Developing a Venous Access Guideline in Malta – A Modified Delphi Study

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Abstract

Background
Venous access (VA) is a common practice, however, locally the process is not guided by a standard operating procedure creating challenges among clinicians on selecting the best venous access device (VAD) for patients. This is the first study aiming to inform local policy by developing an evidence-based VA guideline including peripheral intravenous cannulas (PIVCs), midlines, peripherally inserted central catheters (PICCs), portacaths and Hickman to be used by clinicians.

Method
Two scoping reviews of the most recent evidence-based literature and guidelines were conducted. Six articles and eight guidelines were retrieved and critically appraised. A prototype VA guideline was formulated based on the World Health Organisation Handbook for Guideline Development. A two-round modified Delphi method was implemented aiming at achieving consensus agreement among clinical experts on the prototype guideline. Round one of the modified Delphi consisted of a focus group discussion (FGD) to discuss and explore the perspectives of local experts on the prototype guideline. This was analysed using thematic analysis. Round 2 consisted of an online questionnaire using the Appraisal of Guidelines for Research & Evaluation Instrument. Analysis was done using formulaic analysis.

Findings
Five participants representing the Infection Prevention and Control Department, the VA team and the Interventional Radiology Department made up the expert panel during the FGD. Four main themes were identified: referring patients for a VAD insertion, types of VADs, complications and VAD removal. It was concluded that the guideline should be aimed toward inpatients and outpatients and that an early VAD need assessment should be done within the first 24hours of admission by the firm consultant. PIVCs are recommended for infusions lasting up to six days whilst midlines are preferred for infusions lasting up to three weeks. For non-peripherally compatible infusates lasting up to six months, PICCs are preferred, whilst portacaths and Hickman are ideal for the administration of long-term treatment lasting longer than six months. Portacaths are the line of choice for the administration of treatment for solid tumours whilst Hickman are preferred for haematology patients. PIVCs, midlines, PICCs and Hickman can be removed in the ward whilst portacaths are removed in the Angiosuite Unit. From the guideline assessment questionnaire it was concluded that the finalised guideline is of a ‘high quality’.

Conclusion
Based on the consensus agreement amongst local clinical experts from the FGD and questionnaire, the VAD selection criteria is primarily based on the expected duration of treatment and the type of infusate to be infused. This is presented as a flow diagram to help the VAD selection process.

Keywords: venous access, PIVC, cannula, midline, PICC, Hickman, portacath

Dedication

This thesis is dedicated to all those who have supported me throughout my education.

I also dedicate this work to all patients who might benefit from this dissertation.

Acknowledgements

Firstly, I am grateful for my dissertation supervisor, Dr. Ermira Tartari Bonnici, whose expertise, guidance and advice helped me throughout the writing of this dissertation and made this work possible.

I would also like to show my gratitude to all those individuals who have somehow contributed toward this dissertation. I would like to thank all the participants who have accepted to be a part of this study as well as the two intermediaries who were of great help.

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List of Abbreviations

AAGBI	Association of Anaesthetists of Great Britain and Ireland
AGREE	Appraisal of Guidelines for Research & Evaluation Instrument
BMI	Body Mass Index
CASP	Critical Appraisal Skills Programme
CCI	Charlson Comorbidity Index
CF	Cystic Fibrosis
CI	Confidence Interval
CKD	Chronic Kidney Disease
Cm	Centimetres
CRBSI	Catheter-Related Blood Stream Infection
CRDVT	Catheter-Related Deep Vein Thrombosis
CRT	Catheter Related Thrombosis
CVAD	Central Venous Access Devices
DiVA	Difficult Venous Access
DVT	Deep Vein Thrombosis
ED	Emergency Department
ESI	Exit Site Infection
FGD	Focus Group Discussion
Fr	French
FREC	Faculty of Health Sciences Research Ethics Committee (FREC)
GDP	Guideline Development Process
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
HR	Hazard Ratio

HyDi	Hybrid Discovery
ICU	Intensive Care Unit
IPC	Infection Prevention and Control
IR	Interventional Radiology
ITU	Intensive Therapy Unit
IV	Intravenous
LAPS	Laboratory Based Acute Physiology Score
LR	Literature Review
MAGIC	Michigan Appropriateness Guide for Intravenous Catheters
MDH	Mater Dei Hospital
MeSH	Medical Subject Headings
MID	Medical Imaging Department
MOHSSE	Ministry of Health, Social Services and Equality
N/A	Not Applicable
NICE	National institute for Health and Care Excellence
OR	Odds Ratio
P	Probability Value (P-Value)
PDN	Practice Development Nurses
PICC	Peripherally Inserted Central Catheters
PICO	Population, Intervention, Comparison, Outcome
PIVC	Peripheral Intravenous Cannulas
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
RCT	Randomised Controlled Trial
RNAO	Registered Nurses Association of Ontario
ScR	Scoping Review

SD	Standard Deviation
SE	Standard Error
SR	Systematic Review
TPN	Total Parenteral Nutrition
UK	United Kingdom
UOM	University of Malta
UREC	University of Malta Research Ethics Committee (UREC)
US	Ultrasound
USA	United States of America
VA	Venous Access
VAD	Venous Access Device
VHP	Vessel Health Preservation
WHO	World Health Organisation

Chapter 1
Introduction

1.1 Introduction

This dissertation aims to formulate a venous access (VA) guideline for local practice in both acute and non-acute settings that will help clinicians to select the most appropriate venous access device (VAD) for their patients. This chapter provides an overview of this study including the reasons for selecting this topic, some background information, the current local practice, the aims and objectives, the research question being investigated and the relevance of this study in the field. To conclude, a brief overview of the research methodology guiding the study is provided.

1.2 Reason for selecting this topic

VA together with the administration of intravenous (IV) infusates remains a common practice whether you are a nurse working in a ward setting, operating theatres, nursing home, emergency department (ED) or in the intensive therapy unit (ITU) (Cheung et al., 2009). VA is the most common invasive procedure performed on patients worldwide (Gonzalez & Cassaro, 2021) with an estimated sale of 1.2 billion peripheral intravenous cannulas (PIVCs) each year (Alexandrou et al., 2015). As important as VA is, if not planned properly, it can also be the cause of minor and/or major life threatening complications including thrombosis, infection, phlebitis and permanent vein damage (Lok & Foley, 2013). Catheter-related blood stream infections (CRBSI) remain amongst the highest and most dangerous healthcare complications (Hallam et al., 2016).

Locally, as a nurse working in the Angiosuite Unit, Medical Imaging Department (MID) in Mater Dei Hospital (MDH) for the past four years, I have experienced the referral process for VAD insertion. However, patients are experiencing a delayed referral and/or are being referred for the wrong VAD and as a result they are suffering from repetitive failed cannulation attempts, missing treatment doses and/or

experiencing permanent vein damage. Research has shown that having standardised VA guidelines for practice enhances patients' experience, limits complications, improve vein assessment and vessel preservation (Shaw, 2017). Therefore it is clear that a VA guideline needs to be introduced locally to inform practice.

1.3 Background

VA refers to any device inserted by puncturing through the skin to access a peripheral or central vein for bloodletting or the administration of fluids, medications and/or blood products (Cheung et al., 2009). The concept of VADs has been in existence since 1929. VA has progressed drastically and now VADs are shaping modern medical care (Beheshti, 2011). Presley and Isenberg (2022) state that in the USA alone, approximately 150-200 million PIVCs are inserted each year. From a global audit carried out by Alexandrou et al. (2015), it was found that from 14 hospitals in 13 countries, 59% of patients had a PIVC in situ whilst 16% had other types of VADs. Although being a common practice, in order to provide a good quality service, there needs to be an improvement in staff training, auditing, technology advancement and education (Morrell, 2020).

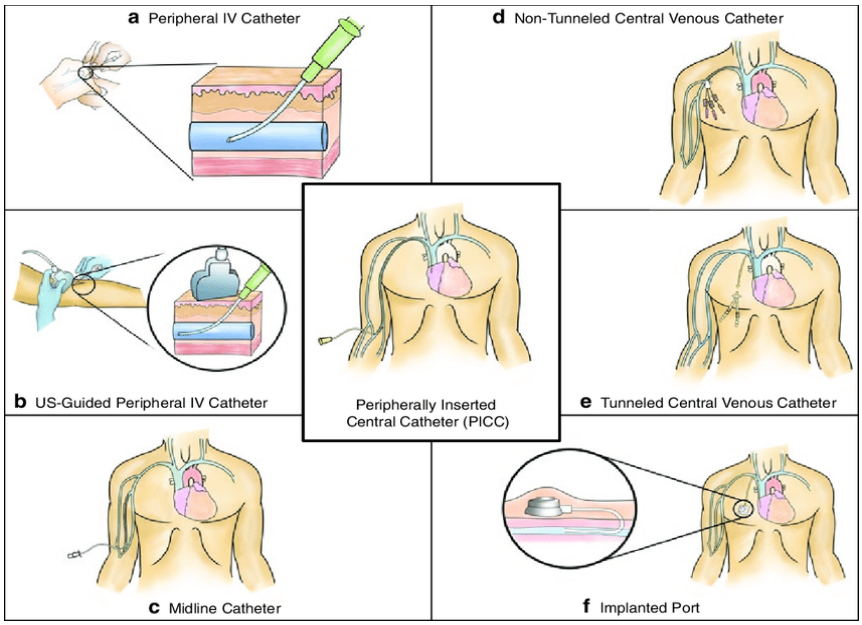
1.3.1 Types of venous access devices

VA is primarily divided into long-term and short-term VA, however, data on what classifies to be long-term and short-term access varies, with some research suggesting short-term access as being less than 12 weeks whilst others suggest less than six weeks (Galloway & Bodenham, 2004). The VADs included in this study are PIVCs, midlines, peripherally inserted central catheters (PICCs), portacaths and Hickman lines. PIVCs **(**Figure 1, a) are short devices (three to six centimetres, cm) which are inserted and terminate in a small peripheral vein; dorsal veins of the hand, volar aspect of the wrist, cubital fossa in the arm and the dorsal arch of the foot (Beecham & Tackling,

2022). Difficult PIVC insertion can be done under ultrasound (US) guidance (b). Midline catheters (c) are longer devices (between eight and 25cm) which are inserted into the basilic, brachial or cephalic veins in the upper arms with the catheter tip positioned just below the axilla (Shanja-Grabarz et al., 2020). Although longer than PIVCs, these are still considered as peripheral lines and cannot be used for the transfusion of irritant/vesicant infusates such as total parenteral nutrition (TPN) and long-term chemotherapy as these might become dislodged leading the extravasation causing permanent vein damage (Matey & Camp-Sorrell, 2016). Contrarily, central VADs provide access to the central circulation where the veins are larger in diameter and there is more blood volume. For instance, PICCs (approximately 45cm in length) are inserted into the peripheral veins of the upper arm (basilic, brachial, cephalic or medial cubital vein) with the tip of the catheter placed in the lower third of the superior vena cava or the upper part of the right atrium (Gonzalez & Cassaro, 2022). Contrarily, portacaths and Hickman lines are inserted directly into larger central veins. For instance, portacaths (f) are totally implantable devices which are placed in the subcutaneous tissue of the chest with the catheter tip placed centrally in the lower third of the superior vena cava (Tempe & Hasija, 2017). These are accessed by introducing a non-coring needle into the implanted port (Madabhavi et al., 2017). Similar to portacaths, Hickmans (e) are also inserted into the subclavian or jugular veins. However, these are referred to as tunnelled lines meaning that the site of insertion of the exterior part of the line and the site of venipuncture are physically separated by creating a tunnel underneath the skin; reducing the risk of bacteraemia (Moureau & Alexandrou, 2019).

Figure 1

Types of venous access devices (Chopra et al., 2015)



1.4 Local practice

Although being a common practice, VAD insertion only started being provided within the local acute hospital by the Angiosuite Unit, MID, in 2016. As seen in Table 1, PICCs have been introduced locally in 2016 with 15 lines a year to 444 insertions in 2021 and portacath insertion initially inserted by cardio-thoracic surgeons under general anaesthesia, were shifted to the outpatient service provided by interventional radiologists (IR) under local anaesthesia in 2017 with 21 insertions to 219 insertions in 2021.

Currently only clinicians informed about the service refer patients for VAD insertion by contacting an IR physician. The main reasons for referrals include chemotherapy, TPN and antibiotic administration. Although the need for a VAD insertion has increased during the past years, the process is not guided by a standard operating procedure. Consequently, patients who would benefit from a VAD are referred late or are not being referred. Evidence-based guidelines to select the

recommended VAD for patients helps in preventing complications associated with VA (Shaw, 2017 and Hadaway, 2002).

