Building a Global, Pediatric Vascular Access Registry: A Scoping Review of Trial Outcomes and Quality Indicators to Inform Evidence-Based Practice

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ABSTRACT

Background: Internationally, there is a lack of comparative vascular access (VA) data for pediatric clinicians and organizations to benchmark outcomes, evaluate quality initiatives, and improve practice. A VA registry is needed to address these knowledge and data capture gaps.

Objectives: To determine the range and heterogeneity of VA outcome measures or quality indicators reported in randomized controlled trials (RCTs) and clinical registries, to inform development of a homogeneous, reliable, minimum dataset for a pediatric VA registry.

Methods: Scoping review framework. A systematic search for RCTs reporting VA outcomes in pediatrics and neonates was undertaken in the Cochrane library, EMBASE, CINAHL, PubMed, MEDLINE, and EBSCO using a medical subject headings and key words related to VA and pediatrics. We included RCTs of children (0–18 years) reporting any VA outcome. We identified clinical registries reporting VA data in children (0–18) through web-based searches using key words related to VA and clinical or quality registries. Additional registries were identified through peer consultation. The frequency and scope of outcome measures and quality indicators were extracted from trials and registries and evaluated.

Results: From 93 RCTs included, 214 different VA measures were reported, reflecting 14 outcome domains. The most commonly reported outcome domains were insertion (44 RCTs; 47%), noninfectious complications (33 RCTs; 35%), and infectious complications (30 RCTs; 32%). Of the 22 registries identified, VA-associated infection was the main quality indicator routinely collected (12 registries; 55%). Outcomes such as mechanical complications and patient-reported outcomes were infrequently collected.

Linking Evidence to Action: Vascular access outcomes reported in pediatric and neonatal RCTs are highly heterogeneous. Internationally, clinical registries currently collect minimal VA data with the exception of infection outcomes. A core dataset of reliable, relevant measures to children and clinicians for VA device quality is needed. This will enable a VA registry that facilitates inter-institutional and international benchmarking.

BACKGROUND

The establishment and maintenance of reliable vascular access (VA) are important across all disciplines, and for children in both inpatient and ambulatory patient settings (Scott-Warren & Morley, 2015). Despite the importance of vascular access devices (VADs), complications and failure of these devices are common, with an estimated 25% of central (Ullman, Marsh, Mihala, Cooke, & Rickard, 2015) and peripheral VADs (Malyon et al., 2014) failing prior to the completion of therapy. Despite recent advances in VA best practice, complications such as dislodgement, venous thrombosis, infiltration, pneumothorax, air embolism, and blood stream infection remain prevalent and often trigger device removal and insertion of replacement devices (Chopra, Anand, Krein, Chenoweth, & Saint, 2012; Ullman, Cooke, Kleidon, & Rickard, 2017a). This situation places enormous burden on children and families, as well as on the healthcare system.

Children and infants are especially vulnerable to VA-related complications due to anatomical factors (e.g., small veins, excess adipose tissue), immature immune systems, and potential for psychological distress (Scott-Warren & Morley, 2015). However, whilst the ability to obtain and
maintain reliable VA in pediatrics is forefront when dealing with an individual patient, quality data to monitor VA safety are rarely available at the institutional level. VA management in pediatrics is further complicated since VA insertion, care, and management of complications are largely decentralized throughout specialties, so the lifetime care of a child’s VA is not reported or managed with a comprehensive, long-term focus (Ullman, Kleidon, Cooke, & Rickard, 2017b). The health sector and families need increased access to data for tracking each patient’s VA journey, and measuring associated outcomes so as to maximize institutional safety and performance, and ensure intact vasculature into adulthood.

