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The I-DECIDED® clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: A clinimetric evaluation

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-035239
Article Type:	Original research
Date Submitted by the Author:	23-Oct-2019
Complete List of Authors:	Ray-Barruel, Gillian; Griffith University, Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, School of Nursing and Midwifery; Queen Elizabeth II Jubilee Hospital, Princess Alexandra Hospital, Royal Brisbane and Women's Hospital, Nursing Research Cooke, Marie; Griffith University, Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, School of Nursing and Midwifery Chopra, Vineet; University of Michigan, Division of Hospital Medicine, Patient Safety Enhancement Program; Ann Arbor VA Medical Center, Center for Clinical Management Research Mitchell, Marion; Griffith University, Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, School of Nursing and Midwifery Rickard, Claire; Griffith University, Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, School of Nursing and Midwifery; Royal Brisbane & Women's Hospital, Princess Alexandra Hospital, The Prince Charles Hospital, Nursing Research & Development, and Critical Care Research Group
Keywords:	INTERNAL MEDICINE, MEDICAL EDUCATION & TRAINING, VASCULAR MEDICINE

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TITLE:

The I-DECIDED® clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: A clinimetric evaluation

Running head: I-DECIDED

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The I-DECIDED® clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: A clinimetric evaluation

ABSTRACT

Objective: To describe the development and clinimetric validation of the I-DECIDED® tool for peripheral intravenous catheter assessment and decision making.

Design and setting: The I-DECIDED® tool was derived from core aspects of the international vascular access guidelines into a structured mnemonic for device assessment and decision-making. The clinimetric evaluation process was conducted in three distinct phases.

Methods: Initial face validity was confirmed with a vascular access working group. Next, content validity testing was conducted via online survey with vascular access experts and clinicians from Australia, UK, USA, and Canada. Finally, inter-rater reliability was conducted between 34 pairs of assessors for a total of 68 PIVC assessments. Assessments were timed to ensure feasibility, and the second rater was blinded to the first's findings. Content validity index (CVI), mean I-CVI, mean proportion of agreement, observed and expected inter-rater agreements, and prevalence- and bias-adjusted kappas were calculated. Ethics approvals were obtained from university and hospital ethics committees.

Results: The I-DECIDED® tool demonstrated strong content validity among international vascular access experts (n = 7; mean I-CVI = 0.91; mean proportion of agreement = 0.91) and clinicians (n = 11; mean I-CVI = 0.93; mean proportion of agreement = 0.94), and high inter-rater reliability in seven adult medical-surgical wards of three Australian hospitals. Overall inter-rater reliability was 87.13%, with prevalence-adjusted bias-adjusted kappa for each principle ranging from 0.5882 ('patient education') to 1.0000 ('document the decision'). Time to complete assessments averaged 2 minutes, and nurse-reported acceptability was high.

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Conclusion: This is the first comprehensive, evidence-based, valid and reliable PIVC assessment and decision tool. We recommend studies to evaluate the outcome of implementing this tool in clinical practice.

Trial registration number ANZCTR: 12617000067370

(276 words)

Keywords:

Assessment, intravenous; Intravenous catheter, peripheral; Decision-making; Reliability; Validity; Measurement

Strengths and limitations of this study

- This is the first validation study of a comprehensive peripheral intravenous catheter assessment and decision tool.
- The I-DECIDED® tool demonstrated strong content validity among a group of international vascular access experts and clinicians.
- The I-DECIDED® tool demonstrated high inter-rater reliability in adult medical-surgical wards of three Australian hospitals**.**
- Studies to evaluate the outcome of implementation of this tool in clinical practice are warranted.

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INTRODUCTION

With 70% of hospital patients needing a vascular access device (VAD) for medical treatment,[1] inadequate assessment may contribute to current poor outcomes, where up to 69% of peripheral intravenous catheters (PIVCs) have painful complications or stop working before treatment is finished, due to occlusion, dislodgement, infiltration, or phlebitis.[2] Equally concerning, clinical audits reveal 25–50% of PIVCs remain in situ for no reason.[3-5]

Improved assessment could prompt removal of idle catheters and early detection of complications.[6] To date, efforts to improve PIVC outcomes using phlebitis tools, care plans, maintenance bundles, electronic records, and journey boards have achieved varied results.[7, 8] Supporting evidence for phlebitis tools is not robust, as they fail to consider complications such as dislodgement, occlusion or infiltration, and do not prompt assessment of device need, function, dressing integrity, securement, and infection prevention strategies.[7, 9] With these items already included in best practice guidelines,[10-15] the reported high rates of idle catheters, device failure, and complications indicate the need for a fresh approach to PIVC assessment and management.

The I-DECIDED® tool was developed to address the high prevalence of idle PIVCs and common shortfalls with assessment and documentation.[16] This is the first comprehensive, evidence-based, point-of-care tool for PIVC assessment and decision-making. The tool guides clinicians to perform a structured assessment and make a decision, based on that assessment. Simple prompts accompany each category. (See Figure 1). This paper reports on the clinimetric properties (reliability, validity, acceptability and feasibility) of this tool.

[Insert Figure 1]

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METHODS

Instrument

International guidelines were reviewed[10-15], with core aspects assembled into the mnemonic, I-DECIDED®, a structured priority matrix for assessment and decision-making. The name (I-DECIDED) conveys accountability for decisions based on the assessment and it has been translated into Latin-based languages while preserving the meaning to enable broader translation into practice.

Study design and setting

Face and content validity assessments were undertaken prior to an interrupted time-series (ITS) study to examine the effect of implementing the tool in three hospitals in Queensland, Australia.[16] Inter-rater reliability was assessed at pre-specified time-points (Baseline; Implementation; Evaluation). Ethical approval was obtained from Griffith University (Ref No. 2017/152), Queensland Health (HREC/17/QPCH/47), and St Vincent's Health and Aged Care Human Research and Ethics Committee (Ref No. 17/28). All participants provided informed consent prior to participation, and the study was conducted in accordance with the Australian Government National Statement on Ethical Conduct in Human Research.[17] The results are reported in accordance with the Guidelines for Reporting Reliability and Agreement Studies (GRRAS).[18]

Sample size and data analysis

Face validity, a subjective assessment that the tool measures what it is designed to measure,[19] was assessed by emailing a draft of the tool to eight members of a vascular access working group, experienced researchers with solid knowledge of current guidelines. Reviewers independently assessed each item and the tool as a whole, and provided recommendations.

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Following discussions between the lead author and reviewers, some item wording was revised.

Content validity, the degree to which the content of an instrument is an adequate reflection of the construct to be measured,[19] of each principle and corresponding items was undertaken with international experts (vascular access researchers and infection control professionals) and experienced clinicians (nurses with weekly PIVC experience) to determine if the tool covered the essentials of PIVC assessment and decision-making. We deliberately targeted experts and clinicians separately to identify any differences between perspectives. Twenty-two experts and 25 clinicians from adult and paediatric specialties in the authors' clinical network were informed of the study by the lead author by email and invited to complete the content validity questionnaire via online survey (REDCap)[20] or paper form and return email (See Appendix 1). Survey completion was accepted as consent, and names of respondents were not collected.

Respondents rated each item in terms of its relevance to the underlying construct on a 4-point ordinal scale (*1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = highly relevant*)[21]. The item-level content validity index (I-CVI) was calculated for each principle and item (number of respondents giving a rating of either 3 or 4, divided by the total number of respondents).[22] Content validity index (CVI) for each item and overall mean I-CVI were calculated for both expert and clinician groups. Proportions of agreement for each participant, each item, and overall mean were calculated. Respondents were asked to review, comment, and suggest changes on wording and structure of each section of the tool, and the tool as a whole. Respondents could participate in a Skype or telephone call with the lead author to

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provide further feedback, if desired. All written and verbal feedback was analysed, and minor wording revisions were made to produce the final tool.

Reliability is the proportion of total variance in the measurements that are due to 'true' differences between subjects.[19] *Inter-rater reliability* is the ratio of variability between subjects to the total variability of all measurements in the sample.[18] Inter-rater reliability was evaluated in three phases. In Phase 1 (Baseline), the lead author provided education on the tool to a research nurse at each hospital (registered nurses with ≥ 10 years' clinical experience). The lead author and research nurses undertook 10 paired PIVC assessments to assess inter-rater reliability; this ensured the research nurses thoroughly understood the tool prior to collecting baseline data for the ITS study. Four months later, in Phase 2 (Implementation), the tool and new VAD form (available in the protocol paper[16]) were rolled out across the participating wards. The lead author and research nurses undertook a further 9 paired PIVC assessments to confirm continued consistency when using the tool. In Phase 3 (Evaluation), after hospital nurses had used the tool for two months, inter-rater reliability was evaluated between the research nurses and 3 to 6 staff nurses at each hospital for a further 15 paired PIVC assessments. All patients and staff nurses provided verbal consent to participate in the assessments. In all, 34 paired assessments were undertaken for a total of 68 assessments. For each assessment, two assessors independently assessed the PIVC five minutes apart using the tool, ranking each item as a categorical binary response (yes/no). The second rater was blinded to the first's findings, and the order of subjects varied between assessors to prevent systematic bias. Staff nurses were unaware that their judgement would be compared to other raters, to remove the possibility of a Hawthorne effect.[18] To assess inter-rater variation, observed and expected agreements for each part of the tool, prevalence-adjusted bias-adjusted kappa (PABAK) and overall proportion of agreement were

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calculated.[23] When prevalence of a given response is very high or low, the kappa value may not be reliable, even when the observed proportion of agreement is quite high; therefore, we calculated the prevalence-adjusted bias-adjusted kappa to more fully characterize the extent of inter-rater reliability between two raters.[23] Standard errors of measurement and Z scores were also calculated.

To assess Principles 1 (Identify presence of device) and 2 (Does patient need the device), raters checked for the presence of a PIVC and checked the patient's chart for current orders; if none were present, the observers asked the patient's nurse if any procedures were planned. For Principle 3 (Effective function), raters asked the patient if an infusion or flush had been administered in the past 12 hours, and if so, had there been any concerns. To assess Principle 4 (Complications), raters asked the patient about pain or tenderness and inspected the PIVC insertion site for signs and symptoms. With Principle 5 (Infection prevention), raters asked the patient if they had observed the nurse perform hand hygiene before touching the PIVC and scrub the needleless connector hub before administering IV medications or fluids. To assess Principle 6 (Dressing and securement), raters assessed the PIVC dressing for cleanliness and integrity and securement of the PIVC or administration set. For Principle 7 (Evaluate and Educate), raters asked the patient if they had questions and if the nurse had provided any education about the PIVC. To assess Principle 8 (Document), raters checked the patient chart for documentation of PIVC assessment in the past 12 hours. To assess Principle 9 (Decision), raters asked the patient if they knew of any plans for the PIVC that day and checked the patient's chart for evidence of plans to remove or continue the PIVC.

Feasibility was assessed by timing inter-rater reliability assessments and by asking staff about the clarity of items and ease of completion of the tool. ***Acceptability*** of introducing the

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tool into practice was assessed with 30 registered nurses who participated in round table discussions at each hospital prior to the study. During these sessions, nurses discussed the terminology of the tool and provided feedback on the proposed VAD form. Suggestions were taken into consideration and minor sections of the care plan (shading, location of comments section) were modified prior to roll-out. Focus groups with staff nurses regarding PIVC assessment were undertaken prior to the roll out of the tool and at the end of the trial (Results of the focus groups are reported elsewhere).

Patient and Public involvement

The I-DECIDED® tool incorporates a prompt to evaluate patients' (and family, if appropriate) knowledge and concerns about their PIVC and to provide education, as needed. This prompt was included after recent research revealed consumers wanted to be included in conversations about the management of their vascular access devices.[24, 25] Specific patient advisers were not consulted for this study.

RESULTS

Content validity

Complete responses for the content validity questionnaire were available for 7 (32%) experts and 11 (44%) clinicians from Australia, UK, USA, and Canada. Two experts (UK, USA) and one clinician (USA) participated in a 30-minute, one-to-one call with the lead author. These discussions focused on clarifying the recommended frequency of assessment, in particular with different nursing shift lengths, and discussions about nursing responsibility for vascular access decisions, which vary between hospitals and countries.

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For vascular access experts, the mean CVI for the principles of the tool was 0.87 (range 0.29–1.00), and the mean I-CVI for all items of the tool was 0.91 (range 0.57–1.00). The mean proportion of agreement was 0.91 (range 0.83–0.98) (See Table 1)

[Insert Table 1]

For experienced clinicians, the mean CVI for the principles of the tool was 0.96 (range 0.82–1.00), and the mean I-CVI for all items of the tool was 0.93 (range 0.55–1.00). The mean proportion of agreement was 0.94 (range 0.65–1.00). (See Table 2)

[Insert Table 2]

The content validity questionnaire elicited comments, which are summarised here. The complete list of responses is provided in Appendix 2.

Principle 1: The presence of an IV device should be assessed each shift.

All 18 respondents agreed. The prompt to assess for post-infusion phlebitis invoked 5 comments, with most respondents agreeing that assessing for post-infusion phlebitis is important but can be difficult if patients have communication difficulties and is not possible after patient discharge.

Principle 2: The need for the IV device should be assessed each shift.

Seventeen respondents agreed; however, one respondent commented that assessing PIVC need each shift was unrealistic and discussing changing to oral medications with the pharmacist and treating team raised workload concerns. Two respondents debated frequency of PIVC assessment, remarking that 'each shift' was unclear because shift length can vary according to the unit. One respondent noted that the Infusion Nurses Society Standards of

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Practice[11] call for daily assessment of need, rather than each shift.

Principle 3: Effective flow and flush of the IV device should be assessed each shift.

Seventeen respondents agreed, and 11 respondents offered diverse questions and opinions. Several argued that 'flow and flush' were subjective assessments and insufficient to determine PIVC function without first checking for obstruction. Flushing frequency was debated, and two respondents recommended adding 'aspiration for blood return'. In response to this feedback, the wording was changed to 'Effective function'.

Principle 4: The IV site should be assessed for complications or concerns each shift.

All 18 respondents agreed with prompts to assess pain, redness, swelling, discharge, infiltration, extravasation, hardness or purulence. One respondent stated that palpable cord should not be included. Another said that this prompt contained too many signs and symptoms, many of which could be too subjective or difficult for the nurse to remember. Respondents' comments varied regarding determining pain scores at the PIVC site. One respondent said a pain score of 1 with associated redness and swelling would be a valid reason to remove the PIVC; another respondent stated pain would not be addressed unless the pain score was greater than 5; yet another recommended the question should prompt the nurse to identify the cause of the pain, rather than rely on a numerical score.

Principle 5: Infection prevention and control practices should be performed each shift.

Sixteen respondents concurred; two experts disagreed with the principle but agreed with all the supporting prompts. Five respondents argued the inclusion of fever and elevated white cell count was inappropriate, as neither would prompt PIVC removal in most cases; one respondent argued that diagnosis of infection would be a team responsibility rather than

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nursing. A Skype respondent expressed concern that a nurse might identify the PIVC as a possible source of infection, which could lead to financial penalties in some health services. One respondent stated 'purulent drainage' fit better with the principle 'complications' and the infection section should focus on identifying signs of sepsis. Two respondents felt aseptic non-touch technique should be removed because it was not taught at every hospital.

Principle 6: Dressing and securement practice should be assessed each shift.

All 18 respondents agreed. Four respondents noted this prompt could be made clearer by requiring that the PIVC site remain visible for ease of inspection; however, the wording of this section was not changed because the guidelines accept either transparent or sterile gauze and tape dressings.[13] Four respondents requested the prompts should specify exactly what should be secured (PIVC or administration set or both).

Principle 7: The patient/family's knowledge and education needs should be assessed each shift, if possible.

Eleven respondents supported this principle. Nine clinicians agreed that patient concerns about the PIVC were important to assess each shift, but only two experts felt this was relevant to include in the tool; five experts expressed concern that assessing patient knowledge needs each shift would be too frequent. Six respondents did not agree it was relevant to evaluate the patient's and/or family's understanding of the reason for the PIVC and plans for its removal.

Principle 8: The IV assessment and actions taken should be documented each shift.

All 18 respondents agreed. One respondent stated that the documentation should include more details (e.g. exact site of insertion, gauge size). Another commented that the tool would

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need to include more frequent prompts for paediatric PIVC assessment. A further suggestion was to include a prompt to replace PIVCs inserted in an emergency where asepsis could have been compromised.

Principle 9: The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.

Seventeen respondents agreed: however, one respondent noted PIVC removal must comply with local institutional policy, rather than a nurse's decision. Two respondents stated it would not be necessary to consult with the treating team before removing the PIVC if the nurse identified complications, as PIVC assessment is a nursing responsibility and nurses have the necessary skills and knowledge to make their own informed decisions in this area. This point was also raised in the Skype/telephone calls. Following this feedback, a clause was added: "Always consider local policy and consult with team and patient as required".

Inter-rater reliability

From 34 paired assessments, item-level proportion of inter-rater agreement ranged from 79.41% (patient education) to 100% (documentation of the decision) (See Table 3). Overall proportion of inter-rater agreement was 87.13%. Using the Landis and Koch[26] categorization, the kappa values for each item of the tool were all in the substantial (0.61–0.80) range, except for 'Identify if patient has a PIVC' and 'Document your decision', which both scored almost perfect (0.81–1.00) and 'Evaluate and Educate', which scored in the moderate (0.41–0.60) range.

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Feasibility

During inter-rater reliability testing, the time to conduct each assessment ranged from 1 to 10 minutes (average 2 minutes). Longer assessments occurred when patients had questions about their PIVC or if troubleshooting the PIVC was required.

Acceptability

Although 25 education sessions were attended by 180 staff over three hospitals in Phase 2, it was not possible to provide education to all staff at each site. Education was provided to all nurse unit managers, nurse educators and clinical facilitators, as well as many registered and enrolled nurses, physicians, and administrative staff. Posters were displayed in staff tearooms and nurses' stations, and lanyard cards were provided for all staff. During Phase 3 focus groups, the lead author asked attendees if they had received instructions how to use the tool. There was no discernible difference in feedback between staff who had or had not received education. General consensus was that the tool was easy to follow and particularly useful for newly registered nurses and nursing students. The structured format for PIVC assessment was popular, but many disliked the added paperwork. Following the inter-rater assessments, the lead author asked nurses if they had attended an education session, and if not, how did they learn to use the tool. Approximately half of the nurses who participated in the inter-rater assessments had not received any formal education about the tool; they reported that they had either asked a colleague about it or that it was self-evident.

DISCUSSION

This paper describes the clinimetric properties of the I-DECIDED® tool for PIVC assessment in an inpatient population. The tool demonstrated strong content validity for adults and paediatrics among vascular experts and clinicians, and high inter-rater reliability, feasibility

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and acceptability in the adult medical-surgical wards of three Australian hospitals. As this is the first comprehensive, evidence-based tool for PIVC assessment and decision-making, the authors expect this will interest clinicians across inpatient settings.

A strength of this study was that content validity of the tool was confirmed by 18 vascular access experts and clinicians from a range of English-speaking countries. Lynn[27] advocated item-level CVI should be around 0.80 when there are six or more experts. The mean CVI and proportion of agreement for the principles and the individual items of the tool scored very highly for both experts (I-CVI 0.91; mean proportion of agreement 0.91) and experienced clinicians (I-CVI 0.93; mean proportion of agreement 0.94), confirming that this tool comprises the essentials of PIVC assessment and decision-making.

Feedback from content validity survey and verbal conversations revealed that some respondents did not think it appropriate to assess all items each 'shift', particularly as nursing shifts can vary in length up to 12 hours. Some respondents commented that daily assessment would be sufficient for items such as "need for the PIVC" and "patient education", while others remarked that daily assessment would not be frequent enough for some patient populations, such as paediatrics, where guidelines recommend hourly assessment for continuous infusions. While current guidelines[11] recommend daily assessment of PIVC need, we believe this assessment is warranted more regularly, particularly if the nurse knows that an administered medication is the final dose and removal is planned in the next few hours. The suggestion to consult the treating team prior to removing the PIVC was criticised by several respondents, who argued nurses possess the skills and knowledge to make their own informed decisions. While this is true for experienced nurses, it cannot be presumed that novice nurses and students will have confidence in their decision to remove or resite a PIVC.

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Patient and family concerns about the PIVC and their education needs are often under-valued by healthcare workers,[28] and this was reflected in our findings that only 11 out of 18 survey respondents agreed with this principle. Surprisingly, only two of seven experts felt regular patient education should be included in the tool. In an Irish study, patients who did not know the reason for their PIVC were seven times more likely not to need the device.[29] In an Australian study of consumer experiences, patients and caregivers expressed the need for improved communication about PIVC insertion and care.[24] A recent survey of eight US hospitals reported that one-third of patients with concerns about their care did not feel empowered to speak up, and patients less likely to speak up included older, sicker, non-English-speaking, or patients with mental health issues.[30] While more hospitals are implementing mechanisms for patients and families to verbalise critical safety concerns, more needs to be done to change hospital culture to encourage patient collaboration in daily care decisions, particularly those that impact on infection management and prevention.[31-33] Including a prompt for clinicians to ask the patient about the PIVC has merit.

Testing inter-rater reliability among a variety of clinicians was another strength of this study. Paired assessments, performed immediately after each other, eliminated the likelihood of altered assessment findings resulting from medication or fluid administration, or time for symptoms to change. Blinding of the second assessor to the first assessor's results and blinding the registered nurses to the research nurses' results also strengthened the findings. While the overall proportion of inter-rater agreement was high for most items, the category of patient education demonstrated the lowest scores. This is not surprising, as the stability of patient-reported variables between assessments can be a confounder of inter-rater reliability testing.[34] For instance, if the first rater asked about pain or tenderness of the PIVC site, and

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received a negative response, this could have suggested concerns to the patient who then answered in the affirmative to the second assessor. Asking patients if their nurse had assessed the PIVC that shift or performed hand hygiene before touching the PIVC, or whether they had received any education about the PIVC, also elicited contradictory answers in some assessments. Some patients answered negatively in the first instance, but when asked the same question by the second rater, they answered in the affirmative. This was possibly due to suggestibility or an unwillingness to implicate the nurse, but we had no way to confirm or refute the findings.