Table 1

The number of venous access devices inserted in the Angiosuite Unit (Mater Dei Hospital) between 2015 and 2021

	YEAR						
	2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
*PIVC**	No Data Available						
Midline	No Data Available						
*PICC** Line*	0	15	113	194	248	271	444
Portacath	0	0	21	31	92	180	219
Hickman Line	0	29	57	63	64	65	36

PIVC* - Peripheral Intravascular Cannula, PICC** – Peripherally Inserted Central Catheter

1.5 Importance of this topic

Central VADs are preferred over peripheral devices for the administration of large amounts of fluids, vesicant or cytotoxic medications including chemotherapy, bloodletting and for long-term VA (Cheung et al., 2009). Administering vesicant or irritant infusates through a peripheral vein can lead to complications like infection, infiltration, repetitive cannulation attempts, patient discomfort, delays in treatment administration due to a lack of VA, frustration amongst staff, needle-stick injuries, phlebitis and permanent vein damage which can all be avoided or limited by using the right VAD (Mercy, 2018).

A qualitative study by Robinson-Reilly et al. (2015) explored patients' experiences with PIVCs for chemotherapy infusion. Common themes including: anxiety, fear, 'necessary evil', 'bad veins', 'cruel', 'pain' and 'feeling vulnerable' were amongst the many negative statements discussed by patients. The study concluded that the introduction of a VA guideline could result in a better overall patient experience. Another study by Cooke et al. (2018) aimed to understand patients' experiences with

PIVC insertion through a cross-sectional survey. Three common themes describing their experience as ‘stressful’, ‘frustrating’ and ‘painful’ emerged. Conclusions were made by researchers that such negative connotations with VA can be improved with staff training, communication and VA guidelines.

It is important to note that every time a device is inserted into a vein, the risk for infection, thrombosis, extravasation, haemorrhage, phlebitis and other potential complications increases (Firstenberg et al., 2015). Therefore, clinicians should select the best and least invasive VAD available for the patients (Matey & Camp-Sorrell, 2016).

1.6 Aims and objectives

The main aim of this dissertation is to inform policy by developing a local evidence-based VA guideline which includes PIVCs, midlines, PICCs, portacaths and Hickman lines. This study aims to identify the best VAD for patients based on the duration that the line is needed for, the type of infusate to be administered and the overall patient’s needs (Cheung et al, 2009).

In order to achieve the study’s aim, the following objectives were set:

- To carry out a scoping review (ScR) of the most recent evidence-based literature and available guidelines on the topic.
- To use the results from the ScR to develop a VA prototype guideline.
- To conduct a modified Delphi study that aims to achieve consensus agreement on the VA prototype guideline.
- To assess the quality of the guideline using the Appraisal of Guidelines for Research & Evaluation Instrument (AGREE II, 2010).
- To provide a finalised version of the proposed VA guideline.

1.7 Research question

After identifying the aims and objectives of this dissertation, the research question was formulated. The PICO Framework (Schardt et al., 2007) was used to identify the main elements; Population: Adult patients (>18 years) in acute, non-acute or outpatient care, Intervention: venous access, Outcome: A local evidence-based VA guideline. This led to the development of the PICO question: 'How to develop a local evidence-based venous access guideline for adults (>18 years) in acute, non-acute or outpatient care settings?'

1.8 Target users

The VA guideline is needed by nurses and physicians when trying to identify the best VAD for their patients based on the type and duration of the IV infusion. Ultimately, the guideline will be recommended for use to inform policy and reform the service organisation. These also provide nurses and physicians with a guide which will allow them to advocate for their patients when they are not referred.

1.9 Guideline development framework

The guideline development method followed a thorough systematic process based on the internationally-recognised methods and standards issued in the World Health Organisation Handbook for Guideline Development (WHO, 2014). This handbook provides advice and support on how to plan and develop scientific and evidence-based guidelines through rigorous and robust adherence to the systematic use of research. It also aims to direct the researchers through the guideline development process (GDP) whilst ensuring that the final guideline is credible, the recommendations are reliable, the method is thorough and the underlying evidence is accessible (WHO, 2014). For the purpose of this dissertation, as outlined by Adebiyi et al. (2018), some of

the steps outlined in the WHO Handbook (2014) were adapted to fit the context of this research.

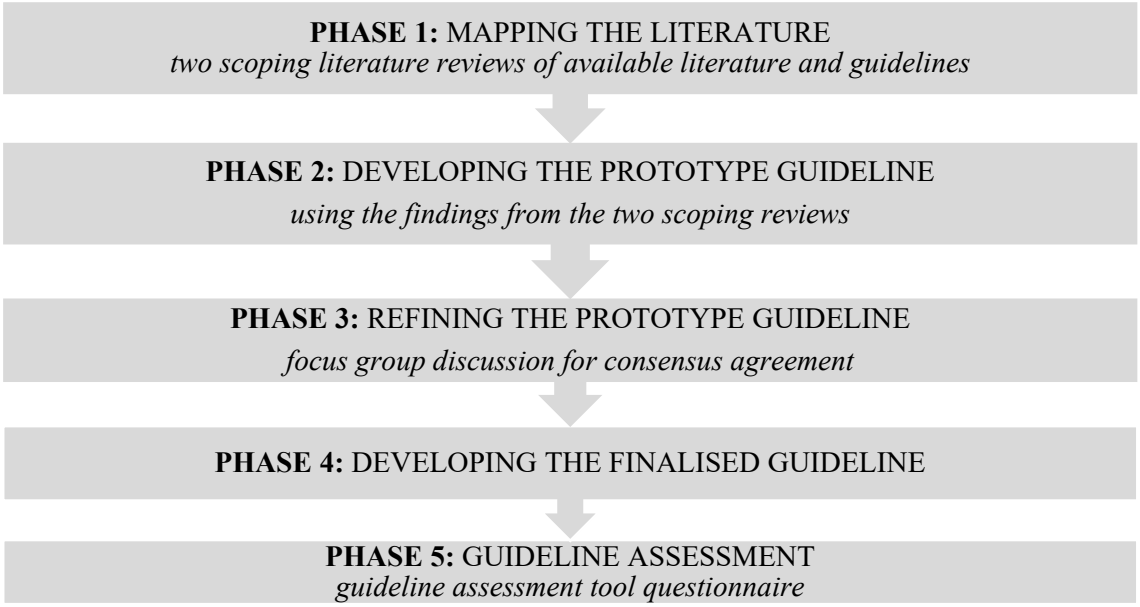
1.9.1 The guideline development process

Based on the WHO Handbook (2014) recommendations, the importance and need to formulate a VA guideline was recognized, the PICO elements were identified, all the necessary permissions were collected and the research proposal was sent for ethics clearance. The GDP (Figure 2) consisted of five main phases:

- **Phase 1: Mapping the literature -** Two ScRs of the most recent evidence-based literature and available guidelines on the topic.
- **Phase 2: Developing the prototype guideline**- The data collected from both ScRs in Phase 1 was used to develop a prototype guideline.
- **Phase 3: Refining the prototype guideline** - A two-round modified Delphi approach was taken in which a FGD was held to discuss the prototype guideline with members of the expert panel to reach consensus agreement. The data was analysed using Thematic Analysis.
- **Phase 4**: **Developing the finalised guideline** - The finalised guideline was formulated based on the results from the FGD.
- **Phase 5**: **Guideline assessment -** The updated guideline along with a guideline assessment tool was sent to all participating experts for the second round of the modified Delphi method. The data on the quality of the guideline was analysed and any recommendations to update the finalised guideline were considered.

Figure 2

The Guideline Development Process



1.10 Conclusion

This section provided a brief introduction and background on the topic being studied, the aims and objectives as well as the methodological process followed guided by the WHO Handbook (2014). The next chapter provides two ScRs of the most recent evidence-based literature and guidelines on VA.

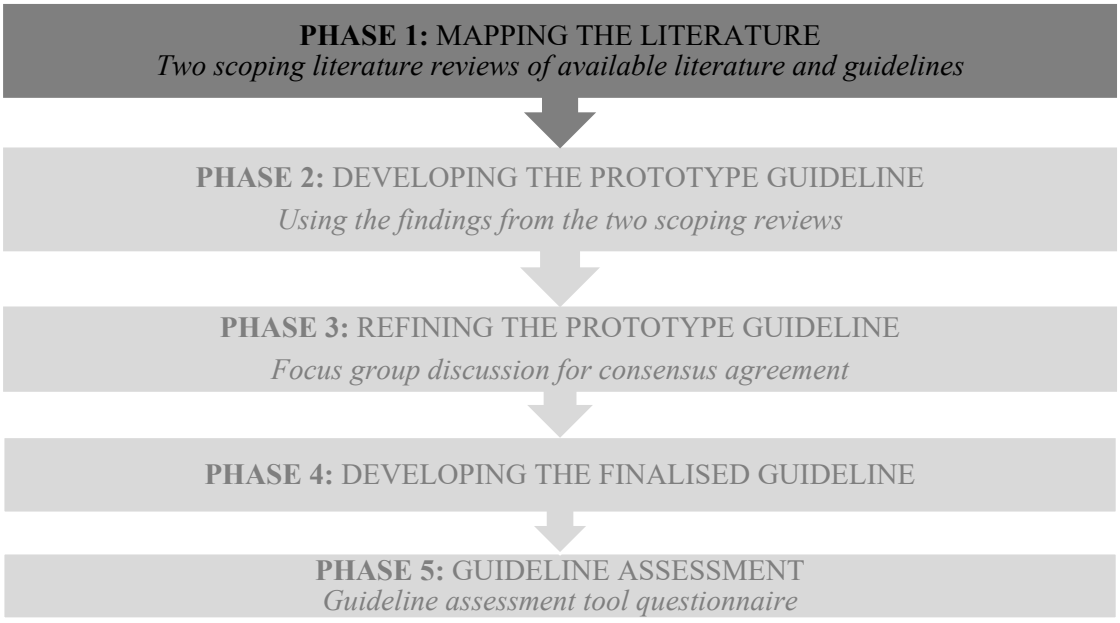
Chapter 2
Scoping review

2.0 Introduction

The WHO Handbook for Guideline Development (2014) specifies that the guideline recommendations must be based on a review of scientific literature. This chapter aimed to provide an overview of the evidence-based research on VA for Phase 1 of the GDP (Figure 3). Two ScRs were carried out to retrieve the relevant literature and guidelines on the topic of interest. This chapter provides a detailed description of both ScRs including the inclusion and exclusion criteria, databases and search engines used, a description of both search trails as well as the study and guideline selection processes allowing for study replicability. Finally, a critical appraisal of the literature using the respective published critical appraisal tools is provided.

Figure 3

Guideline development process: Phase 1



2.1 Scoping review

Two separate ScRs were done: (i) to identify the most recent evidence-based literature studies and (ii) to identify relevant international evidence-based VA guidelines to answer the research question guiding this study: ‘How to develop a local evidence-

based venous access guideline for adults (>18 years) in acute, non-acute or outpatient care settings?' with the main aim being to formulate a local evidence-based VA guideline to inform policy. A ScR was identified as the best type of review for this part of the study as it allowed the author to map the literature found on VADs and also provided the researcher with a comprehensive identification of all relevant articles and guidelines. It also enabled the researcher to gather information on different types of VADs and not on one specific device (Sucharew, 2019). The main findings from the ScRs were used to formulate the prototype guideline for Phase 2 of the GDP. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) for ScRs (Tricco et al., 2018) as suggested by the WHO Handbook (2014) was used to guide this systematic process.

2.2 Information sources

The searches were carried out using Hybrid Discovery (HyDi) search engine accessed through the signed in University of Malta webpage. The databases BMJ Journals, PubMed, EBSCO host interface (selecting: CINAHL Complete, Cochrane Database of Systematic Reviews and MEDLINE Complete) and ProQuest (selecting: Literature Online, ProQuest Central and Science Database) were accessed through HyDi. Google Scholar was also searched. Unpublished gray literature was searched for in Government and independent hospital WebPages and a general Google search (Adams et al., 2016). The systematic searches of the literature and guidelines were conducted between 30th June and 1st November 2021.

2.3 Search criteria

For a more comprehensive search, a set of inclusion and exclusion criteria were established before initiating the search process (Table 2). The eligibility criteria helped the researcher to minimise subjectivity and uncertainty during the selection phase

(Patino & Ferreira, 2018a). The inclusion criterion was primarily based on the Hierarchy of Evidence (Tomlin & Borgetto, 2011).

