The VADER study protocol: Development of a clinical prediction rule to improve peripheral intravenous cannulae first attempt success in the Emergency Department and reduce post insertion failure rates.

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</table>
Title Page

The VADER study protocol: Development of a clinical prediction rule to improve peripheral intravenous cannulae first attempt success in the Emergency Department and reduce post insertion failure rates.


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Abstract

Introduction: Peripheral intravenous cannula (PIVC) insertion is one of the most common clinical interventions performed in emergency care worldwide. Improving the first time insertion success rate and dwell time of PIVCs inserted in the Emergency Department (ED) will prevent repeat needle insertions. This study proposes to determine the predictors of first time PIVC insertion success in ED. Furthermore, it will identify the rationale for removal of the ED-inserted PIVC in patients admitted to the hospital ward.

Methods and Analysis: A prospective observational cohort study of PIVC insertions in a patient population presenting to ED, with follow-up of subsequent admissions to a 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. We will use the medical record, and where possible the patient and appropriate health care professionals as our data collection source. Multivariate regression analyses will be used to identify factors associated with insertions success and PIVC failure.

Ethics and Dissemination: This study has ethical approval and is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12615000588594. 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. Our results will unravel a complexity of factors that contribute to unsuccessful insertion attempts with PIVC, these include patient and clinician factors as well as the products, technologies and infusates used. Reducing failed insertion attempts and improving peripheral intravenous cannulation practice could lead to better staff and patient experiences, as well as improving hospital efficiency.
Keywords: Clinical Prediction, Peripheral Intravenous Cannulation, Emergency Department, peripheral cannula insertion success, difficult intravenous access.
Background

According to our Emergency Department (ED) information system over 33,228 peripheral intravenous cannulas (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. Peripheral intravenous cannula (PIVC) insertion is a clinical procedure that is shared amongst many health care professionals, including: nursing, medical, paramedical, physician assistant, as well as technical and support staff. 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 (1). Factors identified as predictors of insertion failure, and premature device failure are published. However, none has focused on the patient's journey with PIVC from ED to hospital admission using traditional landmark techniques.

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 (2). 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 (3). 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 18-80% in both the paediatric and adult populations (4–11). The variability of first-time insertion success rates suggests that PIVC insertion is frequently difficult. Over 12 risk factors have been reported to predict insertion failure, these include: age, gender, race, BMI, history of chemotherapy, diabetes, dialysis, intravenous drug abuse (IVDA), swelling, sickle cell disease and recent hospitalization or ED visit within 90 days (12–25). It is reasonable to suggest that achieving greater first-time insertion success in ED and increasing the functional dwell time of inserted PIVCs could save money and impact positively on the patient experience. Improving the patient journey with better vascular access care should be a priority for hospital administrators (26).
Post insertion complications

In the adult population, primary literature from a large randomised controlled trial indicate that post-insertion 25% of PIVCs fail (27). This warrants attention, given the reasons as to why such failure occurs are so varied and complex. The causes of post-insertion failure include; infiltration or extravasation, occlusion, and dislodgement, which can lead to a reduced therapeutic effect of prescribed medicines. This results in an increased length of hospital stay, thus interrupting the patient care processes and clinical pathways (28). PIVC insertions in the ED have been reported as a cause of phlebitis and staphylococcus aureus bacteremia, leading to premature device failure. As a result, routine PIVC replacement after 24 hours is recommended for ED PIVCs in an attempt to reduce the risk of infection (29–31).

Studies in the ED are limited to insertion failure and risk factors for difficult insertion (32). Those that do identify dwell time during or post ED are limited to PIVC insertions using ultrasound-guided technology (17,20). Only 56% of PIVCs inserted with ultrasound guidance lasted greater than 96 hours. 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% (33). 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 (27,31,34–38). Post-insertion failure is multifactorial and is influenced by patient characteristics, device characteristics (such as closed system PIVCs, bordered dressing) and the hospital culture in managing these medical devices, for example the adoption of an aseptic technique (39).

The VADER study is a single-site prospective cohort study of patients requiring peripheral intravenous cannulation in the ED with a subsequent follow-up to identify the dwell time of such cannulae. The research aim of the VADER study is to; (i) identify risk factors for peripheral intravenous cannulation success, (ii) identify risk factors for reduced dwell time/failure, (iii) develop a clinical prediction score for PIVC insertion in the ED, and (iv) identify clinical practice standards in the ED and ward settings.

Methods/Research Design
Study Design:
A Prospective Observational Cohort Study.

Participants and setting:
Participants include ED patients who will require a peripheral intravenous cannula and ED clinicians who provide peripheral intravenous cannulation such as nurses and doctors. The proposed study will be undertaken in the ED of Sir Charles Gairdner Hospital (SCGH) Perth, Western Australia. The ED at SCGH provides a 24-hour emergency service for adult patients and is accredited with the Australasian College for Emergency Medicine for training. The department provides a full range of adult tertiary specialties.

Observations:
We will observe the PIVC insertion procedure into the venous anatomy of ED patients by healthcare professionals, including nurses and medical doctors. We will follow up any patients who are admitted and observe their PIVC until it is removed.

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 proposed study include patients that present to the ED and who subsequently require a PIVC. A convenience sampling method will be used. This is because there are occasions when the care of the patient must take priority over the investigation process. 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.

*Inclusion criteria*
All patients who require the insertion of a PIVC. Clinical staff who place PIVCs as part
of their role in the Emergency Department, and who consent to participate.

*Exclusion*
Patients who are under 18 years of age. Clinician participants who decline to provide
consent.

*Sample Size:*
Sample size calculations for this type of study are complex (40) 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%. 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 and colleagues (41) and Vittinghoff and McCulloch (42). This
number would also be sufficient to detect a difference of 5% between the self-reporting
success rate of our clinical survey and this proposed study.

*Content Validity Index:*
The current literature and clinical experts underpin our case report form (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
(2006) with 3 vascular access experts and have excellent content validity (43).

***************Insert Table 1***************

*Data collection method:*
The study will be conducted during a period when the investigator (PJC) or a small team
of research nurses n=2 are available. Data will be gathered from the proposed study
sample during the day, evening and night-time shifts. In adherence with ethical
guidelines, clinicians will be consented to allow the independent observer to collect data
using the CRF; patient data will be obtained from the medical record. A waiver of
consent has been granted for ED patients unable to consent, however, if appropriate, an
explanation of the study will be provided to a family member who may be present.
Similarly, patient participants who have the capacity to understand can decide to have
their procedure observed after hearing an explanation of the study. Each day an
independent observer trained in using the CRF will observe PIVC insertions in ED. Each
patient observation will be re-identified and documented in an Oracle database, which
we have specifically developed for this study.

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 generalizability. These variables are drawn from the literature, and an
itemised list evidenced to predict insertion failure and post-insertion failure is presented
in Table 1. 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.

Validated questions and variables we intend to observe and collect include; presenting
complaint, weight status, number of visible and/or palpable veins, the venous
international assessment scale (VIA), rationale for insertion, prediction that the PIVC
will be used for intravenous therapy, clinician experience, clinician pre-procedural
estimation of success, number of needle actions, additional products used such as add
on-devices, use of ultrasound and any observed blood spillage. 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. The
ward follow-up data to be collected will include the rationale for PIVC removal and any
factors based on the literature that influence failure. 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 hrs), intravenous (IV) therapy completion; device failure rationale; dislodgment (patient pulled it out, other patient factors such as confusion, diaphoresis), dressing failure, patient complained 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 IV medicines prescribed, lost to follow up due to hospital transfer, subsequent PIVC inserted, other vascular access device, venepuncture (daily bloods), and type of IV medicine and/or therapy. 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. Any cases where an infection is suspected in the ward follow up, attending clinicians will be made aware 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. See supplementary files 1 and 2 for our CRF and ward follow-up forms.

**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 odds ratios and 95% confidence intervals will be provided for this final model. Diagnostic measures will be calculated, and receiver operating characteristic (ROC) curves constructed, with the area under the curve (AUC) calculated to quantify the overall prognostic discrimination for first-time insertion success. Analyses for secondary aims will include Cox proportional hazards models and will include; Time zero (T0): IV 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:**

The Sir Charles Gairdner Group Human Research Ethics Committee EC00271 has approved the study. A waiver of consent is granted for the inclusion of the patients receiving a PIVC under section 2.3.10 of the National Statement on Ethical Conduct in
Human Research. 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 insertion failure in emergency settings ranges from 18%-79% (7,10,44,45). 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%-87% (14,46).

Clinical prediction rule:

Previously published PIVC insertion tools, rules and flow charts underpinned the development of our CRF (10,47). However none is specifically focused on ED insertion success and avoidance of premature device failure. The results of this study will develop a clinical prediction rule to establish proactive PIVC insertion in the ED. This could, in theory, preserve patient veins prior to any alternative vascular access methods such as vessel locating devices or the insertion of central venous access devices. Our proposed observational design suggested by Adams and Leveson (2012) to establish a clinical prediction rule (48). 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 (49).

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 (3,27). 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 case report form with international vascular access experts and senior ED clinicians with excellent content validity. However, one obvious limitation is that clinicians will augment 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. It is unlikely we will obtain consent from all clinicians employed in the ED for the duration of the study period.

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. While studies and commentary outline the rationale for and prevention of PIVC failure and independent risk factors for occlusion, phlebitis and accidental removal (27,37,50), a greater focus needs to be on how to implement this knowledge. 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, venepuncture as opposed to PIVC insertion. This is a timely issue in light of the choosing wisely campaign in Australia, which attempts to reduce unnecessary waste in healthcare.

List of abbreviations:
PIVC peripheral intravenous cannulation; ED Emergency Department; CRF Case Report Form
Competing interest: Peter Carr’s research is supported by Becton Dickinson (BD) contribution to the AVATAR group based at Griffith University. BD has no design or input into this study and will not have any role in the collection analysis or interpretation of the data, manuscript development or the influence the journal for publication of results. JR, MC, CB, CAB and NH have no competing interests to declare.

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Author Contributions: All authors have made substantial contributions to the development of this study. PJC conceived and designed this study with JR. CB and CAB are responsibility for statistical analysis. MC, NH, AF and CMR have revised and contributed to the development of this protocol.

