the shift change-over period, using semi-structured interview questions from a prepared script. These 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 enablers to implementation. Nurses will also be asked to discuss their views on patient education and encouraging patient participation in PIVC assessment. Focus groups are a suitable method for enquiring how nurses make clinical decisions and assessing the acceptability of a planned process change.[55] Informed written consent will be sought from all focus group participants. Focus groups will be audio recorded and transcribed, and data analysed for themes.
- *Short bedside interviews with patients* (n = 24, < 5 minutes) will be conducted by CI Ray-Barruel or the research nurse, using semi-structured interview 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. Informed written consent will be sought from all participants. Interviews will be audio recorded and transcribed, and data analysed for themes.

T2. Implementation phase (mid-November 2017–mid-January 2018):

The I-DECIDED tool will be implemented in 6 wards across 3 hospitals. Regular three-monthly meetings with key local opinion leaders will continue during this period. Two staff champions per ward will be identified and trained to support other staff in the use of the tool and facilitate implementation.

- *Education sessions for ward staff* regarding use of the I-DECIDED tool will be provided

by CI Ray-Barruel, in collaboration with hospital educators. Educational materials (webinar, posters, lanyard cards, etc.) will be developed and provided.[56]

- Patient brochures encouraging patient participation in PIVC assessment will be developed and distributed to each patient's bedside on admission. Other strategies are likely to be developed and implemented, following suggestions from stakeholders, focus group participants, and interview-reported patient preference.
- Nurses will be asked to document PIVC assessment and action taken in the patient's chart each shift, using the I-DECIDED tool. It is expected this will be in place of the usual PIVC assessment, but this will be determined by ward preference.
- *Inter-rater and intra-rater reliability* will be assessed with 4 nurses in each hospital (total 12 nurses) by CI Ray-Barruel.
- Ward in-service updates and informal discussions with staff will be conducted by CI Ray-Barruel, and actual barriers and enablers encountered during the implementation period will be noted.
- Data collection will not occur during this phase.

T3. Evaluation phase (mid-January–April 2018):

During this period the tool will continue to be used and the activities of T1 (focus groups, IV assessments, chart audits, and bedside interviews) will be repeated. Regular meetings with key local opinion leaders will continue, and ongoing education and feedback to staff will be provided at ward in-service sessions.[57] The purpose of this phase is to determine the feasibility and acceptability of the I-DECIDED tool for IV assessment, management and documentation of IV care Informed consent will be obtained for all research activities.

- *PIVC assessments and chart audits* (n = 480) will examine device utilisation ratios, PIVC redundancy, complications, dressing integrity, documentation and BSI data, and results will be compared to T1. . Informed verbal consent will be sought from each eligible patient. All eligible patients will be provided with a Participant Information Sheet, and the study will be explained by the Research Nurse and any questions will be addressed. If the patient decides to consent to the project, a sticker confirming verbal consent will be placed in the patient's chart. No identifiable patient information will be collected.
- *Focus groups with staff* (n = 6 groups, 30 minutes) will investigate staff opinions regarding the acceptability and feasibility of using the I-DECIDED tool in clinical practice. Informed written consent will be sought from all focus group participants.
- *Bedside interviews with patients* (n = 24, < 5 minutes) 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 to T1 to assess if there has been any evident change in patients' perceptions of staff assessing their PIVC and engaging them in PIVC care. Informed written consent will be sought from all participants.

Sample size estimate

This is a pilot study, designed to ascertain feasibility of conducting a larger study, and as such is not powered for statistical significance.[58] The predicted outcome of implementing this simple but comprehensive tool is an improved experience of IV therapy, early detection of complications, fewer redundant PIVCs, and improved documentation. The current sample size has been based upon predicted participant availability, based on data from the participating hospitals. As the study has already received enthusiastic verbal support from nursing management at each site, staff recruitment to participate in focus groups is unlikely to be difficult. The I-DECIDED tool encourages patient participation in PIVC assessment, and

from our group's previous research in consumer experience of PIVCs,[59, 60] it is likely that the majority of patients will consent to be involved.

- Content validity assessment (T0) = 5–6 vascular access experts and 5-6 clinicians experienced in PIVC assessment
- Think aloud assessments (T0) = 5 staff nurses experienced in PIVC assessment
- PIVC assessments and chart audits: approximately 20 assessments/hospital x 3 hospitals x 8 time-points x 2 phases (T1, T3) = 960.
- Staff focus groups: 4–6 staff/ward x 6 wards x 2 phases (T1, T3) = 48–72 staff
- Patient bedside interviews: 4 patients/ward x 6 wards x 2 phases (T1, T3) = 48 patients

ETHICAL CONSIDERATIONS

Inclusion criteria:

- Vascular access experts and clinicians with experience in PIVC assessment who provide informed consent to participate in the content validity assessment.
- Staff nurses who provide written informed consent to participate in the 'think aloud' assessment.
- Patients over 18 years with a peripheral intravenous catheter and able to provide informed verbal consent to participate in PIVC assessments and chart audits
- Patients over 18 years with a peripheral intravenous catheter and able to provide informed written consent to participate in bedside interviews
- Nurses working clinically on the medical and surgical wards where the project will take place, and who provide informed written consent to participate in focus groups

Exclusion criteria

- Patients admitted for palliative treatment or who are on a care of the dying pathway

Human Research Ethics Committee approval

Hospital and University Human Research Ethics Committee (HREC) approval has been obtained from Queensland Health (HREC/17/QPCH/47) and Griffith University (Ref No. 2017/152).

