Patient reported outcome and experience measures for peripheral venous catheters: a scoping review protocol.

Emily N Larsen¹²³ GDip(HlthRes), Email: e.larsen@griffith.edu.au [Corresponding Author]

A/Prof Joshua Byrnes¹⁴⁵ PhD, Email: j.byrnes@griffith.edu.au

Dr Nicole Marsh¹²³ PhD, Email: nicole.marsh@health.qld.gov.au

Prof Claire M Rickard¹²³ PhD, Email: c.rickard@griffith.edu.au

¹Alliance for Vascular Access Teaching and Research, Menzies Health Institute Queensland, Brisbane, Queensland, Australia;

²Royal Brisbane and Women's Hospital, Brisbane, Queensland, Australia;

³School of Nursing and Midwifery, Griffith University, Brisbane, Queensland, Australia;

⁴School of Medicine, Griffith University, Queensland, Australia;

⁵Centre for Applied Health Economics, Menzies Health Institute, Queensland, Australia.

Corresponding author:

Ms Emily Larsen

Level 2 (Nursing and Midwifery Research Centre), Bldg. 34, Royal Brisbane and Women's Hospital, Cnr. Bowen Bridge Rd and Butterfield St, Herston QLD 4029

Australia

Phone: +61438343821
Fax: +617364658332

Email: e.larsen@griffith.edu.au

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Abstract

Purpose:

The purpose of this scoping review is to conduct a systematic search and establish the current state of evidence for tools and instruments used to measure self-reported outcomes and experiences, including satisfaction scores, specifically for peripheral venous access devices (PVADs).

Methods:

A systematic search of the literature will be conducted using medical databases including: MEDLINE (Ovid); CINAHL (EbscoHost); PubMed (NCBI); and Scopus (Elsevier); Google (Scholar); and the Cochrane Central Register of Controlled Trials.

Experimental, and observational studies, published in English, after 1990 will be eligible for inclusion if they: consist of (i) a survey, instrument or tool which is designed to (ii) collect outcome, experience and/or satisfaction data, relating to PVAD insertion, care, maintenance and/or removal, among (iii) adult and paediatric participants.

Conclusions:

PVAD-specific patient reported outcome- and experience-measures are necessary for researchers, clinicians and policy decision makers to more thoroughly explore the quality of PVAD care provided, and further inform health economic analyses in the context of quality improvement interventions for vascular access devices. This scoping review will establish the existence – or paucity – of instruments to measure these self-reported outcomes and experiences of PVADs, in order to guide value based healthcare delivery into the future.

Keywords:
Peripheral Venous Catheter, Patient Reported Outcomes, Experience, Satisfaction, Self-Report, Scoping Review
Background

Healthcare delivery is currently experiencing a significant change from what was traditionally a *volume*-based model, to one that is based on the *value* of health-care delivery (Squitieri, Bozic, & Pusic, 2017). The aim of a value based health care (VBHC) delivery model is to improve patient safety, quality of care and cost-efficiency of interventions (Elf et al., 2017) by: effectively engaging consumers (Wilson, Gole, Mishra, & Mishra, 2016); improving care-coordination (Chen, Ou, & Hollis, 2013); and, endeavouring to reduce purchasing costs (Haywood, 2010).

VBHC considers the benefits of care to patients relative to the costs (e.g., staff, consumables) of achieving these. At a policy level, this involves a *cost-utility analysis* which, while more complex than standard economic analysis, has been adopted as core business for many healthcare systems, due to a high rate of health-care inflation, in the context of finite resources (Brown, Brown, Sharma, & Landy, 2003). At the foundation of VBHC delivery, is Evidence Based Medicine, which is the implementation of care that is supported by high level evidence, carried out by skilled/expert clinicians, taking into account patient values, and the perceived value of care provided (Brown et al., 2003; Sackett, Richardson, Rosenberg, & Haynes, 2000). For example, a high-cost procedure which demonstrates little benefit is not an efficient use of funds; while cost-saving poor quality care is similarly inefficient (Porter & Teisberg, 2006). In practice, this has led to Value-Based Insurance Designs (relevant for primarily privatised health systems) which are aimed at minimising both under-use and over-use of healthcare systems (Fendrick, Smith, & Chernew, 2010). Public health systems have similarly begun to implement this concept of *value* in their national systems, such as use in the assessment of pharmaceutical prior to insurance (public or private) subsidisation (Claxton et al., 2008).

In order to assess the impact of VBHC delivery, health outcomes (both clinical and patient-reported) must be (i) measured; (ii) reported and compared; (iii) and used to inform
quality improvement processes (van Deen, Esrailian, & Hommes, 2015). Patient reported measures have therefore become vital in determining the value of healthcare, as patients are at the centre of understanding and defining what benefits are achieved (Deshpande, Rajan, Sudeepthi, & Abdul Nazir, 2011). Typically, these benefits have been conceptualised and reported either as (i) patient reported outcome measures (PROMs), defined as patient’s self-reporting of aspects of their health-status and well-being; or (ii) patient reported experience measures (PREMs), defined as patient’s description of what care they received, and how that care was provided (Tremblay, Roberge, & Berbiche, 2015). In practice, these measures are not only used to inform cost-utility analysis by assessing changes in- and cost of-quality adjusted live years (QALY) (i.e., the health benefit in procedures such as surgery) (Coronini-Cronberg, Appleby, & Thompson, 2013), but also to provide ongoing feedback during routine care (e.g., symptoms experiences during cancer treatment) (Howell et al., 2013).

