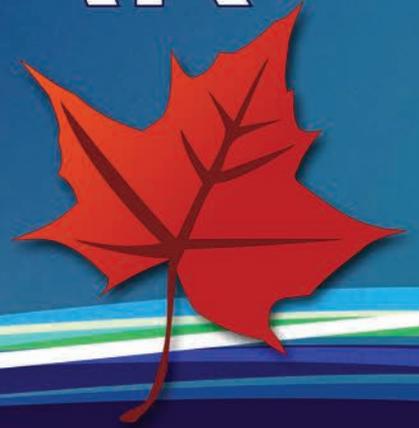


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Patient-reported outcome and experience measures for peripheral venous catheters: A scoping review protocol

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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 that 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 explore more thoroughly 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.

Résumé

Objectif: Le but de cette analyse bibliographique est de réaliser une recherche systématique et d'établir l'état actuel des données probantes relatives aux outils et aux instruments utilisés pour mesurer les résultats et les expériences déclarés volontairement par les patients, y compris les scores de satisfaction, en particulier pour les dispositifs d'accès veineux périphérique.

Méthodes : Une recherche documentaire systématique sera réalisée à l'aide des bases de données médicales comme MEDLINE (Ovid), CINAHL (EbscoHost), PubMed (NCBI),

ainsi que Scopus (Elsevier), Google (Scholar) et le Cochrane Central Register of Controlled Trials.

Les études expérimentales et observationnelles publiées en anglais après 1990 seront prises en compte si elles répondent aux critères d'inclusion suivants : (i) il s'agit d'une enquête, d'un instrument ou d'un outil conçu pour (ii) recueillir des données sur les résultats, les expériences et/ou le degré de satisfaction des participants concernant la pose, les soins, l'entretien et/ou le retrait des dispositifs d'accès veineux périphérique, chez (iii) des adultes et des enfants.

Conclusions : Les mesures des résultats et des expériences dont font état les patients concernant les dispositifs d'accès veineux périphérique sont nécessaires pour que les chercheurs, les cliniciens et les décideurs politiques explorent de manière plus approfondie la qualité des soins associés à ces dispositifs, et continuent à orienter les analyses économiques dans le domaine de la santé axées sur les interventions visant à améliorer la qualité des dispositifs d'accès vasculaire. Cette analyse bibliographique établira l'existence – ou le manque – d'instruments permettant de mesurer les résultats et les expériences déclarés volontairement par les patients relativement aux dispositifs d'accès veineux périphérique afin d'orienter la prestation future de soins de santé axés sur la valeur.

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 healthcare delivery (Squitieri et al., 2017). The aim of a value-based healthcare (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 et al., 2016); improving care-coordination (Chen et al., 2013); and, endeavouring to reduce purchasing costs (Haywood, 2010).

VBHC considers the benefits of care to patients relative to the costs of achieving these (e.g., staff, consumables). 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 healthcare inflation, in the context of finite resources (Brown et al., 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; Svet et al., 2000). For example, a high-cost procedure that 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 privatized health systems), which are aimed at minimizing both under-use and over-use of healthcare systems (Fendrick et al., 2010). Public health systems have similarly begun to implement this concept of value in their national systems, such as use in the assessment of pharmaceuticals prior to insurance (public or private) subsidization (Claxton et al., 2008).

To assess the impact of VBHC delivery, health outcomes (both clinical and patient-reported) must be: (i) measured; (ii) reported and compared; and (iii) used to inform quality improvement processes (van Deen et al., 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 et al., 2011). Typically, these benefits have been conceptualized and reported either as (i) patient-reported outcome measures (PROMs), defined as patients' self-reporting of aspects of their health status and

well-being, or (ii) patient-reported experience measures (PREMs), defined as patients' description of what care they received, and how that care was provided (Tremblay et al., 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 et al., 2013), but also to provide ongoing feedback during routine care (e.g., experiences of symptoms 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-utilized 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 et al., 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 delayed treatment; pain associated with PVAD re-insertion), to long-term effects (e.g., undermined vessel health; patient anxiety and distrust) (Cooke et al., 2018; Larsen et al., 2017).

