

# BMJ Open Development of a clinical prediction rule to improve peripheral intravenous cannulae first attempt success in the emergency department and reduce post insertion failure rates: the Vascular Access Decisions in the Emergency Room (VADER) study protocol

Peter J Carr,<sup>1,2</sup> James C R Rippey,<sup>1,3</sup> Marie L Cooke,<sup>2</sup> Chrianna Bharat,<sup>4</sup> Kevin Murray,<sup>4</sup> Niall S Higgins,<sup>2</sup> Aileen Foale,<sup>5</sup> Claire M Rickard<sup>2</sup>

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For numbered affiliations see end of article.

#### Correspondence to

Peter J Carr;  
petercarriv@gmail.com

#### ABSTRACT

**Introduction:** Peripheral intravenous cannula (PIVC) insertion is one of the most common clinical interventions performed in emergency care worldwide. However, factors associated with successful PIVC placement and maintenance are not well understood. This study seeks to determine the predictors of first time PIVC insertion success in emergency department (ED) and identify the rationale for removal of the ED inserted PIVC in patients admitted to the hospital ward. Reducing failed insertion attempts and improving peripheral intravenous cannulation practice could lead to better staff and patient experiences, as well as improving hospital efficiency.

**Methods and analysis:** We propose an observational cohort study of PIVC insertions in a patient population presenting to ED, with follow-up observation of the PIVC in subsequent admissions to the hospital ward. We will collect specific PIVC observational data such as; clinician factors, patient factors, device information and clinical practice variables. Trained researchers will gather ED PIVC insertion data to identify predictors of insertion success. In those admitted from the ED, we will determine the dwell time of the ED-inserted PIVC. Multivariate regression analyses will be used to identify factors associated with insertions success and PIVC failure and standard statistical validation techniques will be used to create and assess the effectiveness of a clinical prediction rule.

**Ethics and dissemination:** The findings of our study will provide new evidence to improve insertion success rates in the ED setting and identify strategies to reduce premature device failure for patients admitted to hospital wards. Results will unravel a complexity of factors that contribute to unsuccessful PIVC attempts such as patient and clinician factors along with the products, technologies and infusates used.

**Trial registration number:** ACTRN12615000588594; Pre-results.

#### BACKGROUND

Peripheral intravenous cannula (PIVC) insertion is a vascular access clinical procedure that is shared among many professionals, including: nursing, medical, paramedical, physician assistant, as well as technical and support staff. Vascular Access Decisions in the Emergency Room (VADER) or the emergency department (ED) overwhelmingly favour the PIVC as the device of choice. The ubiquity of this procedure was demonstrated in a point prevalence study undertaken in a European hospital; over 84% of patients had a vascular access device (VAD) of some type, with 80% of these PIVCs.<sup>1</sup> Factors identified as predictors of insertion failure in the ED<sup>2,3</sup> and premature device failure in admitted patients are published separately.<sup>4</sup> However, notwithstanding literature concerning PIVCs inserted in ED using ultrasound technology,<sup>5</sup> none has focused on the survival of PIVC from ED to hospital admission and this represents a significant gap in the literature. Previously first time insertion success in our ED population was identified at 86%, however one limitation was the use of a self-report method.<sup>6</sup> We subsequently performed a chart review of this patient population admitted with an ED placed PIVC so we could identify a rationale for removal. We

were unable to identify why the ED inserted PIVC is removed with any great accuracy due to poor documentation. We did however identify documented evidence of repeat PIVCs within 72 h suggesting the ED PIVC is failing to last 3 days. This subjects the patient to repeat attempts. It is this prior work that has motivated this observational study.