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<table>
<thead>
<tr>
<th>Predictors for insertion failure</th>
<th>Predictors for post insertion failure</th>
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<tr>
<td>• Age (48),</td>
<td>• Cannula gauge and length (20,54,16)</td>
</tr>
<tr>
<td>• Gender (27)</td>
<td>• Site of placement (27,54)</td>
</tr>
<tr>
<td>• Patient Size (12–15,43,17,19,49,20,22,24,42)</td>
<td>• Any infection at baseline (27)</td>
</tr>
<tr>
<td>• VIA scale classification / difficult intravenous access scores (12,15,22,42,50,46)</td>
<td>• Antibiotics prescribed IV (27)</td>
</tr>
<tr>
<td>• Previous history of failed attempts and last hospital admission (46,51,7)</td>
<td>• Use of a J-loop or extension set (55),</td>
</tr>
<tr>
<td>• Diabetes (12,22,32)</td>
<td>• Securement device assessment (33)</td>
</tr>
<tr>
<td>• Intravenous drug use (12–15,43,17,20,22,32)</td>
<td>• Number and type of co-morbidities (54)</td>
</tr>
<tr>
<td>• Cancer diagnosis and last chemotherapy (22,7,52),</td>
<td>• Smoking (56)</td>
</tr>
<tr>
<td>• Patient anxiety (needle phobia) (34)</td>
<td></td>
</tr>
<tr>
<td>• Number of PIVC procedures performed (52,4,53,5)</td>
<td></td>
</tr>
<tr>
<td>• Ultrasound use or other vessel locating devices (17,19,41),</td>
<td></td>
</tr>
<tr>
<td>• Experience of the inserter (7,52)</td>
<td></td>
</tr>
</tbody>
</table>
**CASE REPORT FORM**

This form should contain no identifying patient information.

**PIVC = Peripheral Intravenous Cannulation**

### Patient Demeanour:

- [ ] Calm and Co-operative
- [ ] Relaxed
- [x] Aggressive
- [ ] Confused
- [ ] Weak and unwell
- [ ] Shaky/Nervous
- [x] Patient is vomiting
- [x] Patient can eat and drink
- [ ] Patient is fasting
- [ ] Patient is nauseous

### Patient is vomiting
- [ ] Patient can eat and drink

### CLINICIAN DETAILS

- Role in ED: Nurse
- [ ] Med Student
- [ ] Intern
- [ ] RMO
- [ ] Registrar
- [ ] Consultant
- US Consultant
- Experience (successful cannulation): <10
- [ ] 11-50
- [ ] 51-100
- [ ] 101-300
- [ ] 301-600
- [ ] 601-1000
- [x] >1000

### CONFIDENCE AND PREDICTION FOR THIS PIVC:

- How confident are you that the first attempt will be successful? (0-100%)  
  __________

### Primary rationale for PIVC insertion?

- [ ] Blood Samples
- [ ] Possible IVF/Med/Antibiotics
- [ ] Definite IVF/Med/Antibiotics
- [ ] Possible Contrast Scan
- [ ] Definitive Contrast Scan
- [ ] Blood Products
- [ ] Code: Black Sedation
- [ ] Patient Unstable/Requiring Resuscitation
- [ ] Possible Clinical Deterioration

### How likely is it that the cannula will be used for intravenous therapy? (0-100%)  
  __________

### Too early to predict / Until no longer required

- [ ] 4 hrs / 8 hrs
- [ ] 12 hrs
- [ ] 24 hrs / 36 hrs
- [ ] 48 hrs
- [ ] 60 hrs / 72 hrs
- [ ] 84 hrs / 96 hrs (4d)
- [ ] 120 hrs (5d)
- [ ] 144 hrs (6d)
- [ ] 168 hrs (7d)
- [ ] 192 hrs (8d)
- [ ] >200 hrs

### How long do you predict IV therapy will be required?  
  _________

### How long do you predict the PIVC will last?  
  _________

### ARM & SKIN CONDITION

- [ ] Healthy Skin appearance
- Tissue Paper appearance
- [ ] Tough Skin
- [ ] Bruised Skin from Previous PIVC
- [ ] Lower Arm Oedema

### Skin Temperature:

- [ ] Cold
- [ ] Normal
- [ ] Warm
- [ ] Daphoretic

### Vein Quality:

- [ ] Straight
- [ ] Mobile/Wobbly
- [ ] Poor
- [ ] Short Identifiable Veins
- [ ] None Visible

### Hair:

- [ ] None
- [ ] Sparse
- [ ] Moderate
- [ ] Thick

### ASEPTIC TECHNIQUE AND INFECTION PREVENTION PRACTICE

- Size cannula: 14g (orange)
- [ ] 16g (grey)
- [ ] 18g (green)
- [ ] 20g (pink)
- [ ] 22g (blue)
- [ ] 24g (yellow)
- [ ] 26g (purple)

### Re-palpation of insertion site after asepsis applied?

- [ ] Yes
- [ ] No

### Hand protection:

- [ ] No gloves
- [ ] Clean gloves
- [ ] Sterile gloves

### Notes/observations:

### BLOOD SAMPLING

- If blood samples were obtained, what method was used?  
  N/A
- [ ] Unsuccessful draw

### Syringe and hub
- Syringe and NFC
- Syringe and J-loop

### Syringe size =  
  _________

### What method was used to transfer blood?

- [ ] Vacutainer
- [ ] Needle
- [ ] Other

### What method was used to take VBG sample?

- N/A
- [ ] Transferred from syringe via needle
- [ ] From hub/NFC/J-loop

### Was order of draw as per policy?  
  Blue (if required) → Green → Purple
- [ ] Yes
- [ ] No

### Were blood cultures obtained?  
  Yes
- [ ] No

---

**Case Report Number**

**Triage Category**

**Chief Complaint**

**Age of Patient**

**Gender of Patient**: Male
- [ ] Female

**Date and Time of Review**: / / 2015  ____:____ am/pm

---

**Notes/observations:**

- Were the key parts protected at all times?  
  Yes
- [ ] No

- If No, what items were compromised?  
  Cannula
- NFC/Bung
- Flush
- Dressing
- Patient’s Skin
- Gloves
- Sterile field

- Hair trimmed at site of cannula insertion?  
  Yes
- [ ] No

- Hair trimmed at area for adhesive?  
  Yes
- [ ] No

---

**VADER Study Data Collection Form V2, 23 June 2015**
VEIN ASSESSMENT BY CLINICIAN

How many reasonable veins are there to cannulate at each site?

RIGHT ARM: ACF____ Forearm____ Hand____
LEFT ARM: ACF____ Forearm____ Hand____
☐ Not performed on this side

How many visible veins?
RIGHT: _______ LEFT: _______

How many palpable veins?
RIGHT: _______ LEFT: _______

Does the patient display signs of intravascular depletion? ☐ Yes ☐ No

VEIN ASSESSMENT BY RESEARCHER

VIA grade and the number of visible veins (VV) Grade I & II = Good, III = Fair, IV & V = Poor
I (6 VV) II (4 VV) III (3 VV) IV (1 VV) V (0 VV)

Circle the location of visible veins. Number the location of the selected vein (i.e. number attempts 1, 2, 3, etc.)

RIGHT ARM: Volar Aspect Dorsum Aspect
LEFT ARM: Volar Aspect Dorsum Aspect

PROCEDURE AND TIMING

Location of tourniquet: ______________ Location of tourniquet: ______________ Location of tourniquet: ______________
If ACF, arm is: ☐ flexed ☐ straight If ACF, arm is: ☐ flexed ☐ straight If ACF, arm is: ☐ flexed ☐ straight

Number items according to procedure order, noting time of event:

☐ Tourniquet on __________ ☐ Tourniquet on __________ ☐ Tourniquet on __________
☐ Asepsis __________ ☐ Asepsis __________ ☐ Asepsis __________
☐ Insertion attempt __________ ☐ Insertion attempt __________ ☐ Insertion attempt __________
☐ Flashback in cannula __________ ☐ Flashback in cannula __________ ☐ Flashback in cannula __________
☐ Blood aspirated __________ ☐ Blood aspirated __________ ☐ Blood aspirated __________
☐ Blood transferred __________ ☐ Blood transferred __________ ☐ Blood transferred __________
☐ Tourniquet off __________ ☐ Tourniquet off __________ ☐ Tourniquet off __________
☐ Flushing __________ ☐ Flushing __________ ☐ Flushing __________
☐ Dressing __________ ☐ Dressing __________ ☐ Dressing __________

Total procedure time __________ Total procedure time __________ Total procedure time __________
Time of insertion __________ Time of insertion __________ Time of insertion __________

Needle motions: ______________ Needle motions: ______________ Needle motions: ______________
☐ Unsuccessful / Successful ☐ Unsuccessful / Successful ☐ Unsuccessful / Successful
### RESEARCHER'S OBSERVATIONS OF CLINICAL PROCEDURE

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the patient's blood exposed on their skin?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did blood soil any gauze/sterile field?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Did blood soil the patient's clothes?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Did blood contaminate the clinician's gloves?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Did blood soil the bed linen?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Did blood soil the floor?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

### CONNECTORS AND DRESSING

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was a J-loop or extension set applied?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the clamp on or off?</td>
<td>Off</td>
<td></td>
</tr>
<tr>
<td>Is it flushed and clear of blood?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Is the dressing clean and intact?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Is the dressing dated?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other vascular access device used: PICC CVC Midline Arterial Catheter for upper arm insertion</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### POST INSERTION

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the first attempt successful?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>If Not, was any rationale given to the patient as to why?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Patient too unwell/unable to comprehend</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How many attempts were required?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was anyone else asked for help?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>How many people attempted to cannulate this patient?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who (level)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was ultrasound used?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>If Yes, use separate data collection tool.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### DOCUMENTATION

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the procedure documented in EDIS?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### MEDICATIONS ADMINISTERED IN ED

| Fluids: N/Saline-Lactate, Colloid, Blood products |     |
| Meds: Antibiotics, Steroids, Analgesia, Anti-pyretic, Cardiac drugs, Other with CRF below |     |

Was the patient admitted? Yes No

If No, the patient is OFF trial.