In recent years, interest in clinical registries has grown substantially. Globally, registries are used to collect epidemiological data (Saraiya, Tangka, Asma, & Richardson, 2016), to identify variations in practice (O’Byrne, Kennedy, Rome, & Glatz, 2018), and to assess the utilization and cost-effectiveness of therapies (Parnes et al., 2003). When implemented correctly and given time to mature, registries can have a measurable impact on clinical practice, healthcare processes and outcomes (Hoque et al., 2017). A study of 13 disease registries across five countries suggests the outcome of well-managed clinical registries is improved health outcomes for lower cost (Larson, Lawyer, Garellick, Lindahl, & Lundstrom, 2012). This was demonstrated in a recent, rigorous economic evaluation by the Australian Commission on Safety and Quality in Health Care who estimated the net economic benefit of five Australian registries to range from $2.4 (Victorian Prostate Cancer Registry) to $53 million (Australian Orthopaedic Association National Joint Replacement Registry; Australian Dollars [AUD]; Australian Commission on Safety and Quality in Health Care, 2016), the period of analysis ranged from 5 to 14 years.

The development of a pediatric VA registry is likely to benefit and advance quality, patient-centered VA care. Quality indicators derived from a VA registry such as complications and infection could then be used to benchmark practice and improve performance (Australian Commission on Safety and Quality in Health Care, 2014). Consideration of the minimum dataset is a fundamental first step in registry planning and design (Australian Commission on Safety and Quality in Health Care, 2008). A minimum dataset for pediatric VA outcomes has not yet been established, and it is necessary initially to understand the breadth and type of VA data that organizations currently value. The primary objective of the review was to determine the range and consistency of VAD outcomes reported in pediatric randomized controlled trials (RCTs). A secondary objective of the review was to determine the scope of VAD quality indicators reported in existing registries.

METHODS
Review Framework
The review used the scoping review framework developed by Arksey and O’Malley (2005). This consists of five stages: (a) identification of the research question, (b) identification of the relevant studies, (c) study selection, (d) charting the data, and (e) collating, summarizing, and reporting the results. The scoping review framework is as an appropriate method to examine the breadth of evidence on a given topic.

Identification of the Research Question
The objectives of the review were to identify core VAD outcomes and quality indicators as respectively reported in pediatric RCTs and clinical registries. These objectives led to the following research questions:

1. To determine what outcomes are reported in RCTs of pediatric patients with a VAD.
2. To assess what VA data are collected by clinical quality registries for pediatric patients.

Identification of the Relevant Trials
A systematic search for RCTs examining VAD interventions in neonates and pediatrics was conducted. We used the standard methods of The Cochrane Collaboration (Higgins & Green, 2011) to undertake a comprehensive search of the Cochrane Library, United States National Library of Medicine National Institutes of Health (PubMed), Cumulative Index to Nursing and Allied Health (CINAHL) and Embase (from January 2007). Databases were independently searched on the September 11, 2017. Medical subject headings were identified with a healthcare librarian and included “VA devices,” “catheterization, peripheral,” “catheterization, central venous,” “neonatal,” and “pediatrics.” Studies were eligible for inclusion if they met the predefined inclusion criteria: (a) RCT design; (b) study participants aged from birth to 18 years (neonates included); and (c) measured outcomes related to VADs including peripheral intravenous catheters (PIVCs), midlines, umbilical venous catheters (UVVs), arterial catheters (ACs), and central venous access devices (CVADs which include tunneled and nontunneled central lines, hemodialysis catheters, peripherally inserted central catheters, and totally implanted venous port devices). If studies reported both adult and pediatric data, we extracted only the pediatric data. No restrictions were placed on patient pathology or clinical setting. We excluded studies which reported educational outcomes, studies not reported in English, or studies greater than 10 years old to reflect practice and research outcome currency. Study authors did not need to be contacted since trial inclusion eligibility and data were extractable from the published reports.

Identification of the Relevant Registries
A search for clinical registries reporting VA data in pediatric and neonatal populations was undertaken. Clinical registries were identified through web-based searches using key words: VA, CVAD, PICC, healthcare-associated infections, CLABSI, clinical/device/quality registry. Further searches
were conducted in the web pages of national health agencies and safety and quality organizations. Hand searches of systematic review bibliographies were also undertaken. Additional registries were identified through peer consultation with pediatric VA experts in Europe, Northern America, and Australia. A post was uploaded to pediatric medical blog “Don’t forget the bubbles” asking for information pertaining to any registry which reports VA data. Registries were eligible for inclusion in the review if: (a) registry population was birth-18 years (neonates included) and (b) reported VAD outcomes or quality indicators. If not evident on review of clinical registries home page, registries were contacted to determine whether the registry dataset included VA variables. We did not exclude registries if they collected VA data in adults in addition to pediatric and neonatal patients.