Decision-making is a subjective process based on assessment, but the assessment itself should be a standardised process to ensure care is evidence-based and comprehensive. PIVC decisions are often based on clinicians' education and experience, and not all clinicians are conversant with current guidelines.[35-38] The I-DECIDED® tool prompts clinicians to perform a structured PIVC assessment and document their decision based on that assessment. It is not a prescriptive tool designed to overrule local policies, although we do believe that decisions to continue or remove a PIVC should be based on comprehensive clinical assessment, and not simply dwell time or absence of phlebitis symptoms.[6]

Limitations. Construct validity could not be evaluated as PIVC assessment is highly subjective, and no gold standard exists for PIVC assessment and decision making. Criterion validity could not be evaluated because there are no other comprehensive PIVC assessment tools in the literature. While multiple phlebitis tools exist, evaluation of their measurement properties is rare, and validity and reliability data are limited or absent. Inter-rater reliability assessments of the tool were completed by different sets of coders for different subjects, which can lead to a higher level of systematic bias or make it difficult to detect bias.[39] We

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tried to control for this by alternating the order of assessments and blinding each assessor to the other's findings. Finally, inter-rater reliability was tested in seven medical-surgical wards in three hospitals. Testing the tool's reliability in other settings is necessary.

CONCLUSION

The I-DECIDED® tool demonstrated strong content validity and high inter-rater reliability, feasibility and acceptability in medical-surgical wards of three hospitals. Implementation of this tool could prompt clinicians to provide comprehensive care and remove PIVCs when no longer needed or as soon as complications arise. Early detection and action could prevent painful PIVC complications, reduce the risk of bloodstream infection, and result in cost savings for healthcare services. Studies to evaluate the outcome of implementing this tool in clinical practice are recommended.

(4000 words)

SUPPORTING INFORMATION

A video of the I-DECIDED® device assessment and decision tool is available:

https://www.youtube.com/watch?v=kMHOjWJWbsI

DATA SHARING STATEMENT: No additional data are available.

ACKNOWLEDGEMENTS

The authors would like to thank Joan Webster, Nicole Marsh, Marianne Wallis, Amanda Ullman, Tricia Kleidon, and Amy Johnston, who reviewed the face validity of the tool; the experts and clinicians who anonymously participated in the content validity questionnaire; the research assistants Josephine Lovegrove, Kathie Roberts and Elizabeth Herron for assisting with the inter-rater reliability testing; and Gabor Mihala for statistical support.

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FUNDING

Financial support for this study was provided in part by grants from Griffith University and the Australian College of Infection Prevention and Control. The funding agreements ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report. The following authors are employed by the sponsor, Griffith University: Gillian Ray-Barruel, Marie Cooke, Marion Mitchell, Claire M Rickard.

COMPETING INTERESTS

Griffith University has received on GRB's behalf unrestricted research grants (3M and Becton Dickinson) and consultancy payments (Ausmed, 3M, BD, Medline, and Wolters Kluwer). MC has received investigator-initiated research and educational grants and speaker fees provided to Griffith University by vascular access product manufacturers (Baxter, BD, Entrotech Life Sciences). VC receives funding from the Veterans Health Administration, National Institute for Health, Agency for Healthcare Research and Quality, and Centers for Disease Control. MM: No conflicts of interest. CMR: Griffith University has received on CMR's behalf unrestricted investigator-initiated research or educational grants from product manufacturers (3M, AngioDynamics; BD-Bard, Baxter; BBraun, Cardinal Health, Medtronic, Smiths Medical); and consultancy payments (3M, BD-Bard; BBraun, ResQDevices, Smiths Medical). No commercial entity had any role in the design or undertaking of this study.

AUTHOR CONTRIBUTIONS

All authors contributed to the study concept and design. GRB acquired and interpreted the data, and drafted the article, and all authors provided critical review and input. All authors contributed to revisions of the manuscript and take public responsibility for its content. All authors approved the final manuscript.

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TABLES

Table 1. Ratings on a 48-item scale by 7 vascular access experts: Items rated 3 or 4 on a 4-point relevance scale

Table 2. Ratings on a 48-item scale by 11 experienced clinicians: Items rated 3 or 4 on a 4-point relevance scale

Table 3. Inter-rater reliability of I-DECIDED® tool

FIGURE LEGENDS

Figure 1. I-DECIDED® IV assessment and decision tool

APPENDICES

Appendix 1. Content Validity Questionnaire: I-DECIDED® device assessment and removal tool

Appendix 2. Principles of the I-DECIDED® tool and CVI survey respondents' comments

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Table 1. Ratings on a 48-item scale by 7 vascular access experts: Items rated 3 or 4 on a 4-point relevance scale

Item	Description	E1	E2	E3	E4	E5	E6	E7	Number in agreement	Item CVI
1	***Key principle: The presence of an IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	7	**1.00**
2	Does the patient have an IV device? (Inspect the patient and ask the patient if unsure)	✓	✓	✓	✓	✓	✓	✓	7	1.00
3	Has the patient had an IV device removed in the past 48 hrs? (Ask the patient)	✓	✓	✓	✓	✓	✓	✓	7	1.00
4	If the patient has had an IV device removed in the past 48 hrs, observe site for complications (post-infusion phlebitis and purulence).	✓	✓	✓	✓	✓	✓	✓	7	1.00
5	***Key principle: The need for the IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	7	**1.00**
6	Has the IV device been used in the past 24 hours, or is it likely to be used in the next 24 hrs?	✓	✓	✓	✓	✓	✓	✓	7	1.00
7	Can the patient switch to oral medications? Discuss with pharmacist and treating team.	✓	✓	✓	✓	✓	✓	✓	7	1.00
8	When no longer needed, the IV device should be removed.	✓	✓	✓	✓	✓	✓	✓	7	1.00
9	***Key principle: Effective flow and flush of the IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	6	**.86**
10	Does the IV device flow well?	✓	✓	✓	-	✓	✓	✓	6	.86
11	Does the IV device flush well?	✓	✓	✓	-	✓	✓	✓	5	.71
12	If the IV device does not flow and flush, it should be removed.	✓	✓	✓	✓	✓	✓	✓	6	.86
13	***Key principle: The IV site should be assessed for complications or concerns each shift.***	✓	✓	✓	✓	✓	✓	✓	7	**1.00**
14	Patient-reported pain ≥ 2 out of 10?	✓	✓	✓	✓	✓	✓	✓	7	1.00
15	Redness > 1 cm from insertion site	✓	✓	✓	✓	✓	✓	✓	7	1.00
16	Swelling > 1 cm from insertion site	✓	✓	✓	✓	✓	✓	✓	7	1.00
17	Any discharge at site	✓	✓	✓	✓	✓	✓	✓	7	1.00
18	Infiltration (IV fluid in surrounding tissues)	✓	✓	✓	✓	✓	✓	✓	7	1.00
19	Hardness (induration) of insertion site	✓	✓	✓	✓	✓	✓	✓	7	1.00
20	Palpable cord	✓	✓	✓	✓	✓	✓	✓	7	1.00
21	Other concerns? (itch, rash, blistering, etc.)	✓	✓	✓	✓	✓	✓	✓	7	1.00
22	If complications occur, the IV device should be removed, after consultation with the treating team. Insert new IV device if needed.	✓	✓	✓	✓	✓	✓	✓	7	1.00
23	***Key principle: Infection prevention and control practices should be performed each shift.***	✓	-	-	✓	✓	✓	✓	5	**.71**
24	Use Aseptic Non-Touch Technique (ANTT)	✓	✓	✓	✓	✓	✓	✓	7	1.00
25	Hand hygiene	✓	✓	✓	✓	✓	✓	✓	7	1.00
26	Scrub the hub as per protocol and allow to dry before accessing IV device	✓	✓	✓	✓	✓	✓	✓	7	1.00
27	Any fever of unknown origin?	✓	✓	✓	-	✓	-		5	.71

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											I-DECIDED
28	Elevated white blood cell count?	✓	✓	✓	-	✓	-	5		.71
29	If the patient has a fever and/or elevated white blood cell count, with no obvious source of infection, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	✓	✓	✓	✓	✓	-	6		.86
30	Purulent discharge at the insertion site?	-	✓	✓	✓	✓	✓	6		.86
31	If the IV site has purulent discharge, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	✓	✓	✓	✓	✓	✓	7		1.00
32	***Key principle: Dressing and securement practice should be assessed each shift.***	✓	✓	✓	✓	✓	✓	7	**1.00**	
33	Is the IV dressing clean, dry, and intact?	✓	✓	✓	✓	✓	✓	7		1.00
34	If the IV dressing is moist, visibly soiled, or has loose/lifting edges, it should be changed.	✓	✓	✓	✓	✓	✓	7		1.00
35	Is the IV device and infusion tubing secured?	✓	✓	✓	✓	✓	✓	7		1.00
36	Secure well with securement device, tape, net or bandage.	✓	✓	✓	-	✓	✓	6		.86
37	***Key principle: The patient/family's knowledge and education needs should be assessed each shift, if possible.***	-	-	✓	-	-	✓	2	**.29**	
38	Evaluate patient/family understanding of reason for IV and plan for removal, if possible.	✓	-	✓	-	✓	✓	4		.57
39	Educate patient/family as needed, if possible.	✓	-	✓	-	✓	✓	5		.71
40	***Key principle: The IV assessment and actions taken should be documented each shift.***	✓	✓	✓	✓	✓	✓	7	**1.00**	
41	Insertion date and time	✓	✓	✓	✓	✓	✓	6		.86
42	I-DECIDED® assessment and relevant action taken	✓	✓	✓	✓	✓	✓	6		.86
43	Removal date and time	✓	✓	✓	✓	✓	✓	7		1.00
44	***Key principle: The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.***	✓	✓	✓	✓	✓	✓	7	**1.00**	
45	Decision 1. IV device should remain in place. No other change.	✓	✓	✓	✓	✓	-	6		.86
46	Decision 2. IV device should remain in place, but dressing change done. IV and infusion tubing well secured.	✓	✓	✓	✓	✓	-	6		.86
47	Decision 3. IV device removed and not replaced, in consultation with the treating team.	✓	✓	✓	✓	✓	-	6		.86
48	Decision 4. IV device removed and replaced. Consulted with patient and team about best device and site.	✓	✓	✓	✓	✓	-	6		.86
	Proportion relevant	.96	.92	.98	.83	.98	.85	.85	0.87 (mean)	0 .91 (mean)
									Mean expert proportion = 0.91	

IV = intravenous; E = vascular access expert

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Table 2. Ratings on a 48-item scale by 11 experienced clinicians: Items rated 3 or 4 on a 4-point relevance scale

Item	Description	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	Number in agreement	Item CVI
1	***Key principle: The presence of an IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**
2	Does the patient have an IV device? (Inspect the patient and ask the patient if unsure)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
3	Has the patient had an IV device removed in the past 48 hrs? (Ask the patient)	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	-	9	.82
4	If the patient has had an IV device removed in the past 48 hrs, observe site for complications (post-infusion phlebitis and purulence).	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	10	.91
5	***Key principle: The need for the IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	**.91**
6	Has the IV device been used in the past 24 hours, or is it likely to be used in the next 24 hrs?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
7	Can the patient switch to oral medications? Discuss with pharmacist and treating team.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	.91
8	When no longer needed, the IV device should be removed.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
9	***Key principle: Effective flow and flush of the IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**
10	Does the IV device flow well?	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	-	9	.82
11	Does the IV device flush well?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	.91
12	If the IV device does not flow and flush, it should be removed.	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	9	.82
13	***Key principle: The IV site should be assessed for complications or concerns each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**
14	Patient-reported pain ≥ 2 out of 10?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	.91
15	Redness > 1 cm from insertion site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
16	Swelling > 1 cm from insertion site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
17	Any discharge at site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
18	Infiltration (IV fluid in surrounding tissues)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
19	Hardness (induration) of insertion site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00

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I-DECIDED

20	Palpable cord	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10		.91
21	Other concerns? (itch, rash, blistering, etc.)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
22	If complications occur, the IV device should be removed, after consultation with the treating team. Insert new IV device if needed.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
23	***Key principle: Infection prevention and control practices should be performed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**	
24	Use Aseptic Non-Touch Technique (ANTT)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
25	Hand hygiene	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
26	Scrub the hub as per protocol and allow to dry before accessing IV device	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
27	Any fever of unknown origin?	-	✓	✓	✓	✓	✓	✓	✓	-	✓	-	8		.73
28	Elevated white blood cell count?	-	✓	✓	✓	✓	-	-	✓	-	✓	-	6		.55
29	If the patient has a fever and/or elevated white blood cell count, with no obvious source of infection, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10		.91
30	Purulent discharge at the insertion site?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10		.91
31	If the IV site has purulent discharge, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	-	✓	-	✓	✓	✓	-	✓	✓	✓	-	7		.64
32	***Key principle: Dressing and securement practice should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**	
33	Is the IV dressing clean, dry, and intact?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
34	If the IV dressing is moist, visibly soiled, or has loose/lifting edges, it should be changed.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
35	Is the IV device and infusion tubing secured?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
36	Secure well with securement device, tape, net or bandage.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10		.91
37	***Key principle: The patient/family's knowledge and education needs should be assessed each shift, if possible.***	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	-	9	**.82**	
38	Evaluate patient/family understanding of reason for IV and plan for removal, if possible.	✓	✓	✓	✓	✓	✓	-	✓	-	✓	-	8		.73
39	Educate patient/family as needed, if possible.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10		.91

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I-DECIDED

40	***Key principle: The IV assessment and actions taken should be documented each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**	
41	Insertion date and time	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
42	I-DECIDED® assessment and relevant action taken	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
43	Removal date and time	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
44	***Key principle: The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	**.91**	
45	Decision 1. IV device should remain in place. No other change.	✓	✓	-	✓	✓	✓	✓	✓	✓	✓	✓	10		.91
46	Decision 2. IV device should remain in place, but dressing change done. IV and infusion tubing well secured.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
47	Decision 3. IV device removed and not replaced, in consultation with the treating team.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
48	Decision 4. IV device removed and replaced. Consulted with patient and team about best device and site.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
	Proportion relevant	.90	1.00	.96	1.00	1.00	.94	.90	1.00	.94	1.00	.65		0.96 (mean)	0.93 (mean)
														Mean clinician proportion	0.94

IV = intravenous; C = clinician

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Table 3. Inter-rater reliability of I-DECIDED® tool

	Observed Agreement (%)†	PABAK‡	Standard error	Z	Prob>Z
Identify if patient has PIVC	97.06	0.9412	0.1712	5.50	0.0000
Does patient need PIVC	88.24	0.7647	0.1715	4.46	0.0000
Effective function of PIVC	85.29	0.7059	0.1712	4.12	0.0000
Complications at PIVC site	82.35	0.6471	0.1715	3.77	0.0001
Infection prevention	82.35	0.6471	0.1715	3.77	0.0001
Dressing and securement	82.35	0.6471	0.1715	3.77	0.0001
Evaluate and educate	79.41	0.5882	0.1712	3.44	0.0003
Document your decision	100.0	1.0000	0.1715	5.83	0.0000
OVERALL	87.13				

†Expected agreement 50% for all items; ‡PABAK: prevalence-adjusted bias-adjusted kappa

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Figure 1. I-DECIDED® IV assessment and decision tool

I-DECIDED®

IV ASSESSMENT & DECISION TOOL

I **IDENTIFY if an IV is in situ**

D **DOES patient need the IV?**
Unused in last 24hrs? Use unlikely in next 24hrs?
Consider removal. Change to oral meds?

E **EFFECTIVE function?**
Follow local policy for flushing and locking.

C **COMPLICATIONS at IV site?**
Pain ≥2/10, redness, swelling, discharge, infiltration, extravasation, hardness, palpable cord or purulence.

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

D **DRESSING & securement**
Clean, dry, and intact. IV and lines secure.

E **EVALUATE & EDUCATE**
Discuss IV plan with patient & family.

D **DOCUMENT your decision**
Continue, change dressing, or remove IV.

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

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Appendix 1. Content Validity Questionnaire: I-DECIDED device assessment and removal tool

Each item of the tool is based on a 'Key principle', with prompts for assessment and action.

Please ***circle the number*** that best rates the relevance of the statements listed below about the proposed components of the I-DECIDED tool.

Each section is followed by a space for your comment (E.g. Are any important concepts missing? Ease of comprehension? Language issues?).

KEY FOR SCORING ITEMS:
1 =NOT RELEVANT, 2 = SOMEWHAT RELEVANT, 3 = QUITE RELEVANT, 4 = HIGHLY RELEVANT

	I. IDENTIFY presence of IV device	**Please circle the relevant number**			
1	*Key principle 1: The presence of an IV device should be assessed each shift.*	1	2	3	4
2	Does the patient have an IV device? (Inspect the patient and ask the patient if unsure)	1	2	3	4
3	Has the patient had an IV device removed in the past 48 hours? (Ask the patient)	1	2	3	4
4	If the patient has had an IV device removed in the past 48 hours, observe site for complications (post-infusion phlebitis and purulence).	1	2	3	4

Comments:_____

_____

	II. DOES the patient need this IV device?	**Please circle the relevant number**			
5	*Key principle 2: The need for the IV device should be assessed each shift.*	1	2	3	4
6	Has the IV device been used in the past 24 hours, or is it likely to be used in the next 24 hours?	1	2	3	4
7	Can the patient switch to oral medications? Discuss with pharmacist and treating team.	1	2	3	4
8	When no longer needed, the IV device should be removed.	1	2	3	4

Comments:_____

_____

	III. EFFECTIVE flow and flush?	**Please circle the relevant number**			
9	*Key principle 3: Effective flow and flush of the IV device should be assessed each shift.*	1	2	3	4
10	Does the IV device flow well?	1	2	3	4
11	Does the IV device flush well?	1	2	3	4
12	If the IV device does not flow and flush, it should be removed.	1	2	3	4

Comments:_____

_____

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	IV. COMPLICATIONS or CONCERNS	Please circle the relevant number			
13	*Key principle 4: The IV site should be assessed for complications or concerns each shift.*	1	2	3	4
14	Patient-reported pain ≥ 2 out of 10?	1	2	3	4
15	Redness > 1 cm from insertion site	1	2	3	4
16	Swelling > 1 cm from insertion site	1	2	3	4
17	Any discharge at site	1	2	3	4
18	Infiltration (IV fluid in surrounding tissues)	1	2	3	4
19	Hardness (induration) of insertion site	1	2	3	4
20	Palpable cord	1	2	3	4
21	Other concerns? (itch, rash, blistering, etc.)	1	2	3	4
22	If complications occur, the IV device should be removed, after consultation with the treating team. Insert new IV device if needed.	1	2	3	4

Comments:_____

_____

	V. INFECTION prevention and control	Please circle the relevant number			
23	*Key principle 5: Infection prevention and control practices should be performed each shift.*	1	2	3	4
24	Use Aseptic Non-Touch Technique (ANTT)	1	2	3	4
25	Hand hygiene	1	2	3	4
26	Scrub the hub as per protocol and allow to dry before accessing IV device	1	2	3	4
27	Any fever of unknown origin?	1	2	3	4
28	Elevated white blood cell count?	1	2	3	4
29	If the patient has a fever and/or elevated white blood cell count, with no obvious source of infection, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	1	2	3	4
30	Purulent discharge at the insertion site?	1	2	3	4
31	If the IV site has purulent discharge, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	1	2	3	4

Comments:_____

_____

	VI. DRESSING and securement	Please circle the relevant number			
32	*Key principle 6: Dressing and securement practice should be assessed each shift.*	1	2	3	4
33	Is the IV dressing clean, dry, and intact?	1	2	3	4
34	If the IV dressing is moist, visibly soiled, or has loose/lifting edges, it should be changed.	1	2	3	4
35	Is the IV device and infusion tubing secured?	1	2	3	4

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36	Secure well with securement device, tape, net or bandage.	1	2	3	4

Comments:_____

_____

	VII. EVALUATE and EDUCATE	Please circle the relevant number			
37	*Key principle 7: The patient/family's knowledge and education needs should be assessed each shift, if possible.*	1	2	3	4
38	Evaluate patient/family understanding of reason for IV and plan for removal, if possible.	1	2	3	4
39	Educate patient/family as needed, if possible.	1	2	3	4

Comments:_____

_____

	VIII. DOCUMENT	Please circle the relevant number			
40	*Key principle 8: The IV assessment and actions taken should be documented each shift.*	1	2	3	4
41	Insertion date and time	1	2	3	4
42	I-DECIDED assessment and relevant action taken	1	2	3	4
43	Removal date and time	1	2	3	4

Comments:_____

_____

	IX. DECIDE and ACT	Please circle the relevant number			
44	*Key principle 9: The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.*	1	2	3	4
45	**Based on this assessment (in consultation with treating team and patient), I-DECIDED . . .**	1	2	3	4
46	IV device should remain in place. No other change.	1	2	3	4
47	IV device should remain in place, but dressing change done. IV and infusion tubing well secured.	1	2	3	4
48	IV device removed and not replaced, in consultation with the treating team.	1	2	3	4
49	IV device removed and replaced. Consulted with patient and team about best device and site.	1	2	3	4

Comments:_____

_____

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Appendix 2. Key principles of the I-DECIDED® tool and CVI survey respondents' comments

E = Expert; C = Clinician

Key principle 1. The presence of an IV device should be assessed each shift.

Post-infusion phlebitis is a rare event. (E4)

All relevant questions (E5)

Difficult to check site if patient has been sent home. (E6)

I am glad you incorporated the assessment of site post removal. This is not a standard practice and should be. (C1)

Not sure the relevance of item Q4 & Q5 in the context of identifying presence of an IV (i.e. although they are relevant it depends on context) - it potentially belongs to other principles. Q4 & Q5 are about identifying absence in the context of potentially infective/inflammatory processes. That said, the questioning of a patient- i.e. the interaction with a patient may include questions in this order. (C6)

48hrs [post-removal] assessment will be difficult with some patients (stoke; capacity to understand etc) 2-3 are also dependent on capacity to feedback (C8)

Check IV device is documented? (C11)

Key principle 2. The need for the IV device should be assessed each shift.