### Insertion success

Preserving the venous anatomy from damage caused by repeated skin punctures through failed PIVC insertion attempts is a challenge in high-paced environments such as the ED. Reducing the number of needle insertions and skin punctures should become a priority for clinical science. Moreover, reducing the number of inappropriate PIVC insertions or those not clinically justified is another priority.<sup>7</sup> A reduction in repeated PIVC insertions has been identified as a cost-saving strategy that can save tens of millions of dollars for the Australian healthcare service each year.<sup>8</sup> Staff time to re-insert a device, lost therapy time that impacts on treatment options and an increase in length of stay, along with additional products such as dedicated PIVC packs and 'once only use' equipment makes repeat attempts expensive. So-called 'first time PIVC insertion success' (where the inserter only pierces the skin once and successfully places the PIVC in the vein) ranges from 65% to 86% in the paediatric and adult populations.<sup>6 9–16</sup> The variability of first-time insertion success rates suggests that PIVC insertion is frequently difficult however improved and sustained first-time insertion success of 98–99% occurs when specialist insertion teams provide PIVC insertion.<sup>17</sup>

Specific patient factors are reported to contribute to insertion failure such as: age<sup>18</sup>; patient size<sup>3 5 6 19–28</sup>; limited and suitable veins contributing to a difficult intravenous access<sup>3 19 22 27 29 30</sup>; previous history of failed attempts and recent hospital admission<sup>12 30 31</sup>; diabetes<sup>2 19 27</sup>; intravenous drug use<sup>2 5 19–23 26 27</sup>; cancer diagnosis and recent chemotherapy<sup>12 27 32</sup>; patient anxiety (needle phobia).<sup>33</sup> Additionally technologies purported to enhance insertion success such as ultrasound or other vessel locating devices report first-time insertion success that ranges from 18% to 87%<sup>5 21 24 34</sup> suggesting re-evaluation is required. However, clinician factors such as experience of the inserter and number of PIVC procedures performed<sup>6 9 10 12 32 35</sup> contribute to improved insertion success. Over 12 risk factors have been reported to predict insertion failure in the emergency care setting, these include: age, gender, race, body mass index, history of chemotherapy, diabetes, dialysis patients, intravenous drug abuse (IVDA), swelling, non-visible veins, sickle cell disease and recent hospitalisation or ED visit within 90 days.<sup>2 3 5 6 19–24 26–28 36–41</sup> Improving the patient journey with better vascular access care should be a priority for hospital administrators.<sup>42</sup>

### Post insertion complications

In the adult population, secondary data analysis from a large randomised controlled trial indicate that post insertion 25% of PIVCs fail.<sup>4</sup> The causes of post insertion failure warrant attention, and include; infection, infiltration or extravasation, occlusion and dislodgement, which can lead to a reduced therapeutic effect of prescribed medicines.<sup>4</sup> Post insertion failure is complex multifactorial and is influenced by patient characteristics, such as: age<sup>4 18</sup>; gender<sup>4</sup>; any infection at baseline<sup>4</sup>; number and type of comorbidities<sup>43</sup>; smoking<sup>44</sup>; and device characteristics such as: PIVC gauge and length<sup>26 36 43</sup>; site of placement<sup>4 43</sup>; antibiotics prescribed intravenous<sup>4</sup>; not using a J-loop or extension set or closed system catheters<sup>45 46</sup>; securement device failure<sup>47</sup> and the hospital culture in managing these medical devices, for example, the adoption of an aseptic technique.<sup>48</sup> PIVC insertions in the ED have been reported as a cause of phlebitis and *Staphylococcus aureus* bacteraemia, leading to premature device failure. As a result, routine PIVC replacement after 24 h is recommended for ED PIVCs in an attempt to reduce the risk of infection.<sup>49–51</sup>

Studies in the ED are limited to insertion failure and risk factors for difficult insertion.<sup>2</sup> Those that do identify dwell time during or post-ED are limited to PIVC insertions using ultrasound-guided technology<sup>5 26</sup> and 47% of PIVCs inserted with ultrasound guidance failing within 24 h.<sup>5</sup> It is unknown how long the ED-inserted PIVC (using traditional attempts) remains intravenous and what the rationale for removal is. Added to this is another unknown; that is, the number of repeat attempts that occur after the removal of an ED PIVC.