Anecdotal evidence suggests that commonly used generic PROMs (e.g., EuroQual-5D) (Herdman et al., 2011) and PREMs (e.g., HCAHPS) (Giordano et al., 2010) may not be adequate for use within this context; and further research is required to ensure the use of purpose-built vascular

List of abbreviations:

CSH: CINAHL Subject Headings

MeSH: Medical Subject Headings

PVAD: Peripheral Venous Access Device

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: Randomized Controlled Trial

VBHC: Value Based Health Care

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); Scopus (Elsevier); Embase (Elsevier); and the Cochrane Central Register of Controlled Trials. Searches will systematically use appropriate subject headings in the databases (see Table 1).

Table 1: Search Strategy
<p>MeSH/CSH terms: ['Catheterization, Peripheral'] (<i>explode</i>), or Keywords: 'peripheral venous'; 'venous catheter'; 'intravenous'; 'cannula'; 'PIV' or 'PVC'. AND</p> <p>MeSH terms: ['Patient Reported Outcome Measures']; ['Self Report']; ['Patient Outcome Assessment'] (<i>explode</i>); ['Treatment Outcome'] (<i>explode</i>); ['Quality of Life'] (<i>explode</i>); or ['Patient Satisfaction'] (<i>explode</i>), or</p> <p>CSH terms: ['Outcomes (Health Care)'] (<i>explode</i>); or ['Patient-Reported Outcomes'], or</p> <p>Keywords: 'experience'; 'satisfaction'; 'opinion'; or 'perspective'. AND</p> <p>MeSH terms: ['Surveys and Questionnaires'] (<i>explode</i>); ['Health Care Surveys'] (<i>explode</i>); ['Health Surveys'] (<i>explode</i>); or ['Visual Analog Scale'], or</p> <p>CSH terms: ['Surveys'] (<i>explode</i>); or ['Research Instruments'] (<i>explode</i>), or</p> <p>Keywords: 'questionnaire'; 'survey'; 'instrument'; 'tool'; 'likert'; or 'numerical rating scale'; or 'measure'. AND</p> <p>MeSH/CSH terms: ['Tertiary Healthcare'] (<i>explode</i>); ['Tertiary Care Centers'] (<i>explode</i>); ['Inpatients'] (<i>explode</i>); ['Hospitals'] (<i>explode</i>) or ['Episode of Care'], or</p> <p>Keywords: 'patient'; or 'consumer'.</p>

Inclusion Criteria

Experimental (e.g., randomized controlled trials [RCT], including quasi-experimental) and observational (e.g., cohort) studies, published in English, after 1990, will be eligible for inclusion if they (i) include a survey, instrument or tool that 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

Studies prior to 1990 will be excluded to ensure included tools and measures reflect modern healthcare practices. Further exclusion criteria will be grey literature, studies related to healthy volunteers, and hypothetical-only scenario surveys (e.g., 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 flowchart presenting studies excluded at a title, abstract and 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 versus 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 et al., 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, and (iii) 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 prioritization 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 healthcare 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 internationally), 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.

Disclosures

Emily Larsen'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).

Joshua Byrne's employer, Griffith University, has received on his behalf: an investigator-initiated grant-in-aid from Becton Dickinson.

Nicole Marsh'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).

Claire M. Rickard's employer, Griffith University, 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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About the Authors



Emily Larsen,* RN, has a joint appointment as a Research Fellow, Vascular Access, between Griffith University and the Royal Brisbane and Women's Hospital, Australia. Emily has been a Clinical Trial Co-ordinator for multi-centre vascular access trials since 2013. Her own research has focused on patient engagement and experiences of vascular access, and the use of vascular access devices within a Cancer Care setting.

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Dr. Josh Byrnes, PhD, is an Associate Professor and health economist at the Centre for Applied Health Economics, School of Medicine, Griffith University. Previously, Josh was employed as a Health Economist at the National Drug and Alcohol Research Centre (NDARC), University of New South Wales. Here he successfully studied for his PhD while generating reports and research outputs for government and non-government organizations. Josh has degrees in Commerce, Economics and Health Economics and received his PhD in 2012. Dr. Byrnes has authored numerous articles for peer reviewed scientific journals and is an invited speaker at both national and international conferences.