The articles and guidelines included were peer-reviewed, published/translated in English/Maltese and performed on human adults (>18years) from any ethnic group. No exclusion on the year of publication was done. The guidelines and articles needed to include information on the insertion, duration, purpose and/or maintenance on at least one of the following: PIVCs, midlines, PICCs, portacaths and/or Hickman with the following study design: meta-analyses, systematic review (SR), randomised/non-randomised controlled trial (RCT) or observational studies. The guidelines included were accepted on the basis of their systematic methodology used to search for evidence: the search sources and search strategy, the tool/s used for classifying levels of evidence and the method used for formulating the recommendations. Exclusion on the year of publication was made for guidelines published before 2014. This is because guidelines need to be updated regularly based on new evidence to remain valid (Clark et al., 2006).

Table 2

The Inclusion Criteria for selecting the evidence-based studies and guidelines

Inclusion Criteria
Published peer-reviewed articles
Available in English or Maltese
Include information on the insertion, duration, purpose and/or maintenance of at least one of the following: • Peripheral venous catheters • Peripherally inserted central catheters • Midlines • Portacaths • Hickman Lines

Study Design • Meta-analyses • Systematic reviews • Randomised controlled trials • Non-randomised controlled trials • Observational Studies (including cross-sectional, qualitative, case-control and cohort studies)
Inclusion Criteria for Guidelines: • Published/updated during or after 2014 • Systematic processes used to search for the evidence
Human adults (≥18years old) from any ethnic group

2.4 Identifying the main key terms, synonyms and medical subject headings

The main key concepts were identified through the research question being studied. These were converted into key words and their respective synonyms (Table 3) were established through personal communication with experts in the field, the thesaurus, Medical Subject Headings (MeSH) generator, personal clinical experience and through the reading of literature and VA guidelines. These synonyms increased the likelihood of retrieving all relevant articles and guidelines, thus conducting a more thorough search (Cooper et al., 2018).

Table 3

The Main Key Terms and Synonyms to Identify Relevant Articles and Guidelines

The Main Key Terms and Synonyms to Identify Relevant Articles	
Key Term	*Synonyms*
venous access	vascular access
peripheral intravenous cannula	PIVC, peripheral cannula, PIVC, peripheral line
midline	short line
peripherally inserted central catheter	peripheral line, PICC,
portacath	port-a-cath, port, totally implanted,

hickman	*N/A*
The Main Key Terms and Synonyms to Identify Relevant Guidelines	
Key Term	*Synonyms*
venous access	vascular access
guideline	protocol, algorithm, pathway, standard operating procedure, SOP

2.5 Formulating search phrases

Search phrases were formulated by combining key terms and synonyms using Boolean operators "AND" and "OR". The former operator was used to find articles and guidelines including all key terms in the search term whilst the latter was used to generate results which included at least one of the key terms (Grewal et al., 2016). Once all terms were formulated, the asterisk symbol "*" was used for the Truncation of all terms (Vieira et al., 2021) (Tables 4&5).

Table 4

Formulating Search Phrases using Boolean operators and Truncation to Find Relevant Articles

Phrase	Main Key Terms/Synonyms/MeSH	Search Phrase with Boolean Operators and Truncation
1	venous access, vascular access, peripheral intravenous cannula, PIVC, peripheral line, PIVC, peripheral cannula, use, duration	(venous access) OR (vascular access) AND (peripheral intravenous cannula*) OR (PIVC) OR (peripheral line*) OR (PIVC*) OR (peripheral cannula*) AND (use) or (duration)
2	venous access, vascular access, midline, short line, use, duration	(venous access) OR (vascular access) AND (midline*) AND (short line*) AND (duration) OR (use)
3	venous access, vascular access, peripherally inserted central catheter, PICC, peripheral line, use, duration	(venous access) OR (vascular access) AND (peripherally inserted central catheter*) OR (PICC) OR (peripheral line*) AND (duration) OR (use)

4	venous access, vascular access, portacath, port-a-cath, port, totally implanted, use, duration	(venous access) OR (vascular access) AND (portacath*) OR (port-a-cath) OR (port*) OR (totally implant*) AND (use*) OR (duration)
5	venous access, vascular access, hickman, use, duration	(venous access) OR (vascular access) AND (hickman*) AND (use) OR (duration)

Table 5

Formulating Search Phrases Using Boolean Operators and Truncation to Retrieve Relevant Guidelines

Main Key Terms/Synonyms/MeSH	Search Phrase with Boolean Operators and Truncation
venous access, vascular access, guideline, protocol, pathway, algorithm, standard operating procedure, SOP	(venous access*) OR (vascular access) AND (guideline*) OR (protocol) OR (pathway*) OR (algorithm) OR (standard operating procedure*) OR (SOP)

2.6 Search trail for articles and guidelines

This section provides a detailed description of the search strategy followed to identify relevant articles (Table 6) and guidelines (Table 7). All search engines and databases identified in section 2.2 were searched. The 'Advanced Search' option was used for HyDi, BMJ Journals, PubMed and EBSCO Host and the respective filters found in Tables 6&7 were selected based on the inclusion and exclusion criteria of this study.

Table 6

Search trail for relevant articles results

Search Engine/ Database	Search Phrase	Results	Filters	Results
HyDi	Search Phrase 1	1,898,198	Full Text Online, Peer-reviewed Journals, Articles, Journals, Humans, Male, Female, Adult, Middle aged, Research Article	10,249
	Search Phrase 2	50,165,935		30,259
	Search Phrase 3	50,619,167		10,165
	Search Phrase 4	33,800,486		21,586
	Search Phrase 5	5,714,096		2,168
BMJ Journals	Search Phrase 1	443,592	Open access	48,143
	Search Phrase 2	68		18
	Search Phrase 3	476,129		31,598
	Search Phrase 4	551,630		34,631
	Search Phrase 5	790		125
PubMed	Search Phrase 1	674,411	Free full text, Randomised Controlled Trials, Systematic Review	19,717
	Search Phrase 2	5,710,912		97,054
	Search Phrase 3	5,712,238		87,156
	Search Phrase 4	776,043		12,156
	Search Phrase 5	664,523		17,259
EBSCO Host	Search Phrase 1	666,070	Full Text, English, Academic Journals	147,490
	Search Phrase 2	5,131,948		268,778
	Search Phrase 3	5,132,902		267,469
	Search Phrase 4	1,376,243		52,964
	Search Phrase 5	658,932		32,459
ProQuest	Search Phrase 1	10,626,212	Full text, Peer-reviewed, Scholarly Journals	853,332
	Search Phrase 2	127,063,144		3,156,887
	Search Phrase 3	127,136,003		8,268,495
	Search Phrase 4	99,635,144		4,155,723
	Search Phrase 5	8,925,161		1,653,168
Google Scholar	Search Phrase 1	28,600	None Available	28,600
	Search Phrase 2	80,300		80,300
	Search Phrase 3	20,900		20,900
	Search Phrase 4	3,400		3,400
	Search Phrase 5	14,600		14,600
Total Results:		**543,707,777**		**19,426,849**

Table 7
Search trail for available guidelines results

Search Engine/ Database	Results	Filters	Results
HyDi	13,209,139	Exclude guidelines on: Cell Biology, Animals, Psychology, Dissertations, Conference Proceedings, Web Resources, Audio, Audio visual, Videos, Images, Newspaper Articles, Books, Book Chapters, Engineering, Technology, Social Science and Adolescents. Exclude guidelines published/ updated before 2016 Include articles on: Humans, Peer-Reviewed Journals, Adults, Males, Females, Middle-Aged, Ages, Young Adults and Medicine	21,838
BMJ Journals	298,515	Open-access guidelines	45,492
PubMed	2,359,208	Include: guidelines in free full text, published/updated between 2016 to 2021, on humans and in the English language Exclude: Books and Documents	99,684
EBSCO Host	2,652,898	Include: guidelines in full text, written in the English language and on adults	116,070
ProQuest	13,859,458	Exclude: Conference papers and Proceedings, trade journals, magazines and working papers. Exclude articles on animals, gene expression, Kinases, apoptosis, rodents, mice, enzymes, predictive value of tests, socioeconomic factors, deoxyribonucleic acid dna, analysis of variance, genes, decision making, polymorphism, single nucleotide, diet, pain, survival rate, smoking, bacteria, survival analysis, antineoplastic agents, treatment, outcome, sensitivity & specificity, statistical analysis, laboratories, infant, newborn, tomography, x-ray computed, epidemiology, exercise, biological markers, incidence, mathematical models, computer simulation, aging, experiments, neoplasms, immunohistochemistry, brain research, nuclear magnetic resonance—nmr, software, hypotheses, cells, cultured, diabetes mellitus, type 2, health risk assessment, education, heart rate, physical fitness) Include: studies on humans, published/updated between 2016 to 2021written in the English language	52,151
Google Scholar	65,400	None	65,400
Total	32,444,618		400,635

2.7 Study selection

In order to ensure that the studies and guidelines were selected in a systematic process, RefWorks and the PRISMA flow diagram (Moher et al., 2009) were followed.

2.7.1 Selecting relevant articles

The articles retrieved were imported to RefWorks and duplicate results were removed. The remaining records were screened by their title and abstract. The main reasons for excluding articles at this stage of the study selection process included: they did not include any of the VADs being studied, studies performed on animals and studies performed on humans <18years. A total of 4,616 full-text articles and their reference lists were screened and 4,610 articles were eliminated. A total of six articles were considered eligible for inclusion in the ScR (Figure 4).

2.7.2 Selecting relevant guidelines

The guidelines identified through the search strategy and through the reading of reference lists of the selected guidelines were imported to RefWorks. The titles of the remaining guidelines were read and assessed against the inclusion and exclusion criteria. Any papers which did not meet these criteria were eliminated. After screening the abstracts of the remaining guidelines, their full-text was read and 778 guidelines were eliminated leaving eight relevant guidelines (Figure 5).

2.8 Data collection process

The full text of all six articles and eight guidelines selected was reviewed and data extraction was performed. Tianjing et al. (2022) in the 'Cochrane Handbook for Systematic Reviews of Interventions' state that an outcome is an event/measurement recorded for a specific intervention under study. Therefore since this study aims to compile a VA guideline, the outcomes recorded from the findings of all retrieved

articles and guidelines were those which provided information on the use and duration of PIVCs, midlines, PICCs, portacaths and Hickmans. This was done using a pre-structured template for data collection formulated by the researcher on an Excel Spreadsheet (Tables 8&9).