As health systems transition to VBHC, PROMs and PREMs have been adopted as key performance measures, resulting in an influx of various ‘generic’ and ‘disease/dimension’ specific tools (Deshpande et al., 2011). However, the use and quality of PROMs and PREMs vary significantly (Frost et al., 2007). In many cases, these measures have not been validated, nor have they had patient/consumer input during development (Frost et al., 2007). Despite this, evidence suggests that reliable and well-utilised PROMs, can result in healthcare improvement specifically related to clinician-patient communication, treatment-response assessment, and early detection of complications (Chen et al., 2013).

Vascular access is an area for which valid and reliable PROMs and PREMs are particularly needed, to enable care quality improvement. It is estimated that 70% of all patients undergoing treatment in a tertiary facility will require a peripheral venous access device (PVAD) (Zingg & Pittet, 2009). Despite their ubiquity, both insertion failure and subsequent PVAD failure remain high. It is estimated that between 14-35% of patients will require two or more attempts prior to PVAD insertion (Carr et al., 2016; Cuper et al., 2012); and 32-41% of
PVADs fail, prior to completion of therapy, often requiring re-insertion (Abolfotouh, Salam, Bani-Mustafa, White, & Balkhy, 2014; Marsh et al., 2018; Rickard et al., 2018). The negative physical and emotional impacts of these healthcare failures are broad, ranging from immediate effects (e.g., missed or delay treatment; pain associated with PVAD re-insertion), to long-term effects (e.g., undermined vessel health; anxiety and distrust) (Cooke et al., 2018; Larsen, Keogh, Marsh, & Rickard, 2017).

Anecdotal evidence suggests that commonly used generic PROMs (e.g., EuroQual-5D (Herdman et al., 2011)) and PREMs (e.g., HCAHPS) (Giordano, Elliott, Goldstein, Lehrman, & Spencer, 2010) may not be adequate for use within this context; and further research is required to ensure the use of purpose-built vascular access PROMs and PREMs, developed in partnership with consumers. The aim of this scoping review is to establish the existence of tools/instruments/surveys used to measure self-reported outcomes and experiences related to PVADs and synthesize and compare how these tools are used in the context of both adult and paediatric settings.

**Methods**

**Review Questions/Objective**

1. What tools and instruments are currently used to measure patient-reported outcomes, experiences and satisfaction for PVADs?
2. What similarities and dissimilarities exist between self-reporting measures/tools?
3. What are the characteristics of the populations for which self-reporting has been measured/studied?

**Searches**

A systematic search of the literature will be conducted using electronic medical databases including: MEDLINE (Ovid); CINAHL Complete (EbscoHost); PubMed (NCBI); and Scopus (Elsevier); Embase (Elsevier) and the Cochrane Central Register of Controlled Trials.
Searches will be systematically using appropriate subject headings in the databases (see Table 1).

Table 1. Search Strategy

<table>
<thead>
<tr>
<th>MeSH/CSH terms</th>
<th>MeSH terms</th>
<th>CSH terms</th>
<th>Keywords</th>
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<tbody>
<tr>
<td>[Catheterization, Peripheral] (explode), or peripheral venous; venous catheter; intravenous; cannula; PIV or PVC.</td>
<td>[Patient Reported Outcome Measures]; [Self Report]; [Patient Outcome Assessment] (explode); [Treatment Outcome] (explode); [Quality of Life] (explode); or [Patient Satisfaction] (explode), or</td>
<td>['Outcomes (Health Care)'] (explode); or [Patient-Reported Outcomes], or experience; satisfaction; opinion; or perspective.</td>
<td>AND</td>
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<tr>
<td>[Surveys and Questionnaires] (explode); [Health Care Surveys] (explode); [Health Surveys] (explode); or [Visual Analog Scale], or</td>
<td>[Surveys'] (explode); or [Research Instruments'] (explode), or questionnaire; survey; instrument; tool; likert; or numerical rating scale; or measure.</td>
<td>AND</td>
<td></td>
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<tr>
<td>[Tertiary Healthcare] (explode); [Tertiary Care Centers'] (explode); [Inpatients'] (explode); [Hospitals'] (explode) or [Episode of Care], or</td>
<td>[patient]; or 'consumer'.</td>
<td></td>
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Inclusion Criteria

Experimental (e.g., randomised controlled trials (RCT), including quasi-experimental), and observational (e.g., cohort) studies, published in English, after 1990, will be eligible for inclusion if they: include (i) a survey, instrument or tool, which is designed to (ii) collect outcome, experience and/or satisfaction data, relating to (iii) PVAD insertion, care, maintenance and/or removal (including relating processes and features including education, and PVAD
attachments/related equipment), from (iv) adult and paediatric participants. Studies will also be eligible if a relevant instrument/tool has been developed, but not yet tested. In addition, the reference list of retrieved studies will be reviewed to identify further eligible reports. Following screening, full text articles of eligible titles will be retrieved and screened for inclusion.