If Yes, add patient ward destination to corresponding URM and Case Report Number in SCGH W drive VADER Case Report file. Continue with CRF Ward Follow Up.
<table>
<thead>
<tr>
<th>PATIENT DETAILS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BMI:</strong> Height</td>
</tr>
<tr>
<td>Patient Size: ☐ Emaciated ☐ Underweight ☐ Normal ☐ Overweight ☐ Obese</td>
</tr>
<tr>
<td>Skin Shade: ☐ ☐ ☐ ☐ ☐ ☐</td>
</tr>
<tr>
<td>Chronic Condition: ☐ Obesity ☐ Diabetes T1 ☐ Diabetes T2 ☐ Heart Disease ☐ AF ☐ COPD ☐ Renal Failure</td>
</tr>
<tr>
<td>Smoking Status: ☐ Yes ☐ No ☐ Ex Smoker ☐ Unable to answer</td>
</tr>
<tr>
<td>Observations: BP <em><strong><strong><strong>/</strong></strong></strong></em>_ HR __________ Temp __________ RR __________</td>
</tr>
<tr>
<td>Recent Hospitalisations: ☐ &lt;1 month ☐ 3 months ☐ 6 months ☐ 12 months</td>
</tr>
<tr>
<td>Access Limitations: ☐ CVA ☐ Mastectomy ☐ AV fistula ☐ Trauma ☐ RA ☐ IVDU ☐ Needle phobia</td>
</tr>
<tr>
<td>Handedness: ☐ Left ☐ Right ☐ Ambidextrous</td>
</tr>
<tr>
<td>Site Preference: ☐ Hand ☐ Wrist ☐ Lower Forearm ☐ Mid Forearm ☐ Upper Forearm ☐ ACF ☐ Upper Arm</td>
</tr>
<tr>
<td>Food ☐ Internal Jugular ☐ No Preference</td>
</tr>
<tr>
<td>☐ Left ☐ Right ☐ No Preference</td>
</tr>
</tbody>
</table>

**Ask patient:**

- On a scale of 0-10, how satisfied were you with this cannula? ________
- How many attempts do you think is reasonable? ________

**EXTERNAL DIAMETER OF VEIN MEASUREMENT (Using a 1cm ruler)**

What was the external diameter of the target vein?

1. 1st attempt __________
2. 2nd attempt __________
3. 3rd attempt __________

If unable to obtain measurement, the reason was:

☐ Unable to interfere
☐ None visible
☐ Other ________________
# WARD FOLLOW UP

<table>
<thead>
<tr>
<th>Case Report Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ward</td>
</tr>
<tr>
<td>Room Number</td>
</tr>
<tr>
<td>Day in Hospital</td>
</tr>
<tr>
<td>Specialty</td>
</tr>
<tr>
<td>Gender of Patient</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date and Time of Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date: ______________     Time: ____ : _____ am/pm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site &amp; Type of infection:</td>
</tr>
</tbody>
</table>

| ED PIVC Remains? | Yes [ ], No [ ] |

---

**IF ED CANNULA IS NO LONGER PRESENT PLEASE COMPLETE.**

**ED CANNULA NO LONGER INTRAVENOUS BECAUSE:**

- PIVC infiltration
- Occlusion, blocked not flushing
- Pain
- PVAS > 2
- Swelling
- No longer required
- Patient pulled it out
- Needed to ask patient to get answer
- Unable to identify from health records
- Needed to ask nurse/Dr reason for removal

Please ask patient the following question:

- What has been your experience with this IV catheter? 0 = Worst possible 10 = Best possible ________
- Patient cannot verbalise/understand
- Patient discharged from ward

| Time of PIVC Removal: | ______ : _____ am/pm |

| Evidence of other VAD | Type/Location and Size: | |

---

**IF ED CANNULA REMAINS, PLEASE COMPLETE**

**Filming**

- Picture taken? Yes [ ], No [ ]
- Video taken? Yes [ ], No [ ]

**IV Dressing & Vascular Access Assessment**

- Borderless transparent polyurethane dressing
- Window transparent polyurethane dressing
- Sterile gauze and tape dressing
- Clean, dry and intact
- Loose or lifting edges
- Other

- Sterile tape strips around PIVC
- Non-sterile tape around PIVC
- Non-sterile tape around administration set
- Bandage
- Tubular net

**IV Connectors (check all that apply)**

- J-Loop Clamp On [ ], Off [ ]
- Stopcock/3-way tap [ ]
- Needleless connector (NC) [ ]
- IV end cap
- Direct connection to IV administration set
- Other [ ]

---

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VADER Study Ward Follow Up Form, 22 June 2015
### PIVC Site Assessment

<table>
<thead>
<tr>
<th>No clinical symptoms</th>
<th>Palpable hard vein cord beyond IV tip</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain/tenderness on palpation</td>
<td>Streak/red line along vein</td>
</tr>
<tr>
<td>Erythema/redness &gt;1cm from insertion site</td>
<td>Induration/hardness of tissues &gt; 1 cm</td>
</tr>
<tr>
<td>Swelling &gt;1cm from insertion site</td>
<td>Leaking PIVC</td>
</tr>
<tr>
<td>Purulence</td>
<td>Extravasation</td>
</tr>
<tr>
<td>Itch / rash under dressing</td>
<td>Infiltration</td>
</tr>
<tr>
<td>Blistering/skin tears under dressing</td>
<td>Blood in NC</td>
</tr>
<tr>
<td>Partial blood around PIVC</td>
<td>Blood in J-loop</td>
</tr>
<tr>
<td>Partial/complete dislodgement of PIVC</td>
<td>Other</td>
</tr>
</tbody>
</table>

### PVAS

- Present and Signed for today: Yes [ ] No [ ]
  - Signed for previous day: Yes [ ] No [ ]
- Date: _______________ AM [ ] PM [ ] Night [ ]
  - PVAS Score for today: _______________
  - PVAS Score for previous day: _______________

### Flushing

- N/Saline Flush prescribed PRN [ ]
- N/Saline Flush prescribed every: ___________
- No N/Saline Flush prescribed [ ]
- Patient or Staff-Reported Flush [ ]

### Type of Infusion

- Continuous infusion [ ]
- Intermittent infusion [ ]
- Bolus injection [ ]
- Combination of intermittent and bolus [ ]

### IV Fluids Today (check all that apply)

- Crystalloid List: ____________________________ [ ]
- Colloid or blood products [ ]
- Parenteral nutrition [ ]
- Not documented [ ]
- Chart unavailable [ ]

### IV Medications Today – via PIVC (check all that apply)

- Electrolytes [ ]
- Antibiotics List: ____________________________ [ ]
- Analgesia/PCA [ ]
- Sedation [ ]
- Anti-emetic [ ]
- Insulin [ ]
- Gastric protection [ ]
- Anti-convulsant [ ]
- Chemotherapy [ ]
- None [ ]
- Other [ ]

### Other

- CTPA (Possible/Definite): [ ]
- Acute deterioration [ ]

### Blood Sampling

- Venepuncture (steel needle): [ ]
  - Date/Time: ____________________________
- Bloods from PIVC [ ]
  - Date/Time: ____________________________

### Patient Experience

What has been your experience with this IV catheter? 0 = Worst possible 10 = Best possible ________
- Patient cannot verbalise/understand [ ]
- Patient gone off ward [ ]
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

<table>
<thead>
<tr>
<th>Journal:</th>
<th>BMJ Open</th>
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<tbody>
<tr>
<td>Manuscript ID</td>
<td>bmjopen-2015-009196.R1</td>
</tr>
<tr>
<td>Article Type:</td>
<td>Protocol</td>
</tr>
<tr>
<td>Date Submitted by the Author:</td>
<td>20-Nov-2015</td>
</tr>
<tr>
<td>Complete List of Authors:</td>
<td>Carr, Peter; The University of Western Australia, Emergency Medicine Rippey, James; The University of Western Australia, Emergency Medicine Cooke, Marie; Griffith University, NHMRC Centre for Research Excellence in Nursing Interventions, Menzies Health Institute Queensland, Griffith University, Brisbane, Australia Bharat, Chrianna; The University of Western Australia, Statistics Murray, Kevin; University of Western Australia, Centre for Applied Statistics Higgins, Niall; Griffith University, NHMRC Centre for Research Excellence in Nursing Interventions, Menzies Health Institute Queensland, Griffith University, Brisbane, Australia Foale, Aileen; The University of Western Australia, Medicine Rickard, Claire; Griffith University, NHMRC Centre for Research Excellence in Nursing Interventions, Menzies Health Institute Queensland, Griffith University, Brisbane, Australia</td>
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<td>Primary Subject Heading:</td>
<td>Emergency medicine</td>
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<td>Secondary Subject Heading:</td>
<td>Evidence based practice</td>
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<tr>
<td>Keywords:</td>
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</table>
Title Page

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 1,2,4,5* James Rippey 1, 5, 6, 7 Marie L. Cooke 4, 5, Chrianna Bharat 3, 6, Kevin Murray 3, 6, Niall S. Higgins 5, Aileen Foale 7, Claire M. Rickard 4, 5

1 Emergency Medicine, School of Primary, Aboriginal and Rural Health Care, Faculty of Medicine, Dentistry and Health Services, University of Western Australia, Nedlands, Australia.
2 Fiona Stanley Hospital, Murdoch, Perth, Western Australia.
3 Sir Charles Gairdner Hospital, QEII Medical Centre, Nedlands, Perth, Western Australia.
4 NHMRC Centre for Research Excellence in Nursing Interventions, Menzies Health Institute Queensland, Griffith University, Brisbane, Australia.
5 Alliance for Vascular Access Teaching & Research (AVATAR) Group, Menzies Health Institute Queensland, Griffith University, Brisbane, Australia.
6 Centre for Applied Statistics, University of Western Australia, Perth, Western Australia.
7 Medical Student, The University of Western Australia, Perth, Western Australia.

*corresponding author
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 proposes to determine the predictors of first time PIVC insertion success in the 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 a prospective 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 predication rule.