Would instead assess for need daily instead of every shift which at least in US is not realistic. (E2)

INS standards call for a daily assessment of need rather than each shift. Sometimes it is hard to define a 'shift' as this can be 8 hours or 12 hours. Most American nurses work 12-hour shifts. (E7)

It is the Treating team who will make the decision to switch to orals. The pharmacist could have input but the Treating team is the decider. May not always take on the pharmacist's advice (C7)

Your definition of no longer needed is important. (C8)

Discussions with treating team and/or pharmacist is a BIG workload. Needs to be established by? in conjunction with? treating team (medical team) (C11)

Key principle 3. Effective flow and flush of the IV device should be assessed each shift.

Flow and flush would be hard to assess unless the person checks the flow and flush themselves. The most important issue is removal. (E4)

Difficult to define a 'shift' as there are a mixture of 3 shifts per 24 hours and 2 shifts per 24 hours. Q15 relevant question but the wording is subjective, what does 'well' mean? (E5)

Due to poor renal function IV antibiotic may be every other day...? Flush or not... need to describe difference between flush and lock. (E6)

Flow and flush is very important but not sufficient by itself. There should be aspiration for a blood return using appropriate technique - slow and gentle, small syringe, and/or a tourniquet above the site. This is critical if the medications are vesicants. Also, this assessment should be before each infusion and not limited to only once per shift. (E7)

I feel there would need to have more assessment prior to removal. What site look like? Is it secure properly? Is the obstructed duty to taping or being kinked? Is it leaking at the site? (C1)

No use having a cannula if it is not meeting the most basic design parameter. (C4)

Q15 would come down to clinical context and how desperate the need for the IV is and how tricky obtaining access is (C6)

Flow well question is a bit ambiguous. May not know if it 'flows' well if no IV infusion. The PIVC should be flushed before anything is administered so flush should be first and if it doesn't flush it is not going to flow. Maybe infusing easily if IV infusion (C7)

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The type of volume; flush rate; and size of PIVC impact on Q13-Q14 (C8)

Clinicians will be confused by flow and flush and why it is separated. We assess for resistance with flushing and free flowing of IV therapy. In oncology we also assess for blood return. (C10)

Q12 & Q13 & Q14 the same? Q15 - move? wiggle? reposition? (C11)

Key principle 4. The IV site should be assessed for complications or concerns each shift.

Some questions appear to be redundant or overlapping as in swelling/infiltration, redness/hardness induration. These questions could be combined. (E1)

Q25 is likely a dressing issue rather than catheter issue (E2)

Q26 - most clinicians would not necessarily consult team... they would just remove and insert a new IV (E3)

Shifts vary for 8 hours to 12 hours, may need to be more specific (E5)

Not sure how relevant 1cm is? (E6)

These are a little troubling because they imply that pain of level 1 or redness and swelling of 1 cm are acceptable. All changes in color, temperature, any degree of pain is a valid reason to immediately remove the PIVC. Also consultation from the 'treating team' is not necessary. Not sure who this team includes. Any nurse should be capable of assessing these sites, making the decision to remove it if there are any signs or symptoms, remove and assess for the need to insert a new PIVC without consultation by the treatment team. (E7)

I would relook at scoring pain greater than 2. Maybe does patient have pain yes or no? We usually don't provide interventions for pain when using scale unless pain is greater than 5. (C1)

Have graded the pain assessment at a lower value due to subjectiveness of numerical scoring. I would want to drill deeper: e.g. is it because of the site and its tendency to be bumped that is causing the pain? Would an arm board or better dressing help? (C4)

Do you think that the signs need to be signposted for different complications? (C6)

When asking pts about pain in PIVC they think of pain at insertion; specify pain at present time. Do we accept a pain score of 1? Add extravasation with infiltration (C7)

How many attempts they had? Did they did *[sic]* the clinician was skilled enough; reassured them; understood their fears if any; respected their suggestion where it should go? (C8)

What is a palpable cord? How will the nurse remember all of these components? Condense to red/swollen/painful/Other? (C11)

Key principle 5. Infection prevention and control practices should be performed each shift.

It seemed that the purulent drainage was a carry-over from the previous section on complications and not part of infection practices. Maybe changing the wording to are there any signs of sepsis/infection? (E1)

Q28 is institution-dependent, may not be relevant; Q34, Q35, Q36 draw blood cultures. Note: Qs and order of questions are different on printed version and electronic version (E2)

Would suggest rewording Q28....to make it more specific to IV. (E3)

Fever and WCC are subsumed under Q36 (E4)

Q30 - needs to be more specific, e.g. before and after each manipulation/access of the device (E5)

Removal of IV if ? source of infection... other sources must be considered (E6)

Same comment about shift as previous screen. Not sure what is being asked in Q34. FUO alone is not a reason to remove any VAD. Neither is elevated WBC. Also not sure what is meant by culture IV site - drainage, catheter, blood? Fever and WBC could be from lots of other causes and not the PIVC. Removal depends on many factors such as venous difficulty, length of therapy planned, etc. It is relevant but I would not automatically remove the PIVC under only the conditions listed. (E7)

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I have seen recent presentation on ANTT. If this is recommendation it would require large education for users to under concept, terms and practices. I have mixed feeling related to culturing PIV sites and site removal if pt has fever and positive blood culture. (C1)

Q36 will depend on clinical context (C6)

Q35 and Q36. WCC may be already elevated due to infection and why we have PIVC in. So an increase in Temperature and increase in WCC as to what it was. And think wording in Q36 that PIVC should be considered as possible source of infection and if clinically appropriate remove ASAP (C7)

Has their infusion pump alarmed during the treatment? Have they missed antibiotics/treatment delay? (C8)

WCC elevated is late sign of infection (C10)

ANTT - would they necessarily know what this means??? purulent discharge and Q33 belong in the previous page. Fever/WBC should have been identified by treating team...not nurse? Q36 not relevant to ED (C11)

Key principle 6. Dressing and securement practice should be assessed each shift.

Q40 not sure if edges of dressing lifting if this is proven to correlate with risk of infection or phlebitis for PIVs (E2)

Q42 - reword? Secure the IV itself? Or the tubing? Could also be extension tubing? (E3)

Q41 should come first. Q42 isn't necessary. (E4)

Q42 - we wouldn't advocate a bandage as they deter staff from observing the insertion site (but we do advocate securement) (E5)

Some of these questions are multiple questions in one... e.g. Securement device, net or bandage... also tube securement and cannula securement are two different questions (E6)

Same shift comment. Also define 'securement' for the PIVC. Is this referring to a completely stable and secure catheter, dressing, and joint if close to a joint? Q42, what type of bandage? Too many variables in this question. Tape alone is not sufficient iMHO. Net is only needed for specific ages or patient populations and bandages should never cover the site. Nurses will not remove it to assess completely. (E7)

You might just need to be certain that the IV site can still be inspected easily and not overly covered with tape etc. (C2)

Secure, dry and not moving and aggravating the vessel wall and venipuncture site => reduced risk of infection and complications. (C4)

Does Q42 need further information- e.g. relevance of being able to see the insertion site? (C6)

Is there evidence of a date on the dressing in the note on informatics? (C8)

Q41 - liked this one. Q42 – repeats (C11)

Key principle 7. The patient/family's knowledge and education needs should be assessed each shift, if possible.

I'm not sure if it is highly relevant to assess educational needs every shift. (E1)

I think only important that they know to contact nurse if pain, swelling, redness at or near insertion site, so would change wording to be more specific in this regard (E2)

Q46 - educate on complications? Or just in general? (E3)

Q44 - not sure this is relevant each shift, might be setting people up to fail (E5)

Same shift comments. Not sure this is required every 8-hour shift but it is required periodically. I would not tie it to a shift. Shift work equates to common laborers and not the knowledge workers that nurses actually are. (E7)

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I think these questions are vital as we incorporate patients in care. They are their own best advocate and can keep us accountable. (C1)

The best nursing and clinical care is irrelevant if the person cannulated is not on board the narrative. (C4)

I think by assessing and evaluating patient education each shift would not be done. Just continuous education and reinforcement to the patient of how their input is required. (C7)

[Educate] pt/family every shift is excessive. Q46 repeats (C11)

Key principle 8. The IV assessment and actions taken should be documented each shift.

Same shift comment. Much more detail is needed, exact site of insertion, gauge size, etc as listed in INS Standards. (E7)

Curious as populate tool be used or if you will have variation for peds and unconscious to align with INS recommendations to check PIV site more frequently. (C1)

Gives the clinician ownership of device management (C4)

Accreditation standards require removal plan. Also nothing noted about insertion in an emergency/or asepsis compromised at insertion may need replacing. (C7)

The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.

I would use different wording for Option 2. Something like: IV device should remain in place with securement and dressing replaced. (E1)

If purulent, painful, swollen, etc. then nurse should remove and wouldn't need 'consultation with treating team or patient' but would add need to document in medical record. I think this section should be revised. Does this all go into medical record? Again, for many of these, don't need to consult with patient or team (E2)

Dressing change only done if required. i.e. loose, soiled, coming off (E3)

I think I am missing the point of this screen. Decisions about PIVCs are nursing responsibility and accountability in the USA. No consultation with the treatment team is required before it is removed. Our MD, NP, and PA would think the nurse has lost her mind if a nurse asked them to assess a PIVC site. I strongly believe that all staff nurses must understand when a PIVC is no longer the most appropriate device for a specific patient. These factors then trigger a consultation by the infusion/vascular access nurse for what would be the most appropriate VAD. This recommended VAD may or may not require action by the medical team (MD, NP, PA = LIP in USA) The general staff nurse will not know what is most appropriate and I don't think we should expect them to have this knowledge. But each facility must have a team that can make this assessment. That is not the case in many facilities. (E7)

Great project. Let me know if you want to be a testing site. (C1)

A proactive management approach rather than reactive. (C4)

Are administration set changes covered anywhere? (C6)

I know AVATAR promotes clinically indicated PIVC resiting but this is not what is happening in most facilities so should mention based on Organisational Policy, treating team and patient (C7)

Did the pt want another device type or inserter or method of insertion? (C8)

Very exciting tool indeed (C10)

2 D's??? Q53 - repeats Q56 - 'in consultation...' repeated replaced = PIC/other line??? (C11)

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Guidelines for Reporting Reliability and Agreement Studies (GRRAS)

			Page
Title and abstract	1	Identify in title or abstract that interrater/intrarater reliability or agreement was investigated	3
Introduction	2	Name and describe the diagnostic or measurement device of interest explicitly	5
	3	Specify the subject population of interest	5
	4	Specify the rater population of interest (if applicable)	5
	5	Describe what is already known about reliability and agreement and provide a rationale for the study (if applicable)	5
Methods	6	Explain how the sample size was chosen. State the determined number of raters, subjects/objects, and replicate observations	6-9
	7	Describe the sampling method	7-8
	8	Describe the measurement/rating process (e.g., time interval between repeated measurements, availability of clinical information, blinding)	7-8
	9	State whether measurements/ratings were conducted independently	8
	10	Describe the statistical analysis	8-9
Results	11	State the actual number of raters and subjects/objects that were included and the number of replicate observations that were conducted	10-15
	12	Describe the sample characteristics of raters and subjects (e.g., training, experience)	6-8
	13	Report estimates of reliability and agreement including measures of statistical uncertainty	11, 14
Discussion	14	Discuss the practical relevance of results.	15-19
Auxiliary material	15	Provide detailed results if possible (e.g., online)	Appendix 2
Ref: Kottner J, Audige L, Brorson S, Donner A, Gajewski BJ, Hrobjartsson A, et al. Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. *Int J Nurs Stud*. 2011;48(6):661-71.			

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The I-DECIDED® clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: A clinimetric evaluation

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-035239.R1
Article Type:	Original research
Date Submitted by the Author:	17-Dec-2019
Complete List of Authors:	Ray-Barruel, Gillian; Griffith University, Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, School of Nursing and Midwifery; Queen Elizabeth II Jubilee Hospital, Princess Alexandra Hospital, Royal Brisbane and Women's Hospital, Nursing Research Cooke, Marie; Griffith University, Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, School of Nursing and Midwifery Chopra, Vineet; University of Michigan, Division of Hospital Medicine, Patient Safety Enhancement Program; Ann Arbor VA Medical Center, Center for Clinical Management Research Mitchell, Marion; Griffith University, Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, School of Nursing and Midwifery Rickard, Claire; Griffith University, Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, School of Nursing and Midwifery; Royal Brisbane & Women's Hospital, Princess Alexandra Hospital, The Prince Charles Hospital, Nursing Research & Development, and Critical Care Research Group
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Evidence based practice, Nursing, Infectious diseases
Keywords:	INTERNAL MEDICINE, MEDICAL EDUCATION & TRAINING, VASCULAR MEDICINE, GENERAL MEDICINE (see Internal Medicine), STATISTICS & RESEARCH METHODS

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TITLE:

The I-DECIDED® clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: A clinimetric evaluation

Running head: I-DECIDED

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Word count:

Keywords:

Assessment, intravenous; Intravenous catheter, peripheral; Decision-making; Reliability; Validity; Measurement

Funding

Financial support for this study was provided in part by grants from Griffith University and the Australian College of Infection Prevention and Control. The funding agreements ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report. The following authors are employed by the sponsor, Griffith University: Gillian Ray-Barruel, Marie Cooke, Marion Mitchell, Claire M Rickard.

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The I-DECIDED® clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: A clinimetric evaluation

ABSTRACT

Objective: To describe the clinimetric validation of the I-DECIDED® tool for peripheral intravenous catheter assessment and decision making.

Design and setting: I-DECIDED® is an 8-step tool derived from international vascular access guidelines into a structured mnemonic for device assessment and decision-making. The clinimetric evaluation process was conducted in three distinct phases.

Methods: Initial face validity was confirmed with a vascular access working group. Next, content validity testing was conducted via online survey with vascular access experts and clinicians from Australia, UK, USA, and Canada. Finally, inter-rater reliability was conducted between 34 pairs of assessors for a total of 68 PIVC assessments. Assessments were timed to ensure feasibility, and the second rater was blinded to the first's findings. Content validity index (CVI), mean I-CVI, internal consistency, mean proportion of agreement, observed and expected inter-rater agreements, and prevalence- and bias-adjusted kappas were calculated. Ethics approvals were obtained from university and hospital ethics committees.

Results: The I-DECIDED® tool demonstrated strong content validity among international vascular access experts (n = 7; mean I-CVI = 0.91; mean proportion of agreement = 0.91) and clinicians (n = 11; mean I-CVI = 0.93; mean proportion of agreement = 0.94), and high inter-rater reliability in seven adult medical-surgical wards of three Australian hospitals. Overall inter-rater reliability was 87.13%, with prevalence-adjusted bias-adjusted kappa for each principle ranging from 0.5882 ('patient education') to 1.0000 ('document the decision'). Time to complete assessments averaged 2 minutes, and nurse-reported acceptability was high.

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Conclusion: This is the first comprehensive, evidence-based, valid and reliable PIVC assessment and decision tool. We recommend studies to evaluate the outcome of implementing this tool in clinical practice.

Trial registration number ANZCTR: 12617000067370

(270 words)

Keywords:

Assessment, intravenous; Intravenous catheter, peripheral; Decision-making; Reliability; Validity; Measurement

Strengths and limitations of this study

- This is the first validation study of a comprehensive peripheral intravenous catheter assessment and decision tool.
- The I-DECIDED® tool demonstrated strong content validity among a group of international vascular access experts and clinicians.
- The I-DECIDED® tool demonstrated high inter-rater reliability in adult medical-surgical wards of three Australian hospitals**.**
- Studies to evaluate the outcome of implementation of this tool in clinical practice are warranted.

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INTRODUCTION

With 70% of hospital patients needing a vascular access device (VAD) for medical treatment,[1] inadequate assessments may contribute to current poor outcomes, where up to 69% of peripheral intravenous catheters (PIVCs) have painful complications or stop working before treatment is finished, due to occlusion, dislodgement, infiltration, or phlebitis.[2] Equally concerning, clinical audits reveal 25–50% of PIVCs remain in situ for no reason.[3-5]

Improved assessment could prompt removal of idle catheters and early detection of complications.[6] To date, efforts to improve PIVC outcomes using phlebitis tools, care plans, maintenance bundles, electronic records, and journey boards have achieved varied results.[7, 8] Supporting evidence for phlebitis tools is not robust, as they fail to consider complications such as dislodgement, occlusion or infiltration, and do not prompt assessment of device need, function, dressing integrity, securement, and infection prevention strategies.[7, 9] With these items already included in best practice guidelines,[10-15] the reported high rates of idle catheters, device failure, and complications indicate the need for a fresh approach to PIVC assessment and management.

The I-DECIDED® tool was developed to address the high prevalence of idle PIVCs and common shortfalls with assessment and documentation.[16] This is the first comprehensive, evidence-based, point-of-care tool for PIVC assessment and decision-making. The tool guides clinicians to perform a structured assessment and make a decision, based on that assessment. Simple prompts accompany each category. (See Figure 1). This paper reports on the clinimetric properties (reliability, validity, acceptability and feasibility) of this tool.

[Insert Figure 1]

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METHODS

Instrument

International guidelines were reviewed[10-15], with core aspects assembled into the mnemonic, I-DECIDED®, a structured priority matrix for assessment and decision-making. The name (I-DECIDED) conveys accountability for decisions based on the assessment and it has been translated into Latin-based languages while preserving the meaning to enable broader translation into practice.

Study design and setting

Face and content validity assessments were undertaken prior to an interrupted time-series (ITS) study to examine the effect of implementing the tool in three hospitals in Queensland, Australia.[16] Inter-rater reliability was assessed at pre-specified time-points (Baseline; Implementation; Evaluation). Ethical approval was obtained from Griffith University (Ref No. 2017/152), Queensland Health (HREC/17/QPCH/47), and St Vincent's Health and Aged Care Human Research and Ethics Committee (Ref No. 17/28). All participants provided informed consent prior to participation, and the study was conducted in accordance with the Australian Government National Statement on Ethical Conduct in Human Research.[17] The results are reported in accordance with the Guidelines for Reporting Reliability and Agreement Studies (GRRAS).[18]

Sample size and data analysis

Face validity, a subjective assessment that the tool measures what it is designed to measure,[19] was assessed in December 2015 by emailing a draft of the tool to eight members of a vascular access working group, all experienced Australian nurse researchers with solid knowledge of current evidence and guidelines. Reviewers independently assessed each item and the tool as

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a whole and provided recommendations. Following discussions between the lead author and reviewers, some item wording was revised.

Content validity, the degree to which the content of an instrument is an adequate reflection of the construct to be measured,[19] of each principle and corresponding items was undertaken with international experts (vascular access researchers and infection control professionals who had contributed to the most recent evidence-based vascular access guidelines) and experienced clinicians (nurses with weekly PIVC experience) to determine if the tool covered the essentials of PIVC assessment and decision-making. We deliberately targeted experts and clinicians separately to identify any differences between perspectives. During June–July 2017, the content validity surveys were emailed to male and female respondents with diverse expertise and skills, from a range of English-speaking countries. Twenty-two experts and 25 clinicians from adult and paediatric specialties in the authors' clinical networks were informed of the study by the lead author by email and invited to complete the content validity questionnaire via online survey (REDCap)[20] or paper form and return email (See Appendix 1). Survey completion was accepted as consent and identifying details of respondents were not collected.

Respondents rated each item in terms of its relevance to the underlying construct on a 4-point ordinal scale (*1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = highly relevant*)[21]. The item-level content validity index (I-CVI) was calculated for each principle and item (number of respondents giving a rating of either 3 or 4, divided by the total number of respondents).[22] Content validity index (CVI) for each item and overall mean I-CVI were calculated for both expert and clinician groups. Proportions of agreement for each participant, each item, and overall mean were calculated. Respondents were asked to review, comment,

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and suggest changes on wording and structure of each section of the tool, and the tool as a whole. Respondents could participate in a Skype or telephone call with the lead author to provide further feedback, if desired. All written and verbal feedback was analysed, and minor wording revisions were made to produce the final tool.

Reliability is the proportion of total variance in the measurements that are due to 'true' differences between subjects.[19] *Inter-rater reliability* is the ratio of variability between subjects to the total variability of all measurements in the sample.[18] Inter-rater reliability was evaluated in three phases. In August 2017 (Phase 1 – Baseline), the lead author provided education on the tool to a research nurse at each hospital (registered nurses with ≥ 10 years' clinical experience). The lead author and research nurses undertook 10 paired PIVC assessments to assess inter-rater reliability; this ensured the research nurses thoroughly understood the tool prior to collecting baseline data for the ITS study. Four months later, in Phase 2 (Implementation), the tool and new VAD form (available in the protocol paper[16]) were rolled out across the participating wards. In February 2018, the lead author and research nurses undertook a further 9 paired PIVC assessments to confirm continued consistency when using the tool. In April 2018 (Phase 3 – Evaluation), after hospital nurses had used the tool for two months, inter-rater reliability was evaluated between the research nurses and a convenience sample of 3 to 6 staff nurses (male and female, aged 25–60) at each hospital for a further 15 paired PIVC assessments. The number of participants available for each inter-rater reliability assessment depended on how many nurses had patients with a PIVC in situ at the time of the assessment. Each staff nurse only participated in one inter-rater reliability assessment. All patients and staff nurses provided verbal consent to participate in the assessments. In all, 34 paired assessments were undertaken for a total of 68 assessments. For each assessment, two assessors independently assessed the PIVC five minutes apart using the

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tool, ranking each item as a categorical binary response (yes/no). The second rater was blinded to the first's findings, and the order of subjects varied between assessors to prevent systematic bias. Staff nurses were unaware that their judgement would be compared to other raters, to remove the possibility of a Hawthorne effect.[18] Cronbach's coefficient α was used to calculate the internal consistency of the items in the tool. To assess inter-rater variation, observed and expected agreements for each part of the tool, prevalence-adjusted bias-adjusted kappa (PABAK) and overall proportion of agreement were calculated.[23] When prevalence of a given response is very high or low, the kappa value may not be reliable, even when the observed proportion of agreement is quite high; therefore, we calculated the prevalence-adjusted bias-adjusted kappa to more fully characterize the extent of inter-rater reliability between two raters.[23] Standard errors of measurement and Z scores were also calculated.