Study Selection and Charting the Data
All data were extracted by two independent researchers (JS and RH) using a standardized data extraction form. References were exported, screened, and managed in EndNote™ (Clarivate Analytics, Philadelphia, PA, USA). Upon satisfying the inclusion criteria, study and registry data were extracted regarding country of origin, VAD type, outcome measures reported; outcome measure definitions; and safety and quality metrics. Due to the aim of the scoping review framework (Arksey & O’Malley, 2005), we did not formally evaluate the methodological quality. One registry was a “fee for service” product which limited data extraction (Sherline & Girgenti, 2018). Due to the scope and objective of the review, we did not report on registries consent approach, governance structures, or data quality with respect to coding validation and reliability checks.

Collating, Summarizing, and Reporting the Results
Descriptive statistics were used to summarize study populations, device characteristics, and registry attributes. The range and heterogeneity of outcome measures and safety and quality indicators were collated. Outcome measures from RCTs were grouped into an overarching list of outcome domains (Sinha, Jones, Smyth, & Williamson, 2008). Outcome domain classifications and groupings of outcome measures were cross-checked by four reviewers until consensus was achieved.

RESULTS
Research Question 1: What VA Outcomes Are Reported in Pediatric RCTs?
Identification and selection of relevant studies
Figure 1 describes the flow of studies included in the review, in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher, Liberati, Tetzlaff, & Altman, 2009). Following removal of duplicates (n = 206), the title and abstracts of 657 articles were screened and 463 papers were excluded as they did not meet the inclusion criteria. The full texts of 194 articles were retrieved and reviewed with 101 articles excluded as they did not meet the inclusion criteria. Two articles did not provide segregated pediatric data (Gabrail et al., 2010; Goossens et al., 2013); however, information regarding the number of pediatric patients and outcome measure definitions was adequate to facilitate data extraction. We excluded one publication (Harron et al., 2016), since it was a cost-analysis of an RCT published separately (which was included Gilbert et al., 2016). Finally, 93 met the inclusion criteria and were included in the review.

Characteristics of included studies
Characteristics of the 93 studies reviewed are provided in Table S1. Trial settings spanned 32 countries. Studies originated from North America (30 RCTs; 32%), Asia (25 RCTs; 27%), Europe (21 RCTs; 23%), South America (9 RCTs; 10%), Australia and Oceania (6 RCTs; 6%), and Africa (2 RCTs; 2%). The largest number of trials was published in 2013 (13 RCTs; 14%), followed by 2010 (12 RCTs; 13%). Study populations were aged less than 18 years with pediatric populations studied in 62 trials (67%) and neonates in 31 trials (33%). Pediatric patients comprised 79% (10,170) of the total sample size compared to neonates (2,708, 21%). The most common VADs studied were CVADs (39 trials; 42%); followed by PIVCs (31 trials; 33%); a combination of VAD types (12 trials; 13%); ACs (8 trials; 9%); UVCs (2 trials; 2%); and midlines (1 trial; 1%). Studies were conducted in the clinical specialties of intensive care (37, 40%), general inpatients (21, 22%), operating theater or anesthetic department (19, 21%), oncology or hematology settings (10, 11%), and the emergency department (6, 6%). Insertion technique was the most common interventional theme with 54 studies (58%), followed by patency (23 RCTs; 25%), catheter material (8 RCTs; 9%), dressing and securement studies (6 RCTs; 6%), infection prevention (1 RCT; 1%), and blood conservation (1 RCT; 1%). The reference list of included trials is outlined in supplementary material (Table S2).

