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International recommendations for a vascular access minimum dataset: a Delphi consensus-building study

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ABSTRACT

Background Data regarding vascular access device use and outcomes are limited. In part, this gap reflects the absence of guidance on what variables should be collected to assess patient outcomes. We sought to derive international consensus on a vascular access minimum dataset.

Methods A modified Delphi study with three rounds (two electronic surveys and a face-to-face consensus panel) was conducted involving international vascular access specialists. In Rounds 1 and 2, electronic surveys were distributed to healthcare professionals specialising in vascular access. Survey respondents were asked to rate the importance of variables, feasibility of data collection and acceptability of items, definitions and response options. In Round 3, a purposive expert panel met to review Round 1 and 2 ratings and reach consensus (defined as ≥70% agreement) on the final items to be included in a minimum dataset for vascular access devices.

Results A total of 64 of 225 interdisciplinary healthcare professionals from 11 countries responded to Round 1 and 2 surveys (response rate of 34% and 29%, respectively). From the original 52 items, 50 items across five domains emerged from the Delphi procedure.Items related to demographic and clinical characteristics (n=5; eg, age), device characteristics (n=5; eg, device type), insertion (n=16; eg, indication), management (n=9; eg, dressing and securement), and complication and removal (n=15, eg, occlusion) were identified as requirements for a minimum dataset to track and evaluate vascular access device use and outcomes.

Conclusion We developed and internally validated a minimum dataset for vascular access device research. This study generated new knowledge to enable healthcare systems to collect relevant, useful and meaningful vascular access data. Use of this standardised approach can help benchmark clinical practice and target improvements worldwide.

INTRODUCTION

International healthcare systems have made advances in promoting a safety culture with high levels of reporting. Despite this, data collected by routine sources on vascular access devices are fragmented, incomplete or non-specific, failing to capture important vascular access or patient outcomes. While other routine data sources or surveillance systems focus on incidence, prevalence and mortality data for specific health or patient groups (eg, minimum dataset (MDS) on ageing and older persons)[1] standardised, routine vascular access data capture exists for relatively few countries. Therefore, aggregate data are difficult to obtain, and concerns arise regarding the paucity and quality of available data. Further, use of non-standardised item measurement and definitions make benchmarking performance, conducting risk factor analyses or cost-effectiveness investigations difficult. At present, there is no common standard name for each type of vascular access device, and this inconsistency leads to confusion and further affects data capture and performance measurement. The lack of vascular access data capture severely hinders the measurement of safety performance and establishing best practice worldwide, thus adversely impacting outcomes in hospitalised patients.

Annually, millions of vascular access devices are used across the globe, for indications ranging from intravenous medication and fluid administration to haemodynamic monitoring and the delivery of life-saving treatments such as vasopressors and chemotherapy. Despite their prevalence, 69% of peripheral[2 3] and

25% of central venous catheters[4–6] fail prior to treatment completion. High failure rates and associated complications have been recognised internationally for their contribution to patient harm and increased healthcare expenditure.[7] Yet, how best to define failure and measure specific aspects related to device characteristics, device care and outcomes remains unclear. In fact, limited guidance exists regarding which data items related to vascular access devices are necessary to benchmark practice and evaluate improvement initiatives.

A vascular access MDS for use within healthcare organisations could help quantify and evaluate the number of vascular access devices inserted, rate of catheter complications, failure and performance gaps. This approach would mirror quality improvement efforts in other healthcare specialities and industries, including cardiac surgery,[8] geriatric care,[1] system level incident reporting[9] and aviation.[10] While several MDS have been developed for specific healthcare specialities in a range of countries, these datasets are either generic to the country or specialty, or specific to a patient device (eg, central venous catheter) or population (eg, intensive care patients).[11–13] As vascular access devices are required by most hospitalised patients, existing datasets do not reflect the unique needs of clinicians, consumers and health services seeking to evaluate vascular access care delivery and outcomes. The objective of this study was to gain international consensus from healthcare professionals specialising in vascular access regarding clinically important and feasible items to include in a vascular access MDS.

METHODS
Study design
We used a modified Delphi[14–16] process consisting of two electronic survey rounds, followed by an in-person panel meeting, to define an international MDS for vascular access practice and outcome measurement.[17] The aim of this Delphi process was to devise a final MDS and accompanying device nomenclature that (1) support evidence-based practice, (2) are pragmatic to collect and valuable to the health service and (3) facilitate benchmarking and practice evaluation and improve practice.