Ethics and Dissemination: This study has ethical approval and is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12615000588594. 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.
**Keywords:** Clinical Prediction, Peripheral Intravenous Cannulation, Emergency Department, Peripheral Cannula Insertion success, Difficult Intravenous Access, Device Failure.
Background

Peripheral intravenous cannula (PIVC) insertion is a vascular access clinical procedure that is shared amongst 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; 84% of patients had a vascular access device of some type, with 80% of these PIVCs (1). Factors identified as predictors of insertion failure in the Emergency Department (2,3) and premature device failure in admitted patients are published separately (4). However, notwithstanding literature concerning PIVCs inserted in ED using ultrasound technology (5), 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 (6). 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 72hrs 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, skin punctures and inappropriate insertions should become a priority for clinical science (7). 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 (8). 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 18-86% in both the paediatric and adult populations.
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 (17). Specific patient factors are reported to contribute to insertion failure such as: age (18); patient size (3,5,6,19–28); limited and suitable veins contributing to a difficult intravenous access (3,19,22,27,29,30); previous history of failed attempts and recent hospital admission (12,30,31); diabetes (2,19,27); intravenous drug use (2,5,19–23,26,27); cancer diagnosis and recent chemotherapy (12,27,32); and patient anxiety (needle phobia) (33). Additionally technologies purported to enhance insertion success such as ultrasound or other vessel locating devices report first time insertion success that ranges from 18%-87% (5,21,24,34) suggesting re-evaluation is required. However, clinician factors such as experience of the inserter and number of PIVC procedures performed (6,9,10,12,32,35) 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/skin shade, extremes of BMI, limited or small veins, history of chemotherapy, diabetes, dialysis, intravenous drug abuse (IVDA), swelling, sickle cell disease and recent hospitalization or an ED visit within 90 days (2,3,5,6,19–24,26–28,36–41). It is reasonable to suggest that achieving greater first-time insertion success in ED and increasing the functional dwell time of inserted PIVCs could save money and impact positively on the patient experience. Improving the patient journey with better vascular access care should be a priority for hospital administrators (42).

Post insertion complications

In the adult population, secondary data analysis from a large randomised controlled trial indicate that post-insertion 25% of PIVCs fail (4). 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 (4). Post-insertion failure is complex multifactorial and is influenced by patient characteristics, such as: age (4,18); gender (4); any infection at baseline (4); number and type of co-morbidities (43); smoking (44); and device characteristics such as: PIVC gauge and length (26,43); site of placement (4,43); intravenous antibiotics prescribed (4); not using a J-loop (extension set) or closed system catheters (45,46); securement
device failure (47) and the hospital culture in managing these medical devices, for example the adoption of an aseptic technique (48).

PIVC insertions in the ED have been reported as a cause of phlebitis and staphylococcus aureus bacteremia, leading to premature device failure. As a result, routine PIVC replacement after 24 hours is recommended for ED PIVCs in an attempt to reduce the risk of infection (49–51). Studies in the ED are limited to insertion failure and risk factors for difficult insertion (2). Those that do identify dwell time during or post ED are limited to PIVC insertions using ultrasound-guided technology (5,26) and 47% of PIVCs inserted with ultrasound guidance failing within 24 hours (5). 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 (47). 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 (4,51,33,52–55). Such failures are unacceptable. These contribute to increased length of hospital stay, thus interrupting the patient care processes and clinical pathways (56).

**Study Design:** The VADER study will use a prospective observational cohort design using two Emergency Departments. This study will focus on the insertion of peripheral intravenous cannulae in patients in the ED with a subsequent follow-up of those patients admitted to the hospitals to identify the dwell time of such cannulae. The research aim of the VADER study is to; (i) identify risk factors for peripheral intravenous cannulation success, (ii) identify risk factors for reduced dwell time/failure, and (iii) 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-hour 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 Emergency Department (ED) of SCGH information system over 33,228 peripheral intravenous cannulas (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 one hundred 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 proposed study will 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. 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 Emergency Department, 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 (57) 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% (6). 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 and colleagues (58) and Vittinghoff and McCulloch (59). Furthermore, this would more than adequately satisfy the minimum recommendation of Steyerberg (60) 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 - Dec 2015. We will initially collect data during business hours and late evening and attempt to gather night duty procedures as our study progresses in an attempt to reduce selection bias. 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, all of which have contributed to the 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 (2006) with both ED clinicians and
vascular access experts resulting in excellent content validity (61). The developed CRF was also used in our self-report study (6) 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 generalizability. 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 (62) and vein assessment quality (6,29,63) used in previous studies. Insertion success will be defined by venous blood return and subsequent flush of 5-10mls of normal saline 0.9% into the inserted PIVC without evidence of complication such as infiltration and/or pain.

Validated questions and variables we intend to observe and collect in relation to the PIVC insertion include: presenting complaint; weight status; number of visible and/or palpable veins; vein size (small 1mm, medium 2-3mm or large >4mm); the venous international assessment (VIA) scale; skin type/temperature (we will use a similar definitions for skin assessment quality (62) and vein assessment quality (6,29,63) 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. 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 (64). 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 (72hrs); intravenous (IV) therapy completion; device failure rationale - dislodgment (patient pulled it out, other patient factors such as confusion), dressing failure, patient complaint of pain, a peripheral venous assessment 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 IV medicines prescribed; those lost to follow up due to hospital transfer; subsequent PIVC inserted; other vascular access device inserted; venepuncture (daily bloods); and, type of IV medicine and/or therapy, see appendix 2.

Data will be mapped with the census and reporting of 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 odds ratios and 95% confidence intervals 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 (i.e. discrimination) will be assessed using the C statistic. 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. These can be compared to a pre-determined 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): IV 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:**
The Sir Charles Gairdner Group, Human Research Ethics Committee (HREC) has approved the study (HREC reference SCGH 2014-138) and both SCGH and FSH authorised site approval. A waiver of consent has been 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. Each potential clinician 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%-86% (3,6,12,15,34). 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 insertion failure is all too common with rates of first-time insertion success ranging from 42%-87% (21,23). Such results warrant further scrutiny as the inclusion or
referral criteria for an ultrasound inserted PIVC is two or more failed traditional
attempts (40, 65, 66). Reducing failure with a clinical prediction rule would improve
patient experience, reduce costs, and improve ED processes and patient flow.

**Clinical prediction rule:**
Previously published PIVC insertion tools, rules and flow charts underpinned the
development of our CRF (15, 67). However none is specifically focused on ED insertion
success and avoidance of premature device failure. The results of this study will develop
a clinical prediction rule to establish proactive PIVC decisions 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 ultrasound-
guided placement, and initiate the insertion of other vascular access devices. Our proposed
observational design follows suggestions by Adams and Leveson (2012) to establish a
clinical prediction rule (68). 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 (30).

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 (4, 69). 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 case report
form 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 health care 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. Due 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 (4,70), and prevention of PIVC insertion failure with the use of specialist teams is growing (17), 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 and post insertion failure 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, best practice standards when performing PIVC insertion in ED and promote venepuncture as opposed to PIVC insertion for blood sampling. The latter is a timely issue in light of the choosing wisely campaign in Australia, which attempts to reduce unnecessary waste in healthcare.

List of abbreviations:
PIVC peripheral intravenous cannulation; ED Emergency Department; CRF Case Report Form

Competing interest: Peter Carr’s (PJC) research is supported by a Becton Dickinson (BD) contribution to the AVATAR group based at Griffith University. BD has no design
or input into this study and will not have any role in the collection analysis or
interpretation of the data, manuscript development or the influence the journal for
publication of our results.

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and Teleflex. None of these companies had any involvement with this study.

Author Contributions: All authors have made substantial contributions to the
development of this study. PJC conceived this study with JR and designed it with NH,
MC, CMR. CB and KM contributed to the statistical plan and are responsible for
statistical analysis. PJC, JR, MC, CB, KM, NH, AF and CMR have revised and
contributed to the development of this protocol and CRFs.

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Reference List


11. Jacobson AF. Intradermal normal saline solution, self-selected music, and insertion difficulty effects on intravenous insertion pain. *Heart Lung*


55. Stevens RJG, Mahadevan V, Moss ALH. Injury to the lateral cutaneous nerve of


67. Mbamalu D, Banerjee A. Methods of obtaining peripheral venous access in


The VADER Study, Case Report Form:
This form should contain no identifying patient information.

### Patient Demeanour
- Calm and co-operative: [ ] Yes [ ] No
- Confused: [ ] Yes [ ] No
- Unable to eat and drink: [ ] Yes [ ] No

### Gender of Patient
- Male: [ ] Yes
- Female: [ ] Yes

### Age of Patient

### Date and Time of Review
[ ] Male [ ] Female

### Triage Category

### Chief Complaint

### Age of Patient
- Date and Time of Review: [ ] Male [ ] Female

### Clinician Details
- Role in ED:
  - Nurse
  - Med Student
  - Intern
  - RMO
  - Registrar
  - Consultant
  - US Consultant
  - Phlebotomist
  - Paramedic

### Experience
- Successful cannulation:
  - <10
  - 11-50
  - 51-100
  - 101-300
  - 301-600
  - 601-1000
  - >1000

### Confidence and Prediction for this PIVC
- How confident are you that the first attempt will be successful? (0-100%) [ ] Male [ ] Female

### Primary rationale for PIVC insertion?
- Blood Samples
- Possible IVF/Med/Antibiotics
- Definite IVF/Med/Antibiotics
- Possible Contrast Scan
- Definite Contrast Scan
- Blood Products
- Code Black Sedation
- Patient Unstable / Requiring Resuscitation

### How likely is it that the cannula will be used for intravenous therapy? (0-100%)

### Too early to predict / Until no longer required
- 4 hrs / 8 hrs / 12 hrs / 24 hrs / 36 hrs / 48 hrs / 60 hrs / 72 hrs / 84 hrs / 96 hrs (4d) / 120 hrs (5d) / 144 hrs (6d) / 168 hrs (7d) / 192 hrs (8d) / >200 hours

### Arm, Skin, Vein Condition
- Healthy skin appearance - hydrated (Good)
- Midly hydrated intact (Fair)
- Tissue paper / skin turgor paper (Poor)
- Tough skin
- Bruised skin from previous PIVC