Figure 4

PRISMA Flow Diagram for scoping review 1: evidence-based research articles

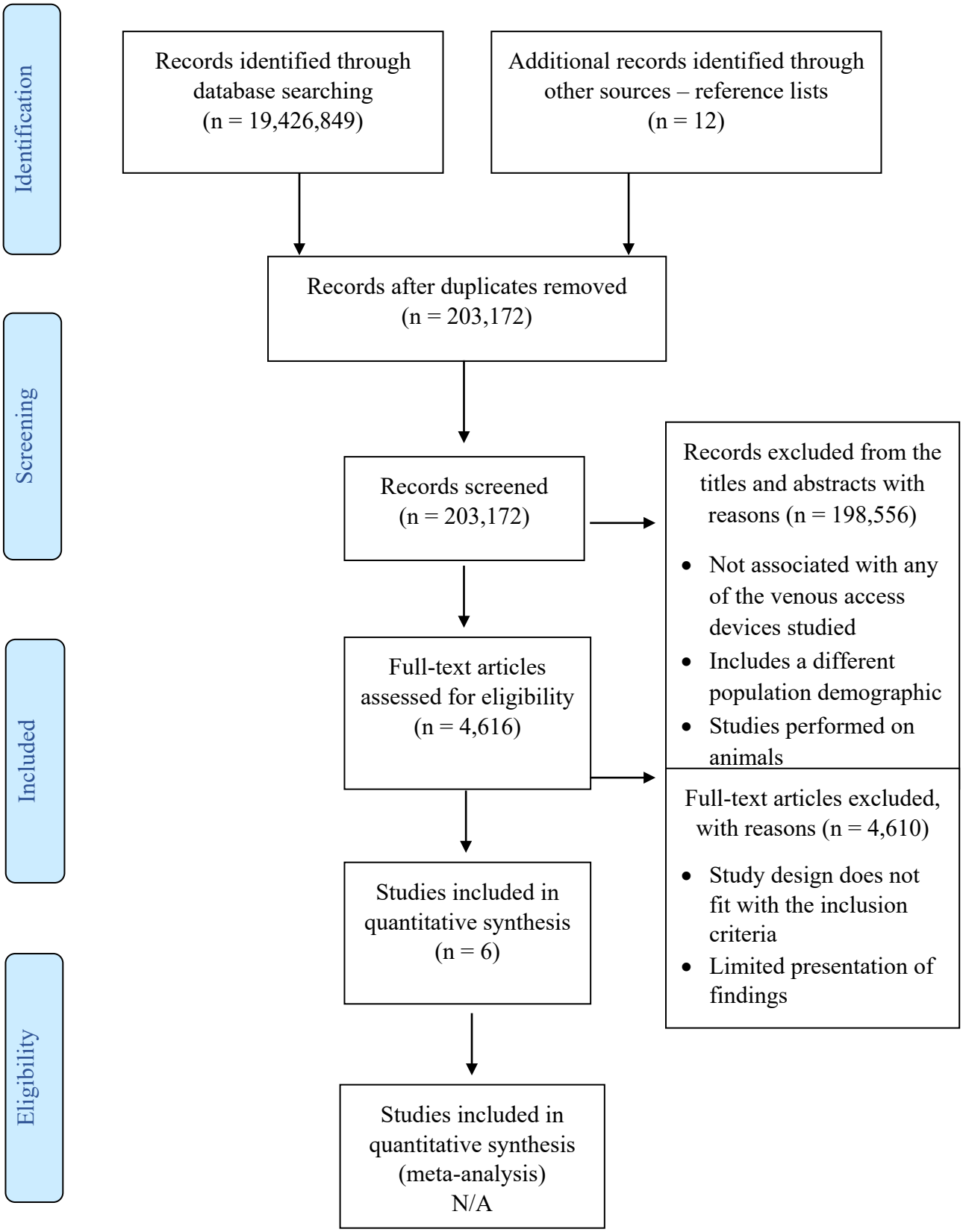


Figure 5

PRISMA Flow Diagram for scoping review 2: evidence-based venous access Guidelines

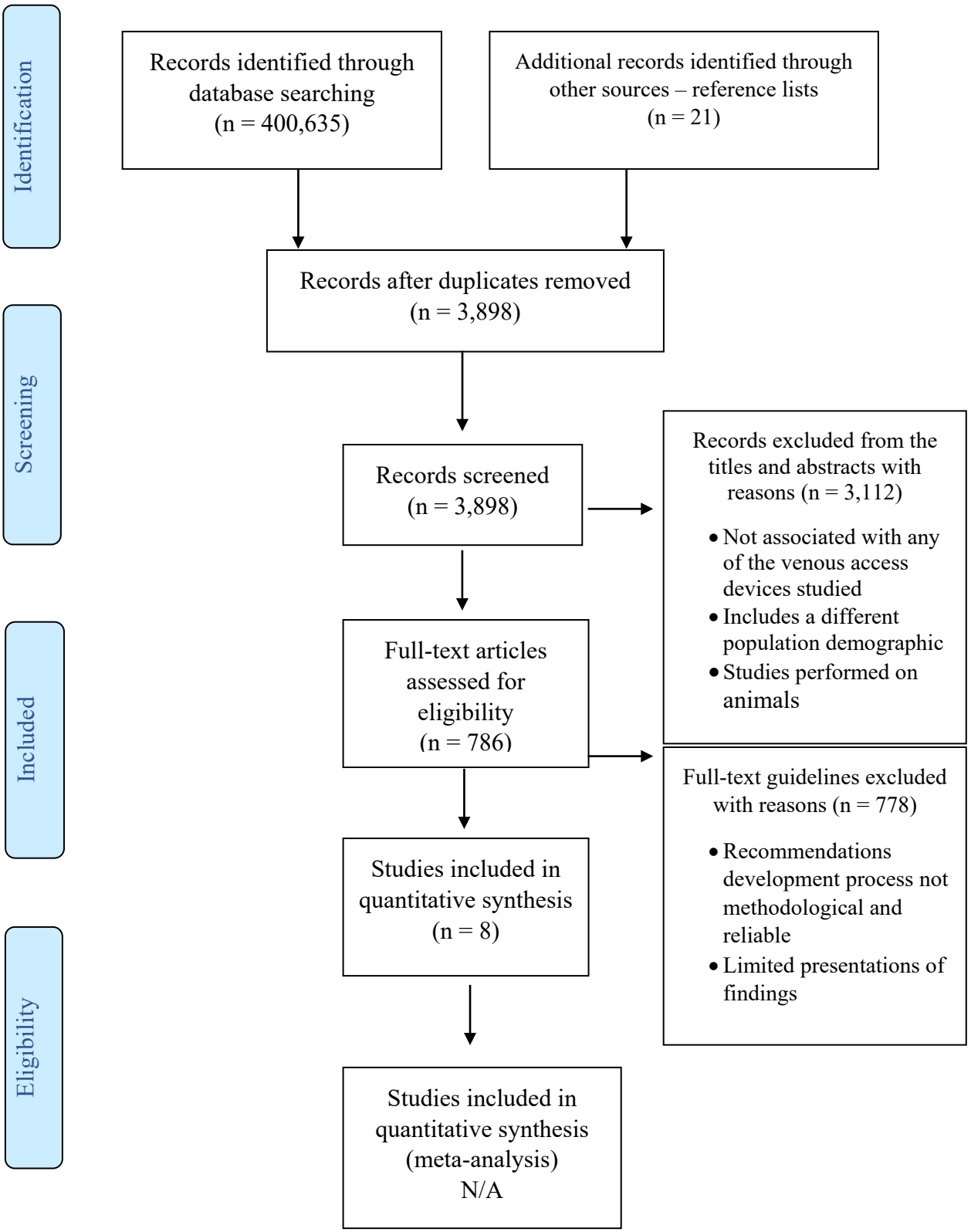


Table 8

The Selected Relevant Articles

Authors and Date	Title	Country	Design	Aim
Moss, J.G., Wu, O., Bodenham, A. R., Agarwal, R., Menne, T. F., Jones, B. L., Heggie, R., Hill, S., Dixon-Hughes, J., Soulis, E., Germeni, E., Dillon, S., McCarthney, E. (2021)	'Central venous access devices for the delivery of systemic anticancer therapy (CAVA): a randomised controlled trial'	UK	RCT	Compare PICCs, portacaths and Hickman lines to establish acceptability, clinical and cost-effectiveness of the devices for patients receiving chemotherapy
Verma, A. V., Kumachev, A., Shah, S., Guo, Y., Jung, Y. H., Rawal, S., Lapointe-Shaw, L., Kwan, L. J., Welnerman, A., Tang, T., Razak, F. (2020)	'Appropriateness of peripherally inserted central catheter use among general medical inpatients: an observational study using routinely collected data'	Canada	Cross-Sectional Study	To study the proportions of appropriate and inappropriate inpatient PICC use based on MAGIC recommendations
Bertoglio, S., Faccini, F., Lalli, L., Cafiero, F., Bruzzi, P. (2016)	'Peripherally Inserted Central Catheters (PICCs) in Cancer Patients Under Chemotherapy: A prospective Study on the Incidence of Complications and Overall Failures'	Italy	Cohort study	To investigate PICC failures in cancer patients
Wu, O., Boyd, K., Paul, J., McCartney, E., Ritchie, M., Mellon, D., Kelly, L., Dixon-Hughes, J., Moss, J. (2016)	'Hickman catheter and implantable port devices for the delivery of chemotherapy: a phase II randomised controlled trial and economic evaluation'	Scotland	RCT	To generate relevant data to inform the design of a larger definitive RCT
Patel, G.S., Jain, K., Kumar, R., Strickland, L., Pellegrini, L., Slavotinek, J., Eaton, M., McLeay, W., Price, T., Ly, M., Ullah, S., Kaczwara, B., Kichenadasse, G., Karapetis, C. S. (2013)	'Comparison of peripherally inserted central venous catheters(PICC) versus subcutaneously implanted port-chamber catheters by complication and cost for patients receiving chemotherapy for non-haematological malignancies'	Australia	RCT	To compare the safety and cost of PICCs and portacaths, in the delivery of chemotherapy in patients with non-haematological malignancies
Alexandrou, E., Ramjan, L. M., Spencer, T., Frost, S. A., Salamonson, Y., Davidson, P. M., Hillman, K. M. (2011)	'The Use of Midline Catheters in the Adult Acute Care Setting – Clinical Implications and Recommendations for Practice'	Australia	Modified Integrative LR	Review published manuscripts on the use of midline catheters
RCT: Randomised controlled Trial, UK: United Kingdom, PICC: Peripherally Inserted Central Catheter, LR: Literature Review				

Table 9

The Selected Venous Access Guidelines

Authors and Date	Title	Country	Aim
Registered Nurses' Association of Ontario (RNAO) (2021)	Vascular Access	Ontario, Canada	Formulating a vascular access guideline
Hallam, C., Denton, A., Weston, V., Dunn, H., Jackson, T., Keeling, S. & Hill, S. (2020)	UK Vessel Health and Preservation (VHP) Framework: a commentary on the updated VHP 2020	England	Updating the Vessel Health Preservation Guidelines (2016)
Sou, V., McManus, C., Mifflin, N., Frost. S. A., Ale, J. & Alexandrou, E. (2017)	A clinical pathway for the management of difficult venous access (DiVA Pathway)	Australia	Formulating a difficult venous access guideline with an after-working hours guide.
Bodenham, A., Babu, S., Bennett, J., Binks, R., Fox, F. B., Johnston, A. J., Klein, A. A., Langton, J.A., Mclure, H. & Tighe S. Q. M. (2016)	Association of Anaesthetists of Great Britain and Ireland: Safe vascular access 2016	Great Britain and Ireland	Formulating a vascular access guideline
Gorski, L., Hadaway, L., Hagle, M. E., McGoldrick, M., Marsha & Doellman D. (2016)	Infusion Therapy Standards of Practice	United States of America	Formulating a vascular access guideline
Chopra, V., Flanders, S.A., Saint, S., Woller, S. C., O'Grady, N.P., Safdar, N., Trerotola, S. O., Saran, R., Moureau, N., Wiseman, S., Pittiruti, M., Akl, E. A., Lee, A. Y., Courey, A., Swaminathan, L., LeDonne, J., Becker, C., Krein S. L. & Bernstein S. J. (2015)	The Michigan Appropriateness Guide for Intravenous Catheters (MAGIC): Results From a Multispecialty Panel Using the AND/UCLA Appropriateness Method	Michigan, United States of America	Formulating a vascular access guideline
Ministry of Health, Social Services and Equality (MOHSSE) (2014)	Clinical Practice Guideline on Intravenous Therapy with Temporary Devices in Adults	Spain	Formulating a vascular access guideline
Loveday, H.P., Wilson, H.P., Pratt, R.J., Golsorkhi, M., Tingle, A., Bak, A., Browne, J., Prieto, J., Wilcox, M. (2014)	Epic3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England	England	Updating the epic2 (2007) venous access guidelines

2.9 Critical appraisal of the selected articles

The WHO Handbook for Guideline Development (2014) specifies that the retrieved scientific evidence must be critically evaluated. A total of six articles were identified: three RCTs, one modified integrative literature review, one cross-sectional study and one cohort study. These were critically appraised using the respective Critical Appraisal Skills Programme (CASP) Tools which are the most commonly used tools for appraising health-related articles (CASP, 2019). The cohort study was appraised using the Joanna Briggs Critical Appraisal Tool which is reliable in assessing the relevance and validity of papers (Joanna Briggs Institute, 2020) (Appendices A-D). Results are discussed and summarised in chapter 4. In the next section, 'study validity' refers to how much the study's results reflect true findings outside the study (Patino & Ferreira, 2018b).

2.10 Critical appraisal of the randomised controlled trials

2.10.1 Aim, consent and ethics approval

It is important for studies to clearly identify the aim/s as this is the backbone on which the article is based on (Schober & Vetter, 2019). Patel et al. (2013) clearly state that the aim of their study was to compare the safety and cost-effectiveness between PICCs and portacaths for the infusion of chemotherapy. Wu et al. (2016) state that their aim was to gather data on Hickman and portacaths whilst Moss et al. (2021) declare that their aim was to compare complication rates between PICCs, portacaths and Hickmans. The primary end-point of all three studies was the occurrence of a line-associated complication including catheter-related deep vein thrombosis (CRDVT), line dislodgement/occlusion, CRBSI and pneumothorax.