Outcome measures
Across 93 trials, 214 VA outcome measures were reported. The number of outcome measures per trial ranged from 1 to 14 (median 3; IQR 2–4). The five most frequently reported outcome measures (author defined) across all trials were as follows: number of insertion attempts (19 trials; 20%); first attempt success (15 trials; 16%); adverse events (13 trials; 14%); pain (10 trials; 11%); and catheter-related bloodstream infection (CRBSI; 10 trials; 11%). The 214 outcome measures were grouped into 14 outcome domains, and these were further classified into clinical, patient or user reported, and key health indicator outcomes. Figure 2 depicts the proportion of trials that reported each outcome domain and the number of unique outcome measures for each domain. The three most commonly reported outcome domains were as follows: insertion complications (44
RCTs; 69 outcome measures), noninfectious complications (33 RCTs; 35 outcome measures), and infectious complications (30 RCTs; 33 outcome measures).

For clinical outcomes relating to catheter function or patient physiology, there were 22 (20 trials) and 14 (17 trials) outcome measures, respectively. Patient or user reported outcomes comprised four domains: pain (13 trials, 6 outcome measures); psychological impact (five trials, five outcome measures); parent satisfaction (three trials, three outcome measures); and staff satisfaction (four trials, five outcome measures). The five domains for healthcare quality indicators covered: mortality (six trials, five outcome measures); length of stay (five trials, five outcome measures); adverse events (13 trials, four outcome measures); cost (three trials, two outcome measures); and “other” (four trials, six outcome measures). The domain “other” included the outcome measures of feasibility (two trials), dressing dwell time, time to first dressing change, and completion of parenteral nutrition.

Research Question 2: What VA Data Are Currently Collected by Clinical Registries?

General attributes of included registries

A total of 21 registries were identified through electronic search methods. An additional eight registries were identified through peer consultation. Seven registries did not collect VA data and were excluded from the review including the Children’s Hospital Association and Vermont Oxford Network. The final review included 22 registries that collected some aspect of VA data. Table S3 outlines the general attributes of included registries. A total of eight registry custodians were contacted for further information.

Registries provided local (four registries; 18%), national (13 registries; 59%), and international (five registries; 23%) surveillance. In general, local surveillance systems were data-linked with larger umbrella registries (e.g., the European Renal Association [ERA]–European Dialysis and Transplant Association [EDTA] Registry). Registry target populations were intensive care patients (five registries;
23%), patients with renal pathology (11 registries; 50%), patients with a CVAD (two registries; 9%), children with cancer (one registry; 4%), and hospital inpatients (three registries; 14%). Nine registries collected data in pediatric or neonatal populations (41%), and 13 registries included all age patients (59%).

Registry dataset
Vascular access complication data were collected by 15 (68%) registries. Infection was the most commonly collected VA outcome (12 registries; 55%), with central line associated blood stream infection (CLABSI) rates surveilled in six registries. Various measures of insertion variables and catheter characteristics were reported across 18 registries.

The review identified and contacted two registries which solely focused on VADs originating in the USA (Sherline & Girgenti, 2018) and Serbia (Jemcov & Dimkovic, 2017). The CVAD Registry (Sherline & Girgenti, 2018), based in the USA, offers international VA surveillance to healthcare organizations for an annual fee (pay per use or private data). It expanded from a national PICC registry established in 2013 and collects CVAD data related to insertion, care and maintenance and infection control. This registry’s scope, data variables, and definitions are not publicly available, requiring registration; however, some variables could be extracted from the website. The Vascular Access Registry of Serbia, linked with the Serbian Society of Nephrology Dialysis and Kidney Transplantation (Jemcov & Dimkovic, 2017), collects VA data on CVAD location and type, in addition to arteriovenous fistula and graft information.