### Skin Temperature
- Cold
- Normal
- Warm
- Diaphoretic

### Vein Quality
- Straight
- Mobile/Wobbly
- Tortuous
- Short Identifiable Veins
- None Visible

### Hair
- None
- Sparse
- Moderate
- Thick

### Aseptic Technique and Infection Prevention Practice
- Size cannula:
  - 14g (orange)
  - 16g (grey)
  - 18g (green)
  - 20g (pink)
  - 22g (blue)
  - 24g (yellow)
  - 26g (purple)
- Length / type of cannula
- Hand protection:
  - No gloves
  - Clean gloves
  - Sterile gloves
- Type of asepsis:
  - Swabstick (alcohol + chlorhexidine)
  - Alcowipe (alcohol only)
  - Chlorhexidine solution
- Handwashing prior to set up: [ ] Yes [ ] No
- Re-palpation of insertion site after asepsis applied?: [ ] Yes [ ] No
- Were the key parts protected at all times?: [ ] Yes [ ] No
- If No, what items were compromised? (choose below)
  - Cannula
  - NFC/Bung
  - Flush
  - Dressing
  - Patient's Skin
  - Gloves
  - Sterile field

### Hair trimmed at site of cannula insertion?: [ ] Yes [ ] No
- Hair trimmed at area for adhesive?: [ ] Yes [ ] No [ ] N/A
Vein Assessment by Clinician and Researcher

Is there a pre-hospital PIVC in place? □ Yes □ No

VIA grade and the number of visible veins (VV) Grade I & II = Good, III = Fair, IV & V = Poor
□ I (6 VV) □ II (4 VV) □ III (3 VV) □ IV (1 VV) □ V (0 VV) □ Both arms □ Only one arm assessed

Target Vein Size □ Small (< 1mm) □ Medium (2-3mm) □ Large (≥ 4mm) Number of reasonable veins to cannulate

Target vein visible without Tourniquet? □ Yes □ No

Place a dot where the insertion attempt occurred.

Procedure and Timing

Location of the tourniquet _______________________________________________________________________________

If ACF, arm is □ flexed □ straight

Total procedure time __:__ Time of insertion __:__ am/pm Needle redirections ___

Procedural Flow: Tourniquet __, Asepsis __, Insertion Attempt __, Flashback __, Blood Aspirated __, ***Blood Transfer __, Tourniquet off __, Flushing __, Dressing application __ (items will be numbered at the stage they occurred)

Were any additional methods used to encourage vasodilation? □ Yes □ No

Skin Slapping □ Skin Rubbing □ Warm Compress □ Lights □ Other ________________ □ None

Researcher’s Observations of Clinical Procedure

Was the patient’s blood exposed on their skin? □ Yes □ No Did blood soil gauze /’bluey’? □ Yes □ No

Did blood soil the patient’s clothes? □ Yes □ No Did blood contaminate the clinician’s gloves? □ Yes □ No

Did blood soil the bed linen? □ Yes □ No Did blood soil the floor? □ Yes □ No

Connectors and Dressing

What connectors were used? □ J-loop □ NFC/bung □ Other ________________

If a J-loop was connected; Is the clamp on or off? □ Yes □ No

If a NFC/bung was connected; Is it flushed and clear of blood? □ Yes □ No

Is it flushed and clear of blood? □ Yes □ No

Is the dressing clean and free of any blood spillage? □ Yes □ No

Is the dressing dated? □ Yes □ No

Are there loose or lifting edges □ Yes □ No Additional tape securement □ Yes □ No If yes what _______

Other vascular access device used □ PICC □ CVC □ Midline □ IO

***We will gather observations that concern blood sampling methods, such as the syringe or vacutainer method, and if these are attached to the cannula hub, a connector, or a J-loop. If the transfer of blood is by syringe we will record if a needle or vacutainer is used or if an open cap method is used. Additionally the order of draw/transfer of blood will be recorded. We will also observe blood culture practice; including the order and if the bottles are swabbed with antiseptic.

This will data will be linked with the Aspetic Technique and Infection Prevention observations and form a separate study.
Post Insertion

Was the first attempt successful? □ Yes □ No

How many attempts were required? ______________________

Was anyone else asked for help? □ Yes □ No  Who (level)?

How many people attempted to cannulate this patient? __________________

Was ultrasound used? □ Yes □ No  If Yes, see ultrasound data collection form.

Medications Administered in ED

Frequency and type of medication administered in ED?

Fluids □ N/Saline-Lactate □ Colloid □ Blood products □ None

Meds □ Antibiotics □ Steroids □ Analgesia □ Anti-pyretic □ Cardiac drugs □ Other with CRF below

Was the patient admitted? □ Yes □ No

If No, the patient is OFF trial.  If Yes, continue with CRF Ward Follow Up.
### Patient Details

**BMI**

- [] Emaciated
- [] Underweight
- [] Normal
- [] Overweight
- [] Obese

**Height**

- [ ] Unable to record

**Weight**

- [ ] Unable to record

**Patient Size**

- [ ] Emaciated
- [ ] Underweight
- [ ] Normal
- [ ] Overweight
- [ ] Obese

**Skin Shade**

- [ ] [ ] [ ] [ ] [ ]

**Chronic Condition**

- [ ] Obesity
- [ ] Diabetes T1
- [ ] Diabetes T2
- [ ] Heart Disease
- [ ] AF
- [ ] COPD
- [ ] Renal Failure
- [ ] Other
- [ ] None

**Smoking Status**

- [ ] Yes
- [ ] No
- [ ] Ex-Smoker
- [ ] Unable to answer

**Observations**

- BP _______ / _______
- HR _______
- Temp _______
- RR _______
- [ ] Not performed

**Recent Hospitalisations**

- [ ] <1 month
- [ ] 3 months
- [ ] 6 months
- [ ] 12 months
- [ ] N/A
- [ ] With device
- [ ] PIVC
- [ ] PICC
- [ ] Port-a-Cath
- [ ] Unable to retrieve data
- [ ] Unable to identify

**Access Limitations**

- [ ] CVA
- [ ] Mastectomy
- [ ] AV fistula
- [ ] Trauma
- [ ] RA
- [ ] IVDU
- [ ] Needle phobia
- [ ] Recent chemo
- [ ] Unable to retrieve data
- [ ] Other
- [ ] None

**Handedness**

- [ ] Left
- [ ] Right
- [ ] Ambidextrous
- [ ] Patient too unwell / unable to comprehend

**Site Preference**

- [ ] Hand
- [ ] Wrist
- [ ] Lower Forearm
- [ ] Mid Forearm
- [ ] Upper Forearm
- [ ] ACF
- [ ] Upper Arm
- [ ] Foot
- [ ] External Jugular
- [ ] No Preference
- [ ] Unable to interfere
- [ ] Left
- [ ] Right
- [ ] No Preference

**Ask Patient**

- On a scale of 0 - 10, how satisfied were you with this cannula? _____________
- [ ] Patient too unwell / unable to comprehend

- How many attempts do you think is reasonable? ____________________________

- How many would you want? ______________________________________________
- [ ] Patient too unwell / unable to comprehend
<table>
<thead>
<tr>
<th>Ward Follow Up</th>
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<tr>
<td><strong>Case Report Number</strong></td>
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<td><strong>Ward</strong></td>
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<tr>
<td><strong>Room Number</strong></td>
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<tr>
<td><strong>Day in Hospital</strong></td>
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<tr>
<td><strong>Specialty</strong></td>
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<td><strong>Gender of Patient</strong></td>
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</table>
| □ Male  
| □ Female |
| **Date and Time of Review** |  
| Date _________________  
| Time _____: _____ am/pm |
| **ED PIVC Remains?** |  
| □ Yes  
| □ No |

| If ED Cannula is no longer present please complete.  
**ED Cannula no longer intravenous because:** |
| □ PIVC infiltration  
| □ Accidental dislodgement |
| □ Occlusion, blocked not flushing  
| □ Removed for patient safety |
| □ Pain  
| □ Securement device failed |
| □ PVAS > 2  
| □ Routine removal at 72 hrs |
| □ Swelling  
| □ Subsequent PIVC |
| □ No longer required  
| □ Changed to other VAD ________________ |
| □ Patient pulled it out  
| □ Unable to identify from health records |
| □ Needed to ask patient to get answer  
| □ Needed to ask nurse / Dr reason for removal |

| Please ask patient the following question:  
**What has been your experience with this IV catheter?**  
0 = Worst possible  
10 = Best possible  
□ Patient cannot verbalise / understand  
□ Patient discharged from ward |

| **Date of removal:** _____/_____/______  
**Time of PIVC Removal:** _____: _____ am/pm  
**Tick if no IVT/IVM was infused** |

| □ Evidence of other VAD  
**Type / Location and Size** ________________ |

| If ED Cannula remains, please complete  
**IV Dressing and Vascular Access Assessment** |
| **Borderless transparent polyurethane dressing**  
□ Yes  
□ No |
| **Window transparent polyurethane dressing**  
□ Yes  
□ No |
| **Sterile gauze and tape dressing**  
□ Yes  
□ No |
| **Clean, dry and intact**  
□ Yes  
□ No |
| **Loose or lifting edges**  
□ Yes  
□ No |
| **Other** ________________  
□ Bandage  
□ Tubular net |

| **IV Connectors (check all that apply)**  
□ J-Loop  
□ Clamp  
□ Off  
□ IV end cap |
| □ Stock / 3-way tap  
□ Direct connection to IV administration set |
| □ Needleless connector (NC)  
□ Other ________________ |
### PIVC Site Assessment

- **No clinical symptoms** ☐ Yes ☐ No
- **Pain / tenderness on palpation** ☐ Yes ☐ No
- **Palpable hard vein cord beyond IV tip** ☐ Yes ☐ No
- **Induration / hardness of tissues > 1 cm** ☐ Yes ☐ No
- **Streak / red line along vein** ☐ Yes ☐ No
- **Pain / tenderness on palpation** ☐ Yes ☐ No
- **Extravasation and infiltration** ☐ Yes ☐ No
- **Erythema/redness >1cm from insertion site** ☐ Yes ☐ No
- **Induration / hardness of tissues > 1cm** ☐ Yes ☐ No
- **Swelling > 1cm from insertion site** ☐ Yes ☐ No
- **Leaking PIVC** ☐ Yes ☐ No
- **Purulence** ☐ Yes ☐ No
- **Extravasation and infiltration** ☐ Yes ☐ No
- **Itch / rash under dressing** ☐ Yes ☐ No
- **Blood in NC** ☐ Yes ☐ No
- **Blistering / skin tears under dressing** ☐ Yes ☐ No
- **Blood in J-Loop** ☐ Yes ☐ No
- **Bruising at site of PIVC** ☐ Yes ☐ No
- **Dried blood around PIVC** ☐ Yes ☐ No
- **Partial / complete dislodgement of PIVC** ☐ Yes ☐ No
- **Other** ☐ Yes ☐ No