All three RCTs reported to have received signed patient consent and ethics committee approval from all participating centres which is a fundamental ethical

principle in research ethics (Manti & Licari, 2018). This increases the quality of the studies.

2.10.2 Population and demographics

In the study by Patel et al. (2013), 70 participants (PICC n=36, portacath n=34) were recruited from three centres (Australia), whilst Wu et al. (2016) state that they recruited 100 participants (Hickman n=74, portacath n=26) from two oncology centres (Scotland) and in the study by Moss et al. (2021), 1,061 participants were recruited (PICC:Hickman n=424 [212,212], portacath:Hickman n=556 [253,303], portacath:PICCs n=346 [147,199] respectively) from 18 oncology centres (UK). Since the latter was a larger multicentre study, the results from this study were given more importance.

Patel et al. (2013) included male and female adults >18years with a non-haematological/solid malignancy who were planned for chemotherapy with a life-expectancy over three months whilst Moss et al. (2021) state that they included patients who were >18years and receiving chemotherapy (≥12 weeks) for haematological and non-haematological malignancies. Patients who had a CVAD removed in the previous two weeks or had an infection were excluded. Wu et al. (2016) excluded participants who had haematological malignancies or other medical or psychiatric disorders which could influence the results. All studies clearly identified the population demographics which according to Tarsi and Tuff (2012) this is important to include as it provides a general understanding of the population's characteristics. Apart from the discrepancy in the number of participants in both groups in the study by Wu et al. (2016), all studies had a similar demographic at baseline amongst all study groups. This increases the quality of the studies (Tarsi & Tuff, 2012).

2.10.3 Randomisation and blinding

Patel et al. (2013) state that they randomised participants on a 1:1 basis (PICC:portacath) which according to Edwards (2000), equal randomisation is considered more ethical and efficient than unequal randomisation. Contrarily, Wu et al. (2016) used a 3:1 randomisation (Hickman:portacath). A 1:1 ratio was not used due to limited resources and the high cost of portacaths. However, Wu et al. (2016) used randomisation with minimisation methods based on their body mass index (BMI) with random element which according to Altman and Bland (2005), minimisation methods are better in maintaining balance amongst groups; even if randomisation is unequal. Unlike the other two studies, Moss et al. (2021) used four randomisation options: Hickman:PICC:portacath (2:2:1), PICC:Hickman (1:1), portacath:Hickman (1:1) and portacath:PICC (1:1). Like the study by Wu et al. (2016), Moss et al. (2021) used a minimisation algorithm stratified according to the centre, BMI, type of cancer, CVAD history and the type of treatment. Overall these randomisation methods are considered as being reliable (Scott et al., 2002). Therefore this increases the studies' validity.

In all three RCTs, no blinding of participants, researchers and healthcare providers was done which according to Boutron et al. (2006) this might result in inflated treatment effects. However, since the VAD is visible, blinding would not be possible.

2.10.4 Intervention

In the study by Patel et al. (2013), six French dual-lumen PICCs were inserted in the upper arm under US by an IR and portacaths were inserted by a surgeon using the jugular vein. Wu et al. (2016) confirm that single and dual-lumen Hickman and single-lumen portacaths were inserted using the jugular vein under US by a senior IR or nurse-led VA teams. Both studies confirmed catheter positioning by x-ray whilst Moss et al.

(2021) state that devices were inserted by nurse-practitioners, IR, anaesthetists and/or surgeons.

2.10.5 Follow-up

Patel et al. (2013) state that they collected data on the VAD every three weeks until the CVAD was removed or after six months following the initiation of the study. Wu et al. (2016) and Moss et al. (2021) state that a 12-month follow-up of the participants was done. Based on Salkind (2010) follow-up increases the overall effectiveness of the study as it provides a long-term assessment on the effects of the intervention.

2.10.6 Statistical analysis

Patel et al. (2013) analysed their data using STATA version 12.0 and Multivariate Cox proportional hazards models to detect independent complication predictors which according to Bradburn et al. (2003), this provides more flexibility than parametric alternatives. The standard Kaplan-Meier survival curves were used to evaluate complication-free survival and both participant groups were compared by a log-rank test, which is a popular and reliable method to estimate the survival function (Bewick et al., 2004). Statistical significance was tested using Fishers, Chi-squared, Mann Whitney U and t tests; increasing the validity of the results (Dickson & Baird, 2011). Wu et al. (2016) used the intention to treat principle to carry out analysis. Primary analysis was done using logistic regression whilst like Patel et al. (2013), Cox regression was used to study the time-to-first complication. Moss et al. (2021) used the SAS version 9.3/9.4 and SAS Enterprise Guide, version 5.0/7.1 to analyse their data based on the intention-to-treat principles. This was done by an independent committee; limiting bias and increasing the study's quality (Abraham et al., 2018). Primary analysis was done using the per-protocol sensitivity analysis and logistic regression and the

index value scores were calculated using a Mann-Whitney U test. All studies provided detailed statistical analysis methods; increasing their quality and validity of the findings (Dickson & Baird, 2011).

2.11 Critical appraisal of a modified integrative literature review

Alexandrou et al. (2011) reviewed published data on the effectiveness of midlines to inform practice in adult acute care settings through a modified integrative literature review. The authors provide a detailed description of the methodology adopted in this study, including a list of the key terms, synonyms and MeSH terms used to search for the literature. This increased the study's quality and validity (Middleton, 2022). A healthcare librarian was consulted and the reference lists of the included studies were searched. The authors did not comment on whether they searched for grey literature which could have increased the overall review quality as they might have missed relevant unpublished articles (Adams et al., 2016). Two authors reviewed the abstracts of 232 papers against the inclusion/exclusion criteria. Having two individual authors screen the articles separately, it lowers the risk of selection bias (Waffenschmidt et al., 2019). After the assessment was complete, a total of 30 papers which met a pre-identified inclusion and exclusion criteria were reviewed by co-authors to confirm their validity. Only a small number of studies showing the effectiveness of midlines were retrieved.

2.12 Critical appraisal of a cross-sectional study

2.12.1 Aim and study demographics

Verma et al. (2020) sought to investigate the relevance of PICC placements in medical wards in five hospitals in Toronto, Canada, using the 'Michigan Appropriateness Guide for Intravenous Catheters' (MAGIC) (Chopra et al., 2015) which explains the appropriateness criteria of PICC use. The study included 4,825

participants who had a PICC inserted during hospitalisation by an IR and discharged between April 2010 and March 2015.

2.12.2 Data collection

Retrospective PICC insertion records were collected from the respective IR department, administrative and clinical data was collected from the General Medicine Inpatient Initiative which collects data from hospital information systems, patient demographics were collected from the Canadian Institute for Health Information for the Discharge Abstract Database and laboratory tests were collected from the respective hospitals to calculate the Laboratory-based Acute Physiology Score (LAPS). Upon collecting all the required data, each patient was given a Charlson Comorbidity Index (CCI) Score which is a weighted index predicting the risk of death within a year of hospitalisation. Charlson et al. (2022) write that the CCI is a useful indication of patients' clinical situation and it also helps to demarcate any major diagnostic and prognostic differences among subgroups. Due to the lack of information on PICC removal, an assumption was made that PICCs were left in situ until discharge. This assumption might have resulted in an over-estimation on the duration that the PICC was left in situ, underestimating PICC inappropriateness; therefore lowering the study's quality (Pautasso, 2013).

2.12.3 Data analysis

Four uses for PICCs were identified: infused medication, ICU, bloodletting and chronic kidney disease (CKD). Each group was assessed using the MAGIC guidelines to categorise each PICC placement as 'appropriate', 'uncertain' or 'inappropriate'. The Wilson procedure with a two-sided 95% confidence interval (CI) was calculated for each category and X^2 tests were used to calculate statistical significance of hospital-level differences. The R V.3.5.0 was used for statistical analysis. Since this is a

retrospective study, one of the main study limitations which might have drastically altered the results and therefore lowers the study's validity is the lack of a specific indication for PICC insertion and the assumption that the line was 'inappropriate'; leading to the overestimation of 'inappropriate' PICC insertions. Sedgwick (2014) identifies the use of retrospective data collection as a factor which might lower a study's quality. Another limitation in this study is that the risk of bias was not addressed (Ramirez-Santana, 2018).

2.13 Critical appraisal of a cohort-study

2.13.1 Aim and demographics

Bertoglio et al. (2016) studied the effectiveness of PICCs in 291 adult patients diagnosed with a non-haematological cancer receiving chemotherapy and/or TPN in San Martino National Cancer Institute, Italy, between January 2012 and June 2014 with the primary outcome being PICC failure. Patients with upper limb oedema and CKD were excluded. Data on patient demographics, type and tumour staging, type of chemotherapy, growth factor use, size and site of PICC, duration in situ, CRDVT, CRBSI and line occlusion/dislodgement was extracted from hospital records. The detailed participant demographical data increases the study's quality (Schober & Vetter, 2019).

2.13.2 Data analysis

Time-to-PICC-failure was estimated using standard-survival-analysis with the Kaplan-Meier curves to study the cumulative probability that the PICC would still be in situ at any given time since implant. Kishore et al. (2010) writes that the Kaplan-Meier estimate is the best way to measure the standard-survival-analysis. The log-rank test was used to calculate the univariate PICC-survival time in different subgroups. It can be observed that there was a majority of female participants (70%) with breast cancer

(37%) and 60% of the total number of participants received palliative care. The majority of lines were 5Fr, single-lumen (75%). Confounding effects were excluded by fitting a multivariate proportional hazards regression model with the time-to-PICC-failure as the dependent variable. This increases the validity of the study (Thomas, 2022).

2.14 Summary on the quality of the selected articles

From the critical appraisal of all six articles, it can be concluded that all articles are considered of high quality evidence based on the results from the respective highly-cited critical appraisal tools used.

2.15 Critical appraisal of the selected guidelines

Guideline appraisal of all eight guidelines retrieved through the thorough systematic search process detailed in section 2.7 was done using the AGREE II tool (Brouwers et al., 2010) (Appendix E). This was the preferred guideline assessment tool as it is a robust tool which looks at the overall quality of the guideline by assessing six main domains: scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability and editorial independence through 23 questions on a 7-point Likert scale; one representing the least quality and seven representing the highest quality (Graham et al., 2011). A summary of the scores for each guideline is given in Table 10.

2.15.1 Guidelines' objectives and specificity

All eight guidelines clearly state the aims and objectives being the development of a VA guideline to ultimately prevent the risk of healthcare-associated CRBSI. The Registered Nurses' Association of Ontario (RNAO, 2021) aimed at updating the RNAO (2005) and providing nurses and the interprofessional team with an evidence-based guideline on the insertion, assessment and maintenance of VADs in infants, paediatric

and adult patients. Loveday et al. (2014), funded by the Department of Health to update the epic3 (2007) guideline, aimed at limiting the number of CRBSI in the National Health Service (NHS), UK, by updating the guideline based on current evidence. The UK Vessel Health and Preservation (VHP) Framework (Hallam at al., 2020) aimed to update the VHP (2014). The VHP (2020) highlights that early VA planning within the first 24hours of admission is crucial in the management of adequate VA. Similarly, the DiVA pathway (Sou et al., 2017) provides recommendations for the Liverpool Hospital, Australia on the management of VA on patients with non-palpable veins which often leads to repetitive painful cannulation attempts. Bodenham et al. (2016) published the 'Association of Anaesthetists of Great Britain and Ireland (AAGBI): Safe vascular access 2016' guideline. Their main aim was to review current practices, evidence and expert opinion on VA. This led to the formation of a consensus document which provides recommendations on the insertion and removal of VADs. The Infusion Nurses Society USA, published the 'Infusion Therapy Standards of Practice' (Gorski et al., 2016). This guideline aims to limit the number of catheter-related complications, improve patient care and promote vein preservation. Chopra et al. (2015) published the MAGIC guideline, USA, which aimed to develop appropriateness criteria for the use of PICCs using the RAND/UCLA method. The Ministry of Health, Social Services and Equality of Spain (MOHSSE, 2014) published VA guidelines to provide healthcare professionals with recommendations to make informed decisions based on evidence. Therefore, all guidelines were specific with clear aims and objectives.