Even when a dedicated intravenous team with a first-time insertion success rate of 98% perform the initial insertion, the PIVC post insertion failure in an orthopaedic ward was 49% attributed to securement device failure.<sup>47</sup> The range of possible complications that have been reported in the literature related to PIVCs are; phlebitis/thrombophlebitis, psychological distress (needle phobia), nerve injury, dislodgement (due to dressing failure), occlusion, air embolism, tissue necrosis, infiltration/extravasation, infection and death.<sup>4 33 51–55</sup>

Such failures are unacceptable. These contribute to increased length of hospital stay, thus interrupting the patient care processes and clinical pathways.<sup>56</sup>

### STUDY DESIGN

VADER is a prospective cohort study, which will observe PIVC insertions at two EDs with a subsequent follow-up of admitted patients to identify the dwell time of such cannulae. The research aim of the VADER study is to; (1) identify risk factors for peripheral intravenous cannulation success, (2) identify risk factors for reduced dwell time/failure and (3) develop a clinical prediction score for PIVC insertion in the ED.

## Participants and setting

The proposed study will be undertaken in the EDs of Sir Charles Gairdner Hospital (SCGH) and Fiona Stanley Hospital (FSH) Perth, Western Australia. Both EDs provide 24 h emergency service for adult patients and are accredited with the Australasian College for Emergency Medicine for training. The departments provide a full range of adult tertiary specialties. According to the ED of SCGH information system over 33 228 PIVC insertion procedures were recorded between July 2012 and June 2013 with over 64 000 patients registered. This is a substantial number of vascular access devices used by one department. FSH is a new hospital campus and annual numbers of PIVC use are unknown at present. Bed capacity at SCGH is 650, while FSH has a capacity of 783.

Participants will include ED patients and ED clinicians. There are over 100 nurses and over 70 medical doctors eligible to participate at each site.

## Outcomes

### Primary outcome

First-time insertion success is the primary outcome and will be recorded as a dichotomous variable, either yes or no. PIVC insertion failure is the outcome of interest for analysis along with associated risk factors, which will be identified using regression techniques.

### Secondary outcome

A second statistical model is proposed to identify risk factors for failure of the PIVC in patients admitted to the wards. This will also be a dichotomous measure of either yes or no.

## Sampling framework

### Sampling method

The sample population for this will proposed study include patients that present to the ED and who subsequently require a PIVC. A convenience sampling method will be used because of limited funding and resources. An attempt will be made to gather all ED patient presentation types and exclude none, thus reducing sampling bias toward the inclusion of only difficult patients. An attempt will be made to gather all ED patient presentation types and exclude none, thus reducing sampling bias toward the inclusion of only difficult patients. All patients over the age of 18 years who require the insertion of a PIVC and clinical staff, who place PIVCs as part of their role in the ED, will be included in the study. We will exclude patients who are under 18 years of age and any clinician inserters who decline to provide consent to be observed. A requirement of our ethical approval states we must consent clinicians before we observe their practice.

### Sample size

Sample size calculations for this type of study are complex<sup>57</sup> and often the decision on how many

observations to record is really a pragmatic one. They can be derived when there is one explanatory variable, but, there is no agreed method to calculate sample sizes when there are a number of explanatory variables proposed in this study. As the primary outcome is first-time insertion success our sample size is calculated from a previous clinical survey we performed resulting in a successful first attempt rate of 86%.<sup>6</sup> With our proposed sample size of 1000, we would have sufficient numbers to adequately investigate approximately 10 variables using a multivariate logistic regression technique. Additionally this number would be sufficient based on guidelines suggested by Peduzzi *et al*<sup>58</sup> and Vittinghoff and McCulloch.<sup>59</sup> Furthermore, this would more than adequately satisfy the minimum recommendation of Steyerberg<sup>60</sup> for validation purpose.