The Delphi process is a method of generating consensus among experts, while the survey gives anonymity and equal influence to all participants (figure 1).[18] This method is increasingly used to attain consensus regarding core outcomes in clinical trials,[19] implementation strategies[20] and MDS.[16 21] Written consent was waived for survey participants as participation implied consent, and written informed consent was obtained from Round 3 consensus panel participants for audio recording.

Participants
Using purposive sampling, healthcare professionals specialising in vascular access were identified via global professional and investigator networks (ie, the Association for Vascular Access, the Vascular Access Management Global Initiative, World Congress of Vascular Access (WoCoVA) to participate in defining an MDS. We invited individuals via email to participate in the study, and later expanded to a general invitation via social media. We convened healthcare professionals specialising in vascular access across health disciplines (ie, medicine or nursing), clinical specialty (ie, infectious disease, critical care, emergency medicine, anaesthesiology, interventional radiology, haematology/oncology, surgery, paediatrics, neonatology, infection prevention and patient safety and quality) and geography (Oceania, Canada, Europe, Southwest Asia, North and South America) to generate consensus regarding data items.
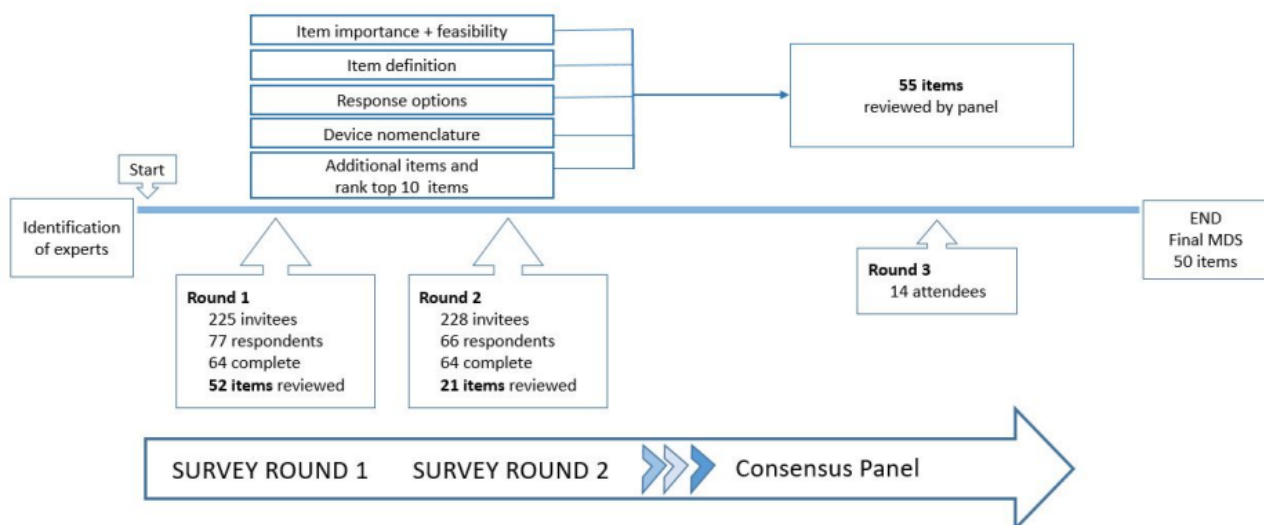
Figure 1 Delphi rounds. MDS, minimum dataset.

For Round 3, leading international experts across disciplines who are respected scholars or researchers, represent professional societies, or have substantial clinical experience in the field were invited to participate.[22 23] Panel representation, including specialty, is outlined in online supplemental material 1.

Definition of methodological terms

Participants were asked to assess all items' importance, feasibility and acceptance over three rounds. Measurement scales were based on scales reported in studies of similar methods.[9 15 16] Item importance was defined as the importance of including an item in the MDS. Item importance was assessed on a 9-point Likert scale. A score of 7–9 indicated the item was of 'critical importance', a score of 4–6 indicated 'important but not critical' and a score of 1–3 indicated 'limited importance'.[24] Item feasibility assessed the feasibility of collecting data on the item. Item feasibility was measured using a 3-point Likert scale as 'not feasible', 'somewhat feasible' or 'feasible'. Acceptability of item definition and response options (eg, for gender, male, female, indeterminate) and device nomenclature were assessed on a 4-point Likert scale from 'not acceptable', 'acceptable with major revision', 'acceptable with minor revision' or 'acceptable'. Consensus for those questions answered by a scale was prespecified as ≥70% of participants in agreement (eg, of an item's importance).[25 26]