DISCUSSION
This is the first study to describe the range and heterogeneity of VA outcomes and quality measures reported in pediatric RCTs and clinical registries. Although VA complications can be grouped into a relatively small set of insertion, infectious, and noninfectious complications, we identified little consistency in the 93 reviewed RCTs with 214 different VA outcomes reported for children and neonates. In addition, we noted 22 registries in existence collecting at least one VA-related outcome for pediatric patients. In comparison with RCTs, registries collected limited VA insertion and complication data. In general, registries adopted a more uniform approach to the collection of blood stream infection data, applying standardized CLABSI definitions, typically the National Healthcare Safety Network. This is likely to facilitate benchmarking of infection rates across organizations and national or state reporting. Across RCTs, there was widespread heterogeneity of outcome measures with large variability in definitions and time points used. In contrast to registries, bloodstream infections associated with VA devices were reported by RCTs in 33 different ways, for example CRBSI, probable CRBSI, colonization, tunnel infection, and biofilm. This severely limits the comparability of treatment effect across studies.
In clinical trials, endpoint selection is crucial to determining intervention effect. Further, selection of surrogate or inappropriate endpoints can compromise the utility and generalizability of trial results (Sinha et al., 2008). The decision regarding choice of outcome measures should be based upon a core outcome set achieved through consensus, such as is the case with The Initiative on Methods, Measurement, and Assessment in Clinical Trials (PedIMMPACT, McGrath et al., 2008) and The Outcome Measures in Rheumatology (OMERACT, Tugwell et al., 2007). Although core outcomes in pediatrics are generally lacking (Chong et al., 2017), OMERACT and PedIMMPACT have contributed to improved trial feasibility (in these populations) and relevance and acceptability of trial endpoints on a global scale (Bertinotti, Nacci, & Matucci-Cerinic, 2006; Sinha et al., 2008). This has not yet been addressed for VA outcomes, and in the context of a registry dataset, standardization of outcome measures and time points would be essential to positively impact the useability of registry data by researchers, clinicians, and health care.

Approximately one third of included registries and trials collected VAD insertion data; however, there was a noticeable disconnect between insertion practices and the long-term VA outcomes. A recent case report of a 2-year-old child with gastroschisis (Ullman et al., 2017b) describes the journey of a young child who required 10 CVAD insertions due to recurrent device failure. For clinicians, reinsertion VA assessment and planning should strongly influence choice of VAD type; however, we found no trial or registry focussed on vein assessment tools or inserter decision making frameworks, nor measuring the effect of VADs on long-term vessel health. Vessel health and preservation is an important consideration that would require linked insertion and longer term follow-up data to inform both inserting and treating clinicians, particularly in the context of a child with a chronic disease. Current VA data capture systems are limited and do not provide a platform to collect or report this data.

Among trials and registries, there was a clear dominance of clinical outcome measures compared to patient-reported outcomes. Patient-reported outcomes were reported in <20% of trials, and not by any registry. The minimal patient-reported outcome data available are in direct contrast to public policy and health sector focus in recent decades on consumers. Internationally, health systems and researchers are urged to better consider the experience of patients and family members for an accurate appreciation of the safety and quality of care (National Health Institute for Health Research, United Kingdom Burt et al., 2017; Agency for Healthcare Research and Quality, 2016). Despite this, few studies have elicited perspectives from children with VADs and more importantly from children with chronic disease who require prolonged VA and multiple devices. Although measuring pediatric patient-reported outcomes can be challenging due to multiple factors such as a lack of standardized, age-specific tools (Cella et al., 2010), such outcomes reflect the child’s subjective experience and may help clinicians drive change at an organizational level. Valid patient-reported outcomes would need to be established in the context of a pediatric VA registry.