Nicole Marsh, RN, PhD, is the Nursing Director, Research, at the Royal Brisbane and Women's Hospital, and is an inaugural member of the AVATAR group. Since 2007, she has been a Project Manager on single- and multi-centre clinical trials related to vascular access devices. Her research focus is on preventing peripheral intravenous catheter complications.



Claire Rickard, PhD Grad Dip Nursing (Critical Care), is Professor of Nursing at Griffith University in Brisbane, Australia, and Visiting Professor at the Royal Brisbane and Women's, Princess Alexandra and Prince Charles Hospitals. Her vision is complication-free vascular access devices and infusion therapy. She founded the Alliance for Vascular Access Teaching and Research (AVATAR), a clinician-academic network with >\$13 million research funding and >200 publications. Claire's publications in the leading medical journal, *The Lancet*, have seen global change from time-based removal to assessment-based removal of peripheral intravenous catheters, and provided evidence for better dressings and securements. She has been inducted into the Sigma Theta Tau International Nurse Researcher Hall of Fame and is an elected Fellow of the Australian Academy of Health and Medical Sciences and the Australian College of Nursing. She has delivered invited presentations in more than 10 countries.

À propos des auteurs

Emily Larsen, inf. aut., occupe un poste de chercheuse dans le domaine de l'accès vasculaire attachée à la fois à l'Université Griffith et au Royal Brisbane and Women's Hospital, en Australie. Depuis 2013, elle coordonne des essais cliniques multicentriques sur l'accès vasculaire. Ses propres recherches portent principalement sur la participation du patient et son expérience concernant l'accès vasculaire, ainsi que sur l'utilisation de dispositifs d'accès vasculaire en oncologie.

Le **Dr Josh Byrnes, Ph. D.**, est professeur agrégé et économiste de la santé au Centre for Applied Health Economics, à l'école de médecine de l'Université Griffith. Antérieurement, il a occupé un poste d'économiste de la santé au National Drug and Alcohol Research Centre (NDARC), à l'Université de Nouvelle-Galles du Sud, où il a mené avec succès ses études de doctorat tout en produisant des rapports et des résultats de recherche pour des organisations gouvernementales et non gouvernementales. Il est titulaire de diplômes en commerce, en économie et en économie de la santé, et il a obtenu son doctorat en 2012. Le Dr Byrnes

est l'auteur de nombreux articles dans des revues scientifiques à comité de lecture et participe à des conférences nationales et internationales à titre de conférencier invité.

Nicole Marsh, inf. aut., Ph. D. est directrice de la recherche en soins infirmiers au Royal Brisbane and Women's Hospital et membre fondatrice du groupe AVATAR. Depuis 2007, elle dirige en tant que chargée de projet des essais cliniques multicentriques et monocentriques portant sur les dispositifs d'accès vasculaire. Ses recherches portent principalement sur la prévention des complications associées au cathéter veineux périphérique.

Claire Rickard, Ph. D., titulaire d'un diplôme d'études supérieures en soins infirmiers (soins intensifs), est professeure de sciences infirmières à l'Université Griffith de Brisbane, en Australie, et professeure invitée aux hôpitaux Royal Brisbane and Women's, Princess Alexandra et Prince Charles. Sa vision des dispositifs d'accès vasculaire et des traitements par perfusion est sans complications. Elle est la fondatrice de l'Alliance for Vascular Access Teaching and Research (AVATAR), un réseau de cliniciens et d'universitaires bénéficiant d'un financement de plus de 13 millions de dollars consacré à la recherche et ayant à son actif plus de 200 publications. Les publications de la professeure Rickard dans l'importante revue médicale *The Lancet* ont entraîné des changements à l'échelle mondiale en ce qui a trait au retrait des cathéters veineux périphériques en fonction d'une évaluation plutôt qu'en fonction du temps, et ont fourni des données probantes pour améliorer les pratiques relatives aux pansements et à la fixation du cathéter. La professeure Rickard a été intronisée au panthéon Sigma Theta Tau International Nurse Researcher et est membre élue de l'Australian Academy of Health and Medical Sciences et du Australian College of Nursing. Elle a été invitée à donner des conférences dans plus de 10 pays.

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