Study procedures

Dataset development

Original (Round 1) items were based on our scoping review of vascular access outcome measures and quality indicators[27]; interviews with healthcare professionals[28]; international peripheral intravenous catheter (PIVC)[29] and central venous access device research[30]; and international[31] and local quality databases.[32] To facilitate development and ensure appropriate domains were included, data items were categorised into five areas: patient characteristics, device characteristics, insertion characteristics, management characteristics, and complication and removal items. Device nomenclature were developed following a review of international vascular access standards and guidelines.[22 33] Participant demographic data (eg, age, geography, discipline) were collected with data items. Sequential surveys were administered online via REDCap.[34 35]

Delphi survey rounds

Round 1: Survey participants were asked to rate item importance and feasibility of collecting item data. Participants also assessed item definitions, response options and device nomenclature acceptability. At the end of Round 1, survey respondents were invited to suggest revisions to item definitions, response options,

device nomenclature and additional items for consideration in Round 2.

Round 2: Survey participants reviewed items excluded from Round 1 (those who failed to reach consensus for importance and feasibility) and re-rated these items as yes/no/unsure for inclusion.[9 16] Survey participants were provided Round 1 median scores and range for excluded items (those who failed to reach consensus for importance and feasibility) and re-rated. We performed this re-review to ensure that items were not inadvertently selected for removal. Additional items proposed by Round 1 respondents were reviewed in Round 2 and rated for importance and feasibility of data collection. In this way, Round 2 helped to further refine Round 1 ratings. Round 2 participants were also invited to rank their top 10 priority items. Only data items that were rated as important (median score of ≥7) and feasible to collect (median score of somewhat feasible or feasible) advanced into Round 3.[24] In this way, we ensured the creation of a minimum set of variables that were considered most important. All definitions that did not reach consensus for acceptable were discussed in Round 3 and amended as per panel recommendations. We did not prohibit Round 1 and 2 participants from sharing the survey link with other colleagues.

Expert consensus panel

Round 3: To generate final recommendations, an international panel of 14 healthcare professionals specialising in vascular access from 11 countries (all of whom had been participants in Rounds 1 and 2) were convened in São Paulo, Brazil, on 16 July 2019 (coinciding with the WoCoVA conference) for a 1-day face-to-face meeting. This smaller group was tasked with the role of reaching consensus on item importance and feasibility, acceptability of item definition, response options and device nomenclature for final consideration. Expert panellists were provided with a study document outlining all item definitions, response options, Round 1 and 2 responses (median scores and range) and proposed additional and excluded items (115 pages). JS and CR facilitated the consensus panel, ensuring all panellists had an equal voice to express viewpoints. If consensus was unable to be reached, this was recorded as the proportion of agreement for the relevant item and associated elements. The panel meeting was audio-recorded with panellists' consent.

Statistical analysis

Data were analysed using IBM Statistical Package for the Social Sciences (SPSS) V.25. Descriptive statistics were used to summarise respondents' characteristics and demographic details. For each item outcome, the median, mean and proportion rating were calculated. For ranking scores, the median and IQR for each item outcome was calculated to determine rank.

RESULTS

The flow of Delphi rounds and participants are presented in figure 1. Following electronic distribution to 225 clinicians, Round 1 and 2 surveys had a response rate of 34% and 29%, respectively. In total, 64 participants completed Round 1. Of these, 61 went on to complete Round 2. There were three additional respondents in Round 2 who did not participate in the first survey. Round 2 had an additional three invitees as the survey link was shared between colleagues who wanted to include feedback from a broader pool. Round 3 panellists completed all three Delphi rounds. Table 1 describes the respondent characteristics from Rounds 1 and 2.

The majority of respondents were females (Round 1; 37 of 64, 58%), aged between 30 and 50 years (Round 1; 35 of 64, 55%). Approximately 34% of respondents were physicians from diverse fields including anaesthesia and intensive care (Round 1; 9 of 22, 41%), surgery (4 of 22, 18%) and paediatrics (3 of 22, 14%). The remaining respondents were nurses (~60% Rounds 1 and 2) mainly practising in vascular access (Round 1; 8 of 39, 21%) or other intensive care providers (7 of 39, 18%). Round 3 involved 14 experts from 11 countries with specialities spanning infectious disease, oncology, surgery, paediatrics, neonates, hospitalists and intensive care.