## Data collection

This prospective study will be conducted when the investigator (PJC) or a small team of research nurses/assistants are available during the time period June 2015—December 2015. Data will be collected each day by the investigator/research nurses/assistants trained in using our case report form (CRF). They will prospectively collect patient data and observe the PIVC insertion by the ED clinician and record the first-time insertion success. In addition, the number and reason for any clinicians to refuse to have an observation recorded will be collected. Each morning, the unique medical number of the previous days observations (which will be stored and secured in a database on the hospital network) will be identified for admission or discharge. Patients who are discharged will contribute to our planned risk factors for insertion success analysis. Patients who are admitted will be followed up on the ward daily and data collected until the PIVC that was placed in the ED has been removed. This will assist identify the dwell time of the ED inserted PIVC and the rationale for removal. The form includes demographic, historical and clinical risk factors. The current literature and clinical experts underpin our CRF, which contribute to face and content validity of our CRF, respectively. We have also assessed our CRF quantitatively using the content validity index outlined by Pilot and Beck<sup>61</sup> with both ED clinicians and vascular access experts resulting in excellent content validity. The developed CRF was also used in our self-report study<sup>6</sup> and proved to be clear, logically flowing, relevant and acceptable in the ED clinical environment.

## Proposed demographic and clinical data variables

Various variables will be collected to describe the patient population that is not dissimilar to that found in the majority of Australian adult emergency departments, thus facilitating generalisability. These variables, evidenced to predict insertion failure and post insertion failure are drawn from the literature. Some of the potential risk factors for insertion failure could conceivably be

the same evaluated risk factors for post insertion failure, with a small number of additional variables. We will use a similar definitions for skin assessment quality<sup>62</sup> and vein assessment quality<sup>6 29 63</sup> used in previous studies. Insertion success will be defined by the visible presence of venous blood at the PIVC hub after the PIVC pierces through the skin into a vein, in addition to a small volume (up to 10 mL) of normal saline 0.9% connected to the PIVC being flushed into the vein without evidence of any complication such as infiltration.

Validated questions and variables we intend to observe and collect include; presenting complaint, weight status, number of visible and/or palpable veins, vein size (small 1 mm, medium 2–3 mm or large >4 mm); the venous international assessment scale (VIA), skin type/temperature (we will use a similar definitions for skin assessment quality<sup>62</sup> and vein assessment quality<sup>6 29 63</sup> used in previous studies); skin shade; rationale for insertion, prediction that the PIVC will be used for intravenous therapy, clinician experience, clinician pre-procedural estimation of success, aseptic technique; number of needle redirections, additional products used such as add on-devices referred to as needle-free connectors and J-loops; use of ultrasound and any observed blood spillage. Online supplementary appendix 1 displays our CRF that will be used to collect our observational data in ED.

The ward follow-up data to be collected will include the rationale for PIVC removal and any factors based on the aforementioned literature that influence failure. Items included in the ward follow-up CRF contain additions and refinements from a validated data collection tool used in an international PIVC prevalence study.<sup>64</sup> Data will be obtained from patient's medical records, patients and the healthcare professional allocated to care for the admitted patient. We propose to obtain the following information; PIVC removal time, patient discharge time, routine replacement (72 h), intravenous (IV) therapy completion; device failure rationale; dislodgment (patient pulled it out, other patient factors such as confusion, diaphoresis), dressing failure, patient reported of pain, a peripheral venous access score (PVAS) recommending replacement, occlusion (inability to flush PIVC), infiltration/extravasation, suspected phlebitis/thrombophlebitis, suspected infection, hours in situ, numbers of patient hours in hospital, number of infusions or intravenous medicines prescribed, lost to follow-up due to hospital transfer, subsequent PIVC inserted, other vascular access device, venepuncture (daily bloods) and type of intravenous medicine and/or therapy see online supplementary appendix 2. Data will be mapped with the census reporting any reportable infection control episodes from PIVCs and with the hospitals peripherally inserted central venous catheter database. Attending clinicians will be made aware of any cases where an infection is suspected in the ward follow-up, so that a clinical assessment of the patient can occur.