To assess Principles 1 (Identify presence of device) and 2 (Does patient need the device), raters checked for the presence of a PIVC and checked the patient's chart for current orders; if none were present, the observers asked the patient's nurse if any procedures were planned. For Principle 3 (Effective function), raters asked the patient if an infusion or flush had been administered in the past 12 hours, and if so, had there been any concerns. To assess Principle 4 (Complications), raters asked the patient about pain or tenderness and inspected the PIVC insertion site for signs and symptoms. With Principle 5 (Infection prevention), raters asked the patient if they had observed the nurse perform hand hygiene before touching the PIVC and scrub the needleless connector hub before administering IV medications or fluids. To assess Principle 6 (Dressing and securement), raters assessed the PIVC dressing for cleanliness and integrity and securement of the PIVC or administration set. For Principle 7 (Evaluate and Educate), raters asked the patient if they had questions and if the nurse had provided any education about the PIVC. To assess Principle 8 (Document), raters checked the

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patient chart for documentation of PIVC assessment in the past 12 hours. To assess Principle 9 (Decision), raters asked the patient if they knew of any plans for the PIVC that day and checked the patient's chart for evidence of plans to remove or continue the PIVC.

Feasibility was assessed by timing inter-rater reliability assessments and by asking staff about the clarity of items and ease of completion of the tool. ***Acceptability*** of introducing the tool into practice was assessed with 30 registered nurses who participated in round table discussions at each hospital prior to the study. During these sessions, nurses discussed the terminology of the tool and provided feedback on the proposed VAD form. Suggestions were taken into consideration and minor sections of the care plan (shading, location of comments section) were modified prior to roll-out. Focus groups with staff nurses regarding PIVC assessment were undertaken prior to the roll out of the tool and at the end of the trial (Results of the focus groups are reported elsewhere).

Patient and Public involvement

The I-DECIDED® tool incorporates a prompt to evaluate patients' (and family, if appropriate) knowledge and concerns about their PIVC and to provide education, as needed. This prompt was included after recent research revealed consumers wanted to be included in conversations about the management of their vascular access devices.[24, 25] Specific patient advisers were not consulted for this study.

RESULTS

Content validity

Complete responses for the content validity questionnaire were available for 7 (32%) experts and 11 (44%) clinicians from Australia, UK, USA, and Canada. Two experts (UK, USA) and

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one clinician (USA) (all female) participated in a 30-minute, one-to-one call with the lead author. These discussions focused on clarifying the recommended frequency of assessment, in particular with different nursing shift lengths, and discussions about nursing responsibility for vascular access decisions, which vary between hospitals and countries.

For vascular access experts, the mean CVI for the principles of the tool was 0.87 (range 0.29–1.00), and the mean I-CVI for all items of the tool was 0.91 (range 0.57–1.00). The mean proportion of agreement was 0.91 (range 0.83–0.98). (See Table 1)

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Table 1. Ratings on a 48-item scale by 7 vascular access experts: Items rated 3 or 4 on a 4-point relevance scale

Item	Description	E1	E2	E3	E4	E5	E6	E7	Number in agreement	Item CVI
1	***Key principle: The presence of an IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	7	**1.00**
2	Does the patient have an IV device? (Inspect the patient and ask the patient if unsure)	✓	✓	✓	✓	✓	✓	✓	7	1.00
3	Has the patient had an IV device removed in the past 48 hrs? (Ask the patient)	✓	✓	✓	✓	✓	✓	✓	7	1.00
4	If the patient has had an IV device removed in the past 48 hrs, observe site for complications (post-infusion phlebitis and purulence).	✓	✓	✓	✓	✓	✓	✓	7	1.00
5	***Key principle: The need for the IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	7	**1.00**
6	Has the IV device been used in the past 24 hours, or is it likely to be used in the next 24 hrs?	✓	✓	✓	✓	✓	✓	✓	7	1.00
7	Can the patient switch to oral medications? Discuss with pharmacist and treating team.	✓	✓	✓	✓	✓	✓	✓	7	1.00
8	When no longer needed, the IV device should be removed.	✓	✓	✓	✓	✓	✓	✓	7	1.00
9	***Key principle: Effective flow and flush of the IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	6	**.86**
10	Does the IV device flow well?	✓	✓	✓	-	✓	✓	✓	6	.86
11	Does the IV device flush well?	✓	✓	✓	-	✓	✓	✓	5	.71
12	If the IV device does not flow and flush, it should be removed.	✓	✓	✓	✓	✓	✓	✓	6	.86
13	***Key principle: The IV site should be assessed for complications or concerns each shift.***	✓	✓	✓	✓	✓	✓	✓	7	**1.00**
14	Patient-reported pain ≥ 2 out of 10?	✓	✓	✓	✓	✓	✓	✓	7	1.00
15	Redness > 1 cm from insertion site	✓	✓	✓	✓	✓	✓	✓	7	1.00
16	Swelling > 1 cm from insertion site	✓	✓	✓	✓	✓	✓	✓	7	1.00
17	Any discharge at site	✓	✓	✓	✓	✓	✓	✓	7	1.00
18	Infiltration (IV fluid in surrounding tissues)	✓	✓	✓	✓	✓	✓	✓	7	1.00
19	Hardness (induration) of insertion site	✓	✓	✓	✓	✓	✓	✓	7	1.00
20	Palpable cord	✓	✓	✓	✓	✓	✓	✓	7	1.00
21	Other concerns? (itch, rash, blistering, etc.)	✓	✓	✓	✓	✓	✓	✓	7	1.00
22	If complications occur, the IV device should be removed, after consultation with the treating team. Insert new IV device if needed.	✓	✓	✓	✓	✓	✓	✓	7	1.00
23	***Key principle: Infection prevention and control practices should be performed each shift.***	✓	-	-	✓	✓	✓	✓	5	**.71**
24	Use Aseptic Non-Touch Technique (ANTT)	✓	✓	✓	✓	✓	✓	✓	7	1.00

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25	Hand hygiene	✓	✓	✓	✓	✓	✓	7		1.00
26	Scrub the hub as per protocol and allow to dry before accessing IV device	✓	✓	✓	✓	✓	✓	7		1.00
27	Any fever of unknown origin?	✓	✓	✓	-	✓	-	5		.71
28	Elevated white blood cell count?	✓	✓	✓	-	✓	-	5		.71
29	If the patient has a fever and/or elevated white blood cell count, with no obvious source of infection, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	✓	✓	✓	✓	✓	-	6		.86
30	Purulent discharge at the insertion site?	-	✓	✓	✓	✓	✓	6		.86
31	If the IV site has purulent discharge, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	✓	✓	✓	✓	✓	✓	7		1.00
32	***Key principle: Dressing and securement practice should be assessed each shift.***	✓	✓	✓	✓	✓	✓	7	**1.00**	
33	Is the IV dressing clean, dry, and intact?	✓	✓	✓	✓	✓	✓	7		1.00
34	If the IV dressing is moist, visibly soiled, or has loose/lifting edges, it should be changed.	✓	✓	✓	✓	✓	✓	7		1.00
35	Is the IV device and infusion tubing secured?	✓	✓	✓	✓	✓	✓	7		1.00
36	Secure well with securement device, tape, net or bandage.	✓	✓	✓	-	✓	✓	6		.86
37	***Key principle: The patient/family's knowledge and education needs should be assessed each shift, if possible.***	-	-	✓	-	-	✓	2	**.29**	
38	Evaluate patient/family understanding of reason for IV and plan for removal, if possible.	✓	-	✓	-	✓	✓	4		.57
39	Educate patient/family as needed, if possible.	✓	-	✓	-	✓	✓	5		.71
40	***Key principle: The IV assessment and actions taken should be documented each shift.***	✓	✓	✓	✓	✓	✓	7	**1.00**	
41	Insertion date and time	✓	✓	✓	✓	✓	✓	6		.86
42	I-DECIDED® assessment and relevant action taken	✓	✓	✓	✓	✓	✓	6		.86
43	Removal date and time	✓	✓	✓	✓	✓	✓	7		1.00
44	***Key principle: The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.***	✓	✓	✓	✓	✓	✓	7	**1.00**	
45	Decision 1. IV device should remain in place. No other change.	✓	✓	✓	✓	✓	-	6		.86
46	Decision 2. IV device should remain in place, but dressing change done. IV and infusion tubing well secured.	✓	✓	✓	✓	✓	-	6		.86
47	Decision 3. IV device removed and not replaced, in consultation with the treating team.	✓	✓	✓	✓	✓	-	6		.86
48	Decision 4. IV device removed and replaced. Consulted with patient and team about best device and site.	✓	✓	✓	✓	✓	-	6		.86

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									I-DECIDED	
	Proportion relevant	.96	.92	.98	.83	.98	.88	.85	0.87 (mean)	0 .91 (mean)
									Mean expert proportion = 0.91	
IV = intravenous; E = vascular access expert										

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For experienced clinicians, the mean CVI for the principles of the tool was 0.96 (range 0.82–1.00), and the mean I-CVI for all items of the tool was 0.93 (range 0.55–1.00). The mean proportion of agreement was 0.94 (range 0.65–1.00). (See Table 2)

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Table 2. Ratings on a 48-item scale by 11 experienced clinicians: Items rated 3 or 4 on a 4-point relevance scale

Item	Description	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	Number in agreement	Item CVI
1	***Key principle: The presence of an IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**
2	Does the patient have an IV device? (Inspect the patient and ask the patient if unsure)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
3	Has the patient had an IV device removed in the past 48 hrs? (Ask the patient)	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	-	9	.82
4	If the patient has had an IV device removed in the past 48 hrs, observe site for complications (post-infusion phlebitis and purulence).	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	10	.91
5	***Key principle: The need for the IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	**.91**
6	Has the IV device been used in the past 24 hours, or is it likely to be used in the next 24 hrs?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
7	Can the patient switch to oral medications? Discuss with pharmacist and treating team.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	.91
8	When no longer needed, the IV device should be removed.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
9	***Key principle: Effective flow and flush of the IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**
10	Does the IV device flow well?	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	-	9	.82
11	Does the IV device flush well?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	.91
12	If the IV device does not flow and flush, it should be removed.	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	9	.82
13	***Key principle: The IV site should be assessed for complications or concerns each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**
14	Patient-reported pain ≥ 2 out of 10?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	.91
15	Redness > 1 cm from insertion site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
16	Swelling > 1 cm from insertion site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
17	Any discharge at site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
18	Infiltration (IV fluid in surrounding tissues)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
19	Hardness (induration) of insertion site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
20	Palpable cord	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	.91
21	Other concerns? (itch, rash, blistering, etc.)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00

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22	If complications occur, the IV device should be removed, after consultation with the treating team. Insert new IV device if needed.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
23	***Key principle: Infection prevention and control practices should be performed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**	
24	Use Aseptic Non-Touch Technique (ANTT)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
25	Hand hygiene	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
26	Scrub the hub as per protocol and allow to dry before accessing IV device	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
27	Any fever of unknown origin?	-	✓	✓	✓	✓	✓	✓	✓	-	✓	-	8		.73
28	Elevated white blood cell count?	-	✓	✓	✓	✓	-	-	✓	-	✓	-	6		.55
29	If the patient has a fever and/or elevated white blood cell count, with no obvious source of infection, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10		.91
30	Purulent discharge at the insertion site?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10		.91
31	If the IV site has purulent discharge, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	-	✓	-	✓	✓	✓	-	✓	✓	✓	-	7		.64
32	***Key principle: Dressing and securement practice should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**	
33	Is the IV dressing clean, dry, and intact?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
34	If the IV dressing is moist, visibly soiled, or has loose/lifting edges, it should be changed.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
35	Is the IV device and infusion tubing secured?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
36	Secure well with securement device, tape, net or bandage.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10		.91
37	***Key principle: The patient/family's knowledge and education needs should be assessed each shift, if possible.***	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	-	9	**.82**	
38	Evaluate patient/family understanding of reason for IV and plan for removal, if possible.	✓	✓	✓	✓	✓	✓	-	✓	-	✓	-	8		.73
39	Educate patient/family as needed, if possible.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10		.91
40	***Key principle: The IV assessment and actions taken should be documented each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**	
41	Insertion date and time	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
42	I-DECIDED® assessment and relevant action taken	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
43	Removal date and time	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00

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I-DECIDED

44	***Key principle: The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	**.91**	
45	Decision 1. IV device should remain in place. No other change.	✓	✓	-	✓	✓	✓	✓	✓	✓	✓	✓	10		.91
46	Decision 2. IV device should remain in place, but dressing change done. IV and infusion tubing well secured.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
47	Decision 3. IV device removed and not replaced, in consultation with the treating team.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
48	Decision 4. IV device removed and replaced. Consulted with patient and team about best device and site.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
	Proportion relevant	.90	1.00	.96	1.00	1.00	.94	.90	1.00	.94	1.00	.65		0.96 (mean)	0.93 (mean)
													Mean clinician proportion		0.94

IV = intravenous; C = clinician

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The content validity questionnaire elicited comments, which are summarised here. The complete list of responses is provided in Appendix 2.

Principle 1: The presence of an IV device should be assessed each shift.

All 18 respondents agreed. The prompt to assess for post-infusion phlebitis invoked 5 comments, with most respondents agreeing that assessing for post-infusion phlebitis is important but can be difficult if patients have communication difficulties (e.g. stroke, capacity to understand, or capacity to give feedback) and is not possible after patient discharge.

Principle 2: The need for the IV device should be assessed each shift.

Seventeen respondents agreed; however, one respondent commented that assessing PIVC need each shift was unrealistic and discussing changing to oral medications with the pharmacist and treating team raised workload concerns. Two respondents debated frequency of PIVC assessment, remarking that 'each shift' was unclear because shift length can vary according to the unit. One respondent noted that the Infusion Nurses Society Standards of Practice[11] call for daily assessment of need, rather than each shift.

Principle 3: Effective flow and flush of the IV device should be assessed each shift.

Seventeen respondents agreed, and 11 respondents offered diverse questions and opinions. Several argued that 'flow and flush' were subjective assessments and insufficient to determine PIVC function without first checking for obstruction. Flushing frequency was debated, and two respondents recommended adding 'aspiration for blood return'. In response to this feedback, the wording was changed to 'Effective function'.

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Principle 4: The IV site should be assessed for complications or concerns each shift.

All 18 respondents agreed with prompts to assess pain, redness, swelling, discharge, infiltration, extravasation, hardness or purulence. One respondent stated that palpable cord should not be included. Another said that this prompt contained too many signs and symptoms, many of which could be too subjective or difficult for the nurse to remember. Respondents' comments varied regarding determining pain scores at the PIVC site. One respondent said a pain score of 1 with associated redness and swelling would be a valid reason to remove the PIVC; another respondent stated pain would not be addressed unless the pain score was greater than 5; yet another recommended the question should prompt the nurse to identify the cause of the pain, rather than rely on a numerical score.

Principle 5: Infection prevention and control practices should be performed each shift.

Sixteen respondents concurred; two experts disagreed with the principle but agreed with all the supporting prompts. Five respondents argued the inclusion of fever and elevated white cell count was inappropriate, as neither would prompt PIVC removal in most cases; one respondent argued that diagnosis of infection would be a team responsibility rather than nursing. A Skype respondent expressed concern that a nurse might identify the PIVC as a possible source of infection, which could lead to financial penalties in some health services. One respondent stated 'purulent drainage' fit better with the principle 'complications' and the infection section should focus on identifying signs of sepsis. Two respondents felt aseptic non-touch technique should be removed because it was not taught at every hospital.

Principle 6: Dressing and securement practice should be assessed each shift.

All 18 respondents agreed. Four respondents noted this prompt could be made clearer by requiring that the PIVC site remain visible for ease of inspection; however, the wording of

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this section was not changed because the guidelines accept either transparent or sterile gauze and tape dressings.[13] Four respondents requested the prompts should specify exactly what should be secured (PIVC or administration set or both).

Principle 7: The patient/family's knowledge and education needs should be assessed each shift, if possible.

Eleven respondents supported this principle. Nine clinicians agreed that patient concerns about the PIVC were important to assess each shift, but only two experts felt this was relevant to include in the tool; five experts expressed concern that assessing patient knowledge needs each shift would be too frequent. Six respondents did not agree it was relevant to evaluate the patient's and/or family's understanding of the reason for the PIVC and plans for its removal.

Principle 8: The IV assessment and actions taken should be documented each shift.

All 18 respondents agreed. One respondent stated that the documentation should include more details (e.g. exact site of insertion, gauge size). Another commented that the tool would need to include more frequent prompts for paediatric PIVC assessment. A further suggestion was to include a prompt to replace PIVCs inserted in an emergency where asepsis could have been compromised.

Principle 9: The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.

Seventeen respondents agreed: however, one respondent noted PIVC removal must comply with local institutional policy, rather than a nurse's decision. Two respondents stated it would not be necessary to consult with the treating team before removing the PIVC if the nurse

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identified complications, as PIVC assessment is a nursing responsibility and nurses have the necessary skills and knowledge to make their own informed decisions in this area. This point was also raised in the Skype/telephone calls. Following this feedback, a clause was added: "Always consider local policy and consult with team and patient as required".

Inter-rater reliability

From 34 paired assessments, item-level proportion of inter-rater agreement ranged from 79.41% (patient education) to 100% (documentation of the decision) (See Table 3). Overall Cronbach's alpha was 0.746 and proportion of inter-rater agreement was 87.13%. Using the Landis and Koch[26] categorization, the kappa values for each item of the tool were all in the substantial (0.61–0.80) range, except for 'Identify if patient has a PIVC' and 'Document your decision', which both scored almost perfect (0.81–1.00) and 'Evaluate and Educate', which scored in the moderate (0.41–0.60) range.

Table 3. Inter-rater reliability of I-DECIDED® tool

	Observed Agreement (%)†	PABAK‡	Standard error	Z	Prob>Z
Identify if patient has PIVC	97.06	0.9412	0.1712	5.50	0.0000
Does patient need PIVC	88.24	0.7647	0.1715	4.46	0.0000
Effective function of PIVC	85.29	0.7059	0.1712	4.12	0.0000
Complications at PIVC site	82.35	0.6471	0.1715	3.77	0.0001
Infection prevention	82.35	0.6471	0.1715	3.77	0.0001
Dressing and securement	82.35	0.6471	0.1715	3.77	0.0001
Evaluate and educate	79.41	0.5882	0.1712	3.44	0.0003
Document your decision	100.0	1.0000	0.1715	5.83	0.0000
OVERALL	87.13				

†Expected agreement 50% for all items; ‡PABAK: prevalence-adjusted bias-adjusted kappa

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Feasibility

During inter-rater reliability testing, the time to conduct each assessment ranged from 1 to 10 minutes (average 2 minutes). Longer assessments occurred when patients had questions about their PIVC or if troubleshooting the PIVC was required.

Acceptability

Although 25 education sessions were attended by 180 staff over three hospitals in Phase 2, it was not possible to provide education to all staff at each site. Education was provided to all nurse unit managers, nurse educators and clinical facilitators, as well as many registered and enrolled nurses, physicians, and administrative staff. Posters were displayed in staff tearooms and nurses' stations, and lanyard cards were provided for all staff. During Phase 3 focus groups, the lead author asked attendees if they had received instructions how to use the tool. There was no discernible difference in feedback between staff who had or had not received education. Consensus was that the tool was easy to follow and particularly useful for newly registered nurses and nursing students. The structured format for PIVC assessment was popular, but many disliked the added paperwork. Following the inter-rater assessments, the lead author asked nurses if they had attended an education session, and if not, how did they learn to use the tool. Approximately half of the nurses who participated in the inter-rater assessments had not received any formal education about the tool; they reported that they had either asked a colleague about it or that it was self-evident.

DISCUSSION

This paper describes the clinimetric properties of the I-DECIDED® tool for PIVC assessment in an inpatient population. The tool demonstrated strong content validity for adults and paediatrics among vascular experts and clinicians, and high inter-rater reliability, feasibility

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and acceptability in the adult medical-surgical wards of three Australian hospitals. As this is the first comprehensive, evidence-based tool for PIVC assessment and decision-making, the authors expect this will interest clinicians across inpatient settings.

A strength of this study was that content validity of the tool was confirmed by 18 vascular access experts and clinicians from a range of English-speaking countries. Lynn[27] advocated item-level CVI should be around 0.80 when there are six or more experts. The mean CVI and proportion of agreement for the principles and the individual items of the tool scored very highly for both experts (I-CVI 0.91; mean proportion of agreement 0.91) and experienced clinicians (I-CVI 0.93; mean proportion of agreement 0.94), confirming that this tool comprises the essentials of PIVC assessment and decision-making.

Feedback from content validity survey and verbal conversations revealed that some respondents did not think it appropriate to assess all items each 'shift', particularly as nursing shifts can vary in length up to 12 hours. Some respondents commented that daily assessment would be sufficient for items such as "need for the PIVC" and "patient education", while others remarked that daily assessment would not be frequent enough for some patient populations, such as paediatrics, where guidelines recommend hourly assessment for continuous infusions. While current guidelines[11] recommend daily assessment of PIVC need, we believe this assessment is warranted more regularly, particularly if the nurse knows that an administered medication is the final dose and removal is planned in the next few hours. The suggestion to consult the treating team prior to removing the PIVC was criticised by several respondents, who argued nurses possess the skills and knowledge to make their own informed decisions. While this is true for experienced nurses, it cannot be presumed that novice nurses and students will have confidence in their decision to remove or resite a PIVC.