Data items

Table 2 summarises the flow of data items through the Delphi study.

Round 1 survey results

From the initial 52 items considered, there were high levels of agreement for inclusion of 49 data items, with medians indicating strong agreement (7–9 on the 9-point Likert scale). Three items were excluded based on median importance ratings: patient skin colour (median importance 5, IQR 2–7; range 1–9); catheter lot number (5, IQR 3–7; range 1–9) and level of sedation during device insertion (6, IQR 4–8; range 3–9). Of the remaining 49 items, 36 were rated as feasible to collect and 13 as somewhat feasible to collect (eg, number of attempts or replacement insertion required). There was agreement for minor revisions of 10 item definitions; for example, catheter length was revised to include options for external length measurement, internal length or intravascular length. Response options for 33 items were rated as acceptable, and 20 items achieved consensus for 'minor revision'. For example, site of insertion was broken into two categories for peripheral intravenous catheters (body site) and central venous catheters (vein). Round 1 respondents proposed 18 additional items for inclusion, including 'insertion by another facility'.

Table 1 Demographic characteristics of Round 1 and 2 respondents

Variable	Round 1 N=64	Round 2 N=64
Gender, n (%)		
Male	27 (42)	25 (39)
Female	37 (58)	39 (61)
Age, n (%)		
20–29 years	1 (2)	1 (1)
30–39 years	14 (22)	11 (17)
40–49 years	21 (33)	21 (33)
50–59 years	17 (27)	18 (28)
≥60 years	11 (17)	13 (20)
Country of practice, n (%)		
Africa	1 (2)	1 (2)
Asia	6 (9)	6 (9)
Europe	13 (20)	13 (20)
Middle East	3 (5)	3 (5)
North America	12 (19)	15 (24)
Oceania	22 (34)	20 (31)
South America	6 (9)	6 (9)
Discipline and specialty, n (%)		
Doctor	**22 (34)**	**22 (34)**
Anaesthesia/ICU	9 (41)	7 (32)
Surgery	4 (18)	5 (23)
Paediatrics	3 (14)	5 (23)
Interventional radiology	2 (9)	2 (9)
Other	4 (20)	3 (15)
Nurse	**39 (61)**	**38 (60)**
Vascular access	8 (21)	9 (24)
Intensive care	7 (18)	7 (18)
Academia/research	5 (13)	5 (13)
Oncology/haematology	5 (13)	5 (13)
Infection prevention and control	4 (10)	3 (8)
Paediatrics	3 (8)	3 (8)
Infusion therapy*	7 (18)	6 (16)
Other	**3 (5)**	**4 (6)**
Formal vascular access qualification, n (%)†		
No	28 (43)	25 (38)
Yes	11 (17)	13 (21)
Not applicable	25 (39)	26 (41)
Patient population		
Adult	30 (47)	25 (39)
Mixed	24 (38)	26 (41)
Paediatric/neonate	10 (16)	13 (20)

*Includes home infusion.
†Nurse only, n=39.
ICU, intensive care unit.

Round 2 survey results

Of the additional items (n=18) proposed in Round 1, four achieved high levels of agreement for inclusion (patient comorbidities, catheter materials, organism identified and catheter-to-vein ratio). Consistent with Round 1, the three excluded items achieved consensus

Table 2 Flow of data items through Delphi rounds

Initial dataset	Demographic items	Device characteristic items	Insertion items	Management items	Complication/removal items
Round 1	Considered 5 Included 4 Excluded 1 Added* 1	Considered 5 Included 4 Excluded 1 Added* 1	Considered 16 Included 15 Excluded 1 Added* 9	Considered 9 Included 9 Added* 4	Considered 17 Included 17 Added* 3
Round 2	Considered 5 Excluded 1 Added 1	Considered 5 Excluded 1 Added 1	Considered 23 Excluded 8 Added 2	Considered 13 Excluded 4	Considered 20 Excluded 1
Round 3	Considered 5 Included 5	Considered 5 Included 5	Considered 17 Included 16†	Considered 9 Included 9‡	Considered 19 Included 15†
Dataset	5 items	5 items	16 items	9 items	15 items

Consensus = ≥70% of survey respondents or panellists.
*Additional variables proposed by participants in Round 1.
†Items merged.
‡Flushing variable relabelled to locking solution only.

for exclusion (yes to exclude; 57 respondents, 89%). A top 10 priority list was also achieved and included items such as date and time of insertion, indication, number of attempts and catheter tip position (online supplemental material 2).