2.15.2 Guideline development group

Hallam et al. (2020) report the work of a multidisciplinary team to review and update the VHP (2014). This was done by reviewing national and international guidelines and expert opinions published in or after 2014. The literature search was conducted using Cinahl and Medline. They identified nine articles and three guidelines

relevant for their study. Sou et al. (2017) explain that the after-hour clinical support team together with the CVAD service developed the guidelines. However, they do not disclose what clinical-background these individuals have. This lowers the guideline's quality (Coulter et al., 2016). Bodenham et al. (2016) report that a consensus document guideline was produced by members of a Working Party established by the AAGBI. Panel experts included consultant anaesthetists, a nurse consultant in anaesthesia, an anaesthesia specialist registrar and a speciality doctor in anaesthesia. These guidelines were also endorsed by the Royal College of Anaesthetists, the Faculty of Intensive Care Medicine and the Association of Paediatric Anaesthetists of Great Britain and Ireland. Based on the findings by Choi et al. (2014), this increases the guideline's quality. Gorski et al. (2016) included a multidisciplinary nursing team with different backgrounds in VA, increasing the guideline's quality (Coulter et al., 2016). Chopra et al. (2015) used a 15-member multidisciplinary expert panel to carry out a SR of literature on PICC use and maintenance. Loveday et al. (2014) incorporated a nurse-led multi-professional team of specialists and researchers, including a nursing director, infection prevention and control (IPC) doctor, a surveillance manager in IPC and a Professor in microbiology. The expert panel in MOHSSE (2014) guideline included nurses coming from different backgrounds, including oncology and pain management specialists. The RNAO (2021) expert panel also included a multi-disciplinary team of nurses.

2.15.3 Views of the target population

All guidelines explain the importance of VA and how this can be very painful and uncomfortable; increasing the risk of morbidity and mortality if not planned properly. However, they do not go into detail on patients' preferences and views; lowering the quality of the guidelines (Eccles et al., 2012). In addition, the RNAO (2021) and Loveday et al. (2014) explain the complications experienced by patients in

the event of CRBSI whilst Hallam et al. (2020) identified patient discomfort in the event of multiple-attempt cannulation; increasing the guidelines' quality (Eccles et al., 2012).

2.15.4 Target users

Hallam et al. (2020) state that the guidelines are aimed for healthcare professionals to select the best CVAD for their patients. RNAO (2021) also write that these guidelines can be used by clinicians, administrators and educators who want to effect change by informing policies. Bodenham et al. (2016), Chopra et al. (2015), Gorski et al. (2016), Loveday et al. (2014) and MOHSSE (2014) clearly state that the guidelines are targeted towards anyone requiring VA and can be used by all practitioners. Loveday et al. (2014) specifies that their guideline is targeted towards hospital managers, IPC teams and individual healthcare practitioners. Sou et al. (2017) identifies that the guidelines are also to be used by the after-hour clinical team by training them in US-guided cannulation. Therefore all guidelines report their target users, increasing the guidelines' quality (Eccles et al., 2012).

2.15.5 Search for evidence

Bodenham et al. (2016) and Sou et al. (2017) do not give a thorough description of how the review was conducted, lowering the guidelines' quality (National institute for Health and Care Excellence, NICE, 2014). Their review was conducted based on current practice and literature as well as expert panel opinion. Chopra et al. (2015), Gorski et al. (2016), Hallam et al. (2020), MOHSSE (2014) and RNAO (2021) provide a thorough description of their SR and search strategy; increasing their guideline quality (NICE, 2014). MOHSSE (2014) use the 'Methodological Manual for Preparing Clinical Practice Guidelines' of the National Health System, NHS, (2007) to guide their GDP. Hallam et al. (2020) describe the literature search process including the search engines and databases used and the key terms used for the search. Chopra et al. (2015) used the help of two librarians and provided a list of the search engines and databases used as

well as the process for selecting the research papers by first by having two authors independently scan all papers for their eligibility and had any disagreements discussed and resolved by consensus. Loveday et al. (2014) explain that data was systematically gathered through a SR of peer-reviewed literature and assessment of the literature was done using validated appraisal tools.

2.15.6 Selecting the evidence

Whilst Chopra et al. (2015), Loveday et al. (2014), MOHSSE (2014) and RNAO (2021) provide the inclusion and exclusion criteria used to select the relevant studies, Bodenham et al. (2016), Gorski et al. (2016), Hallam et al. (2020) and Sou et al. (2017) do not provide this; lowering their guideline quality (NICE, 2014). The RNAO (2021) only included peer-reviewed studies published after 2013 in English with full-text access. Chopra et al. (2015) only included articles in English which were available in free-full text and excluded studies on paediatrics and studies which did not compare VADs with PICCs. MOHSEE (2014) report that they included studies published between 2000 and 2011 and papers of a regulatory/administrative nature were excluded. A detailed description of the inclusion/exclusion criteria increases the guidelines' quality and validity (Schober & Vetter, 2019).

2.15.7 Strengths and limitations of the body of evidence

RNAO (2021) provide a thorough description on the strength of evidence included along with pre-identified criterion which they used to ensure that good-level guidelines were provided (balancing benefits and harms, values and equity). They also provide a thorough assessment on the strength of evidence using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) guideline assessment tool. This increases the guidelines quality (NICE, 2014). Bodenham et al. (2016) and Hallam et al. (2020) do not report the strengths and limitations of the included literature. However, the latter does compare data from different contrasting

studies and use expert opinion to give their finalised recommendations. Gorski et al. (2016), Loveday et al. (2014) and MOHSSE (2014) used the 'Scottish Intercollegiate Guideline Network' to rate the body of evidence. This increases the guideline quality (Siering et al., 2013). Chopra et al. (2015) used the literature found through the systematic search to create clinical scenarios. These scenarios were then used by the expert panel to rate the appropriateness of PICCs insertion. However, they do not provide the strengths and limitations of the evidence used, lowering the overall guideline quality (NICE, 2014). One main guideline limitation by Sou et al. (2017) is that previous studies have shown that training of physicians in using US for VA has not always proven to be successful. Therefore, even though they concluded that the guideline was useful, for after-hour care, it might not prove to be as successful once introduced.

2.15.8 Methods for formulating the recommendations

RNAO (2021) provide a detailed description of how the guidelines were formulated through a systematic search for evidence and a group discussion with a multidisciplinary nursing team. The guidelines were formulated using consensus agreement using the GRADE. Gorski et al. (2016) and Hallam et al. (2020) only state that the literature retrieved was reviewed by all members and discussed. Sou et al. (2017) write that the guidelines were formulated by the after-hour clinical support team together with the central VA service. However, like Hallam et al. (2020) they do not provide any details on the process. Bodenham et al. (2016) provide a consensus document reflecting a systematic literature review of current literature and practices conducted. Then, using an expert panel, the guidelines were formulated using consensus agreement. However, they do not provide details on the process of how consensus was reached; if through a FGD or questionnaires. MOHSSE (2014) write that the guideline development phase was very thorough and included a development group which

assessed and synthesized evidence whilst compiling recommendations. Finally, a series of group discussions on the level of strength of evidence, the benefits and risks for the users and patient's and user's preferences was done. Chopra et al. (2015) and Loveday et al. (2014) provided a thorough description of how their guidelines were developed through consensus after conducting a SR of the literature. Chopra et al. (2015) used a validated method to develop appropriate indications for PICC use.

2. 15.9 Health benefits, side effects and risks

Sou et al. (2017) do not provide any information on the benefits and/or risks taken into consideration during the formulation of the guidelines. This lowers the study's quality (Woolf et al., 1999). Bodenham et al. (2016), Chopra et al. (2015), Gorski et al. (2016), Hallam et al. (2020), Loveday et al. (2014), MOHSSE (2014) and RNAO (2021) look into the health benefits gained from having these guidelines introduced into practice. These mainly include a reduction in catheter-related complications and increased patient satisfaction. They also look into any risks and complications which may arise from such procedures and how they are to be managed (including haemothorax, pneumothorax, myocardial perforation and venous air embolism). This increases the quality of the guidelines (Woolf et al., 1999).

2. 15.10 Link between the recommendations and evidence

Looking at the guidelines by Bodenham et al. (2016), Chopra et al. (2015), Gorski et al. (2016), Hallam et al. (2020), Loveday et al. (2014), MOHSSE (2014) and RNAO (2021), there is a link between the evidence they systematically retrieved and the recommendations given. This is an important aspect in the GDP and it also increases the guidelines' quality (NICE, 2014). Contrarily, Sou et al. (2017) do not provide information on existing knowledge on the topic to support the guidelines.

2. 15.11 External review

The guidelines published by Bodenham et al. (2016), Gorski et al. (2016), Hallam et al. (2020), Loveday et al. (2014), RNAO (2021) and Sou et al. (2017) were externally reviewed prior to their publication. Shekelle et al. (2012) state that external reviewing of guidelines help in increasing the quality of a guideline. Loveday et al. (2014) state that the guidelines were reviewed by an external panel of stakeholders and comments on the format, content, practice applicability of the guidelines and any other recommendations were collected and taken into consideration by the guideline development group and other advisors. Chopra et al. (2015) and MOHSSE (2014) do not report whether the guidelines were externally reviewed. This lowers the guidelines' quality (Shekelle et al., 2012).

2.15.12 Updating the guideline

Gorski et al. (2016) and RNAO (2021) state that the guidelines should be reviewed after five years from the date of their publication. In fact, Gorski et al. (2016) updated their guideline in 2021 after the systematic evidence search process of this dissertation was done. Bodenham et al. (2016), Chopra et al. (2015), Hallam et al. (2020) and Sou et al. (2017) disclose no plans for updating the guidelines. Loveday et al. (2014) emphasise the importance that guidelines are updated frequently using new data and knowledge on the subject. The original epic2 guidelines published in 2001 were funded by the Department of Health and updated in 2007 and 2014 and due to be updated in 2017; however this has not been published to date. The guidelines by MOHSSE (2014) are currently being updated. Martínez García et al. (2012) state that providing and adhering to planned guideline updates increases guideline quality.

2.15.13 Options for the management of the condition/health issue

All guidelines give specific recommendations for different needs. For instance, Bodenham et al. (2016) give recommendations on when it is better to insert a PIVC when compared to a midline or a PICC. These recommendations are detailed and well explained.

2.15.14 Facilitators and barriers

MOHSSE (2014) and RNAO (2021) provide a good description of the facilitators and limitations of their guidelines, including staff education and training programmes. Bodenham et al. (2016), Chopra et al. (2015), Gorski et al. (2016), Sou et al. (2017) and Loveday et al. (2014) do not go into this detail. Hallam et al. (2020) identify their main limitation being that they do not provide details on insertion techniques that can be used. However they do not provide any tools/instruments which facilitate the introduction of their guidelines. Abrahamson et al. (2012) writes that providing guideline facilitators and barriers, it increases the overall quality of the guidelines.

2.15.15 Tools to help put the guidelines into practice

RNAO (2021) suggest that the guidelines are reviewed and applied within the context of the health organisation. Sou et al. (2017) recommend that clinicians are to be trained in US-guided VA. They also provide detailed pathways for physicians to follow during and after business-hours. Bodenham et al. (2016) and Gorski et al. (2016) provide recommendations on how these guidelines can be implemented which include training in VA, introducing hospital policies and systems on how patients should be provided with effective, timely and safe VA and recommendations that all hospitals should have VA guidelines in place. Chopra et al. (2015) and Hallam et al. (2020) do not provide any recommendations on how to use these guidelines. Loveday et al. (2014)

recommend that all hospitals can introduce these guidelines in their hospital policies. MOHSSE (2014) provides a detailed guideline implementation plan. Providing tools/recommendations on how to successfully introduce guidelines into practice increases the guidelines' quality (Abrahamson et al., 2012).

2.15.16 Resource implications

Hallam et al. (2020), RNAO (2021) and Sou et al. (2017) do not comment about any potential resource implications. Bodenham et al. (2016) identify that not all hospitals have access to all devices included in the guidelines, they do however recommend that should a hospital not have access to a specific device, they choose the next best option provided in the guideline. Gorski et al. (2016) identify the main resource needed as being education; including healthcare professional education on the use of the guidelines. Chopra et al. (2016) focus mainly on the use of PICCs; however, they do provide recommendations to use other lines in the case where these are not available. Loveday et al. (2014) write that in cases where VAD are not available, the cost of covering CRBSI is higher than that of investing in getting new equipment. MOHSSE (2014) take recourse implications into account in the guideline implementation section.