We will initially pilot our CRF so that the research observers understand and accept any limitations that may occur to ensure a standardised data collection process. Inter-rater reliability between the research observers will be performed to assess for congruency.

### Planned statistical analysis

Univariate and multivariate binary logistic regression will be conducted to determine the predictor variables of first-time insertion success. Variables that are significant at a 5% significance level will be retained in the final model. Adjusted ORs and 95% CIs will be provided for this final model. A cross validation of the final model will be carried out by cross validating this model with a hold out sample. Predictive performance of the validated prognostic model will be assessed by measures of calibration and discrimination. Calibration refers to the agreement between the observed probability and predicted probability of experiencing a successful first-time cannulation. We will categorise the predicted probabilities into bins of equal width, and compare these to the actual proportions successful in each of these bins graphically by plotting observed proportions versus predicted probabilities. Measures of diagnostic performance, including sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratios for several probability thresholds will also be used to assess model performance. The models ability to distinguish between patients with a low probability and high probability of experiencing a successful cannulation (ie, discrimination) will be assessed using the C statistic. These can be compared to a predetermined cut-off score to identify patients more likely to have an unsuccessful attempt to allow for intervention in a practical clinical setting. Analyses for secondary aims will include Cox proportional hazards models and will include; Time zero (T0): intravenous insertion, Time of event (T1): PIVC failure, Time censored (T2): PIVC removal or transfer to another hospital. Kaplan-Meier curves will identify the survival time of ED inserted PIVC.

### Ethical considerations

A waiver of consent is granted for the inclusion of the patients receiving a PIVC under section 2.3.10 of the Australian national statement on ethical conduct in human research. Patients who have the capacity to understand will have a patient study flyer read to them, and therefore will have an option to decline the researchers observe them receiving a PIVC insertion. In adherence with the approved HREC conditions, clinicians will be consented by PJC or JR to allow the research team to collect observational data using the CRF; patient data will be obtained from the medical record. The clinician performing the insertion will provide informed consent for the duration of the study. The clinician performing the insertion will provide informed consent for the duration of the study. Each

potential participant will receive a study information guide and based on this will sign a consent form. No coercion whatsoever will take place. The study is registered with the Australian New Zealand Clinical Trials Registry ACTRN12615000588594.

## DISCUSSION

The majority of acute patients that require a hospital admission have a PIVC inserted in the ED. Unfortunately, adult first-time insertion success in emergency settings vary considerably in range from 18% to 86%.<sup>3 6 12 15 34</sup> A clinical prediction rule could conceivably reduce insertion failure and initiate a proactive attempt. When traditional attempts are exhausted, commonly employed rescue techniques to ensure PIVC insertion is through the use of ultrasound guidance. However, even this method is not without its faults and failure rates of first-time insertion success range from 42% to 87%.<sup>14 46</sup> Such results warrant further scrutiny as the inclusion or referral criteria for an ultrasound inserted PIVC is two or more failed traditional attempts.<sup>40 65 66</sup> Reducing failure with a clinical prediction rule would improve patient experience, reduce costs and improve ED processes and patient flow.