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Patient and family concerns about the PIVC and their education needs are often under-valued by healthcare workers,[28] and this was reflected in our findings that only 11 out of 18 survey respondents agreed with this principle. Surprisingly, only two of seven experts felt regular patient education should be included in the tool. In an Irish study, patients who did not know the reason for their PIVC were seven times more likely not to need the device.[29] In an Australian study of consumer experiences, patients and caregivers expressed the need for improved communication about PIVC insertion and care.[24] A recent survey of eight US hospitals reported that one-third of patients with concerns about their care did not feel empowered to speak up, and patients less likely to speak up included older, sicker, non-English-speaking, or patients with mental health issues.[30] While more hospitals are implementing mechanisms for patients and families to verbalise critical safety concerns, more needs to be done to change hospital culture to encourage patient collaboration in daily care decisions, particularly those that impact on infection management and prevention.[31-33] Including a prompt for clinicians to ask the patient about the PIVC has merit.

Testing inter-rater reliability among a variety of clinicians was another strength of this study. Paired assessments, performed immediately after each other, eliminated the likelihood of altered assessment findings resulting from medication or fluid administration, or time for symptoms to change. Blinding of the second assessor to the first assessor's results and blinding the registered nurses to the research nurses' results also strengthened the findings. While the overall proportion of inter-rater agreement was high for most items, the category of patient education demonstrated the lowest scores. This is not surprising, as the stability of patient-reported variables between assessments can be a confounder of inter-rater reliability testing.[34] For instance, if the first rater asked about pain or tenderness of the PIVC site, and

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received a negative response, this could have suggested concerns to the patient who then answered in the affirmative to the second assessor. Asking patients if their nurse had assessed the PIVC that shift or performed hand hygiene before touching the PIVC, or whether they had received any education about the PIVC, also elicited contradictory answers in some assessments. Some patients answered negatively in the first instance, but when asked the same question by the second rater, they answered in the affirmative. This was possibly due to suggestibility or an unwillingness to implicate the nurse, but we had no way to confirm or refute the findings.

Decision-making is a subjective process based on assessment, but the assessment itself should be a standardised process to ensure care is evidence-based and comprehensive. PIVC decisions are often based on clinicians' education and experience, and not all clinicians are conversant with current guidelines.[35-38] The I-DECIDED® tool prompts clinicians to perform a structured PIVC assessment and document their decision based on that assessment. It is not a prescriptive tool designed to overrule local policies, although we do believe that decisions to continue or remove a PIVC should be based on comprehensive clinical assessment, and not simply dwell time or absence of phlebitis symptoms.[6]

Limitations. Construct validity could not be evaluated as PIVC assessment is highly subjective, and no gold standard exists for PIVC assessment and decision making. Criterion validity could not be evaluated because there are no other comprehensive PIVC assessment tools in the literature. While multiple phlebitis tools exist, evaluation of their measurement properties is rare, and validity and reliability data are limited or absent. Inter-rater reliability assessments of the tool were completed by different sets of coders for different subjects, which can lead to a higher level of systematic bias or make it difficult to detect bias.[39] We

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tried to control for this by alternating the order of assessments and blinding each assessor to the other's findings. Finally, inter-rater reliability was tested in seven medical-surgical wards in three hospitals. Each assessor only assessed each PIVC on one occasion, therefore it was not possible to evaluate intra-rater reliability. Testing the tool's reliability in other settings is strongly recommended. Feasibility and acceptability of the tool were reported as generally positive in this study, but further research is recommended to evaluate the strain on nursing workload of introducing this tool.

CONCLUSION

The I-DECIDED® tool demonstrated strong content validity and high inter-rater reliability, feasibility and acceptability in medical-surgical wards of three hospitals. Implementation of this tool could prompt clinicians to provide comprehensive care and remove PIVCs when no longer needed or as soon as complications arise. Early detection and action could prevent painful PIVC complications, reduce the risk of bloodstream infection, and result in cost savings for healthcare services. Studies to evaluate the outcome of implementing this tool in clinical practice are recommended.

(4177 words)

SUPPORTING INFORMATION

A video of the I-DECIDED® device assessment and decision tool is available:

https://www.youtube.com/watch?v=kMHOjWJWbsI

ACKNOWLEDGEMENTS

The authors would like to thank Joan Webster, Nicole Marsh, Marianne Wallis, Amanda Ullman, Tricia Kleidon, and Amy Johnston, who reviewed the face validity of the tool; the

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experts and clinicians who anonymously participated in the content validity questionnaire; the research assistants Josephine Lovegrove, Kathie Roberts and Elizabeth Herron for assisting with the inter-rater reliability testing; and Gabor Mihala for statistical support.

FUNDING

Financial support for this study was provided in part by grants from Griffith University and the Australian College of Infection Prevention and Control. The funding agreements ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report. The following authors are employed by the sponsor, Griffith University: Gillian Ray-Barruel, Marie Cooke, Marion Mitchell, Claire M Rickard.

COMPETING INTERESTS

Griffith University has received on GRB's behalf unrestricted research grants (3M and Becton Dickinson) and consultancy payments (Ausmed, 3M, BD, Medline, and Wolters Kluwer). MC has received investigator-initiated research and educational grants and speaker fees provided to Griffith University by vascular access product manufacturers (Baxter, BD, Entrotech Life Sciences). VC receives funding from the Veterans Health Administration, National Institute for Health, Agency for Healthcare Research and Quality, and Centers for Disease Control. MM: No conflicts of interest. CMR: Griffith University has received on CMR's behalf unrestricted investigator-initiated research or educational grants from product manufacturers (3M, AngioDynamics; BD-Bard, Baxter; BBraun, Cardinal Health, Medtronic, Smiths Medical); and consultancy payments (3M, BD-Bard; BBraun, ResQDevices, Smiths Medical). No commercial entity had any role in the design or undertaking of this study.

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AUTHOR CONTRIBUTIONS

GR-B conceived and developed the I-DECIDED tool. GR-B, MC, VC, MM and CR conceived the study concept and contributed to the design. GR-B acquired, analysed and interpreted the data, and wrote the first draft. MC, VC, MM and CR provided critical review and intellectual input. All authors read and approved the final version of the manuscript and take public responsibility for its content.

DATA SHARING STATEMENT

All data relevant to the study are included in the article or uploaded as supplementary information.

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TABLES

Table 1. Ratings on a 48-item scale by 7 vascular access experts: Items rated 3 or 4 on a 4-point relevance scale

Table 2. Ratings on a 48-item scale by 11 experienced clinicians: Items rated 3 or 4 on a 4-point relevance scale

Table 3. Inter-rater reliability of I-DECIDED® tool

FIGURE LEGENDS

Figure 1. I-DECIDED® IV assessment and decision tool

APPENDICES

Appendix 1. Content Validity Questionnaire: I-DECIDED® device assessment and removal tool

Appendix 2. Principles of the I-DECIDED® tool and CVI survey respondents' comments

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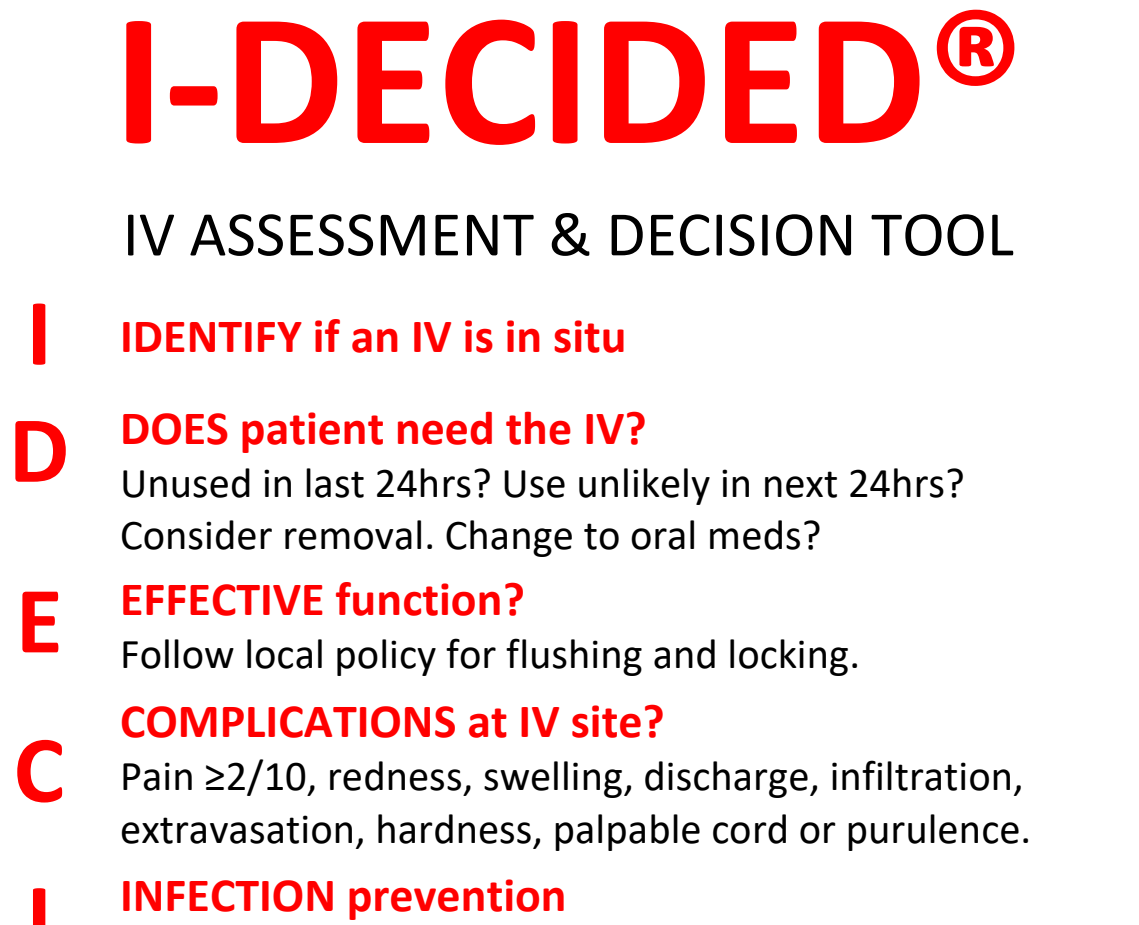
Figure 1. I-DECIDED® IV assessment and decision tool



Appendix 1. Content Validity Questionnaire: I-DECIDED device assessment and removal tool

Each item of the tool is based on a 'Key principle', with prompts for assessment and action.

Please ***circle the number*** that best rates the relevance of the statements listed below about the proposed components of the I-DECIDED tool.

Each section is followed by a space for your comment (E.g. Are any important concepts missing? Ease of comprehension? Language issues?).

KEY FOR SCORING ITEMS:
1 =NOT RELEVANT, 2 = SOMEWHAT RELEVANT, 3 = QUITE RELEVANT, 4 = HIGHLY RELEVANT

	I. IDENTIFY presence of IV device	**Please circle the relevant number**			
1	*Key principle 1: The presence of an IV device should be assessed each shift.*	1	2	3	4
2	Does the patient have an IV device? (Inspect the patient and ask the patient if unsure)	1	2	3	4
3	Has the patient had an IV device removed in the past 48 hours? (Ask the patient)	1	2	3	4
4	If the patient has had an IV device removed in the past 48 hours, observe site for complications (post-infusion phlebitis and purulence).	1	2	3	4

Comments:_____

_____

	II. DOES the patient need this IV device?	**Please circle the relevant number**			
5	*Key principle 2: The need for the IV device should be assessed each shift.*	1	2	3	4
6	Has the IV device been used in the past 24 hours, or is it likely to be used in the next 24 hours?	1	2	3	4
7	Can the patient switch to oral medications? Discuss with pharmacist and treating team.	1	2	3	4
8	When no longer needed, the IV device should be removed.	1	2	3	4

Comments:_____

_____

	III. EFFECTIVE flow and flush?	**Please circle the relevant number**			
9	*Key principle 3: Effective flow and flush of the IV device should be assessed each shift.*	1	2	3	4
10	Does the IV device flow well?	1	2	3	4
11	Does the IV device flush well?	1	2	3	4
12	If the IV device does not flow and flush, it should be removed.	1	2	3	4

Comments:_____

_____

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	IV. COMPLICATIONS or CONCERNS	Please circle the relevant number			
13	*Key principle 4: The IV site should be assessed for complications or concerns each shift.*	1	2	3	4
14	Patient-reported pain ≥ 2 out of 10?	1	2	3	4
15	Redness > 1 cm from insertion site	1	2	3	4
16	Swelling > 1 cm from insertion site	1	2	3	4
17	Any discharge at site	1	2	3	4
18	Infiltration (IV fluid in surrounding tissues)	1	2	3	4
19	Hardness (induration) of insertion site	1	2	3	4
20	Palpable cord	1	2	3	4
21	Other concerns? (itch, rash, blistering, etc.)	1	2	3	4
22	If complications occur, the IV device should be removed, after consultation with the treating team. Insert new IV device if needed.	1	2	3	4

Comments:_____

_____

	V. INFECTION prevention and control	Please circle the relevant number			
23	*Key principle 5: Infection prevention and control practices should be performed each shift.*	1	2	3	4
24	Use Aseptic Non-Touch Technique (ANTT)	1	2	3	4
25	Hand hygiene	1	2	3	4
26	Scrub the hub as per protocol and allow to dry before accessing IV device	1	2	3	4
27	Any fever of unknown origin?	1	2	3	4
28	Elevated white blood cell count?	1	2	3	4
29	If the patient has a fever and/or elevated white blood cell count, with no obvious source of infection, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	1	2	3	4
30	Purulent discharge at the insertion site?	1	2	3	4
31	If the IV site has purulent discharge, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	1	2	3	4

Comments:_____

_____

	VI. DRESSING and securement	Please circle the relevant number			
32	*Key principle 6: Dressing and securement practice should be assessed each shift.*	1	2	3	4
33	Is the IV dressing clean, dry, and intact?	1	2	3	4
34	If the IV dressing is moist, visibly soiled, or has loose/lifting edges, it should be changed.	1	2	3	4
35	Is the IV device and infusion tubing secured?	1	2	3	4

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36	Secure well with securement device, tape, net or bandage.	1	2	3	4

Comments:_____

_____

	VII. EVALUATE and EDUCATE	**Please circle the relevant number**			
37	*Key principle 7: The patient/family's knowledge and education needs should be assessed each shift, if possible.*	1	2	3	4
38	Evaluate patient/family understanding of reason for IV and plan for removal, if possible.	1	2	3	4
39	Educate patient/family as needed, if possible.	1	2	3	4

Comments:_____

_____

	VIII. DOCUMENT	**Please circle the relevant number**			
40	*Key principle 8: The IV assessment and actions taken should be documented each shift.*	1	2	3	4
41	Insertion date and time	1	2	3	4
42	I-DECIDED assessment and relevant action taken	1	2	3	4
43	Removal date and time	1	2	3	4

Comments:_____

_____

	IX. DECIDE and ACT	**Please circle the relevant number**			
44	*Key principle 9: The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.*	1	2	3	4
45	**Based on this assessment (in consultation with treating team and patient), I-DECIDED . . .**	1	2	3	4
46	IV device should remain in place. No other change.	1	2	3	4
47	IV device should remain in place, but dressing change done. IV and infusion tubing well secured.	1	2	3	4
48	IV device removed and not replaced, in consultation with the treating team.	1	2	3	4
49	IV device removed and replaced. Consulted with patient and team about best device and site.	1	2	3	4

Comments:_____

_____

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Appendix 2. Key principles of the I-DECIDED® tool and CVI survey respondents' comments

E = Expert; C = Clinician

Key principle 1. The presence of an IV device should be assessed each shift.

Post-infusion phlebitis is a rare event. (E4)

All relevant questions (E5)

Difficult to check site if patient has been sent home. (E6)

I am glad you incorporated the assessment of site post removal. This is not a standard practice and should be. (C1)

Not sure the relevance of item Q4 & Q5 in the context of identifying presence of an IV (i.e. although they are relevant it depends on context) - it potentially belongs to other principles. Q4 & Q5 are about identifying absence in the context of potentially infective/inflammatory processes. That said, the questioning of a patient- i.e. the interaction with a patient may include questions in this order. (C6)

48hrs [post-removal] assessment will be difficult with some patients (stoke; capacity to understand etc) 2-3 are also dependent on capacity to feedback (C8)

Check IV device is documented? (C11)

Key principle 2. The need for the IV device should be assessed each shift.

Would instead assess for need daily instead of every shift which at least in US is not realistic. (E2)

INS standards call for a daily assessment of need rather than each shift. Sometimes it is hard to define a 'shift' as this can be 8 hours or 12 hours. Most American nurses work 12-hour shifts. (E7)

It is the Treating team who will make the decision to switch to orals. The pharmacist could have input but the Treating team is the decider. May not always take on the pharmacist's advice (C7)

Your definition of no longer needed is important. (C8)

Discussions with treating team and/or pharmacist is a BIG workload. Needs to be established by? in conjunction with? treating team (medical team) (C11)

Key principle 3. Effective flow and flush of the IV device should be assessed each shift.

Flow and flush would be hard to assess unless the person checks the flow and flush themselves. The most important issue is removal. (E4)

Difficult to define a 'shift' as there are a mixture of 3 shifts per 24 hours and 2 shifts per 24 hours. Q15 relevant question but the wording is subjective, what does 'well' mean? (E5)

Due to poor renal function IV antibiotic may be every other day...? Flush or not... need to describe difference between flush and lock. (E6)

Flow and flush is very important but not sufficient by itself. There should be aspiration for a blood return using appropriate technique - slow and gentle, small syringe, and/or a tourniquet above the site. This is critical if the medications are vesicants. Also, this assessment should be before each infusion and not limited to only once per shift. (E7)

I feel there would need to have more assessment prior to removal. What site look like? Is it secure properly? Is the obstructed duty to taping or being kinked? Is it leaking at the site? (C1)

No use having a cannula if it is not meeting the most basic design parameter. (C4)

Q15 would come down to clinical context and how desperate the need for the IV is and how tricky obtaining access is (C6)

Flow well question is a bit ambiguous. May not know if it 'flows' well if no IV infusion. The PIVC should be flushed before anything is administered so flush should be first and if it doesn't flush it is not going to flow. Maybe infusing easily if IV infusion (C7)

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The type of volume; flush rate; and size of PIVC impact on Q13-Q14 (C8)

Clinicians will be confused by flow and flush and why it is separated. We assess for resistance with flushing and free flowing of IV therapy. In oncology we also assess for blood return. (C10)

Q12 & Q13 & Q14 the same? Q15 - move? wiggle? reposition? (C11)

Key principle 4. The IV site should be assessed for complications or concerns each shift.

Some questions appear to be redundant or overlapping as in swelling/infiltration, redness/hardness induration. These questions could be combined. (E1)

Q25 is likely a dressing issue rather than catheter issue (E2)

Q26 - most clinicians would not necessarily consult team... they would just remove and insert a new IV (E3)

Shifts vary for 8 hours to 12 hours, may need to be more specific (E5)

Not sure how relevant 1cm is? (E6)

These are a little troubling because they imply that pain of level 1 or redness and swelling of 1 cm are acceptable. All changes in color, temperature, any degree of pain is a valid reason to immediately remove the PIVC. Also consultation from the 'treating team' is not necessary. Not sure who this team includes. Any nurse should be capable of assessing these sites, making the decision to remove it if there are any signs or symptoms, remove and assess for the need to insert a new PIVC without consultation by the treatment team. (E7)

I would relook at scoring pain greater than 2. Maybe does patient have pain yes or no? We usually don't provide interventions for pain when using scale unless pain is greater than 5. (C1)

Have graded the pain assessment at a lower value due to subjectiveness of numerical scoring. I would want to drill deeper: e.g. is it because of the site and its tendency to be bumped that is causing the pain? Would an arm board or better dressing help? (C4)

Do you think that the signs need to be signposted for different complications? (C6)

When asking pts about pain in PIVC they think of pain at insertion; specify pain at present time. Do we accept a pain score of 1? Add extravasation with infiltration (C7)

How many attempts they had? Did they did *[sic]* the clinician was skilled enough; reassured them; understood their fears if any; respected their suggestion where it should go? (C8)

What is a palpable cord? How will the nurse remember all of these components? Condense to red/swollen/painful/Other? (C11)

Key principle 5. Infection prevention and control practices should be performed each shift.

It seemed that the purulent drainage was a carry-over from the previous section on complications and not part of infection practices. Maybe changing the wording to are there any signs of sepsis/infection? (E1)

Q28 is institution-dependent, may not be relevant; Q34, Q35, Q36 draw blood cultures. Note: Qs and order of questions are different on printed version and electronic version (E2)

Would suggest rewording Q28....to make it more specific to IV. (E3)

Fever and WCC are subsumed under Q36 (E4)

Q30 - needs to be more specific, e.g. before and after each manipulation/access of the device (E5)

Removal of IV if ? source of infection... other sources must be considered (E6)

Same comment about shift as previous screen. Not sure what is being asked in Q34. FUO alone is not a reason to remove any VAD. Neither is elevated WBC. Also not sure what is meant by culture IV site - drainage, catheter, blood? Fever and WBC could be from lots of other causes and not the PIVC. Removal depends on many factors such as venous difficulty, length of therapy planned, etc. It is relevant but I would not automatically remove the PIVC under only the conditions listed. (E7)

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I have seen recent presentation on ANTT. If this is recommendation it would require large education for users to under concept, terms and practices. I have mixed feeling related to culturing PIV sites and site removal if pt has fever and positive blood culture. (C1)

Q36 will depend on clinical context (C6)

Q35 and Q36. WCC may be already elevated due to infection and why we have PIVC in. So an increase in Temperature and increase in WCC as to what it was. And think wording in Q36 that PIVC should be considered as possible source of infection and if clinically appropriate remove ASAP (C7)

Has their infusion pump alarmed during the treatment? Have they missed antibiotics/treatment delay? (C8)

WCC elevated is late sign of infection (C10)

ANTT - would they necessarily know what this means??? purulent discharge and Q33 belong in the previous page. Fever/WBC should have been identified by treating team...not nurse? Q36 not relevant to ED (C11)

Key principle 6. Dressing and securement practice should be assessed each shift.