2.15.17 Monitoring and auditing

Auditing/monitoring tools help organisations to keep guidelines relevant and safe. Therefore guidelines which include monitoring/auditing tools are of a higher quality than those which do not (Strategic Management Services, LLC, 2018). The RNAO (2021) recommend using a Best Practice Guideline Order Set or Nursing Quality Indicators for reporting and evaluating data systems to assess the effectiveness of the guidelines within a particular setting. Bodenham et al. (2016) recommend frequent auditing processes by VA organisations and individual practitioners to ensure compliance with the guidelines. They also recommend national audits to set standards.

Loveday et al. (2014) recommend using auditing tools to assess adherence of clinicians to the guidelines. Chopra et al. (2015), Gorski et al. (2016), Hallam et al. (2020), MOHSSE (2014) and Sou et al. (2017) do not provide any auditing/monitoring recommendations.

2.15.18 Funding body

RNAO (2021) report that the GDP was funded by the Government of Ontario, however, no individual authors were funded. Bodenham et al. (2016) report that five of the authors received external funding. This led to additional external review to minimise the risk of bias. Chopra et al. (2015) and Loveday et al. (2014) write that participants in the review panel did report receiving external funding; however, they disclose no conflict of interest. Gorski et al. (2016), Hallam et al. (2020), Sou et al. (2017) and MOHSSE (2014) report no funding. Khamis et al. (2018) write that reporting funding sources in guidelines is important as this could be the source of bias on the choice of topic and evidence included in the guideline.

2.15.19 Competing interests

Bodenham et al. (2016), Chopra et al. (2015) and Loveday et al. (2014) do not report competing interests among the members of the expert panel. Hallam et al. (2020) RNAO (2021) and Sou et al. (2017) declare no competing interests. Additionally, RNAO (2021) add that any conflicts of interest which might have been reported by any of the members in the expert panel were reviewed by the RNAO Best Practice Guideline Development and Research Team and expert panel co-chairs. Gorski et al. (2016) and MOHSSE (2014) report all potential conflict of interest. However none were directly related or could have affected the guideline.

2.16 Summary on the quality of the selected guidelines

From the results obtained through the AGREE II tool, the selected guidelines are all of ‘good quality’. This will help to increase the overall quality of this study.

Table 10

Summary of the Critical Appraisal Based on the AGREE II Tool

Question	RNAO (2021)	Hallam et al. (2020)	Sou et al. (2017)	Bodenham et al. (2016)	Gorski et al. (2016)	Chopra et al. (2015)	MOHSSE (2014)	Loveday et al. (2014)
1. The overall objective(s) of the guideline is (are) described	7	7	7	7	7	7	7	7
2. The health question(s) covered by the guideline is (are) described	7	7	6	6	7	6	7	6
3. The population to whom the guideline is meant for is described	7	5	6	6	5	6	5	6
4. The guideline development group includes individuals from all relevant professional groups	5	6	3	6	7	4	5	6
5. The views and preferences of the target population have been sought	4	6	4	4	5	4	4	4
6. The target users of the guideline are clearly defined	6	5	6	6	5	5	5	5
7. Systematic methods were used to search for evidence	6	6	2	2	7	5	5	7
8. The criteria for selecting the evidence are clearly described	6	1	1	1	3	5	6	6
9. The strengths and limitations of the body of evidence are clearly described	6	1	4	3	7	2	6	6
10. The methods for formulating the recommendations are clearly described	7	4	4	3	4	5	7	5
11. The health benefits, side effects, and risks have been considered	5	4	1	5	5	5	5	5
12. There is an explicit link between the recommendations and the evidence	5	6	1	6	7	6	6	5
13. The guideline has been externally reviewed by experts	6	7	7	6	7	1	1	6
14. A procedure for updating the guideline is provided	7	1	1	1	7	1	1	4
15. Recommendations are specific and unambiguous	7	7	4	6	7	6	7	6
16. The different options for management of the condition or health issue are presented	5	5	6	6	5	6	6	6
17. Key recommendations are easily identifiable	7	6	6	6	5	6	5	6
18. Describes facilitators and barriers to its application	5	3	1	1	1	1	4	1
19. Provides advice and/or tools on how the recommendations can be put into practice	7	1	6	5	7	1	6	3
20. The potential resource implications of applying the recommendations have been considered.	1	1	1	4	5	3	5	5
21. The guideline presents monitoring and/or auditing criteria	6	1	1	6	1	1	1	5
22. The views of the funding body have not influenced the content of the guideline	5	6	6	6	6	6	1	5
23. Competing interests of guideline development group members have been addressed	7	5	6	1	6	1	5	1

Note: This table shows the scores of each individual guideline for each question. The scores are marked on a 7-score Likert Scale with '1' representing the least possible quality and '7' representing the highest possible quality

2.17 Conclusion

The ScRs allowed for a thorough systematic search of recent literature and guidelines on VA. A total of six articles and eight guidelines were retrieved which were then critically appraised using the respective published critical appraisal tools. All articles and guidelines were found to be of ‘good quality’. The next chapter provides a detailed description of the methodological process guiding the GDP.

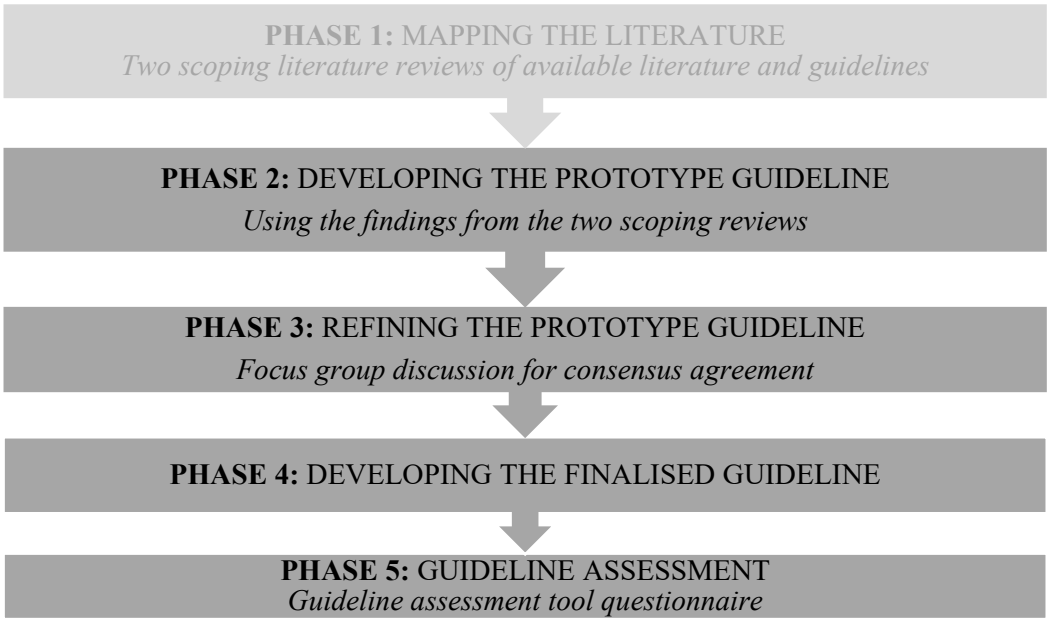
Chapter 3
Methodology

3.0 Introduction

After identifying relevant evidence-based literature and guidelines on VA by conducting two ScRs in chapter 2, this chapter discusses the methodology guiding the development of the VA guideline (Figure 6, Phase 2). This chapter also discusses the research design, the ethics clearance process, the sampling method, the data collection instruments and the data analysis processes applied to carry out Phases 2 to 5 of the GDP (Figure 6).

Figure 6

Guideline Development Process: Phase 2 to 5



3.1 Aims and objectives

The research question guiding this study is 'How to develop a local evidence-based VA guideline for adults (>18 years) in acute, non-acute or outpatient care settings?'. The aim of the study is to develop a local evidence-based VA guideline for nurses and physicians to help them select the best VAD for the patients. In order to achieve this aim, specific objectives are highlighted in section 1.6.

3.1.1 Ethics review committee

Following acceptance of the research proposal, the researcher collected several permissions prior to submitting for ethics clearance. These included the Chairperson of the Medical Imaging Department (Appendix H), the Chief Executive Officer in MDH (Appendix I), the Chief Medical Officer (Appendix J), the Data Protection Officer (Appendix K), the Director of Nursing Services (Appendix L), the Chief Nursing Manager (Appendix M) and the Head of the Department of Infection Control & Sterile Services (Appendix N). After collecting all the necessary permissions, the ethics form was submitted to University of Malta Research Ethics Committee (UREC) (no. 9195_28262021_) and Faculty of Health Sciences Research Ethics Committee (FREC) for filing (Appendix O).

3.2 Phase 2: Developing the prototype guideline

Given that there is a lack of local data on VA, two ScRs were done to retrieve current evidence-based literature and guidelines on the topic. Data collected from the ScRs was used to develop a prototype VA guideline based on the WHO Handbook (2014). A similar process was conducted by Adebiyi et al. (2018) where the authors performed a SR of the literature to formulate a prototype guideline on foetal alcohol spectrum disorders in South Africa. This phase of collating evidence-based findings to develop guideline recommendations is best done by consensus agreement (Carter et al., 2021). However, since there is only one researcher this was done by identifying the relevant information from all six studies and eight guidelines identified in chapter 2 and formulating the prototype guideline based on their conclusions (Appendix F).

3.3 Phase 3: Refining the prototype guideline

This phase of the GDP aimed to refine the prototype guideline by having a consensus discussion with local experts on the prototype VA guideline. This was done by using a two-round modified Delphi method to reach consensus agreement.

3.3.1 Research design: the modified Delphi method

Since the prototype guideline needs to be refined and adapted to the local setting, the WHO Handbook (2012) recommends the Delphi approach to do this since it provides a structured communication technique relying on a panel of experts. The Delphi method was first developed by Olaf Helmer-Hirschberg at the RAND Corporation in the early 1960s and has since been cited by many authors (Ozier, 1998). This method is a multi-round data collection method which mainly relies on the identification of key individuals forming the expert panel who are knowledgeable on the subject being studied and have particular interest in exploring areas of study where data is lacking (Brown, 2018). This method traditionally begins with a series of online open-ended questionnaires with the aim of soliciting specific information about a topic/area that is not well researched (Hsu & Sandford, 2007). The conventional Delphi relies on anonymity with the purpose of refining expert opinion and ultimately reaching consensus ("Delphi Method", n.d.). This method has been used successfully in the development of various guidelines including Ajidahun (2011), Govender (2016) and Pharaoh (2014).

Similarly to the Delphi method, the modified Delphi method basis it's foundations on discussion (usually face-to-face discussion) on the body of research whilst aiming to reach consensus amongst all key experts in a more time-efficient and cost-effective manner (Ozier, 1998). By definition consensus means a general agreement within a group and not necessarily an agreement by all members making up

the group (Schneider et al., 2016). Therefore, consensus involves discussion and compromise among a group with the aim to arrive at a decision that is accepted and/or supported by all/most stakeholders. Various studies have shown that the modified Delphi method is superior to the traditional Delphi method for guideline development (Eubank et al., 2016).

Since VA is a well-researched topic, and the aim of this GDP phase was to critically discuss the prototype guideline with local experts and reaching consensus agreement on a finalised local VA guideline, it was decided that a two-round modified Delphi method was the best approach for Phases 3&5 of this GDP. This consisted of a face-to-face focus group discussion (FGD) and an online questionnaire.

3.3.2 Research approach

Since the aim of Phase 3 was to critically discuss the prototype guideline with local VA experts based on their experience and expertise, a qualitative approach was considered as the best research approach for Phase 3 of the GDP. Lewin et al. (2019) concluded that integrating evidence-based literature together with the experiences and views of relevant stakeholders is the best guideline development technique.

A qualitative approach enabled the researcher to have an in-depth discussion on the prototype guideline and get new ideas, concepts and more practical local results based on the experiences and expertise of local experts (Tomaszewski et al., 2020); especially because no local studies or guidelines on VA were retrieved during the ScRs in chapter 2 and this guideline could be used to inform local policy. Therefore a qualitative approach was the best approach to meet the objective of this phase. The main limitations of taking a qualitative approach were: (i) replication of results is more difficult and (ii) this is the first time that the researcher carried a similar study (Rahman, 2016).