Round 3 consensus panel results

In Round 3, 55 items were considered by the expert panel with associated item definitions and response options. Following expert review, the number of items were reduced to 50, with the merging of items, including the complication 'bloodstream infection'. Round 3 panellists agreed that data on bloodstream infections would be captured under the item 'primary bloodstream infection', with response options to capture severity and level of microbiological confirmation. Panellists discussed the addition of branching logic to include data capture of the micro-organism isolated in the blood or catheter tip, however, recognised this may not be feasible for all healthcare facilities.

Minimum dataset

The 3-Round Delphi process resulted in a 50-item MDS which can be grouped into the broad categories of: patient demographics, device characteristics, insertion characteristics, management, complication and removal items (table 3). Demographic items included patient and clinical characteristics such as age, weight and diagnostic group. Device characteristics captured catheter details such as lumen number and catheter material. Insertion characteristics, the largest category with 16 items, included items such as technology used, insertion-related adverse events, and dressing and securement. Items concerning device management included site assessment, complication identified and device use. For complication and removal items, there was agreement that items including thrombosis, catheter-associated skin injury and dislodgement be included; these items comprised 15 of the final 50 included in the MDS.

Table 3 Vascular access minimum dataset

Patient demographics (n=5)
1. Age
2. Weight
3. Gender
4. Diagnostic group
5. Patient comorbidities

Device characteristics (n=5)
6. Device type
7. Catheter size
8. Catheter length
9. Catheter lumen
10. Catheter material

Insertion items (n=16)
11. Indication
12. Insertion date and time
13. Number of attempts
14. Site of insertion
15. Location of insertion
16. Inserter designation
17. Technique used
18. Technology used
19. Antisepsis used
20. Catheter to vein ratio
21. Tip position
22. Tip position confirmation
23. Pain relief
24. Dressing and securement
25. Insertion-related adverse event
26. Can the patient identify the reason for the device?

Management items (n=9)
27. Is the device being used?
28. Site assessment
29. Lock solution
30. Dressing schedule
31. Dressing and securement
32. Blood sampling
33. Number of other vascular access devices
34. Complication identified
35. Use of antithrombolytics

Complication and removal items (n=15)
36. Phlebitis
37. Infiltration and extravasation
38. Primary bloodstream infection
39. Local infection
40. Dislodgement
41. Thrombosis
42. Occlusion
43. Internal malposition
44. Fracture
45. Catheter-associated skin injury
46. Reason for removal
47. Date time or removal
48. Replacement insertion required
49. Length of stay—hospital
50. Patient-reported pain/discomfort

Vascular access device nomenclature

Vascular access device nomenclature were developed and consensus achieved for the following devices: PIVC (round 3; 14 of 14, 100%); midline catheter (14 of 14 participants, 100%); peripherally inserted central catheter (PICC) (14 of 14 participants, 100%); non-tunnelled central venous catheter (13 of 14 participants, 93%; 1 abstain); tunnelled central venous catheter (14 of 14 participants, 100%); totally implanted venous access device (14 of 14 participants, 100%) and haemodialysis catheter (11 of 12 participants, 92%; 2 abstain). We based the definition of peripheral or central venous catheter on the location of the catheter tip termination. Device nomenclature were intentionally broad as they were developed for global data capture (1).

DISCUSSION

The Delphi study resulted in a 50-item MDS, specifically designed to support the current and ongoing evaluation of vascular access practice and outcomes. Until now, clinicians, researchers and executives have had little-to-no guidance on the clinically relevant and consistent reporting of vascular access-related data.[27 28 36] This has consequences when devices fail or complications occur, with healthcare systems having limited opportunity to explore, intervene or set in place remedies to prevent future events. Lack of a standard data capture methodology is a core aspect of this problem. This study achieved its aim to develop an MDS for a vascular access data capture, with accompanying item definitions and response options. To our knowledge, this is the first consensus-based vascular access dataset in development. This fills a gap in the current evidence, providing an initial, pragmatic and specific dataset for international application.