### PVAS

- **Present and Signed for today** ☐ Yes ☐ No
- **Signed for previous day** ☐ Yes ☐ No
- **Date**  
  - AM ☐ PM ☐ Night
  - AM ☐ PM ☐ Night
- **PVAS Score for today** ____________
- **PVAS Score for previous day** ____________

### Flushing

- **N/Saline Flush prescribed PRN** ☐ Continuous infusion
- **N/Saline Flush prescribed every** ____________
- **No N/Saline Flush prescribed** ☐ Intermittent infusion
- **Patient or Staff-Reported Flush** ☐ Bolus injection
- **Combination of intermittent and bolus**

### IV Fluids Today (check all that apply)

- **Crystalloid List** ____________
- **Colloid or blood products** ☐ Not documented
- **Parenteral nutrition** ☐ Chart unavailable

### IV Medications Today - via PIVC (check all that apply)

- **Electrolytes**
- **Antibiotics List** ____________
- **Analgesia / PCA**
- **Sedation**
- **Anti-emetic**
- **Chemotherapy**
- **None**
- **Other**

### Other rationale for PIVC

- **CTPA (Possible / Definite)**
- **Acute deterioration**

### Blood Sampling

- **Venepuncture (steel needle)** ☐ Yes ☐ No ☐ Unable to identify
  - Date / Time: ____________
  - Date / Time: ____________

### Patient Experience

- What has been your experience with this IV catheter? 0 = Worst possible 10 = Best possible ____________
  - Patient cannot verbalise / understand ☐ Patient gone off ward

### Rationale for PIVC (multiple tick box)

- **IV Therapy Prescribed**
- **Acute deterioration likely**
- **Contrast Scan/Procedure requiring PIVC**
- **None of the above**
SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

<table>
<thead>
<tr>
<th>Section/item</th>
<th>ItemNo</th>
<th>Description</th>
<th>Addressed on page</th>
</tr>
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<td>Names, affiliations, and roles of protocol contributors</td>
<td>Title Page &amp; 14</td>
</tr>
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<td>Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities</td>
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<td>Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)</td>
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<td>Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention</td>
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<td>Explanation for choice of comparators</td>
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<td>Trial design</td>
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<td>Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)</td>
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<tr>
<td>Methods: Participants, interventions, and outcomes</td>
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<td>Study setting</td>
<td>6-10</td>
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<td>Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained</td>
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<td>Eligibility criteria</td>
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<td>Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)</td>
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<td>Interventions</td>
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<td>Interventions for each group with sufficient detail to allow replication, including how and when they will be administered</td>
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<td>Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)</td>
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<tr>
<td>Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)</td>
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<tr>
<td>Relevant concomitant care and interventions that are permitted or prohibited during the trial</td>
<td>9-10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Section</td>
<td>Page(s)</td>
<td>Description</td>
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<tr>
<td>Outcomes</td>
<td>12</td>
<td>Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended.</td>
<td></td>
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<tr>
<td>Participant timeline</td>
<td>13</td>
<td>Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure).</td>
<td></td>
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<tr>
<td>Sample size</td>
<td>14</td>
<td>Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations.</td>
<td></td>
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<tr>
<td>Recruitment</td>
<td>15</td>
<td>Strategies for achieving adequate participant enrolment to reach target sample size.</td>
<td></td>
</tr>
<tr>
<td>Methods: Assignment of interventions (for controlled trials)</td>
<td></td>
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<tr>
<td>Allocation:</td>
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<tr>
<td>Sequence generation</td>
<td>16a</td>
<td>Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions.</td>
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<tr>
<td>Allocation concealment</td>
<td>16b</td>
<td>Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned.</td>
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<tr>
<td>Implementation</td>
<td>16c</td>
<td>Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions.</td>
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<tr>
<td>Blinding (masking)</td>
<td>17a</td>
<td>Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how</td>
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<td></td>
<td>17b</td>
<td>If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial</td>
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<tr>
<td>Methods: Data collection, management, and analysis</td>
<td>18a</td>
<td>Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol</td>
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<td></td>
<td>18b</td>
<td>Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols</td>
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<tr>
<td>Data management</td>
<td>19</td>
<td>Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol</td>
<td></td>
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<tr>
<td>Statistical methods</td>
<td>20a</td>
<td>Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol</td>
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<td>20b</td>
<td>Methods for any additional analyses (eg, subgroup and adjusted analyses)</td>
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<td></td>
<td>20c</td>
<td>Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)</td>
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Methods: Monitoring
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<th>Subsection</th>
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<tr>
<td>Data monitoring</td>
<td>21a</td>
<td>Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed</td>
<td>N/A</td>
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<td></td>
<td>21b</td>
<td>Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial</td>
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<td>Harms</td>
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<td>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct</td>
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<td>Auditing</td>
<td>23</td>
<td>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor</td>
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<td>Ethics and dissemination</td>
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<td>Research ethics</td>
<td>24</td>
<td>Plans for seeking research ethics committee/institutional review board (REC/IRB) approval</td>
<td>11</td>
</tr>
<tr>
<td>Protocol amendments</td>
<td>25</td>
<td>Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)</td>
<td>11</td>
</tr>
<tr>
<td>Consent or assent</td>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
<td>11</td>
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<tr>
<td></td>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
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<td>Confidentiality</td>
<td>27</td>
<td>How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial</td>
<td>8</td>
</tr>
<tr>
<td>Item</td>
<td>Page</td>
<td>Description</td>
<td></td>
</tr>
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<tr>
<td>Declaration of interests</td>
<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
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<tr>
<td>Access to data</td>
<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
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<td>Ancillary and post-trial care</td>
<td>30</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
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<tr>
<td>Dissemination policy</td>
<td>31a</td>
<td>Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions</td>
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<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
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<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
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Appendices

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<thead>
<tr>
<th>Item</th>
<th>Page</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent materials</td>
<td>32</td>
<td>Model consent form and other related documentation given to participants and authorised surrogates</td>
</tr>
<tr>
<td>Biological specimens</td>
<td>33</td>
<td>Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable</td>
</tr>
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</table>

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons Attribution-NonCommercial-NoDerivs 3.0 Unported license.*
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

<table>
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<td>Complete List of Authors:</td>
<td>Carr, Peter; The University of Western Australia, Emergency Medicine Rippey, James; The University of Western Australia, Emergency Medicine Cooke, Marie; Griffith University, NHMRC Centre for Research Excellence in Nursing Interventions, Menzies Health Institute Queensland, Griffith University, Brisbane, Australia Bharat, Chianna; The University of Western Australia, Statistics Murray, Kevin; University of Western Australia, Centre for Applied Statistics Higgins, Niall; Griffith University, NHMRC Centre for Research Excellence in Nursing Interventions, Menzies Health Institute Queensland, Griffith University, Brisbane, Australia Foale, Aileen; The University of Western Australia, Medicine Rickard, Claire; Griffith University, NHMRC Centre for Research Excellence in Nursing Interventions, Menzies Health Institute Queensland, Griffith University, Brisbane, Australia</td>
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Title Page

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, James Rippey, Marie L. Cooke, Chrianna Bharat, Kevin Murray, Niall S. Higgins, Aileen Foale, Claire M. Rickard

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3 NHMRC Centre for Research Excellence in Nursing Interventions, Menzies Health Institute Queensland, Griffith University, Brisbane, Australia.
4 Alliance for Vascular Access Teaching & Research (AVATAR) Group, Menzies Health Institute Queensland, Griffith University, Brisbane, Australia.
5 Centre for Applied Statistics, University of Western Australia, Perth, Western Australia.
6 Medical Student, The University of Western Australia, Perth, Western Australia.
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 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 observational cohort study of PIVC insertions in a patient population presenting to ED, with follow-up of 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 predication rule.

Ethics and Dissemination: This study has ethical approval and is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12615000588594. 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.
Keywords: Clinical Prediction, Peripheral Intravenous Cannulation, Emergency Department, peripheral cannula insertion success, difficult intravenous access, Device Failure.
Background

Peripheral intravenous cannula (PIVC) insertion is a vascular access clinical procedure that is shared amongst 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 (1). Factors identified as predictors of insertion failure in the Emergency Department (2,3) and premature device failure in admitted patients are published separately (4).

However, notwithstanding literature concerning PIVCs inserted in ED using ultrasound technology (5), 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 (6). 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 72hrs 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 (7). 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 (8). 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 18-80% in both the paediatric and adult populations (6,9–16). 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 (17).

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

Post insertion complications

In the adult population, secondary data analysis from a large randomised controlled trial indicate that post-insertion 25% of PIVCs fail (4). 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 (4). Post-insertion failure is complex multifactorial and is influenced by patient characteristics, such as: age (4,18); gender (4); any infection at baseline (4); number and type of co-morbidities (43); smoking (44); and device characteristics such as: PIVC gauge and length (26,36,43); site of placement (4,43); antibiotics prescribed IV (4); not using a J-loop or extension set or closed system catheters (45,46); securement device failure (47) and the hospital culture in managing these medical devices, for example the adoption of an aseptic technique (48). PIVC insertions in the ED have been reported as a cause of phlebitis and staphylococcus aureus bacteremia, leading to premature device
failure. As a result, routine PIVC replacement after 24 hours is recommended for ED PIVCs in an attempt to reduce the risk of infection (49–51).

Studies in the ED are limited to insertion failure and risk factors for difficult insertion (2). Those that do identify dwell time during or post ED are limited to PIVC insertions using ultrasound-guided technology (5,26) and 47% of PIVCs inserted with ultrasound guidance failing within 24 hours (5). 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 (47). 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 (4,51,33,52–55).