Many outcomes that are clinically relevant and important to children were absent from registries reporting VA data. Only two registries solely focussed on VADs, one of which was a commercial entity (CVAD Registry) with data not publicly reported for benchmarking. The VA Registry of Serbia collects VA data in children with renal disease. Registry reports are disseminated in Serbian with accompanying English translated diagrams. Among registries, there was overwhelming focus on VA infection data, with more than 50% of registries collecting a measure of VA infection including six collecting CLABSI data. Insertion data (descriptors) were collected by more than one third of registries. Clinically important VA complications such as catheter-related thrombosis, occlusion, dislodgement, and breakage (Ullman et al., 2015) were infrequently investigated even though these are the predominant contributors to around 25% of CVAD failures (Ullman et al., 2015). If registries are to have a measurable impact on practice, the minimum dataset must comprise measures relevant to the patient, device, clinician, researcher, and organization (Gliklich & Dreyer, 2007). In general, registries reported VA data in the context of CVADs, data concerning other VA devices were inconsistent. The need for a global VA registry has been recognized in specific devices such as PICCs (Girgenti & Moureau, 2013). We did not find any registry that reported variables specifically related to PIVCs. PIVCs are one of the most common devices a child will receive during a hospitalization (Malyon et al., 2014; Reigart et al., 2012), and high rates of PIVC failure may result in a CVAD insertion, but to date no platform exists to comprehensively monitor these devices.

Comprehensive, high quality, and proactive rather than reactive VA management is essential in pediatrics (Scott-Warren & Morley, 2015). A possible solution for the gap in VA data and knowledge is the expansion of current registries to include more comprehensive VA datasets. We have identified through this review that whilst efforts to establish a worldwide CVAD registry have commenced, there is currently no agreed minimum dataset which would form the “data spine” of a VA registry (Australian Commission on Safety and Quality in Health Care, 2008, p. 19). In order to derive maximum benefit from the significant time and resources required to enact such a comprehensive registry, it is vital that clinicians, health service executives, and researchers all derive benefit from the registry. A “common language” and widely understood data outcomes would promote international, national, and local benchmarking to support safety and quality improvements, whilst also providing a core VA outcomes platform for researchers to establish intervention superiority, reporting outcomes that also have shared meaning to health services globally. This,
in turn, would maximize implementation and generalizability of research results to health services. No such core outcome set currently exists in pediatric VA.

**IMPLICATIONS FOR PRACTICE AND FUTURE RESEARCH DIRECTIONS**

Electronic medical records could change the way data are collected and used for VA. Interfacing registries with electronic medical records will become important over the next decade. With the massive datasets generated from the capacity, careful consideration should be given to using common terminology to describe observations to assist in merging from different jurisdictions for analysis. Having access to electronic medical records will expedite the process of collating data for analysis. Given the variety of eHealth solution providers and the associated proprietary software, it is advantageous to establish consensus on the minimum dataset early, so health services implementing electronic medical records and wishing to establish similar registries can share the same lexicon.

These findings will inform the next phase of VA registry development, the establishment of international consensus regarding a minimum dataset. We aim to design a dataset that is meaningful, usable, and desirable for children and their parents, clinicians, researchers, and healthcare systems. The resulting dataset will comprise the minimum dataset for a global, open access, all device VA registry. Initiatives to establish core VA outcomes to be reported in all VA trials, including patient-reported outcomes and economic evaluations, would also be beneficial for researchers, clinicians, and policy makers.

**LIMITATIONS**

Our review has several limitations. Whilst we conducted a rigorous and extensive search for clinical registries, there may be registries which were not captured in the search, such as hospital-based registries. Further, we did not explore how registries have integrated with electronic medical records; however, we note this an area for future exploration.

**CONCLUSIONS**

Extensive variation exists in outcome measures reported in RCTs of VADs in children and neonates published in the last decade, and current registries provide little publicly accessible VA data. Lacking or heterogeneous data make it difficult for clinicians at the bedside to apply evidence into practice, for health executives to prioritize VA improvements, and for researchers to meaningfully use data in systematic reviews and follow-on studies. At present, there is limited capacity within the health system to access system level VA-related data and further investigation into the value of a core outcome set would be valuable. The establishment of a national VA registry is likely to be a complex, yet valuable, undertaking. Consensus is urgently needed regarding clinical and patient-reported outcomes and quality indicators that would best constitute a minimum dataset for a global VA pediatric registry. WVN

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References


Evidence Review


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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article at the publisher’s web site:

Table S1. Characteristics of Included Trials (n = 93)
Table S2. Reference List for Trials Included in the Review
Table S3. Attributes of Registries Included in the Review