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Author

Schults, Jessica A, Rickard, Claire M, Kleidon, Tricia, Hughes, Rebecca, Macfarlane, Fiona, Hung, Jacky, Ullman, Amanda J

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Building a global, pediatric vascular access registry: A scoping review of trial outcomes and quality indicators to inform evidence based practice.

Jessica A Schults^{a,b,c}, Claire M Rickard^{b,c}, Tricia Kleidon^{a,b,c}, Rebecca Hughes^c, Fiona Macfarlane^a, Jacky Hung^d, Amanda Ullman^{b,c}

- a. Department of Anaesthesia and Pain Management, Lady Cilento Children's Hospital, Queensland, Australia.
- b. Alliance for Vascular Access Teaching and Research (AVATAR) Group
- c. Menzies Heath Institute Queensland, School of Nursing and Midwifery, Griffith University, Queensland, Australia
- d. Centre for Children's Health Research, Children's Health Queensland

Jessica Schults, RN, GCert (Specialist Paed), MAppSci (Research)

Research Fellow, PhD Candidate

Department of Anaesthesia and Pain Management, Lady Cilento Children's Hospital, Queensland

Menzies Health Institute Queensland

School of Nursing and Midwifery, Griffith University, Queensland, Australia

Phone: (07) 3069 7625 Fax: (07) 3069 7149, Email: j.schults@griffith.edu.au

(CORRESPONDING AUTHOR)

Abstract

Background: Internationally, there is a lack of comparative vascular access (VA) data for paediatric clinicians and organisations 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 vascular access 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/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%), non-infectious 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: VA 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.

Keywords: Clinical registry, pediatrics, vascular access, quality indicators, evidence based practice

Background

The establishment and maintenance of reliable vascular access (VA) is 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 is 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, 2017). This situation places enormous burden on children and families, as well as on the health care system.

Children and infants are especially vulnerable to VA-related complications due to anatomical factors (small veins, excess adipose tissue), immature immune systems, and potential for psychological distress (Scott-Warren & Morley, 2015). However, while the ability to obtain and maintain reliable VA in pediatrics is forefront when dealing with an individual patient, quality data to monitor VA safety is rarely available at the institutional level. VA

management in pediatrics is further complicated since VA insertion, care and management of complications is largely decentralised 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, 2017). The health sector and families need increased access to data for tracking each patient's VA journey, and measure associated outcomes so as to maximise 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), identify variations in practice (O'Byrne, Kennedy, Rome, & Glatz, 2018) and to assess the utilisation 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). An international study of 13 disease registries across five countries suggested the outcome of a well-managed clinical registry is improved health outcomes for lower cost (Larsson, 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 centred 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 organisations currently value. The primary objective of the review was to determine the range and consistency of VAD outcomes reported in pediatric randomised controlled trials (RCTs). A secondary objective of the review was to determine the scope of VAD quality indicators reported in existing registries.

Method

Review framework

The review used the scoping review framework developed by Arksey and O'Malley (2005). This consists of five stages: 1) identification of the research question, 2) identification of the relevant studies, 3) study selection, 4) charting the data and 5) collating, summarising 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 randomised controlled trials of pediatric patients with a vascular access device.
2. To assess what vascular access 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 11th September 2017. Medical subject headings were with a healthcare librarian and included “vascular access devices”, “catheterization, peripheral”, “catheterization, central venous”, “neonatal” and “pediatrics”. Studies were eligible for inclusion if they met the predefined inclusion criteria: i) RCT design; ii) study participants aged from birth-18 years (neonates included); and iii) measured outcomes related to VADs including peripheral intravenous catheters (PIVCs), midlines, umbilical venous catheters (UVCs), arterial catheters (ACs) and central venous access devices (CVADs) (which include tunnelled and non-tunnelled central lines, haemodialysis 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 ten 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: vascular access, 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 organisations. 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: i) registry population was birth-18years (neonates included); and ii) 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, RH) using a standardised data extraction form. References were exported, screened and managed in EndNote™. 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, 2008). 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, summarising and reporting the results

Descriptive statistics were used to summarise 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 were 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.

>Insert Figure 1. PRISMA flow diagram

Characteristics of included studies

Characteristics of the 93 studies reviewed are provided in Table A1 (Supplementary material, Appendix 1). 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 were 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 theatre/anaesthetic department (19, 21%), oncology/haematology 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%) and infection

prevention (1 RCT; 1%) and blood conservation (1 RCT; 1%). The reference list of included trials is outlined in supplementary material (Appendix 2).