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

Study Design:
VADER is a prospective cohort study, which will observe PIVC insertions at two Emergency Departments 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; (i) identify risk factors for peripheral intravenous cannulation success, (ii) identify risk factors for reduced dwell time/failure, and (iii) 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-hour 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 Emergency Department (ED) of SCGH
information system over 33,228 peripheral intravenous cannulas (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 one hundred 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 Emergency Department, 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 (57) 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% (6). 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 and colleagues (58) and Vittinghoff and McCulloch (59). Furthermore, this would more than adequately satisfy the minimum recommendation of Steyerberg (60) 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 - Dec 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 (2006) with both ED clinicians and vascular access experts resulting in excellent content validity (61). The developed CRF was also used in
our self-report study (6) 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 generalizability. 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 definition for skin assessment quality (62) and vein assessment quality (6,29,63) 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 10mls) 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 1mm, medium 2-3mm or large >4mm); the venous international assessment scale (VIA), skin type/temperature (we will use a similar definitions for skin assessment quality (62) and vein assessment quality (6,29,63) 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. 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 (64). 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 hrs),
intravenous (IV) therapy completion; device failure rationale; dislodgment (patient pulled it out, other patient factors such as confusion, diaphoresis), dressing failure, patient complained 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 IV medicines prescribed, lost to follow up due to hospital transfer, subsequent PIVC inserted, other vascular access device, venepuncture (daily bloods), and type of IV medicine and/or therapy see 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 odds ratios and 95% confidence intervals 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 (i.e. discrimination) will be assessed using the C statistic. These can be compared to a pre-determined 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): IV 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**

The Sir Charles Gairdner Group, Human Research Ethics Committee (HREC) has approved the study (HREC reference SCGH 2014K138) and both SCGH and FSH authorised site approval. 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%-86% (3,6,12,15,34). 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%-87% (14,46). Such results warrant further scrutiny as the inclusion or referral criteria for an ultrasound inserted PIVC is two or more failed traditional attempts (40,65,66). 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 (15,67) however none is specifically focused on ED insertion success and avoidance of premature device failure. An observational design is suggested by Adams and Leveson (2012) to establish a clinical prediction rule (68). 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 (30).

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 (4,69). 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 case report form 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 health care 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. Due 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 (4,70), and prevention of PIVC insertion failure with the use of specialist teams is growing (17), 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.

List of abbreviations:

PIVC peripheral intravenous cannulation; ED Emergency Department; CRF Case Report Form

Competing interest: Peter Carr’s research is supported by Becton Dickinson (BD) contribution to the AVATAR group based at Griffith University. BD has no design or
input into this study and will not have any role in the collection analysis or interpretation of the data, manuscript development or the influence the journal for publication of results. JR, MC,CB,CAB and NH have no competing interests to declare.

James Rippey; none declared
Marie Cooke; none declared
Chrianna Bharat; none declared
Charley Budgeon; none declared
Aileen Foale; none declared
Niall Higgins; none declared

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**Author Contributions:** All authors have made substantial contributions to the development of this study. PJC conceived this study with JR and designed it with NH, MC, and CMR. CB and KM contributed to the statistical plan and are responsible for statistical analysis. MC, NH, AF and CMR have revised and contributed to the development of this protocol.

**Acknowledgements:**
For expert advice on the development and content validity appraisal of our CRFs;
Thanks to the following vascular access specialist contributors, Dr. Lisa Dougherty Royal Marsden Hospital London; Ms Linda Kelly University of the West of Scotland; Ms Shelia Inwood, Royal Berkshire Hospital Reading UK; Ms. Nancy Moureau, PICC excellence & Griffith University; Mr Gavin Jackson, CNC Fiona Stanley Hospital; Dr Evan Alexandrou, Western Sydney University; and Dr Vineet Chopra, Ann Arbor VA Medical Center and the University of Michigan Health System. Thanks also to Emergency Medicine Consultants: Dr David Mountain, Dr Ian Gawthrope, and Dr Sam Phillips of SCGH ED. We wish to thank the committee of the HREC at SCGH for
suggestions and encouragement with this study, as well as the research governance team at FSH and all the staff of the ED’s at SCGH and FSH.
Reference List


11. Jacobson AF. Intradermal normal saline solution, self-selected music, and insertion difficulty effects on intravenous insertion pain. *Heart Lung*


55. Stevens RJG, Mahadevan V, Moss ALH. Injury to the lateral cutaneous nerve of


67. Mbamalu D, Banerjee A. Methods of obtaining peripheral venous access in


The VADER Study, Case Report Form:

This form should contain no identifying patient information.

### Patient Demeanour
- Calm and co-operative: □ Yes □ No
- Confused: □ Yes □ No
- Unable to eat and drink: □ Yes □ No

### Case Report Number

### Triage Category

### Chief Complaint

### Age of Patient

### Gender of Patient
- Male: □ Yes □ No
- Female: □ Yes □ No

### Date and Time of Review
- Time: __ : ___ am/pm

### Clinician Details

#### Role in ED
- Nurse
- Med Student
- Intern
- RMO
- Registrar
- Consultant
- US Consultant
- Phlebotomist
- Paramedic

#### Experience
- <10
- 11-50
- 51-100
- 101-300
- 301-600
- 601-1000
- >1000

### Confidence and Prediction for this PIVC

#### How confident are you that the first attempt will be successful? (0-100%) ___________________________

#### Primary rationale for PIVC insertion?
- Blood Samples
- Possible IVF/Med/Antibiotics
- Definite IVF/Med/Antibiotics
- Possible Contrast Scan
- Definite Contrast Scan
- Blood Products
- Code Black Sedation
- Patient Unstable / Requiring Resuscitation

#### How likely is it that the cannula will be used for intravenous therapy? (0-100%) ______________________

#### Too early to predict / Until no longer required
- 4 hrs / 8 hrs / 12 hrs / 24 hrs / 36 hrs / 48 hrs / 60 hrs / 72 hrs / 84 hrs / 96 hrs (4d) / 120 hrs (5d) / 144 hrs (6d) / 168 hrs (7d) / 192 hrs (8d) / >200 hrs

### Arm, Skin, Vein Condition

#### Skin Temperature
- Cold
- Normal
- Warm
- Diaphoretic

#### Vein Quality
- Straight
- Mobile/Wobbly
- Tortuous
- Short Identifiable Veins
- None Visible

#### Hair
- None
- Sparse
- Moderate
- Thick

### Aseptic Technique and Infection Prevention Practice

#### Size cannula
- 14g (orange)
- 16g (grey)
- 18g (green)
- 20g (pink)
- 22g (blue)
- 24g (yellow)
- 26g (purple)

#### Length / type of cannula

#### Hand protection
- No gloves
- Clean gloves
- Sterile gloves

#### Type of asepsis
- Swabstick (alcohol + chlorhexidine)
- Alcowipe (alcohol only)
- Chlorhexidine solution

#### Handwashing prior to set up
- Yes □ No □

#### Re-palpation of insertion site after asepsis applied?
- Yes □ No □

#### Were the key parts protected at all times?
- Yes □ No □

#### If No, what items were compromised? (choose below)
- Cannula
- NFC/Bung
- Flush
- Dressing
- Patient’s Skin
- Gloves
- Sterile field

#### Hair trimmed at site of cannula insertion?
- Yes □ No □

#### Hair trimmed at area for adhesive?
- Yes □ No □ N/A
Vein Assessment by Clinician and Researcher

Is there a pre-hospital PIVC in place?  □ Yes  □ No  Attempt □ Yes □ No  Location _____________________

VIA grade and the number of visible veins (VV) Grade I & II = Good, III = Fair, IV & V = Poor
□ I (6 VV)  □ II (4 VV)  □ III (3 VV)  □ IV (1 VV)  □ V (0 VV)  □ Both arms  □ Only one arm assessed

Target Vein Size  □ Small (< 1mm)  □ Medium (2-3mm)  □ Large (> 4mm)  Number of reasonable veins to cannulate

Target vein visible without Tourniquet? □ Yes □ No

Target vein palpable without Tourniquet? □ Yes □ No

Place a dot where the insertion attempt occurred.

Procedure and Timing

Location of the tourniquet _______________________________________________________________________________

If ACF, arm is □ flexed  □ straight  Total procedure time __:__  Time of insertion __:__ am/pm  Needle redirections___

Procedural Flow: Tourniquet __, Asepsis __, Insertion Attempt __, Flashback __, Blood Aspirated __, ***Blood Transfer __,

Tourniquet off __, Flushing __, Dressing application __ (items will be numbered at the stage they occurred)

Were any additional methods used to encourage vasodilation?
□ Skin Slapping  □ Skin Rubbing  □ Warm Compress  □ Lights  □ Other ________________________  □ None

Researcher’s Observations of Clinical Procedure

Was the patient’s blood exposed on their skin? □ Yes □ No  Did blood soil gauze /’bluey’? □ Yes □ No

Did blood soil the patient’s clothes? □ Yes □ No  Did blood contaminate the clinician’s gloves? □ Yes □ No

Did blood soil the bed linen? □ Yes □ No  Did blood soil the floor? □ Yes □ No

Connectors and Dressing

What connectors were used? □ J-loop  □ NFC/bung  □ Other ________________________

If a J-loop was connected;  If a NFC/bung was connected;

Is the clamp on or off? □ Yes □ No  Is it flushed and clear of blood? □ Yes □ No

Is it flushed and clear of blood? □ Yes □ No

Is the dressing clean and free of any blood spillage? □ Yes □ No

Is the dressing dated? □ Yes □ No

Are there loose or lifting edges □ Yes □ No  Additional tape securement □ Yes □ No  If yes what ______

Other vascular access device used  □ PICC □ CVC □ Midline □ IO

***We will gather observations that concern blood sampling methods, such as the syringe or vacutainer method, and
if these are attached to the cannula hub, a connector, or a J-loop. If the transfer of blood is by syringe we will record
if a needle or vacutainer is used or if an open cap method is used. Additionally the order of draw/transfer of blood will
be recorded. We will also observe blood culture practice; including the order and if the bottles are swabbed with antiseptic.
This will data will be linked with Aseptic Technique and Infection Prevention observations and form a separate study.
### Post Insertion

Was the first attempt successful? □ Yes □ No

How many attempts were required? ____________

Was anyone else asked for help? □ Yes □ No  
Who (level)?