**Exclusion Criteria [R3]**

Studies prior to 1990 will be excluded to ensure included tools and measures reflect modern health-care practices. Further exclusion criteria will be: grey literature; and studies related to: healthy volunteers; and hypothetical-only scenario surveys (eg. vignettes).

**Study Selection**

Two reviewers will independently assess titles and abstracts for study inclusion against the pre-established inclusion and exclusion criteria, using Endnote X7 software. Duplicates will be removed. Selected titles will be compared for congruence; in the case of any disagreements, an experienced third reviewer will be consulted for final decision. The reason for title exclusion will be documented.

**Data Extraction**

Following study selection, two independent reviewers will extract data using a purpose-built form. Any disagreement will be resolved by a third reviewer. A flow-chart presenting studies excluded at a (i) title, (ii) abstract and (iii) full-text level, will be presented in the scoping review, as per the ‘Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews’ (PRISMA-ScR) (Tricco et al., 2018). Extracted data will include: study design (e.g., RCT); population (e.g., adult, emergency, country); study intervention (if relevant); and details of the PROM, PREM, and/or satisfaction component of the study (e.g., primary v. secondary outcome of interest). Further details of the: domains (e.g., quality of life) and individual attributes (e.g., self-reported pain), scale (e.g., likert, numerical rating scale (NRS)), and collection methods (e.g., prospective questionnaire, number of questions) of self-reported measures will be extracted.
In alignment with the aim of this scoping review, the primary focus of the reviewer data extraction will be: (i) what- (health aspect of interest); and (ii) how- (tool/measure used) self-reports of PVAD insertion, care/maintenance, and removal are collected; sample sizes, results of self-reported measures, and effects of interventions will not be extracted.

**Data Analysis**

Included studies will be presented using descriptive statistics. An ‘Evidence Gap Map’ (Snilstveit, Vojtkova, Bhavsar, Stevenson, & Gaarder, 2016) will be formed to further highlight grouped themes of the current state of the evidence; descriptive (themed) tables will present data using three dimensions including: (i) the health or experience aspect of interest, (ii) the tool/measure used, (ii) a visual representation (e.g., bubble, sized) of the number of times this appeared in the included studies (Snilstveit et al., 2016). Adult and paediatric results will be compared for similarities and presented either together or separately, based on appropriateness.

**Discussion and Dissemination**

The use and dissemination of reliable patient self-reported outcomes and experience measures, to inform future PVAD research and quality improvement strategies, is essential in enabling a new focus on ‘value’ and prioritisation of consumer inclusion in the care and maintenance of vascular access devices. This scoping review will be the first to explore what- and how- PVAD-specific patient self-reported measures are currently used to assess outcomes, experiences and satisfaction in modern day health-care settings.

The authors will ensure wide dissemination of the scoping review findings by ensuring timely publication in a widely-accessible peer-reviewed journal, and through scientific meeting presentations (locally and international), aimed at both vascular access and VBHC-interested parties. Furthermore, results will be disseminated and discussed with local district health VBHC delivery teams, to inform future processes and priorities.
List of abbreviations:

CSH: CINAHL Subject Headings

MeSH: Medical Subject Headings

PVAD: Peripheral Intravenous catheter

PREM: Patient Reported Experience Measure

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews

PROM: Patient Reported Outcome Measure

RCT: Randomised Controlled Trial

VBHC: Value Based Health Care

Declarations

Ethics approval and consent to participate

Not applicable

Consent for publication

Not applicable

Availability of data and materials

Not applicable

Competing Interests

EL’s employer, Griffith University, has received on her behalf: a consultancy payment for an educational lecture, from 3M; and an investigator-initiated grant-in-aid from Medtronic (now Cardinal Health).

JB’s employer, Griffith University, has received on his behalf: an investigator-initiated grant-in-aid from Becton Dickinson.
NM’s previous employer (Griffith University) has received on her behalf: investigator-initiated research grants and unrestricted educational grants from Becton Dickinson, and Cardinal Health and a consultancy payment provided to Griffith University from Becton Dickinson for clinical feedback related to catheter placement and maintenance (unrelated to the current project).

CMR’s (Griffith University) employer has received, on her behalf: investigator-initiated research or educational grants from 3M, Angiodynamics; Becton Dickinson-Bard; Cardinal Health, Eloquest Healthcare Medtronic, Smiths Medical; and consultancy payments for educational lectures/expert advice from 3M, Becton Dickinson-Bard, BBraun, ResQDevices, Smiths Medical.

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Authors’ contributions

All authors meet the International Committee of Medical Journal Editors recommendations and agree to accountability for the manuscript preparation, accuracy, and integrity.

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References