The premise of standardised vascular access data collection is that it enables standardisation of what data elements to capture, process and report for vascular access device use and outcomes across healthcare facilities.[37] This study reached some key conclusions regarding what is 'important vascular access data' to collect. Data were categorised within the following domains of patient characteristics, device characteristics, insertion characteristics, management characteristics, and complication and removal processes. Following a crowd-sourcing exercise through structured rounds of data collection, accessing the collective wisdom of a panel of international vascular access experts enabled us to develop a vascular access dataset that can be codified and applied by small groups or large health systems. In doing so, we have provided standardised data capture for patient, provider and system level monitoring. Experts in this study agreed the standardisation of a vascular access dataset is important, as it enables the uniform collection, processing and reporting of outcomes across healthcare institutions.[38 39] However, panellists agreed that the implementation of standardised vascular access data capture will be challenging, with local hospitals and health services having to take responsibility for the associated costs and supporting infrastructure.

Healthcare professionals specialising in vascular access and quality improvement experts seeking to prevent device complications are generally practising in data poor environments, lacking access to database or registry software and using local, purpose-built data collection tools. This environment impedes clinicians and healthcare facilities' ability to benchmark performance and identify practice variations over time and limits the reporting ability due to data quality or heterogeneity of items or definitions.[27] Our dataset, when implemented with registry or database software, will aid quality monitoring, facilitate benchmarking with national uptake and support national, mandatory reporting requirements (eg, bloodstream infection or deep vein thrombosis (DVT)). Innovations in electronic medical records and clinical quality registries have seen a shift in organisations' abilities to monitor safety and quality of care. Should the elements recommended by the panel be deployed within health systems, evaluation of the impact of interventions using routine healthcare data[40] is possible. In fact, organisations are doing just that, with standardised datasets using registry software currently used for specific devices,[41] specialties[42] or with a specific focus (eg, infection).[12 43] In the USA, the Michigan Hospital Medicine Safety (HMS) Consortium established the HMS *PICC Registry* to facilitate better data sharing, with an overall aim of improving patient safety and healthcare quality. Since its inception, the HMS PICC Registry has been used extensively to identify practice variation and reduce patient harm.[22 44] The registry now routinely tracks BSI and DVT incidence rates, reporting practice variation across 52 sites.[31] In the southern hemisphere, the Australian and New Zealand Intensive Care Society CORE registry abstracts data from 202 intensive care units (ICUs) capturing over 90% of national ICU admissions.[11] A mature registry, the CORE group provides contributing ICUs with comparative benchmarking reports (risk adjusted) for government reporting purposes and supports researchers and quality and education programmes across Australia and New Zealand. A recent economic evaluation showed the ANZICS CORE registry to have a 4:1 benefit to cost ratio, with 80% national coverage and an estimated AUD 26 million cost benefit, measured through reduction in ICU mortality and average length of stay (over 14 years).[45]

We have defined a consensus recommendation for a vascular access MDS and associated elements; this could be operationalised using clinical registry software that could, in time, provide similar gains in terms of value-based healthcare through the provision of higher quality data capture to guide clinical practice, improve patient-centred outcomes and cost-effective

healthcare delivery. The benefits of a vascular access dataset employed as a registry may be vast for both patients and healthcare systems. However, registries need substantial time to mature, and the first step in registry conceptualisation is the development of an MDS.[46]

This study did not address the scope or infrastructure considerations of progressing a dataset to a registry system; however, expert panellists agreed this was a valuable next step. As such, it is important to note the limitations of the study. Broad device nomenclature was developed for the purpose of the registry; further work is needed to guide clinical practice and guideline development. While Round 1 response rates were low, this is comparable with other Delphi studies[9] and reflects our aim to contact as many multidisciplinary experts as possible. Survey response rates may have increased by shortening the first survey and sending email notifications prior to survey distribution of the upcoming survey release date. Further, consumer voices were not included in this study, but a separate survey is being undertaken to evaluate consumer-rated item importance. The dataset, currently only available in the English language, has not been validated, and the resource and capital costs to implement and sustain the dataset remain unknown. Infrastructure to support this dataset will vary across sites and settings. Despite these limitations, our study has numerous strengths including the geographical breadth and multidisciplinary diversity of study participants and the 3-Round Delphi methods, which aimed to provide equal voice to all respondents.

CONCLUSION

This study has produced international expert consensus-based recommendations for a vascular access MDS. This is the first time this has been conducted. The vascular access dataset can now be used by healthcare facilities and clinicians to monitor performance, benchmark outcomes, and further develop vascular access practices. More research is required to maximise the learning from data capture through a standardised vascular access dataset.

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