### Clinical prediction rule

Once the final predictive model has been validated, predicted probabilities of successful first-time cannulation for new patients can be calculated based on the regression parameter estimates from this model. Previously published PIVC insertion tools, rules and flow charts underpinned the development of our CRF<sup>15 67</sup> however none is specifically focused on ED insertion success and avoidance of premature device failure. An observational design is suggested by Adams and Leveson<sup>68</sup> to establish a clinical prediction rule. The results of this study will develop a clinical prediction rule to establish proactive PIVC insertion in the ED. This could, in theory, reduce inappropriate PIVC placement, preserve patient veins prior to any traditional attempts in favour of alternative vascular access methods such as vessel locating devices or the insertion of central venous access devices. Additionally, a clinical prediction score could direct the most appropriate trained clinician to insert a PIVC on patients at greatest risk of failure. The number of patients experiencing failed procedures, whether or not they are painful suggests that clinicians need guidance on how to improve the procedural aspects of PIVC insertion. One study identifies increases in patient pain when multiple insertions are compared to one insertion attempt.<sup>30</sup>

Equally as important as procedural success is the prevention of post insertion PIVC failure. The dwell time of PIVCs inserted with a traditional approach in the ED is largely unknown. The latest evidence of PIVC failure reports an excessive degree of post insertion failure through infiltration, occlusion, phlebitis and

dislodgement, thus contributing to economic waste.<sup>4 69</sup> Many of these failures may stem from suboptimal PIVC insertion procedures and result in further waste and pain for patients.

### Strengths and limitations of this study

The strengths of this proposed work lie in the development of our clinical CRF with international vascular access experts and senior ED clinicians with excellent content validity. One obvious limitation is that clinicians may positively change their practice behaviour in the presence of the researchers observing their performance. Alternatively it may have the opposite effect and may inadvertently add extra stress and cause performance anxiety and therefore performance bias. However, there is also another possibility, which is the potential of the observed clinicians being used to working in a busy ED environment where they are frequently observed by patients, visitors, a variety of healthcare professional and as a result not change practice behaviour at all. It is unlikely we will obtain consent from all clinicians employed in the ED for the duration of the study period. Owing to the few resources we have we can only use a convenience sample as opposed to a consecutive sample and this may be perceived as a bias.

### Conclusion

PIVCs are the most frequently inserted intravascular device in the ED. Successful insertion requires the combination of a small set of significant procedural steps for successful outcomes. Risk factors for PIVC failure have been identified in large prospective studies,<sup>4 70</sup> and prevention of PIVC insertion failure with the use of specialist teams is growing,<sup>17</sup> a greater focus needs to address how to implement this knowledge with observational data specific to the ED setting. Reducing the number of unsuccessful PIVC insertion attempts should become a priority for all EDs given the impact on patient outcomes, clinical outcomes and cost implications. This could improve the journey of patients with ED-inserted PIVCs and reduce the rates of insertion failure and post insertion failure. Reducing failed insertion attempts and improving insertion practice could lead to better staff and patient experiences, as well as greater hospital efficiency by using staff time and equipment effectively. This proposed study seeks to address this gap in our knowledge of how to reduce PIVC insertions, improve first-time insertion success and decrease premature failure of the PIVC. Additionally our study could promote appropriate decision-making, for example, the appropriateness of PIVC insertion in ED. This is a timely issue in light of the choosing wisely campaign in Australia, which attempts to reduce unnecessary waste in healthcare.

### Author affiliations

<sup>1</sup>Department of Emergency Medicine, Faculty of Medicine, Dentistry and Health Services, School of Primary, Aboriginal and Rural Health Care, The University of Western Australia, Nedlands, Perth, Western Australia, Australia

<sup>2</sup>Alliance for Vascular Access Teaching & Research (AVATAR) Group, Menzies Health Institute Queensland, Griffith University, Brisbane, Australia

<sup>3</sup>Sir Charles Gairdner Hospital, QEII Medical Centre, Nedlands, Perth, Western Australia, Australia

<sup>4</sup>Centre for Applied Statistics, University of Western Australia, Perth, Western Australia, Australia

<sup>5</sup>Medical Student, The University of Western Australia, Perth, Western Australia, Australia

**Twitter** Follow Peter Carr at @pcarriv, Claire Rickard at @avatar\_grp, James Rippey at @theSonoCave, Marie Cooke at @MLCooke2 and Niall Higgins at @NiallHiggins5

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