Outcome measures

Across 93 trials, 219 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: 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 blood stream infection (CRBSI) (10 trials; 11%). The 219 outcome measures were grouped into 14 outcome domains, these were further classified into clinical, patient or user reported, and key health indicator outcomes. Figure A2 (Supplementary material, Appendix 3) 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 (Supplementary material, Appendix 4, Fig. A3) were: insertion complications (44 RCTs; 74 outcome measures; Figure A3, A), non-infectious complications (33 RCTs; 35 outcome measures, Figure A3, B); and infectious complications (30 RCTs; 33 outcome measures, Figure A3, C).

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 (5 trials, 5 outcome measures); parent satisfaction (3 trials, 3 outcome measures); and staff satisfaction (4 trials, 5 outcome measures). The five domains for healthcare quality indicators covered: mortality (6 trials, 5 outcome measures); length of stay (5 trials, 5

outcome measures); adverse events (13 trials, 4 outcome measures); cost (3 trials, 2 outcome measures); and, 'other' (4 trials, 6 outcome measures). The domain 'other' included the outcome measures of feasibility (2 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 A2 (Supplementary material, Appendix 5) outlines the general attributes of included registries. A total of eight registry custodians were contacted for further information.

Registries provided local (4 registries; 18%), national (13 registries; 59%), and international (5 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 (5 registries; 23%), patients with renal pathology (11 registries; 50%), patients with a CVAD (2 registries; 9%), children with cancer (1 registry; 4%) and hospital inpatients (3 registries; 14%). Nine registries collected data in pediatric and/or neonatal populations (41%), 13 registries included all age patients (59%).

Registry dataset

VA complication data was 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, 2008) and Serbia (Jemcov & Dimkovic, 2017). The *CVAD Registry* (Sherline, 2008), based in the USA, offers international VA surveillance to healthcare organisations for an annual fee (pay per use/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 publically 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 non-infectious complications, we identified little consistency in the 93 reviewed RCTs with a 219 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 to

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 standardised CLABSI definitions, typically the National Healthcare Safety Network. This is likely to facilitate benchmarking of infection rates across organisations and national/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 e.g. CRBSI, probable CRBSI, colonisation, 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 generalisability 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 Pain 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, standardisation of outcome measures and time points would be essential to positively impact the useability of registry data by researchers, clinicians and healthcare.

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 two year old with gastroschisis (Ullman, Kleidon, et al., 2017) describes the journey of a young child who required 10 CVAD insertions due to recurrent device failure. For clinicians, re-insertion 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 is 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, United States (AHRQ, 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 standardised, age specific tools (Cella et al., 2010), such outcomes reflect the child's subjective experience and may help clinicians drive change at an organisational 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 publically 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) was 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 organisation (Gliklich & Dreyer, 2007). In general, registries reported VA data in the context of CVADs, data concerning other VA devices was inconsistent. The need for a global VA registry has been recognised in specific devices such as PICCs (Girgenti & Moureau). We did not find any registry that reported variables specifically related to peripheral intravenous catheters (PIVCs). PIVCs are one of the most common devices a child will receive during a hospitalisation (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 maximise implementation and generalisability 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 is collected and used for VA.

Interfacing registries with electronic medical records will become important over the next decade. With the massive data sets 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 propriety 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.

Box 1. Linking evidence to action

- There is significant variation in outcome measures reported in randomised controlled trials of pediatric patients with a vascular access device. This makes it hard for clinicians to interpret the relevance of the findings and make comparisons between research studies.
- Many outcomes that are clinically relevant to children are absent from registries reporting vascular access data, making it difficult to assess the effect of evidence based practice initiatives on patient outcomes.
- A pediatric vascular access registry will facilitate the benchmarking of practice and

evaluation of evidence based practice initiatives

- Clinicians and health care organisations can use the information collected in a registry to inform practice and decision making, positively improving children's health outcomes

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.

Conclusion

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 publically accessible VA data. Lacking or heterogeneous data makes it difficult for clinicians at the bedside to apply evidence into practice, for health executives to prioritise 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.

Reference List

AHRQ. (2016). CAHPS: Assessing Health Care Quality From the Patient's Perspective.

Retrieved from https://www.ahrq.gov/cahps/about-cahps/cahps-program/cahps_brief.html

Arksey, H., & O'Malley, L. (2005). Scoping studies: towards a methodological framework.

International Journal of Social Research Methodology, 8(1), 19-32.

doi:10.1080/1364557032000119616

Australian Commission on Safety and Quality in Health Care. (2008). *Operating Principles*

and Technical Standards for Australian Clinical Quality Registries. Retrieved from

Sydney:

Australian Commission on Safety and Quality in Health Care. (2014). *Framework for*

Australian Clinical Quality Registries. Sydney: ACSQHC.