Q40 not sure if edges of dressing lifting if this is proven to correlate with risk of infection or phlebitis for PIVs (E2)

Q42 - reword? Secure the IV itself? Or the tubing? Could also be extension tubing? (E3)

Q41 should come first. Q42 isn't necessary. (E4)

Q42 - we wouldn't advocate a bandage as they deter staff from observing the insertion site (but we do advocate securement) (E5)

Some of these questions are multiple questions in one... e.g. Securement device, net or bandage... also tube securement and cannula securement are two different questions (E6)

Same shift comment. Also define 'securement' for the PIVC. Is this referring to a completely stable and secure catheter, dressing, and joint if close to a joint? Q42, what type of bandage? Too many variables in this question. Tape alone is not sufficient iMHO. Net is only needed for specific ages or patient populations and bandages should never cover the site. Nurses will not remove it to assess completely. (E7)

You might just need to be certain that the IV site can still be inspected easily and not overly covered with tape etc. (C2)

Secure, dry and not moving and aggravating the vessel wall and venipuncture site => reduced risk of infection and complications. (C4)

Does Q42 need further information- e.g. relevance of being able to see the insertion site? (C6)

Is there evidence of a date on the dressing in the note on informatics? (C8)

Q41 - liked this one. Q42 – repeats (C11)

Key principle 7. The patient/family's knowledge and education needs should be assessed each shift, if possible.

I'm not sure if it is highly relevant to assess educational needs every shift. (E1)

I think only important that they know to contact nurse if pain, swelling, redness at or near insertion site, so would change wording to be more specific in this regard (E2)

Q46 - educate on complications? Or just in general? (E3)

Q44 - not sure this is relevant each shift, might be setting people up to fail (E5)

Same shift comments. Not sure this is required every 8-hour shift but it is required periodically. I would not tie it to a shift. Shift work equates to common laborers and not the knowledge workers that nurses actually are. (E7)

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I think these questions are vital as we incorporate patients in care. They are their own best advocate and can keep us accountable. (C1)

The best nursing and clinical care is irrelevant if the person cannulated is not on board the narrative. (C4)

I think by assessing and evaluating patient education each shift would not be done. Just continuous education and reinforcement to the patient of how their input is required. (C7)

[Educate] pt/family every shift is excessive. Q46 repeats (C11)

Key principle 8. The IV assessment and actions taken should be documented each shift.

Same shift comment. Much more detail is needed, exact site of insertion, gauge size, etc as listed in INS Standards. (E7)

Curious as populate tool be used or if you will have variation for peds and unconscious to align with INS recommendations to check PIV site more frequently. (C1)

Gives the clinician ownership of device management (C4)

Accreditation standards require removal plan. Also nothing noted about insertion in an emergency/or asepsis compromised at insertion may need replacing. (C7)

The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.

I would use different wording for Option 2. Something like: IV device should remain in place with securement and dressing replaced. (E1)

If purulent, painful, swollen, etc. then nurse should remove and wouldn't need 'consultation with treating team or patient' but would add need to document in medical record. I think this section should be revised. Does this all go into medical record? Again, for many of these, don't need to consult with patient or team (E2)

Dressing change only done if required. i.e. loose, soiled, coming off (E3)

I think I am missing the point of this screen. Decisions about PIVCs are nursing responsibility and accountability in the USA. No consultation with the treatment team is required before it is removed. Our MD, NP, and PA would think the nurse has lost her mind if a nurse asked them to assess a PIVC site. I strongly believe that all staff nurses must understand when a PIVC is no longer the most appropriate device for a specific patient. These factors then trigger a consultation by the infusion/vascular access nurse for what would be the most appropriate VAD. This recommended VAD may or may not require action by the medical team (MD, NP, PA = LIP in USA) The general staff nurse will not know what is most appropriate and I don't think we should expect them to have this knowledge. But each facility must have a team that can make this assessment. That is not the case in many facilities. (E7)

Great project. Let me know if you want to be a testing site. (C1)

A proactive management approach rather than reactive. (C4)

Are administration set changes covered anywhere? (C6)

I know AVATAR promotes clinically indicated PIVC resiting but this is not what is happening in most facilities so should mention based on Organisational Policy, treating team and patient (C7)

Did the pt want another device type or inserter or method of insertion? (C8)

Very exciting tool indeed (C10)

2 D's??? Q53 - repeats Q56 - 'in consultation...' repeated replaced = PIC/other line??? (C11)

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I-DECIDED

Guidelines for Reporting Reliability and Agreement Studies (GRRAS)

			Page
Title and abstract	1	Identify in title or abstract that interrater/intrarater reliability or agreement was investigated	3
Introduction	2	Name and describe the diagnostic or measurement device of interest explicitly	5
	3	Specify the subject population of interest	5
	4	Specify the rater population of interest (if applicable)	5
	5	Describe what is already known about reliability and agreement and provide a rationale for the study (if applicable)	5
Methods	6	Explain how the sample size was chosen. State the determined number of raters, subjects/objects, and replicate observations	6-9
	7	Describe the sampling method	7-8
	8	Describe the measurement/rating process (e.g., time interval between repeated measurements, availability of clinical information, blinding)	7-8
	9	State whether measurements/ratings were conducted independently	8
	10	Describe the statistical analysis	8-9
Results	11	State the actual number of raters and subjects/objects that were included and the number of replicate observations that were conducted	10-15
	12	Describe the sample characteristics of raters and subjects (e.g., training, experience)	6-8
	13	Report estimates of reliability and agreement including measures of statistical uncertainty	11, 14
Discussion	14	Discuss the practical relevance of results.	15-19
Auxiliary material	15	Provide detailed results if possible (e.g., online)	Appendix 2
Ref: Kottner J, Audige L, Brorson S, Donner A, Gajewski BJ, Hrobjartsson A, et al. Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. *Int J Nurs Stud*. 2011;48(6):661-71.			

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The I-DECIDED® clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: A clinimetric evaluation

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-035239.R2
Article Type:	Original research
Date Submitted by the Author:	06-Jan-2020
Complete List of Authors:	Ray-Barruel, Gillian; Griffith University, Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, School of Nursing and Midwifery; Queen Elizabeth II Jubilee Hospital, Princess Alexandra Hospital, Royal Brisbane and Women's Hospital, Nursing Research Cooke, Marie; Griffith University, Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, School of Nursing and Midwifery Chopra, Vineet; University of Michigan, Division of Hospital Medicine, Patient Safety Enhancement Program; Ann Arbor VA Medical Center, Center for Clinical Management Research Mitchell, Marion; Griffith University, Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, School of Nursing and Midwifery Rickard, Claire; Griffith University, Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, School of Nursing and Midwifery; Royal Brisbane & Women's Hospital, Princess Alexandra Hospital, The Prince Charles Hospital, Nursing Research & Development, and Critical Care Research Group
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Evidence based practice, Nursing, Infectious diseases
Keywords:	INTERNAL MEDICINE, MEDICAL EDUCATION & TRAINING, VASCULAR MEDICINE, GENERAL MEDICINE (see Internal Medicine), STATISTICS & RESEARCH METHODS

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TITLE:

The I-DECIDED® clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: A clinimetric evaluation

Running head: I-DECIDED

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Word count:

Keywords:

Assessment, intravenous; Intravenous catheter, peripheral; Decision-making; Reliability; Validity; Measurement

Funding

Financial support for this study was provided in part by grants from Griffith University and the Australian College of Infection Prevention and Control. The funding agreements ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report. The following authors are employed by the sponsor, Griffith University: Gillian Ray-Barruel, Marie Cooke, Marion Mitchell, Claire M Rickard.

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The I-DECIDED® clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: A clinimetric evaluation

ABSTRACT

Objective: To describe the clinimetric validation of the I-DECIDED® tool for peripheral intravenous catheter assessment and decision making.

Design and setting: I-DECIDED® is an 8-step tool derived from international vascular access guidelines into a structured mnemonic for device assessment and decision-making. The clinimetric evaluation process was conducted in three distinct phases.

Methods: Initial face validity was confirmed with a vascular access working group. Next, content validity testing was conducted via online survey with vascular access experts and clinicians from Australia, UK, USA, and Canada. Finally, inter-rater reliability was conducted between 34 pairs of assessors for a total of 68 PIVC assessments. Assessments were timed to ensure feasibility, and the second rater was blinded to the first's findings. Content validity index (CVI), mean I-CVI, internal consistency, mean proportion of agreement, observed and expected inter-rater agreements, and prevalence- and bias-adjusted kappas were calculated. Ethics approvals were obtained from university and hospital ethics committees.

Results: The I-DECIDED® tool demonstrated strong content validity among international vascular access experts (n = 7; mean I-CVI = 0.91; mean proportion of agreement = 0.91) and clinicians (n = 11; mean I-CVI = 0.93; mean proportion of agreement = 0.94), and high inter-rater reliability in seven adult medical-surgical wards of three Australian hospitals. Overall inter-rater reliability was 87.13%, with prevalence-adjusted bias-adjusted kappa for each principle ranging from 0.5882 ('patient education') to 1.0000 ('document the decision'). Time to complete assessments averaged 2 minutes, and nurse-reported acceptability was high.

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Conclusion: This is the first comprehensive, evidence-based, valid and reliable PIVC assessment and decision tool. We recommend studies to evaluate the outcome of implementing this tool in clinical practice.

Trial registration number ANZCTR: 12617000067370

(270 words)

Keywords:

Assessment, intravenous; Intravenous catheter, peripheral; Decision-making; Reliability; Validity; Measurement

Strengths and limitations of this study

- This is the first validation study of a comprehensive peripheral intravenous catheter assessment and decision tool.
- The I-DECIDED® tool demonstrated strong content validity among a group of international vascular access experts and clinicians.
- The I-DECIDED® tool demonstrated high inter-rater reliability in adult medical-surgical wards of three Australian hospitals**.**
- Studies to evaluate the outcome of implementation of this tool in clinical practice are warranted.

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INTRODUCTION

With 70% of hospital patients needing a vascular access device (VAD) for medical treatment,[1] inadequate assessments may contribute to current poor outcomes, where up to 69% of peripheral intravenous catheters (PIVCs) have painful complications or stop working before treatment is finished, due to occlusion, dislodgement, infiltration, or phlebitis.[2] Equally concerning, clinical audits reveal 25–50% of PIVCs remain in situ for no reason.[3-5]

Improved assessment could prompt removal of idle catheters and early detection of complications.[6] To date, efforts to improve PIVC outcomes using phlebitis tools, care plans, maintenance bundles, electronic records, and journey boards have achieved varied results.[7, 8] Supporting evidence for phlebitis tools is not robust, as they fail to consider complications such as dislodgement, occlusion or infiltration, and do not prompt assessment of device need, function, dressing integrity, securement, and infection prevention strategies.[7, 9] With these items already included in best practice guidelines,[10-15] the reported high rates of idle catheters, device failure, and complications indicate the need for a fresh approach to PIVC assessment and management.

The I-DECIDED® tool was developed to address the high prevalence of idle PIVCs and common shortfalls with assessment and documentation.[16] This is the first comprehensive, evidence-based, point-of-care tool for PIVC assessment and decision-making. The tool guides clinicians to perform a structured assessment and make a decision, based on that assessment. Simple prompts accompany each category. (See Figure 1). This paper reports on the clinimetric properties (reliability, validity, acceptability and feasibility) of this tool.

[Insert Figure 1]

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METHODS

Instrument

International guidelines were reviewed[10-15], with core aspects assembled into the mnemonic, I-DECIDED®, a structured priority matrix for assessment and decision-making. The name (I-DECIDED) conveys accountability for decisions based on the assessment and it has been translated into Latin-based languages while preserving the meaning to enable broader translation into practice.

Study design and setting

Face and content validity assessments were undertaken prior to an interrupted time-series (ITS) study to examine the effect of implementing the tool in three hospitals in Queensland, Australia.[16] Inter-rater reliability was assessed at pre-specified time-points (Baseline; Implementation; Evaluation). Ethical approval was obtained from Griffith University (Ref No. 2017/152), Queensland Health (HREC/17/QPCH/47), and St Vincent's Health and Aged Care Human Research and Ethics Committee (Ref No. 17/28). All participants provided informed consent prior to participation, and the study was conducted in accordance with the Australian Government National Statement on Ethical Conduct in Human Research.[17] The results are reported in accordance with the Guidelines for Reporting Reliability and Agreement Studies (GRRAS).[18]

Sample size and data analysis

Face validity, a subjective assessment that the tool measures what it is designed to measure,[19] was assessed in December 2015 by emailing a draft of the tool to eight members of a vascular access working group, all experienced Australian nurse researchers with solid knowledge of current evidence and guidelines. Reviewers independently assessed each item and the tool as

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a whole and provided recommendations. Following discussions between the lead author and reviewers, some item wording was revised.

Content validity, the degree to which the content of an instrument is an adequate reflection of the construct to be measured,[19] of each principle and corresponding items was undertaken with international experts (vascular access researchers and infection control professionals who had contributed to the most recent evidence-based vascular access guidelines) and experienced clinicians (nurses with weekly PIVC experience) to determine if the tool covered the essentials of PIVC assessment and decision-making. We deliberately targeted experts and clinicians separately to identify any differences between perspectives. During June–July 2017, the content validity surveys were emailed to male and female respondents with diverse expertise and skills, from a range of English-speaking countries. Twenty-two experts and 25 clinicians from adult and paediatric specialties in the authors' clinical networks were informed of the study by the lead author by email and invited to complete the content validity questionnaire via online survey (REDCap)[20] or paper form and return email (See Appendix 1). Survey completion was accepted as consent and identifying details of respondents were not collected.

Respondents rated each item in terms of its relevance to the underlying construct on a 4-point ordinal scale (*1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = highly relevant*)[21]. The item-level content validity index (I-CVI) was calculated for each principle and item (number of respondents giving a rating of either 3 or 4, divided by the total number of respondents).[22] Content validity index (CVI) for each item and overall mean I-CVI were calculated for both expert and clinician groups. Proportions of agreement for each participant, each item, and overall mean were calculated. Respondents were asked to review, comment,

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and suggest changes on wording and structure of each section of the tool, and the tool as a whole. Respondents could participate in a Skype or telephone call with the lead author to provide further feedback, if desired. All written and verbal feedback was analysed, and minor wording revisions were made to produce the final tool.

Reliability is the proportion of total variance in the measurements that are due to 'true' differences between subjects.[19] *Inter-rater reliability* is the ratio of variability between subjects to the total variability of all measurements in the sample.[18] Inter-rater reliability was evaluated in three phases. In August 2017 (Phase 1 – Baseline), the lead author provided education on the tool to a research nurse at each hospital (registered nurses with ≥ 10 years' clinical experience). The lead author and research nurses undertook 10 paired PIVC assessments to assess inter-rater reliability; this ensured the research nurses thoroughly understood the tool prior to collecting baseline data for the ITS study. Four months later, in Phase 2 (Implementation), the tool and new VAD form (available in the protocol paper[16]) were rolled out across the participating wards. In February 2018, the lead author and research nurses undertook a further 9 paired PIVC assessments to confirm continued consistency when using the tool. In April 2018 (Phase 3 – Evaluation), after hospital nurses had used the tool for two months, inter-rater reliability was evaluated between the research nurses and a convenience sample of 3 to 6 staff nurses (male and female, aged 25–60) at each hospital for a further 15 paired PIVC assessments. The number of participants available for each inter-rater reliability assessment depended on how many nurses had patients with a PIVC in situ at the time of the assessment. Each staff nurse only participated in one inter-rater reliability assessment. All patients and staff nurses provided verbal consent to participate in the assessments. In all, 34 paired assessments were undertaken for a total of 68 assessments. For each assessment, two assessors independently assessed the PIVC five minutes apart using the

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tool, ranking each item as a categorical binary response (yes/no). The second rater was blinded to the first's findings, and the order of subjects varied between assessors to prevent systematic bias. Staff nurses were unaware that their judgement would be compared to other raters, to remove the possibility of a Hawthorne effect.[18] Cronbach's coefficient α was used to calculate the internal consistency of the items in the tool. To assess inter-rater variation, observed and expected agreements for each part of the tool, prevalence-adjusted bias-adjusted kappa (PABAK) and overall proportion of agreement were calculated.[23] When prevalence of a given response is very high or low, the kappa value may not be reliable, even when the observed proportion of agreement is quite high; therefore, we calculated the prevalence-adjusted bias-adjusted kappa to more fully characterize the extent of inter-rater reliability between two raters.[23] Standard errors of measurement and Z scores were also calculated.

To assess Principles 1 (Identify presence of device) and 2 (Does patient need the device), raters checked for the presence of a PIVC and checked the patient's chart for current orders; if none were present, the observers asked the patient's nurse if any procedures were planned. For Principle 3 (Effective function), raters asked the patient if an infusion or flush had been administered in the past 12 hours, and if so, had there been any concerns. To assess Principle 4 (Complications), raters asked the patient about pain or tenderness and inspected the PIVC insertion site for signs and symptoms. With Principle 5 (Infection prevention), raters asked the patient if they had observed the nurse perform hand hygiene before touching the PIVC and scrub the needleless connector hub before administering IV medications or fluids. To assess Principle 6 (Dressing and securement), raters assessed the PIVC dressing for cleanliness and integrity and securement of the PIVC or administration set. For Principle 7 (Evaluate and Educate), raters asked the patient if they had questions and if the nurse had provided any education about the PIVC. To assess Principle 8 (Document), raters checked the

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patient chart for documentation of PIVC assessment in the past 12 hours. To assess Principle 9 (Decision), raters asked the patient if they knew of any plans for the PIVC that day and checked the patient's chart for evidence of plans to remove or continue the PIVC.

Feasibility was assessed by timing inter-rater reliability assessments and by asking staff about the clarity of items and ease of completion of the tool. ***Acceptability*** of introducing the tool into practice was assessed with 30 registered nurses who participated in round table discussions at each hospital prior to the study. During these sessions, nurses discussed the terminology of the tool and provided feedback on the proposed VAD form. Suggestions were taken into consideration and minor sections of the care plan (shading, location of comments section) were modified prior to roll-out. Focus groups with staff nurses regarding PIVC assessment were undertaken prior to the roll out of the tool and at the end of the trial (Results of the focus groups are reported elsewhere).

Patient and Public involvement

The I-DECIDED® tool incorporates a prompt to evaluate patients' (and family, if appropriate) knowledge and concerns about their PIVC and to provide education, as needed. This prompt was included after recent research revealed consumers wanted to be included in conversations about the management of their vascular access devices.[24, 25] Specific patient advisers were not consulted for this study.

RESULTS

Content validity

Complete responses for the content validity questionnaire were available for 7 (32%) experts and 11 (44%) clinicians from Australia, UK, USA, and Canada. Two experts (UK, USA) and

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one clinician (USA) (all female) participated in a 30-minute, one-to-one call with the lead author. These discussions focused on clarifying the recommended frequency of assessment, in particular with different nursing shift lengths, and discussions about nursing responsibility for vascular access decisions, which vary between hospitals and countries.