Feasibility

Informed consent will be obtained for all research activities. The I-DECIDED tool adheres to the Australian Commission on Safety and Quality in Health Care *National Safety and Quality Health Service Standards (September 2012)*[61]: Standard 2: Partnering with Consumers, and Standard 3: Preventing and Controlling Healthcare Associated Infections. There have been high recruitment rates with our other cohort studies at Queensland hospitals, so achieving the estimated sample should not be a problem. There is a high level of commitment by stakeholders at each hospital to facilitate this research. In addition, researchers involved in the project have a track record of successfully working together, taking results through to publication and knowledge dissemination.

Confidentiality and Privacy

Patient demographic information including age, gender, admitting diagnosis, and skin integrity will be collected. No identifying patient information (e.g. name, hospital record number, date of birth) will be collected. All patient information will remain anonymous. Each PIVC will be allocated a unique study number.

DATA MANAGEMENT

Data collection

The Research Nurse will enter the IV catheter data into a portable electronic tablet with RedCAP survey software at the bedside.

Outcome measures to be collected

- Presence of confirmed or suspected blood stream infection
- Current IV order (IV fluids, medications, blood products, parenteral nutrition), or documented evidence of continued need for IV (planned procedure, cardiac monitoring, or unstable medical condition)
- Evidence in the chart or verbal report from the patient or the patient's nurse that the IV catheter has been used or flushed in the past 24 hours
- IV site assessment and any complications, defined as any of the following: patient-reported pain ≥ 2/10, redness > 1cm from insertion site, swelling > 1cm from insertion site, infiltration (defined as permeation of IV fluid into the interstitial compartment, causing swelling of the tissue around the site of the catheter), discharge, hardness, palpable cord, purulence
- Any documentation of infection prevention or infection status
- Dressing and securement assessment for integrity and cleanliness
- Evidence (verbal or in the chart) that the patient has been informed of the reason for the IV and possible side effects
- Evidence in the patient chart that IV assessment has taken place.

Data analysis

Clinicometric properties (reliability, validity, acceptability, feasibility) of the I-DECIDED tool will be analysed [Cronbach's alpha (internal consistency), kappa calculations (inter-rater reliability), interclass correlation coefficient (ICC), and content validity index (CVI)] and the tool will be modified accordingly.

CI Ray-Barruel and statistician will have access to the final dataset. Analysis and reporting will follow the SQUIRE 2.0 guidelines.[62] Clinical effectiveness of the I-DECIDED tool will be measured by statistical comparison of prevalence trends (PIVC utilisation, redundancy, all complications, BSI rates, substandard dressings, and missing documentation) across time-points before (n = 10) and after (n = 10) the intervention. Statistical process control (SPC) analysis to assess the effects of the intervention will be used.[63] SPC charts will display data collected at the 20 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 framework[64] using an inductive 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 then the researchers will meet to discuss and achieve consensus on the meaning of the data.

Data storage and Record retention

Stringent processes will be used to ensure that the data of participants are kept confidential. Computer data will be stored on a secure computer located in the Research Room at the Griffith University School of Nursing and Midwifery, Brisbane, Australia, accessible only by the principal researchers. Information will be stored for a mandatory period of seven years in

accordance with the Griffith University research policy. Any research data kept on site at the hospitals will be kept for 5 years, as per Queensland Health policy. Method of destruction of data: Electronic records will be deleted and hard copy will be shredded.

DISSEMINATION OF FINDINGS

As there is currently no validated, evidence-based, IV catheter assessment tool available, the study results likely will be of intense interest to clinicians and hospitals worldwide. It is expected that these findings will have international application and should be rapidly translated into practice. The chief investigators are invited speakers at national/international forums and have excellent networks to promote the results.

Results will be published in high-ranking, peer-reviewed journals (e.g., *BMJ Open*, *Worldviews on Evidence-Based Nursing*, *Journal of Advanced Nursing*) and presented at local hospital meetings and education days, national (e.g., Australian Vascular Access Society) and international conferences (e.g., Association of Vascular Access, World Congress on Vascular Access). A webinar will be prepared and posted on-line, and advertised through the AVATAR website and social media (Twitter, LinkedIn, and Facebook).

The proposed study will test the utility of the I-DECIDED tool in guiding prompt removal, assessment and care of PIVCs. In future, it is likely that the study will be expanded to test the tool for assessing other invasive devices in other hospital units. Additional approvals will be sought at that time, as appropriate.

STUDY TIMELINE

	2017							2018								
		T0	T1 Baseline				T2 Implement	T3 Evaluate					Disseminate			
Activity		J	A	S	O	N	D	J	F	M	A	M	J	J	A	
PREPARATION	x															
CLINICOMETRIC TESTING OF THE I-DECIDED TOOL																
Content validity index assessments		x														
Think aloud assessments		x														
Train research nurses, inter-rater reliability tests		x	x													
STUDY ACTIVITIES																
IV assessments & chart audits			x	x	x	x			x	x	x	x				
BSI data, Device utilisation ratios			x	x	x	x			x	x	x	x				
Focus groups - nurses			x	x					x	x						
Bedside interviews - patients					x						x					
EDUCATION AND ROLL OUT																
Develop education materials						x	x									
Staff training							x	x								
Implementation of the tool in clinical practice							x	x	x	x	x	x	x	x	x	
DATA ANALYSIS AND REPORTS																
Transcription: focus groups/interviews									x	x						
Data analysis											X	x	x			
Prepare & deliver reports												x	x			
DISSEMINATION OF STUDY FINDINGS																
Conference presentations													x	x	x	
Peer-reviewed publications				x	x							x	x	x	x	

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