Australian Commission on Safety and Quality in Health Care. (2016). *Economic evaluation of*

clinical quality registries: Final report. Sydney: ACSQHC.

Bertinotti, L., Nacci, F., & Matucci-Cerinic, M. (2006). The measurement of outcome and the

rheumatoid arthritis core set to lift the prejudice of the 'thaumaturgus cliché'.

Rheumatology, 45(9), 1055-1057. doi:10.1093/rheumatology/kel187

Burt, J., Campbell, J., Abel, G., Aboulghate, A., Ahmed, F., Asprey, A., . . . Roland, M. (2017).

Programme Grants for Applied Research *Improving patient experience in primary*

care: a multimethod programme of research on the measurement and improvement

of patient experience. Southampton (UK): NIHR Journals Library.

Cella, D., Riley, W., Stone, A., Rothrock, N., Reeve, B., Yount, S., . . . Hays, R. (2010). The

Patient-Reported Outcomes Measurement Information System (PROMIS) developed

and tested its first wave of adult self-reported health outcome item banks: 2005-

2008. *Journal of Clinical Epidemiology*, 63(11), 1179-1194.

doi:10.1016/j.jclinepi.2010.04.011

Chong, L. S. H., Sautenet, B., Tong, A., Hanson, C. S., Samuel, S., Zappitelli, M., . . . Craig, J. C.

(2017). Range and Heterogeneity of Outcomes in Randomized Trials of Pediatric Chronic Kidney Disease. *Journal of Pediatrics*, 186, 110-117.e111.

doi:10.1016/j.jpeds.2017.03.034

Chopra, V., Anand, S., Krein, S. L., Chenoweth, C., & Saint, S. (2012). Bloodstream infection, venous thrombosis, and peripherally inserted central catheters: reappraising the evidence. *American Journal of Medicine*, 125(8), 733-741.

doi:10.1016/j.amjmed.2012.04.010

Gabrail, N., Sandler, E., Charu, V., Anas, N., Lim, E., Blaney, M., . . . Begelman, S. M. (2010).

TROPICS 1: a phase III, randomized, double-blind, placebo-controlled study of tenecteplase for restoration of function in dysfunctional central venous catheters.

JVIR, 21(12), 1852-1858. Retrieved from

[http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/600/CN-](http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/600/CN-00779600/frame.html)

00779600/frame.html doi:10.1016/j.jvir.2010.09.002

Gilbert, R. E., Mok, Q., Dwan, K., Harron, K., Moitt, T., Millar, M., . . . Gamble, C. (2016).

Impregnated central venous catheters for prevention of bloodstream infection in children (the CATCH trial): a randomised controlled trial. *Lancet*, 387 (10029), 1732-1742. doi:10.1016/S0140-6736(16)00340-8

Girgenti, C., & Moureau, N. L. The Need for Comparative Data in Vascular Access: The Rationale and Design of the PICC Registry. *J Assoc Vas Access*, 18(4), 219-224.

doi:10.1016/j.java.2013.07.003

- Gliklich, R. E., & Dreyer, N. A. (Eds.). (2007). *Registries for Evaluating Patient Outcomes: A User's Guide. (Prepared by Outcome DEcIDE Center [Outcome Sciences, Inc. dba Outcome] under Contract No. HHS290200500351 TO1.) AHRQ Publication No. 07-EHC001-1*. Rockville, MD: Agency for Healthcare Research and Quality.
- Goossens, G. A., Jérôme, M., Janssens, C., Peetermans, W. E., Fieuws, S., Moons, P., . . . Stas, M. (2013). Comparing normal saline versus diluted heparin to lock non-valved totally implantable venous access devices in cancer patients: a randomised, non-inferiority, open trial. *Annals of Oncology, 24*(7), 1892-1899. Retrieved from doi:10.1093/annonc/mdt114
- Harron, K., Mok, Q., Dwan, K., Ridyard, C. H., Moitt, T., Millar, M., . . . Gilbert, R. E. (2016). CATHeter Infections in CHildren (CATCH): a randomised controlled trial and economic evaluation comparing impregnated and standard central venous catheters in children. *Health technology assessment (winchester, england), 20*(18), vii-xxviii, 1-219. Retrieved from <http://onlinelibrary.wiley.com/doi/10.3310/hta20180>
- Higgins, J. P. T., & Green, S. (Eds.). (2011). *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]*: The Cochrane Collaboration.
- Hoque, D. M. E., Kumari, V., Hoque, M., Ruseckaite, R., Romero, L., & Evans, S. M. (2017). Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review. *PLoS One, 12*(9), e0183667. doi:10.1371/journal.pone.0183667
- Jemcov, T., & Dimkovic, N. (2017). Vascular access registry of Serbia: a 4-year experience. *International Urology and Nephrology, 49*(2), 319-324. doi:10.1007/s11255-016-1378-9