For vascular access experts, the mean CVI for the principles of the tool was 0.87 (range 0.29–1.00), and the mean I-CVI for all items of the tool was 0.91 (range 0.57–1.00). The mean proportion of agreement was 0.91 (range 0.83–0.98). (See Table 1)

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Table 1. Ratings on a 48-item scale by 7 vascular access experts: Items rated 3 or 4 on a 4-point relevance scale

Item	Description	E1	E2	E3	E4	E5	E6	E7	Number in agreement	Item CVI
1	***Key principle: The presence of an IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	7	**1.00**
2	Does the patient have an IV device? (Inspect the patient and ask the patient if unsure)	✓	✓	✓	✓	✓	✓	✓	7	1.00
3	Has the patient had an IV device removed in the past 48 hrs? (Ask the patient)	✓	✓	✓	✓	✓	✓	✓	7	1.00
4	If the patient has had an IV device removed in the past 48 hrs, observe site for complications (post-infusion phlebitis and purulence).	✓	✓	✓	✓	✓	✓	✓	7	1.00
5	***Key principle: The need for the IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	7	**1.00**
6	Has the IV device been used in the past 24 hours, or is it likely to be used in the next 24 hrs?	✓	✓	✓	✓	✓	✓	✓	7	1.00
7	Can the patient switch to oral medications? Discuss with pharmacist and treating team.	✓	✓	✓	✓	✓	✓	✓	7	1.00
8	When no longer needed, the IV device should be removed.	✓	✓	✓	✓	✓	✓	✓	7	1.00
9	***Key principle: Effective flow and flush of the IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	6	**.86**
10	Does the IV device flow well?	✓	✓	✓	-	✓	✓	✓	6	.86
11	Does the IV device flush well?	✓	✓	✓	-	✓	✓	✓	5	.71
12	If the IV device does not flow and flush, it should be removed.	✓	✓	✓	✓	✓	✓	✓	6	.86
13	***Key principle: The IV site should be assessed for complications or concerns each shift.***	✓	✓	✓	✓	✓	✓	✓	7	**1.00**
14	Patient-reported pain ≥ 2 out of 10?	✓	✓	✓	✓	✓	✓	✓	7	1.00
15	Redness > 1 cm from insertion site	✓	✓	✓	✓	✓	✓	✓	7	1.00
16	Swelling > 1 cm from insertion site	✓	✓	✓	✓	✓	✓	✓	7	1.00
17	Any discharge at site	✓	✓	✓	✓	✓	✓	✓	7	1.00
18	Infiltration (IV fluid in surrounding tissues)	✓	✓	✓	✓	✓	✓	✓	7	1.00
19	Hardness (induration) of insertion site	✓	✓	✓	✓	✓	✓	✓	7	1.00
20	Palpable cord	✓	✓	✓	✓	✓	✓	✓	7	1.00
21	Other concerns? (itch, rash, blistering, etc.)	✓	✓	✓	✓	✓	✓	✓	7	1.00
22	If complications occur, the IV device should be removed, after consultation with the treating team. Insert new IV device if needed.	✓	✓	✓	✓	✓	✓	✓	7	1.00
23	***Key principle: Infection prevention and control practices should be performed each shift.***	✓	-	-	✓	✓	✓	✓	5	**.71**
24	Use Aseptic Non-Touch Technique (ANTT)	✓	✓	✓	✓	✓	✓	✓	7	1.00

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25	Hand hygiene	✓	✓	✓	✓	✓	✓	7		1.00
26	Scrub the hub as per protocol and allow to dry before accessing IV device	✓	✓	✓	✓	✓	✓	7		1.00
27	Any fever of unknown origin?	✓	✓	✓	-	✓	-	5		.71
28	Elevated white blood cell count?	✓	✓	✓	-	✓	-	5		.71
29	If the patient has a fever and/or elevated white blood cell count, with no obvious source of infection, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	✓	✓	✓	✓	✓	-	6		.86
30	Purulent discharge at the insertion site?	-	✓	✓	✓	✓	✓	6		.86
31	If the IV site has purulent discharge, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	✓	✓	✓	✓	✓	✓	7		1.00
32	***Key principle: Dressing and securement practice should be assessed each shift.***	✓	✓	✓	✓	✓	✓	7	**1.00**	
33	Is the IV dressing clean, dry, and intact?	✓	✓	✓	✓	✓	✓	7		1.00
34	If the IV dressing is moist, visibly soiled, or has loose/lifting edges, it should be changed.	✓	✓	✓	✓	✓	✓	7		1.00
35	Is the IV device and infusion tubing secured?	✓	✓	✓	✓	✓	✓	7		1.00
36	Secure well with securement device, tape, net or bandage.	✓	✓	✓	-	✓	✓	6		.86
37	***Key principle: The patient/family's knowledge and education needs should be assessed each shift, if possible.***	-	-	✓	-	-	✓	2	**.29**	
38	Evaluate patient/family understanding of reason for IV and plan for removal, if possible.	✓	-	✓	-	✓	✓	4		.57
39	Educate patient/family as needed, if possible.	✓	-	✓	-	✓	✓	5		.71
40	***Key principle: The IV assessment and actions taken should be documented each shift.***	✓	✓	✓	✓	✓	✓	7	**1.00**	
41	Insertion date and time	✓	✓	✓	✓	✓	✓	6		.86
42	I-DECIDED® assessment and relevant action taken	✓	✓	✓	✓	✓	✓	6		.86
43	Removal date and time	✓	✓	✓	✓	✓	✓	7		1.00
44	***Key principle: The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.***	✓	✓	✓	✓	✓	✓	7	**1.00**	
45	Decision 1. IV device should remain in place. No other change.	✓	✓	✓	✓	✓	-	6		.86
46	Decision 2. IV device should remain in place, but dressing change done. IV and infusion tubing well secured.	✓	✓	✓	✓	✓	-	6		.86
47	Decision 3. IV device removed and not replaced, in consultation with the treating team.	✓	✓	✓	✓	✓	-	6		.86
48	Decision 4. IV device removed and replaced. Consulted with patient and team about best device and site.	✓	✓	✓	✓	✓	-	6		.86

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	Proportion relevant	.96	.92	.98	.83	.98	.88	.85	0.87 (mean)	0 .91 (mean)
									Mean expert proportion = 0.91	
IV = intravenous; E = vascular access expert										

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For experienced clinicians, the mean CVI for the principles of the tool was 0.96 (range 0.82–1.00), and the mean I-CVI for all items of the tool was 0.93 (range 0.55–1.00). The mean proportion of agreement was 0.94 (range 0.65–1.00). (See Table 2)

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Table 2. Ratings on a 48-item scale by 11 experienced clinicians: Items rated 3 or 4 on a 4-point relevance scale

Item	Description	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	Number in agreement	Item CVI
1	***Key principle: The presence of an IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**
2	Does the patient have an IV device? (Inspect the patient and ask the patient if unsure)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
3	Has the patient had an IV device removed in the past 48 hrs? (Ask the patient)	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	-	9	.82
4	If the patient has had an IV device removed in the past 48 hrs, observe site for complications (post-infusion phlebitis and purulence).	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	10	.91
5	***Key principle: The need for the IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	**.91**
6	Has the IV device been used in the past 24 hours, or is it likely to be used in the next 24 hrs?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
7	Can the patient switch to oral medications? Discuss with pharmacist and treating team.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	.91
8	When no longer needed, the IV device should be removed.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
9	***Key principle: Effective flow and flush of the IV device should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**
10	Does the IV device flow well?	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	-	9	.82
11	Does the IV device flush well?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	.91
12	If the IV device does not flow and flush, it should be removed.	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	9	.82
13	***Key principle: The IV site should be assessed for complications or concerns each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**
14	Patient-reported pain ≥ 2 out of 10?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	.91
15	Redness > 1 cm from insertion site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
16	Swelling > 1 cm from insertion site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
17	Any discharge at site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
18	Infiltration (IV fluid in surrounding tissues)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
19	Hardness (induration) of insertion site	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00
20	Palpable cord	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	.91
21	Other concerns? (itch, rash, blistering, etc.)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	1.00

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22	If complications occur, the IV device should be removed, after consultation with the treating team. Insert new IV device if needed.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
23	***Key principle: Infection prevention and control practices should be performed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**	
24	Use Aseptic Non-Touch Technique (ANTT)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
25	Hand hygiene	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
26	Scrub the hub as per protocol and allow to dry before accessing IV device	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
27	Any fever of unknown origin?	-	✓	✓	✓	✓	✓	✓	✓	-	✓	-	8		.73
28	Elevated white blood cell count?	-	✓	✓	✓	✓	-	-	✓	-	✓	-	6		.55
29	If the patient has a fever and/or elevated white blood cell count, with no obvious source of infection, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10		.91
30	Purulent discharge at the insertion site?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10		.91
31	If the IV site has purulent discharge, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	-	✓	-	✓	✓	✓	-	✓	✓	✓	-	7		.64
32	***Key principle: Dressing and securement practice should be assessed each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**	
33	Is the IV dressing clean, dry, and intact?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
34	If the IV dressing is moist, visibly soiled, or has loose/lifting edges, it should be changed.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
35	Is the IV device and infusion tubing secured?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
36	Secure well with securement device, tape, net or bandage.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10		.91
37	***Key principle: The patient/family's knowledge and education needs should be assessed each shift, if possible.***	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	-	9	**.82**	
38	Evaluate patient/family understanding of reason for IV and plan for removal, if possible.	✓	✓	✓	✓	✓	✓	-	✓	-	✓	-	8		.73
39	Educate patient/family as needed, if possible.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10		.91
40	***Key principle: The IV assessment and actions taken should be documented each shift.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11	**1.00**	
41	Insertion date and time	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
42	I-DECIDED® assessment and relevant action taken	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
43	Removal date and time	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00

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44	***Key principle: The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.***	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	10	**.91**	
45	Decision 1. IV device should remain in place. No other change.	✓	✓	-	✓	✓	✓	✓	✓	✓	✓	✓	10		.91
46	Decision 2. IV device should remain in place, but dressing change done. IV and infusion tubing well secured.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
47	Decision 3. IV device removed and not replaced, in consultation with the treating team.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
48	Decision 4. IV device removed and replaced. Consulted with patient and team about best device and site.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11		1.00
	Proportion relevant	.90	1.00	.96	1.00	1.00	.94	.90	1.00	.94	1.00	.65		0.96 (mean)	0.93 (mean)
													Mean clinician proportion		0.94

IV = intravenous; C = clinician

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The content validity questionnaire elicited comments, which are summarised here. The complete list of responses is provided in Appendix 2.

Principle 1: The presence of an IV device should be assessed each shift.

All 18 respondents agreed. The prompt to assess for post-infusion phlebitis invoked 5 comments, with most respondents agreeing that assessing for post-infusion phlebitis is important but can be difficult if patients have communication difficulties (e.g. stroke, capacity to understand, or capacity to give feedback) and is not possible after patient discharge.

Principle 2: The need for the IV device should be assessed each shift.

Seventeen respondents agreed; however, one respondent commented that assessing PIVC need each shift was unrealistic and discussing changing to oral medications with the pharmacist and treating team raised workload concerns. Two respondents debated frequency of PIVC assessment, remarking that 'each shift' was unclear because shift length can vary according to the unit. One respondent noted that the Infusion Nurses Society Standards of Practice[11] call for daily assessment of need, rather than each shift.

Principle 3: Effective flow and flush of the IV device should be assessed each shift.

Seventeen respondents agreed, and 11 respondents offered diverse questions and opinions. Several argued that 'flow and flush' were subjective assessments and insufficient to determine PIVC function without first checking for obstruction. Flushing frequency was debated, and two respondents recommended adding 'aspiration for blood return'. In response to this feedback, the wording was changed to 'Effective function'.

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Principle 4: The IV site should be assessed for complications or concerns each shift.

All 18 respondents agreed with prompts to assess pain, redness, swelling, discharge, infiltration, extravasation, hardness or purulence. One respondent stated that palpable cord should not be included. Another said that this prompt contained too many signs and symptoms, many of which could be too subjective or difficult for the nurse to remember. Respondents' comments varied regarding determining pain scores at the PIVC site. One respondent said a pain score of 1 with associated redness and swelling would be a valid reason to remove the PIVC; another respondent stated pain would not be addressed unless the pain score was greater than 5; yet another recommended the question should prompt the nurse to identify the cause of the pain, rather than rely on a numerical score.

Principle 5: Infection prevention and control practices should be performed each shift.

Sixteen respondents concurred; two experts disagreed with the principle but agreed with all the supporting prompts. Five respondents argued the inclusion of fever and elevated white cell count was inappropriate, as neither would prompt PIVC removal in most cases; one respondent argued that diagnosis of infection would be a team responsibility rather than nursing. A Skype respondent expressed concern that a nurse might identify the PIVC as a possible source of infection, which could lead to financial penalties in some health services. One respondent stated 'purulent drainage' fit better with the principle 'complications' and the infection section should focus on identifying signs of sepsis. Two respondents felt aseptic non-touch technique should be removed because it was not taught at every hospital.

Principle 6: Dressing and securement practice should be assessed each shift.

All 18 respondents agreed. Four respondents noted this prompt could be made clearer by requiring that the PIVC site remain visible for ease of inspection; however, the wording of

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this section was not changed because the guidelines accept either transparent or sterile gauze and tape dressings.[13] Four respondents requested the prompts should specify exactly what should be secured (PIVC or administration set or both).

Principle 7: The patient/family's knowledge and education needs should be assessed each shift, if possible.

Eleven respondents supported this principle. Nine clinicians agreed that patient concerns about the PIVC were important to assess each shift, but only two experts felt this was relevant to include in the tool; five experts expressed concern that assessing patient knowledge needs each shift would be too frequent. Six respondents did not agree it was relevant to evaluate the patient's and/or family's understanding of the reason for the PIVC and plans for its removal.

Principle 8: The IV assessment and actions taken should be documented each shift.

All 18 respondents agreed. One respondent stated that the documentation should include more details (e.g. exact site of insertion, gauge size). Another commented that the tool would need to include more frequent prompts for paediatric PIVC assessment. A further suggestion was to include a prompt to replace PIVCs inserted in an emergency where asepsis could have been compromised.

Principle 9: The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.

Seventeen respondents agreed: however, one respondent noted PIVC removal must comply with local institutional policy, rather than a nurse's decision. Two respondents stated it would not be necessary to consult with the treating team before removing the PIVC if the nurse

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identified complications, as PIVC assessment is a nursing responsibility and nurses have the necessary skills and knowledge to make their own informed decisions in this area. This point was also raised in the Skype/telephone calls. Following this feedback, a clause was added: "Always consider local policy and consult with team and patient as required".

Reliability

From 34 paired assessments, item-level proportion of inter-rater agreement ranged from 79.41% (patient education) to 100% (documentation of the decision) (See Table 3). Overall Cronbach's alpha was 0.746 and proportion of inter-rater agreement was 87.13%. Using the Landis and Koch[26] categorization, the kappa values for each item of the tool were all in the substantial (0.61–0.80) range, except for 'Identify if patient has a PIVC' and 'Document your decision', which both scored almost perfect (0.81–1.00) and 'Evaluate and Educate', which scored in the moderate (0.41–0.60) range.

Table 3. Inter-rater reliability of I-DECIDED® tool

	Observed Agreement (%)†	PABAK‡	Cronbach's alpha if item deleted	Standard error	Z	Prob>Z
Identify if patient has PIVC	97.06	0.9412	0.742	0.1712	5.50	0.0000
Does patient need PIVC	88.24	0.7647	0.673	0.1715	4.46	0.0000
Effective function of PIVC	85.29	0.7059	0.775	0.1712	4.12	0.0000
Complications at PIVC site	82.35	0.6471	0.699	0.1715	3.77	0.0001
Infection prevention	82.35	0.6471	0.716	0.1715	3.77	0.0001
Dressing and securement	82.35	0.6471	0.656	0.1715	3.77	0.0001
Evaluate and educate	79.41	0.5882	0.718	0.1712	3.44	0.0003
Document your decision	100.0	1.0000	-	0.1715	5.83	0.0000
OVERALL	87.13		0.746			

†Expected agreement 50% for all items; ‡PABAK: prevalence-adjusted bias-adjusted kappa

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Feasibility

During inter-rater reliability testing, the time to conduct each assessment ranged from 1 to 10 minutes (average 2 minutes). Longer assessments occurred when patients had questions about their PIVC or if troubleshooting the PIVC was required.

Acceptability

Although 25 education sessions were attended by 180 staff over three hospitals in Phase 2, it was not possible to provide education to all staff at each site. Education was provided to all nurse unit managers, nurse educators and clinical facilitators, as well as many registered and enrolled nurses, physicians, and administrative staff. Posters were displayed in staff tearooms and nurses' stations, and lanyard cards were provided for all staff. During Phase 3 focus groups, the lead author asked attendees if they had received instructions how to use the tool. There was no discernible difference in feedback between staff who had or had not received education. Consensus was that the tool was easy to follow and particularly useful for newly registered nurses and nursing students. The structured format for PIVC assessment was popular, but many disliked the added paperwork. Following the inter-rater assessments, the lead author asked nurses if they had attended an education session, and if not, how did they learn to use the tool. Approximately half of the nurses who participated in the inter-rater assessments had not received any formal education about the tool; they reported that they had either asked a colleague about it or that it was self-evident.

DISCUSSION

This paper describes the clinimetric properties of the I-DECIDED® tool for PIVC assessment in an inpatient population. The tool demonstrated strong content validity for adults and paediatrics among vascular experts and clinicians, and high inter-rater reliability, feasibility

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and acceptability in the adult medical-surgical wards of three Australian hospitals. As this is the first comprehensive, evidence-based tool for PIVC assessment and decision-making, the authors expect this will interest clinicians across inpatient settings.

A strength of this study was that content validity of the tool was confirmed by 18 vascular access experts and clinicians from a range of English-speaking countries. Lynn[27] advocated item-level CVI should be around 0.80 when there are six or more experts. The mean CVI and proportion of agreement for the principles and the individual items of the tool scored very highly for both experts (I-CVI 0.91; mean proportion of agreement 0.91) and experienced clinicians (I-CVI 0.93; mean proportion of agreement 0.94), confirming that this tool comprises the essentials of PIVC assessment and decision-making.

Feedback from content validity survey and verbal conversations revealed that some respondents did not think it appropriate to assess all items each 'shift', particularly as nursing shifts can vary in length up to 12 hours. Some respondents commented that daily assessment would be sufficient for items such as "need for the PIVC" and "patient education", while others remarked that daily assessment would not be frequent enough for some patient populations, such as paediatrics, where guidelines recommend hourly assessment for continuous infusions. While current guidelines[11] recommend daily assessment of PIVC need, we believe this assessment is warranted more regularly, particularly if the nurse knows that an administered medication is the final dose and removal is planned in the next few hours. The suggestion to consult the treating team prior to removing the PIVC was criticised by several respondents, who argued nurses possess the skills and knowledge to make their own informed decisions. While this is true for experienced nurses, it cannot be presumed that novice nurses and students will have confidence in their decision to remove or resite a PIVC.

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Patient and family concerns about the PIVC and their education needs are often under-valued by healthcare workers,[28] and this was reflected in our findings that only 11 out of 18 survey respondents agreed with this principle. Surprisingly, only two of seven experts felt regular patient education should be included in the tool. In an Irish study, patients who did not know the reason for their PIVC were seven times more likely not to need the device.[29] In an Australian study of consumer experiences, patients and caregivers expressed the need for improved communication about PIVC insertion and care.[24] A recent survey of eight US hospitals reported that one-third of patients with concerns about their care did not feel empowered to speak up, and patients less likely to speak up included older, sicker, non-English-speaking, or patients with mental health issues.[30] While more hospitals are implementing mechanisms for patients and families to verbalise critical safety concerns, more needs to be done to change hospital culture to encourage patient collaboration in daily care decisions, particularly those that impact on infection management and prevention.[31-33] Including a prompt for clinicians to ask the patient about the PIVC has merit.

Testing inter-rater reliability among a variety of clinicians was another strength of this study. Paired assessments, performed immediately after each other, eliminated the likelihood of altered assessment findings resulting from medication or fluid administration, or time for symptoms to change. Blinding of the second assessor to the first assessor's results and blinding the registered nurses to the research nurses' results also strengthened the findings. While the overall proportion of inter-rater agreement was high for most items, the category of patient education demonstrated the lowest scores. This is not surprising, as the stability of patient-reported variables between assessments can be a confounder of inter-rater reliability testing.[34] For instance, if the first rater asked about pain or tenderness of the PIVC site, and

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received a negative response, this could have suggested concerns to the patient who then answered in the affirmative to the second assessor. Asking patients if their nurse had assessed the PIVC that shift or performed hand hygiene before touching the PIVC, or whether they had received any education about the PIVC, also elicited contradictory answers in some assessments. Some patients answered negatively in the first instance, but when asked the same question by the second rater, they answered in the affirmative. This was possibly due to suggestibility or an unwillingness to implicate the nurse, but we had no way to confirm or refute the findings.

Decision-making is a subjective process based on assessment, but the assessment itself should be a standardised process to ensure care is evidence-based and comprehensive. PIVC decisions are often based on clinicians' education and experience, and not all clinicians are conversant with current guidelines.[35-38] The I-DECIDED® tool prompts clinicians to perform a structured PIVC assessment and document their decision based on that assessment. It is not a prescriptive tool designed to overrule local policies, although we do believe that decisions to continue or remove a PIVC should be based on comprehensive clinical assessment, and not simply dwell time or absence of phlebitis symptoms.[6]

Limitations. Construct validity could not be evaluated as PIVC assessment is highly subjective, and no gold standard exists for PIVC assessment and decision making. Criterion validity could not be evaluated because there are no other comprehensive PIVC assessment tools in the literature. While multiple phlebitis tools exist, evaluation of their measurement properties is rare, and validity and reliability data are limited or absent. Inter-rater reliability assessments of the tool were completed by different sets of coders for different subjects, which can lead to a higher level of systematic bias or make it difficult to detect bias.[39] We

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tried to control for this by alternating the order of assessments and blinding each assessor to the other's findings. Finally, inter-rater reliability was tested in seven medical-surgical wards in three hospitals. Each assessor only assessed each PIVC on one occasion, therefore it was not possible to evaluate intra-rater reliability. Testing the tool's reliability in other settings is strongly recommended. Feasibility and acceptability of the tool were reported as generally positive in this study, but further research is recommended to evaluate the strain on nursing workload of introducing this tool.

CONCLUSION

The I-DECIDED® tool demonstrated strong content validity and high inter-rater reliability, feasibility and acceptability in medical-surgical wards of three hospitals. Implementation of this tool could prompt clinicians to provide comprehensive care and remove PIVCs when no longer needed or as soon as complications arise. Early detection and action could prevent painful PIVC complications, reduce the risk of bloodstream infection, and result in cost savings for healthcare services. Studies to evaluate the outcome of implementing this tool in clinical practice are recommended.

(4177 words)

SUPPORTING INFORMATION

A video of the I-DECIDED® device assessment and decision tool is available:

https://www.youtube.com/watch?v=kMHOjWJWbsI

ACKNOWLEDGEMENTS

The authors would like to thank Joan Webster, Nicole Marsh, Marianne Wallis, Amanda Ullman, Tricia Kleidon, and Amy Johnston, who reviewed the face validity of the tool; the

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experts and clinicians who anonymously participated in the content validity questionnaire; the research assistants Josephine Lovegrove, Kathie Roberts and Elizabeth Herron for assisting with the inter-rater reliability testing; and Gabor Mihala for statistical support.

FUNDING

Financial support for this study was provided in part by grants from Griffith University and the Australian College of Infection Prevention and Control. The funding agreements ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report. The following authors are employed by the sponsor, Griffith University: Gillian Ray-Barruel, Marie Cooke, Marion Mitchell, Claire M Rickard.

COMPETING INTERESTS

Griffith University has received on GRB's behalf unrestricted research grants (3M and Becton Dickinson) and consultancy payments (Ausmed, 3M, BD, Medline, and Wolters Kluwer). MC has received investigator-initiated research and educational grants and speaker fees provided to Griffith University by vascular access product manufacturers (Baxter, BD, Entrotech Life Sciences). VC receives funding from the Veterans Health Administration, National Institute for Health, Agency for Healthcare Research and Quality, and Centers for Disease Control. MM: No conflicts of interest. CMR: Griffith University has received on CMR's behalf unrestricted investigator-initiated research or educational grants from product manufacturers (3M, AngioDynamics; BD-Bard, Baxter; BBraun, Cardinal Health, Medtronic, Smiths Medical); and consultancy payments (3M, BD-Bard; BBraun, ResQDevices, Smiths Medical). No commercial entity had any role in the design or undertaking of this study.

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AUTHOR CONTRIBUTIONS

GR-B conceived and developed the I-DECIDED tool. GR-B, MC, VC, MM and CR conceived the study concept and contributed to the design. GR-B acquired, analysed and interpreted the data, and wrote the first draft. MC, VC, MM and CR provided critical review and intellectual input. All authors read and approved the final version of the manuscript and take public responsibility for its content.