How many people attempted to cannulate this patient? ____________

Was ultrasound used? □ Yes □ No  
If Yes, see ultrasound data collection form.

### Medications Administered in ED

Frequency and type of medication administered in ED?

- Fluids   □ N/Saline-Lactate □ Colloid □ Blood products □ None
- Meds □ Antibiotics □ Steroids □ Analgesia □ Anti-pyretic □ Cardiac drugs □ Other with CRF below

Was the patient admitted? □ Yes □ No

If No, the patient is OFF trial.  If Yes, continue with CRF Ward Follow Up.
<table>
<thead>
<tr>
<th>Patient Details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BMI</strong></td>
<td><strong>Height</strong></td>
</tr>
<tr>
<td>Patient Size</td>
<td>□ Emaciated</td>
</tr>
<tr>
<td>Skin Shade</td>
<td>□ ☹</td>
</tr>
<tr>
<td>Chronic Condition</td>
<td>□ Obesity</td>
</tr>
<tr>
<td>Smoking Status</td>
<td>□ Yes</td>
</tr>
<tr>
<td>Observations</td>
<td>BP _____ / _____</td>
</tr>
<tr>
<td>Recent Hospitalisations</td>
<td>□ &lt;1 month</td>
</tr>
<tr>
<td>Access Limitations</td>
<td>□ CVA</td>
</tr>
<tr>
<td>Handedness</td>
<td>□ Left</td>
</tr>
<tr>
<td>Site Preference</td>
<td>□ Hand</td>
</tr>
<tr>
<td>□ Left</td>
<td>□ Right</td>
</tr>
<tr>
<td>Ask Patient</td>
<td>On a scale of 0 - 10, how satisfied were you with this cannula? ____________</td>
</tr>
<tr>
<td>How many attempts do you think is reasonable? __________________________</td>
<td></td>
</tr>
<tr>
<td>How many would you want? ______________________________________________</td>
<td></td>
</tr>
<tr>
<td>□ Patient too unwell / unable to comprehend</td>
<td></td>
</tr>
</tbody>
</table>

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
### Ward Follow Up

<table>
<thead>
<tr>
<th>Case Report Number</th>
<th>Ward</th>
<th>Room Number</th>
<th>Day in Hospital</th>
<th>Specialty</th>
<th>Gender of Patient</th>
<th>Date and Time of Review</th>
<th>ED PIVC Remains?</th>
</tr>
</thead>
</table>

**Date and Time of Review**  
Date ________________ Time _____: _____ am/pm

**ED PIVC Remains?**  
- Yes  
- No

### If ED Cannula is no longer present please complete.

**ED Cannula no longer intravenous because:**

- PIVC infiltration
- Occlusion, blocked not flushing
- Pain
- PVAS > 2
- Swelling
- No longer required
- Patient pulled it out
- Needed to ask patient to get answer
- Needed to ask nurse / Dr reason for removal

**Please ask patient the following question:**  
What has been your experience with this IV catheter?  
0 = Worst possible  10 = Best possible __________

**Date of removal:** _____/_____/______  
**Time of PIVC Removal:** _____: _____ am/pm  
Tick if no IVT/IVM was infused

**Evidence of other VAD**  
Type / Location and Size ____________________________________

### If ED Cannula remains, please complete

**IV Dressing and Vascular Access Assessment**

<table>
<thead>
<tr>
<th>Borderless transparent polyurethane dressing</th>
<th>Sterile tape strips around PIVC</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Window transparent polyurethane dressing</td>
<td>Non-sterile tape around PIVC</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sterile gauze and tape dressing</td>
<td>Non-sterile tape around admin. set</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Clean and dry</td>
<td>Bandage</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Loose or lifting edges</td>
<td>Tubular net</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Other</td>
<td>Non-sterile tape around dressing</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**IV Connectors (check all that apply)**

- J-Loop   
- Clamp  
- On   
- Off   
- Stock / 3-way tap
- Needless connector (NC)
- IV end cap
- Direct connection to IV administration set
- Other ____________________________________
### PIVC Site Assessment

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>No clinical symptoms</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Pain / tenderness on palpation</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Erythema/redness &gt; 1cm from insertion site</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Swelling &gt; 1cm from insertion site</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Palpable hard vein cord beyond IV tip</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Induration / hardness of tissues &gt; 1cm</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Leaking PIVC</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Extravasation and infiltration</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Itch / rash under dressing</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Blood in NC</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Blood in J-Loop</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Bruising at site of PIVC</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Dried blood around PIVC</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Partial / complete dislodgement of PIVC</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
</tbody>
</table>

### PVAS

<table>
<thead>
<tr>
<th>Status</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present and Signed for today</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Signed for previous day</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>AM</th>
<th>PM</th>
<th>Night</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVAS Score for today</td>
<td>[ ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PVAS Score for previous day</td>
<td>[ ]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Flushing

<table>
<thead>
<tr>
<th>Type of Infusion</th>
<th>[ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/Saline Flush prescribed PRN</td>
<td>[ ]</td>
</tr>
<tr>
<td>N/Saline Flush prescribed every</td>
<td>[ ]</td>
</tr>
<tr>
<td>No N/Saline Flush prescribed</td>
<td>[ ]</td>
</tr>
<tr>
<td>Patient or Staff-Reported Flush</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

### IV Fluids Today (check all that apply)

<table>
<thead>
<tr>
<th>Fluid</th>
<th>[ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystalloid List</td>
<td>[ ] None</td>
</tr>
<tr>
<td>Colloid or blood products</td>
<td>[ ] Not documented</td>
</tr>
<tr>
<td>Parenteral nutrition</td>
<td>[ ] Chart unavailable</td>
</tr>
</tbody>
</table>

### IV Medications Today - via PIVC (check all that apply)

<table>
<thead>
<tr>
<th>Medication</th>
<th>[ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrolytes</td>
<td>[ ] Heparin infusion</td>
</tr>
<tr>
<td>Antibiotics List</td>
<td>[ ] Insulin</td>
</tr>
<tr>
<td>Analgesia / PCA</td>
<td>[ ] Gastric protection</td>
</tr>
<tr>
<td>Sedation</td>
<td>[ ] Anti-convulsant</td>
</tr>
<tr>
<td>Anti-emetic</td>
<td>[ ] Chemotherapy</td>
</tr>
<tr>
<td>None</td>
<td>[ ] Other</td>
</tr>
</tbody>
</table>

### Other rationale for PIVC

<table>
<thead>
<tr>
<th>Rationale</th>
<th>[ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTPA (Possible / Definite)</td>
<td>[ ] Acute deterioration</td>
</tr>
<tr>
<td>Acute deterioration likely</td>
<td>[ ] Contrasct Scan/Procedure requiring PIVC</td>
</tr>
<tr>
<td>None of the above</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

### Blood Sampling

<table>
<thead>
<tr>
<th>Status</th>
<th>[ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Veneupuncture (steel needle)</td>
<td>[ ] Yes</td>
</tr>
<tr>
<td>Date / Time:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

### Patient Experience

<table>
<thead>
<tr>
<th>Experience</th>
<th>[ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient cannot verbalise / understand</td>
<td>[ ] Patient gone off ward</td>
</tr>
</tbody>
</table>

### Rationale for PIVC (multiple tick box)

<table>
<thead>
<tr>
<th>Rationale</th>
<th>[ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV Therapy Prescribed</td>
<td>[ ] Acute deterioration likely</td>
</tr>
<tr>
<td>Contrasct Scan/Procedure requiring PIVC</td>
<td>[ ] None of the above</td>
</tr>
<tr>
<td>Section/item</td>
<td>ItemNo</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Administrative information</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
</tr>
<tr>
<td>Trial registration</td>
<td>2a</td>
</tr>
<tr>
<td></td>
<td>2b</td>
</tr>
<tr>
<td>Protocol version</td>
<td>3</td>
</tr>
<tr>
<td>Funding</td>
<td>4</td>
</tr>
<tr>
<td>Roles and responsibilities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5b</td>
</tr>
<tr>
<td></td>
<td>5c</td>
</tr>
<tr>
<td></td>
<td>5d</td>
</tr>
<tr>
<td>Introduction</td>
<td></td>
</tr>
</tbody>
</table>
### Background and rationale
6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

6b Explanation for choice of comparators

### Objectives
7 Specific objectives or hypotheses

### Trial design
8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

### Methods: Participants, interventions, and outcomes

**Study setting**
9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

**Eligibility criteria**
10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)

**Interventions**
11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)

Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations

Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation 16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism 16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
**Blinding (masking)**

17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how

17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial

**Methods: Data collection, management, and analysis**

**Data collection methods**

18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol

18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols

**Data management**

19 Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol

**Statistical methods**

20a Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol

20b Methods for any additional analyses (eg, subgroup and adjusted analyses)

20c Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

**Methods: Monitoring**
<table>
<thead>
<tr>
<th>Section</th>
<th>Item</th>
<th>Description</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data monitoring</td>
<td>21a</td>
<td>Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>21b</td>
<td>Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial</td>
<td>N/A</td>
</tr>
<tr>
<td>Harms</td>
<td>22</td>
<td>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct</td>
<td>N/A</td>
</tr>
<tr>
<td>Auditing</td>
<td>23</td>
<td>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor</td>
<td>N/A</td>
</tr>
<tr>
<td>Ethics and dissemination</td>
<td>24</td>
<td>Plans for seeking research ethics committee/institutional review board (REC/IRB) approval</td>
<td>11</td>
</tr>
<tr>
<td>Research ethics approval</td>
<td>25</td>
<td>Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)</td>
<td>11</td>
</tr>
<tr>
<td>Protocol amendments</td>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
<td>11</td>
</tr>
<tr>
<td>Consent or assent</td>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>27</td>
<td>How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial</td>
<td>8</td>
</tr>
</tbody>
</table>
### Declaration of interests

28 Financial and other competing interests for principal investigators for the overall trial and each study site

14

### Access to data

29 Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators

N/A

### Ancillary and post-trial care

30 Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

N/A

### Dissemination policy

31a Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

12

31b Authorship eligibility guidelines and any intended use of professional writers

14

31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

N/A

### Appendices

#### Informed consent materials

32 Model consent form and other related documentation given to participants and authorised surrogates

N/A

#### Biological specimens

33 Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.*