- Larsson, S., Lawyer, P., Garellick, G., Lindahl, B., & Lundstrom, M. (2012). Use of 13 disease registries in 5 countries demonstrates the potential to use outcome data to improve health care's value. *Health Affairs, 31*(1), 220-227. doi:10.1377/hlthaff.2011.0762
- Malyon, L., Ullman, A. J., Phillips, N., Young, J., Kleidon, T., Murfield, J., & Rickard, C. M. (2014). Peripheral intravenous catheter duration and failure in paediatric acute care: A prospective cohort study. *Emergency Medicine Australasia, 26*(6), 602-608. doi:10.1111/1742-6723.12305
- McGrath, P. J., Walco, G. A., Turk, D. C., Dworkin, R. H., Brown, M. T., Davidson, K., . . . Zeltzer, L. (2008). Core outcome domains and measures for pediatric acute and chronic/recurrent pain clinical trials: PedIMMPACT recommendations. *Journal of Pain, 9*(9), 771-783. doi:10.1016/j.jpain.2008.04.007
- Moher, D., Liberati, A., Tetzlaff, J., & Altman, D. G. (2009). Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Medicine, 6*(7), e1000097. doi:10.1371/journal.pmed.1000097
- O'Byrne, M. L., Kennedy, K. F., Rome, J. J., & Glatz, A. C. (2018). Variation in practice patterns in device closure of atrial septal defects and patent ductus arteriosus: An analysis of data from the IMproving Pediatric and Adult Congenital Treatment (IMPACT) registry. *American Heart Journal, 196*, 119-130. doi:10.1016/j.ahj.2017.10.018
- Parnes, C., Guillermin, J., Habersang, R., Nicholes, P., Chawla, V., Kelly, T., . . . Smith, C. (2003). Palivizumab prophylaxis of respiratory syncytial virus disease in 2000-2001: results from The Palivizumab Outcomes Registry. *Pediatric Pulmonology, 35*(6), 484-489. doi:10.1002/ppul.10288

- Reigart, J. R., Chamberlain, K. H., Eldridge, D., O'Brien, E. S., Freeland, K. D., Larsen, P., . . . Hartzog, T. H. (2012). Peripheral intravenous access in pediatric inpatients. *Clinical Pediatrics*, 51(5), 468-472. doi:10.1177/0009922811435164
- Saraiya, M., Tangka, F. K., Asma, S., & Richardson, L. C. (2016). Importance of economic evaluation of cancer registration in the resource limited setting: Laying the groundwork for surveillance systems. *Cancer Epidemiology*, 45(Suppl 1), S1-S3. doi:10.1016/j.canep.2016.10.001
- Scott-Warren, V. L., & Morley, R. B. (2015). Paediatric vascular access. *BJA Education*, 15(4), 199-206. doi:10.1093/bjaceaccp/mku050
- Sherline, C. (2008). CVAD Registry.
- Sinha, I., Jones, L., Smyth, R. L., & Williamson, P. R. (2008). A systematic review of studies that aim to determine which outcomes to measure in clinical trials in children. *PLoS Medicine*, 5(4), e96. doi:10.1371/journal.pmed.0050096
- Tugwell, P., Boers, M., Brooks, P., Simon, L., Strand, V., & Idzerda, L. (2007). OMERACT: An international initiative to improve outcome measurement in rheumatology. *Trials*, 8, 38-38. doi:10.1186/1745-6215-8-38
- Ullman, A. J., Cooke, M., Kleidon, T., & Rickard, C. M. (2017). Road map for improvement: Point prevalence audit and survey of central venous access devices in paediatric acute care. *Journal of Paediatrics and Child Health*, 53(2), 123-130. doi:10.1111/jpc.13347
- Ullman, A. J., Kleidon, T., Cooke, M., & Rickard, C. M. (2017). Substantial harm associated with failure of chronic paediatric central venous access devices. *BMJ Case Reports*. doi:10.1136/bcr-2016-218757

Ullman, A. J., Marsh, N., Mihala, G., Cooke, M., & Rickard, C. M. (2015). Complications of Central Venous Access Devices: A Systematic Review. *Pediatrics*, *136*(5), e1331-1344.
doi:10.1542/peds.2015-1507