DATA SHARING STATEMENT

All data relevant to the study are included in the article or uploaded as supplementary information.

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TABLES

Table 1. Ratings on a 48-item scale by 7 vascular access experts: Items rated 3 or 4 on a 4-point relevance scale

Table 2. Ratings on a 48-item scale by 11 experienced clinicians: Items rated 3 or 4 on a 4-point relevance scale

Table 3. Inter-rater reliability of I-DECIDED® tool

FIGURE LEGENDS

Figure 1. I-DECIDED® IV assessment and decision tool

APPENDICES

Appendix 1. Content Validity Questionnaire: I-DECIDED® device assessment and removal tool

Appendix 2. Principles of the I-DECIDED® tool and CVI survey respondents' comments

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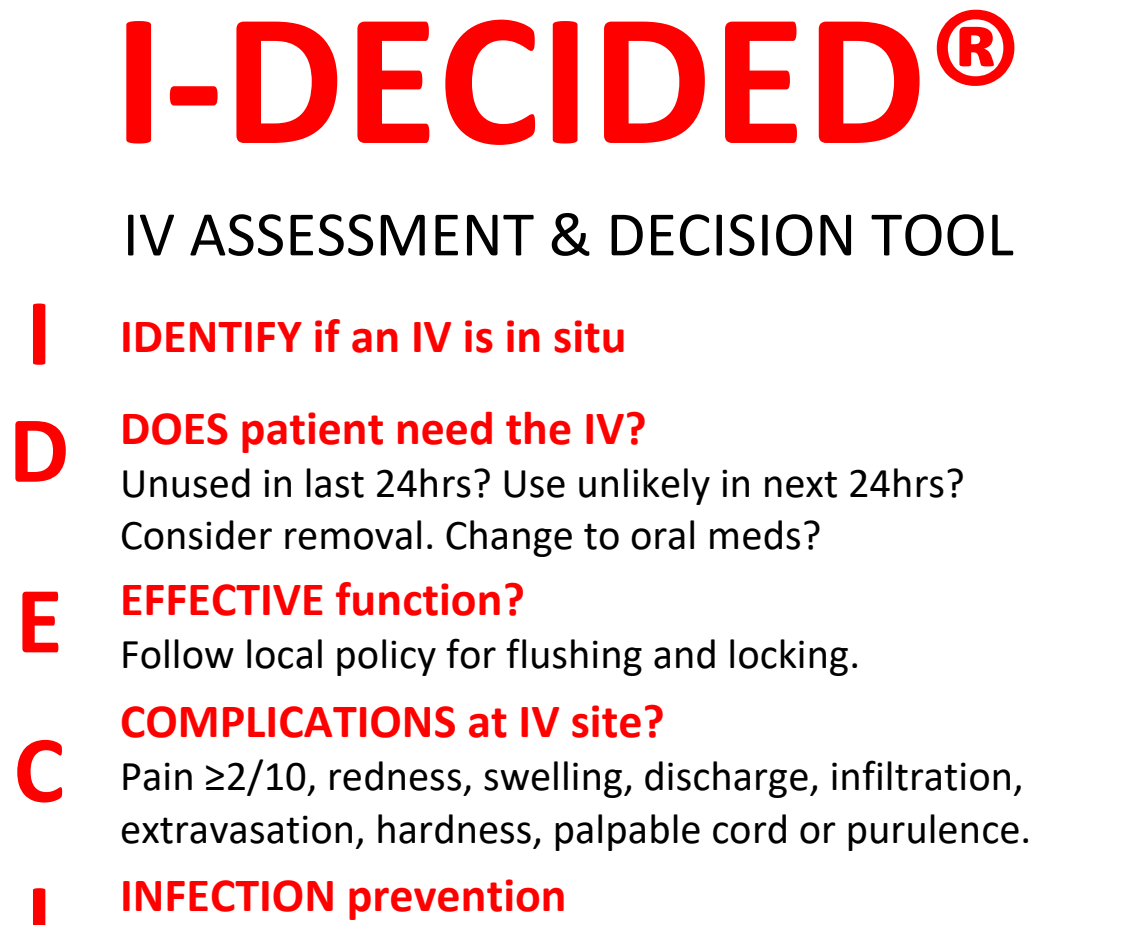
Figure 1. I-DECIDED® IV assessment and decision tool



Appendix 1. Content Validity Questionnaire: I-DECIDED device assessment and removal tool

Each item of the tool is based on a 'Key principle', with prompts for assessment and action.

Please ***circle the number*** that best rates the relevance of the statements listed below about the proposed components of the I-DECIDED tool.

Each section is followed by a space for your comment (E.g. Are any important concepts missing? Ease of comprehension? Language issues?).

KEY FOR SCORING ITEMS:
1 =NOT RELEVANT, 2 = SOMEWHAT RELEVANT, 3 = QUITE RELEVANT, 4 = HIGHLY RELEVANT

	I. IDENTIFY presence of IV device	**Please circle the relevant number**			
1	*Key principle 1: The presence of an IV device should be assessed each shift.*	1	2	3	4
2	Does the patient have an IV device? (Inspect the patient and ask the patient if unsure)	1	2	3	4
3	Has the patient had an IV device removed in the past 48 hours? (Ask the patient)	1	2	3	4
4	If the patient has had an IV device removed in the past 48 hours, observe site for complications (post-infusion phlebitis and purulence).	1	2	3	4

Comments:_____

_____

	II. DOES the patient need this IV device?	**Please circle the relevant number**			
5	*Key principle 2: The need for the IV device should be assessed each shift.*	1	2	3	4
6	Has the IV device been used in the past 24 hours, or is it likely to be used in the next 24 hours?	1	2	3	4
7	Can the patient switch to oral medications? Discuss with pharmacist and treating team.	1	2	3	4
8	When no longer needed, the IV device should be removed.	1	2	3	4

Comments:_____

_____

	III. EFFECTIVE flow and flush?	**Please circle the relevant number**			
9	*Key principle 3: Effective flow and flush of the IV device should be assessed each shift.*	1	2	3	4
10	Does the IV device flow well?	1	2	3	4
11	Does the IV device flush well?	1	2	3	4
12	If the IV device does not flow and flush, it should be removed.	1	2	3	4

Comments:_____

_____

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	IV. COMPLICATIONS or CONCERNS	Please circle the relevant number			
13	*Key principle 4: The IV site should be assessed for complications or concerns each shift.*	1	2	3	4
14	Patient-reported pain ≥ 2 out of 10?	1	2	3	4
15	Redness > 1 cm from insertion site	1	2	3	4
16	Swelling > 1 cm from insertion site	1	2	3	4
17	Any discharge at site	1	2	3	4
18	Infiltration (IV fluid in surrounding tissues)	1	2	3	4
19	Hardness (induration) of insertion site	1	2	3	4
20	Palpable cord	1	2	3	4
21	Other concerns? (itch, rash, blistering, etc.)	1	2	3	4
22	If complications occur, the IV device should be removed, after consultation with the treating team. Insert new IV device if needed.	1	2	3	4

Comments:_____

_____

	V. INFECTION prevention and control	Please circle the relevant number			
23	*Key principle 5: Infection prevention and control practices should be performed each shift.*	1	2	3	4
24	Use Aseptic Non-Touch Technique (ANTT)	1	2	3	4
25	Hand hygiene	1	2	3	4
26	Scrub the hub as per protocol and allow to dry before accessing IV device	1	2	3	4
27	Any fever of unknown origin?	1	2	3	4
28	Elevated white blood cell count?	1	2	3	4
29	If the patient has a fever and/or elevated white blood cell count, with no obvious source of infection, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	1	2	3	4
30	Purulent discharge at the insertion site?	1	2	3	4
31	If the IV site has purulent discharge, the IV device should be removed and the IV site cultured as a possible source of bloodstream infection.	1	2	3	4

Comments:_____

_____

	VI. DRESSING and securement	Please circle the relevant number			
32	*Key principle 6: Dressing and securement practice should be assessed each shift.*	1	2	3	4
33	Is the IV dressing clean, dry, and intact?	1	2	3	4
34	If the IV dressing is moist, visibly soiled, or has loose/lifting edges, it should be changed.	1	2	3	4
35	Is the IV device and infusion tubing secured?	1	2	3	4

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36	Secure well with securement device, tape, net or bandage.	1	2	3	4

Comments:_____

_____

	VII. EVALUATE and EDUCATE	**Please circle the relevant number**			
37	*Key principle 7: The patient/family's knowledge and education needs should be assessed each shift, if possible.*	1	2	3	4
38	Evaluate patient/family understanding of reason for IV and plan for removal, if possible.	1	2	3	4
39	Educate patient/family as needed, if possible.	1	2	3	4

Comments:_____

_____

	VIII. DOCUMENT	**Please circle the relevant number**			
40	*Key principle 8: The IV assessment and actions taken should be documented each shift.*	1	2	3	4
41	Insertion date and time	1	2	3	4
42	I-DECIDED assessment and relevant action taken	1	2	3	4
43	Removal date and time	1	2	3	4

Comments:_____

_____

	IX. DECIDE and ACT	**Please circle the relevant number**			
44	*Key principle 9: The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.*	1	2	3	4
45	**Based on this assessment (in consultation with treating team and patient), I-DECIDED . . .**	1	2	3	4
46	IV device should remain in place. No other change.	1	2	3	4
47	IV device should remain in place, but dressing change done. IV and infusion tubing well secured.	1	2	3	4
48	IV device removed and not replaced, in consultation with the treating team.	1	2	3	4
49	IV device removed and replaced. Consulted with patient and team about best device and site.	1	2	3	4

Comments:_____

_____

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Appendix 2. Key principles of the I-DECIDED® tool and CVI survey respondents' comments

E = Expert; C = Clinician

Key principle 1. The presence of an IV device should be assessed each shift.

Post-infusion phlebitis is a rare event. (E4)

All relevant questions (E5)

Difficult to check site if patient has been sent home. (E6)

I am glad you incorporated the assessment of site post removal. This is not a standard practice and should be. (C1)

Not sure the relevance of item Q4 & Q5 in the context of identifying presence of an IV (i.e. although they are relevant it depends on context) - it potentially belongs to other principles. Q4 & Q5 are about identifying absence in the context of potentially infective/inflammatory processes. That said, the questioning of a patient- i.e. the interaction with a patient may include questions in this order. (C6)

48hrs [post-removal] assessment will be difficult with some patients (stoke; capacity to understand etc) 2-3 are also dependent on capacity to feedback (C8)

Check IV device is documented? (C11)

Key principle 2. The need for the IV device should be assessed each shift.

Would instead assess for need daily instead of every shift which at least in US is not realistic. (E2)

INS standards call for a daily assessment of need rather than each shift. Sometimes it is hard to define a 'shift' as this can be 8 hours or 12 hours. Most American nurses work 12-hour shifts. (E7)

It is the Treating team who will make the decision to switch to orals. The pharmacist could have input but the Treating team is the decider. May not always take on the pharmacist's advice (C7)

Your definition of no longer needed is important. (C8)

Discussions with treating team and/or pharmacist is a BIG workload. Needs to be established by? in conjunction with? treating team (medical team) (C11)

Key principle 3. Effective flow and flush of the IV device should be assessed each shift.

Flow and flush would be hard to assess unless the person checks the flow and flush themselves. The most important issue is removal. (E4)

Difficult to define a 'shift' as there are a mixture of 3 shifts per 24 hours and 2 shifts per 24 hours. Q15 relevant question but the wording is subjective, what does 'well' mean? (E5)

Due to poor renal function IV antibiotic may be every other day...? Flush or not... need to describe difference between flush and lock. (E6)

Flow and flush is very important but not sufficient by itself. There should be aspiration for a blood return using appropriate technique - slow and gentle, small syringe, and/or a tourniquet above the site. This is critical if the medications are vesicants. Also, this assessment should be before each infusion and not limited to only once per shift. (E7)

I feel there would need to have more assessment prior to removal. What site look like? Is it secure properly? Is the obstructed duty to taping or being kinked? Is it leaking at the site? (C1)

No use having a cannula if it is not meeting the most basic design parameter. (C4)

Q15 would come down to clinical context and how desperate the need for the IV is and how tricky obtaining access is (C6)

Flow well question is a bit ambiguous. May not know if it 'flows' well if no IV infusion. The PIVC should be flushed before anything is administered so flush should be first and if it doesn't flush it is not going to flow. Maybe infusing easily if IV infusion (C7)

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The type of volume; flush rate; and size of PIVC impact on Q13-Q14 (C8)

Clinicians will be confused by flow and flush and why it is separated. We assess for resistance with flushing and free flowing of IV therapy. In oncology we also assess for blood return. (C10)

Q12 & Q13 & Q14 the same? Q15 - move? wiggle? reposition? (C11)

Key principle 4. The IV site should be assessed for complications or concerns each shift.

Some questions appear to be redundant or overlapping as in swelling/infiltration, redness/hardness induration. These questions could be combined. (E1)

Q25 is likely a dressing issue rather than catheter issue (E2)

Q26 - most clinicians would not necessarily consult team... they would just remove and insert a new IV (E3)

Shifts vary for 8 hours to 12 hours, may need to be more specific (E5)

Not sure how relevant 1cm is? (E6)

These are a little troubling because they imply that pain of level 1 or redness and swelling of 1 cm are acceptable. All changes in color, temperature, any degree of pain is a valid reason to immediately remove the PIVC. Also consultation from the 'treating team' is not necessary. Not sure who this team includes. Any nurse should be capable of assessing these sites, making the decision to remove it if there are any signs or symptoms, remove and assess for the need to insert a new PIVC without consultation by the treatment team. (E7)

I would relook at scoring pain greater than 2. Maybe does patient have pain yes or no? We usually don't provide interventions for pain when using scale unless pain is greater than 5. (C1)

Have graded the pain assessment at a lower value due to subjectiveness of numerical scoring. I would want to drill deeper: e.g. is it because of the site and its tendency to be bumped that is causing the pain? Would an arm board or better dressing help? (C4)

Do you think that the signs need to be signposted for different complications? (C6)

When asking pts about pain in PIVC they think of pain at insertion; specify pain at present time. Do we accept a pain score of 1? Add extravasation with infiltration (C7)

How many attempts they had? Did they did *[sic]* the clinician was skilled enough; reassured them; understood their fears if any; respected their suggestion where it should go? (C8)

What is a palpable cord? How will the nurse remember all of these components? Condense to red/swollen/painful/Other? (C11)

Key principle 5. Infection prevention and control practices should be performed each shift.

It seemed that the purulent drainage was a carry-over from the previous section on complications and not part of infection practices. Maybe changing the wording to are there any signs of sepsis/infection? (E1)

Q28 is institution-dependent, may not be relevant; Q34, Q35, Q36 draw blood cultures. Note: Qs and order of questions are different on printed version and electronic version (E2)

Would suggest rewording Q28....to make it more specific to IV. (E3)

Fever and WCC are subsumed under Q36 (E4)

Q30 - needs to be more specific, e.g. before and after each manipulation/access of the device (E5)

Removal of IV if ? source of infection... other sources must be considered (E6)

Same comment about shift as previous screen. Not sure what is being asked in Q34. FUO alone is not a reason to remove any VAD. Neither is elevated WBC. Also not sure what is meant by culture IV site - drainage, catheter, blood? Fever and WBC could be from lots of other causes and not the PIVC. Removal depends on many factors such as venous difficulty, length of therapy planned, etc. It is relevant but I would not automatically remove the PIVC under only the conditions listed. (E7)

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I have seen recent presentation on ANTT. If this is recommendation it would require large education for users to under concept, terms and practices. I have mixed feeling related to culturing PIV sites and site removal if pt has fever and positive blood culture. (C1)

Q36 will depend on clinical context (C6)

Q35 and Q36. WCC may be already elevated due to infection and why we have PIVC in. So an increase in Temperature and increase in WCC as to what it was. And think wording in Q36 that PIVC should be considered as possible source of infection and if clinically appropriate remove ASAP (C7)

Has their infusion pump alarmed during the treatment? Have they missed antibiotics/treatment delay? (C8)

WCC elevated is late sign of infection (C10)

ANTT - would they necessarily know what this means??? purulent discharge and Q33 belong in the previous page. Fever/WBC should have been identified by treating team...not nurse? Q36 not relevant to ED (C11)

Key principle 6. Dressing and securement practice should be assessed each shift.

Q40 not sure if edges of dressing lifting if this is proven to correlate with risk of infection or phlebitis for PIVs (E2)

Q42 - reword? Secure the IV itself? Or the tubing? Could also be extension tubing? (E3)

Q41 should come first. Q42 isn't necessary. (E4)

Q42 - we wouldn't advocate a bandage as they deter staff from observing the insertion site (but we do advocate securement) (E5)

Some of these questions are multiple questions in one... e.g. Securement device, net or bandage... also tube securement and cannula securement are two different questions (E6)

Same shift comment. Also define 'securement' for the PIVC. Is this referring to a completely stable and secure catheter, dressing, and joint if close to a joint? Q42, what type of bandage? Too many variables in this question. Tape alone is not sufficient iMHO. Net is only needed for specific ages or patient populations and bandages should never cover the site. Nurses will not remove it to assess completely. (E7)

You might just need to be certain that the IV site can still be inspected easily and not overly covered with tape etc. (C2)

Secure, dry and not moving and aggravating the vessel wall and venipuncture site => reduced risk of infection and complications. (C4)

Does Q42 need further information- e.g. relevance of being able to see the insertion site? (C6)

Is there evidence of a date on the dressing in the note on informatics? (C8)

Q41 - liked this one. Q42 – repeats (C11)

Key principle 7. The patient/family's knowledge and education needs should be assessed each shift, if possible.

I'm not sure if it is highly relevant to assess educational needs every shift. (E1)

I think only important that they know to contact nurse if pain, swelling, redness at or near insertion site, so would change wording to be more specific in this regard (E2)

Q46 - educate on complications? Or just in general? (E3)

Q44 - not sure this is relevant each shift, might be setting people up to fail (E5)

Same shift comments. Not sure this is required every 8-hour shift but it is required periodically. I would not tie it to a shift. Shift work equates to common laborers and not the knowledge workers that nurses actually are. (E7)

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I think these questions are vital as we incorporate patients in care. They are their own best advocate and can keep us accountable. (C1)

The best nursing and clinical care is irrelevant if the person cannulated is not on board the narrative. (C4)

I think by assessing and evaluating patient education each shift would not be done. Just continuous education and reinforcement to the patient of how their input is required. (C7)

[Educate] pt/family every shift is excessive. Q46 repeats (C11)

Key principle 8. The IV assessment and actions taken should be documented each shift.

Same shift comment. Much more detail is needed, exact site of insertion, gauge size, etc as listed in INS Standards. (E7)

Curious as populate tool be used or if you will have variation for peds and unconscious to align with INS recommendations to check PIV site more frequently. (C1)

Gives the clinician ownership of device management (C4)

Accreditation standards require removal plan. Also nothing noted about insertion in an emergency/or asepsis compromised at insertion may need replacing. (C7)

The decision to continue or remove the IV device should be based on assessment and consultation with the treating team and the patient.

I would use different wording for Option 2. Something like: IV device should remain in place with securement and dressing replaced. (E1)

If purulent, painful, swollen, etc. then nurse should remove and wouldn't need 'consultation with treating team or patient' but would add need to document in medical record. I think this section should be revised. Does this all go into medical record? Again, for many of these, don't need to consult with patient or team (E2)

Dressing change only done if required. i.e. loose, soiled, coming off (E3)

I think I am missing the point of this screen. Decisions about PIVCs are nursing responsibility and accountability in the USA. No consultation with the treatment team is required before it is removed. Our MD, NP, and PA would think the nurse has lost her mind if a nurse asked them to assess a PIVC site. I strongly believe that all staff nurses must understand when a PIVC is no longer the most appropriate device for a specific patient. These factors then trigger a consultation by the infusion/vascular access nurse for what would be the most appropriate VAD. This recommended VAD may or may not require action by the medical team (MD, NP, PA = LIP in USA) The general staff nurse will not know what is most appropriate and I don't think we should expect them to have this knowledge. But each facility must have a team that can make this assessment. That is not the case in many facilities. (E7)

Great project. Let me know if you want to be a testing site. (C1)

A proactive management approach rather than reactive. (C4)

Are administration set changes covered anywhere? (C6)

I know AVATAR promotes clinically indicated PIVC resiting but this is not what is happening in most facilities so should mention based on Organisational Policy, treating team and patient (C7)

Did the pt want another device type or inserter or method of insertion? (C8)

Very exciting tool indeed (C10)

2 D's??? Q53 - repeats Q56 - 'in consultation...' repeated replaced = PIC/other line??? (C11)

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Guidelines for Reporting Reliability and Agreement Studies (GRRAS)

			Page
Title and abstract	1	Identify in title or abstract that interrater/intrarater reliability or agreement was investigated	3
Introduction	2	Name and describe the diagnostic or measurement device of interest explicitly	5
	3	Specify the subject population of interest	5
	4	Specify the rater population of interest (if applicable)	5
	5	Describe what is already known about reliability and agreement and provide a rationale for the study (if applicable)	5
Methods	6	Explain how the sample size was chosen. State the determined number of raters, subjects/objects, and replicate observations	6-9
	7	Describe the sampling method	7-8
	8	Describe the measurement/rating process (e.g., time interval between repeated measurements, availability of clinical information, blinding)	7-8
	9	State whether measurements/ratings were conducted independently	8
	10	Describe the statistical analysis	8-9
Results	11	State the actual number of raters and subjects/objects that were included and the number of replicate observations that were conducted	10-15
	12	Describe the sample characteristics of raters and subjects (e.g., training, experience)	6-8
	13	Report estimates of reliability and agreement including measures of statistical uncertainty	11, 14
Discussion	14	Discuss the practical relevance of results.	15-19
Auxiliary material	15	Provide detailed results if possible (e.g., online)	Appendix 2
Ref: Kottner J, Audige L, Brorson S, Donner A, Gajewski BJ, Hrobjartsson A, et al. Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. *Int J Nurs Stud*. 2011;48(6):661-71.			

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