3.3.3 Research tool

Since clear discussion among key experts on the prototype guideline based on their professional experience in having met similar situations and having dealt with different outcomes in their working experience and also because this topic does not require personal opinions of experts but rather their professional opinion on the subject based on literature and backed by their experience, FGD was the preferred data collection tool for the first round of the modified Delphi method which allowed the researcher to reach the aim of the GDP. This concept originated in American marketing and later in the 1980s it started being largely used for academic research (Basnet, 2018). FGD was the preferred research tool over personal interviews and surveys since the group dynamic in a FGD has proven to bring out richer and more detailed answers (Basnet, 2018). During the discussion, the dynamic of the group also allowed participants to challenge each other's remarks and opinions based on their different backgrounds which also allowed for individual participants to change their somewhat uninformed opinions during the process. This method was used in similar studies including Ives et al. (2018). Therefore, as also identified by Hasson et al. (2000) the first round of data collection in a modified Delphi study can be done by collecting qualitative data through FGD.

3.3.3.1 Advantages and disadvantages of the research tool

Even though FGDs are often less accurate than collecting individual opinions due to the possibility of having dominant individuals controlling the discussion leading to conformity bias (Avella, 2016), FGDs give you the opportunity to clarify any pre-conceived notions and uncover ideas and counter-arguments which would have not otherwise been brought up in individualised questionnaires as done in the traditional Delphi method (Acocella, 2011). In order to minimise having biased and controlling

discussions, the researcher ensured that everyone felt comfortable in sharing their ideas and when the conversation started to get dominated by particular individuals, the researcher asked all participants if they understood the scope and content of the question/s, asking individual participants whether they had any comments they would have liked to share and whether they had any questions they wanted to ask (Brown, 2018).

3.3.4 Identifying the expert panel

The researcher identified the disciplines that have a professional interest in achieving the aim of this study and were therefore invited to participate in the expert panel. As Avella (2016) identifies, FGDs cannot include representations from many different population groups as research shows that since their experiences vary, conclusive results will be difficult to achieve.

The researcher identified the expert groups included in the expert panels of the VA guidelines retrieved during the ScRs, and used this information to identify the expert panel for this study. Since this study aims to develop a VA guideline for the service offered in the Angiosuite Unit, MDH, IR physicians with experience in inserting VADs were included. IPC PDNs together with VA PDNs and the Head of the IPC Department all working in MDH, can provide useful insight on VADs based on their experience with using different VADs and were therefore included in the study's population group (Table 11). Therefore, for this dissertation, purposive sampling was used to identify the participants which formed the expert panel (Ames et al., 2019).

Discussions on the number of participants that should be included in a FGD are broad. Morgan (1997) writes that six to ten participants are ideal whilst (Krueger & Casey, 2014) state that 'mini FGDs' consisting of four to six participants are becoming more popular with researchers as these are easier to recruit and are more comfortable for

participants. The main disadvantage with having a small population group is the limited number of experiences encountered by those same participants. However, since the number of people considered as 'experts' in the field is limited, a mini FGD was considered to be the best type of discussion for this study. Therefore, a sample size consisting of five to ten participants as suggested by Krueger and Casey (2014) was considered as appropriate. A list of eligible participants and their contact information was obtained from the two intermediaries. A total of 11 individuals were identified as being 'eligible' to participate in the study. Two further attempts were made to organize a second FGD as most participants who could not attend the discussion had other commitments related to the Covid-19 pandemic, were in quarantine or could not attend due to staff shortage on the wards.

Table 11

Eligibility criteria for the inclusion of the expert panel members

Eligible Expert Panel Members
Infection prevention and control practice development nurses
Head of the infection and control department in Mater Dei hospital
Venous access service providers within the acute care hospital namely Interventional Radiology physicians who provide a venous access service for at least one of the following: - Midlines - Peripherally Inserted Central Catheters - Portacaths - Hickman Lines
Venous access practice development nurses

3.3.5 Focus group discussion

The discussion was held in English as agreed by all participants. A PowerPoint presentation was designed prior to the FGD. The use of similar technology has proven

to be effective in helping participants understand and follow sessions better (Lari, 2014). This also helped the researcher to follow a pre-structure systematic sequence to introduce and lead an effective FGD. A printed copy of the prototype guideline which was to be discussed during the discussion was given to all participants. This was presented in a summarised format with allocated sections for each participant to write their comments with the provided stationary (Appendix F).

3.3.6 Discussion guide

The researcher prepared a pre-structured discussion guide based on Krueger (2002) and Nyumba et al. (2018) which helped guide the FGD (Appendix G). This included a brief welcoming, a short introduction on the topic, some ground rules and pre-formulated guiding, probing and trigger questions which consisted of both open-ended and focused questions (De Chesnay, 2014). A series of questions where the researcher asked questions like: “do you think this is an adequate summary of what we have discussed?” and “do you think we missed anything?” helped the researcher to keep all participants in line with what was being said and also allowed for new opinions to be discussed. Overall, this discussion guide helped the researcher to keep the discussion on track with the aim of the FGD.

3.3.7 The moderator and moderator assistant

The moderator was identified as the researcher carrying out this research. During the discussion, the moderator took field notes in which quotes, body language, new ideas, themes and key points were recorded. Before initiating the FGD, participants were reminded that the session was audio-recorded using the moderator’s mobile phone and stored together with the coded transcripts on the moderator’s personal computer in a password-protected file which was only accessible to the moderator (Basnet, 2018). The moderator’s academic supervisor assisted in the process of setting up and operating

recording equipment, taking field notes, debriefing with the moderator and providing feedback.

3.3.8 Intermediaries, information sheet and consent form

Two intermediaries were identified prior to getting the Data Protection Officer's approval and submitting for ethics clearance. The intermediaries were selected based on their occupation and their accessibility to contact the participants participating in this study. These were the Charge Nurse in charge of the Angiosuite, MID, and the Administration Secretary working with the Nursing Director and the Chief Nursing Manager. They were asked to sign their informed consent forms (Appendix Q) and were informed that participation was voluntary, which according to Patton (2009), this is a very important step in research. The Information Sheet and Consent Forms (Appendix P) were written by the author of this dissertation and co-signed by the author's academic supervisor. The intermediaries' responsibility was to contact the eligible experts through email and provide them with the information sheet. They also asked the participants if they were willing to participate in this study. A consent form indicating that they understood the purpose of the research study and their rights and responsibilities was signed by all participants. The consent form specified that their participation was voluntary and highlighted their right to withdraw from the study at any point. Before starting the discussion, it was ensured that all participants had read and understood their information sheet and signed their consent form.

3.3.9 Environment

A comfortable environment with a circular seating formation allows for a more successful discussion where all participants could get a clear view of everyone in order to be able to note any non-verbal communication and also so that no one feels excluded or unimportant during the discussion (Omar, 2018). It was also ensured that the

environment was well lit, quiet and free from distractions (Vaughn et al., 1996). A "meeting in progress" sign was placed on the door prior to starting the FGD which was held at the conference room of the MID, MDH, which was easily accessible to all participants. The researcher's contact number was sent with the invitation email along with the location for the meeting and the receptionists of the MID were informed about the meeting so that they could direct any participants who might ask for directions. Refreshments were made available and the seating was arranged in a way that each participant was able to see the projector screen and all the other participants clearly (Nyumba et al., 2018). The FGD was held on the 9th December 2021 between 14:00 and 15:00.

3.3.10 Data analysis

The audio-recording was transcribed by the author following the FGD so that the discussion was still salient (Bailey, 2008). This was done using an online programme otter.ai (AlSense, Inc. 2022). When referring to participants, codes P1 to P7 were allocated randomly to each participant as well as to the moderator and the moderator assistant for data protection purposes. Only the researcher has access to the codes. Thematic analysis was employed for data analysis since this provides the possibility of dividing wide emerging ideas/themes into smaller categories which could be analysed better and more systematically (Nowell et al., 2017). These themes were mainly based on subjective information backed by participants' experiences, opinions and expertise. Therefore, a semantic approach was taken rather than a latent one (Byrne, 2021). Analysis was not deductive based on pre-formulated themes but rather an inductive approach by which themes were formed based on the data gathered from the transcript (Byrne, 2021). This process was guided by Nowell et al. (2017). After the analysis was complete, data was used to update the prototype guideline.

3.3.10.1 Familiarising and coding

After the FGD was transcribed, the document was printed and the author read the text several times whilst taking initial notes to get familiar with the text (Nowell et al., 2017). Once the author was confident enough with having a good general picture of the transcript, this was read again and compared with the field notes. At this stage the author started coding by writing general notes next to the sections. Due to the nature of the data and information being gathered, a reflexive thematic analysis was used since this is a more flexible approach to coding as it allowed the researcher to change the codes at any point of the analysis process (Byrne, 2021). Common themes and patterns were identified and annotated/coded based on the concept of the research question being studied (Nowell et al., 2017).

3.3.10.2 Generating themes and reviewing

Following the coding process, data was reviewed and codes which had an association amongst them were collated into broader themes (Nyumba et al., 2018). This was done by colour-coding the codes which had similarities on a Word Document. This was a repetitive process until the author was satisfied that the themes were representative of the FGD. Codes and themes which were found not to be relevant to the research question were eliminated (Nowell et al., 2017). The themes were reviewed multiple times by the researcher and the codes were read over to ensure that they all fit and cohere together under their respective theme. The transcript was read again to analyse any text that had not been coded. These themes were reviewed and named.

3.4 Phase 4: Developing the finalised guideline

The findings from the FGD were used to refine the prototype guideline which was developed in Phase 2 of the GDP based on the findings from the ScRs. This was done by identifying the points of consensus reached amongst the expert panel and using

them as recommendations for the guideline. A similar technique was used by Adebiyi et al. (2018).

3.5 Phase 5: Guideline Assessment

This phase in the GDP aims to assess the finalised VA guideline developed in Phase 4. Guidelines within the healthcare system are viewed as instruments which directly guide care decisions. This therefore puts a responsibility on individuals formulating such guidelines to be accurate, safe and reliable (Eikermann et al., 2014). Therefore for the second round of data collection as a part of the modified Delphi method, a published guideline assessment tool was considered as appropriate to assess the quality, soundness and reliability of the finalised guideline. The use of similar assessment tools has been proven to be useful in detecting conflict of interest amongst participants (Eikermann et al., 2014).

There are various guideline assessment tools available. A systematic comparison of five different assessment tools by Eikermann et al. (2014) concluded that all five identified tools did not assess the actual content of the checklist but rather they assessed their use of systematic processes to retrieve evidence-based data on which the recommendations were based on. After a systematic review conducted by Siering et al. (2013) on the quality of different guideline appraisal tools, it was concluded that the AGREE II tool (Appendix E) was identified as a validated tool widely used internationally for comprehensive guideline appraisal.

3.5.1 Research tool

The AGREE II has undergone validity and reliability testing which have concluded that this tool is both a reliable and a valid instrument with sufficient inter-rater reliability (The AGREE Research Trust, 2014). This tool is a quantitative method used to evaluate guidelines. As Grimmer et al. (2014) explains, the AGREE II tool

consists of 25 questions of which 23 of these are scored on a Likert Scale between one and seven (one representing the least possible quality and seven representing the highest possible quality). These 23 questions are arranged into six main domains with each domain aiming to capture a different dimension on the quality of the guideline: (I) scope and purpose - assessing the guideline's overall objectives, health questions and target population, (II) stakeholder involvement - looking at the key experts making up the guideline development group, (III) rigour of development - looking at the core of how the guideline was developed, (IV) clarity of presentation – assessing whether the recommendations are easily identifiable, (V) applicability - asking about the facilitators and barriers of introducing this guideline into practice and (VI) editorial independence - for funding sources and competing interests (Graham et al., 2011). Two final questions assess the overall quality of the guideline on a scale of one to seven and a final question asking participants on whether they would recommend the guideline for use with space to write any further comments/recommendations. Permission from the AGREE Scientific Research Office - Medical Investigations Institute, University of Antioquia, Medellin, Colombia to use the AGREE II tool for this research study was sought and obtained (Appendix R).

3.5.2 Data collection

The finalised guideline compiled in Phase 4 was sent to all participants along with an offline link to an online Google Form leading to the 25 questions of the AGREE II Tool (2010). This was sent through email by the study intermediaries on 30th March 2022. Participants were reminded that the aim of this questionnaire was to assess the quality of the finalised guideline and get their opinion on whether they were in agreement with the content of the finalised guideline. All questions in the questionnaire were marked as 'required' so that all questions were answered by all participants. Participants were also reminded that their responses were anonymous and no one,

including the researcher, could link the responses to any individual participants. A deadline for completing the questionnaire was set for the 6th of April.

3.5.3 Data analysis of the questionnaire

Once all responses were submitted, the 'summary' option was selected and the results were downloaded as an Excel Document. This was converted into a Word Document Table (Table 14). Analysis of the data collected from the questionnaire was conducted by using a recommended methodology for data analysis; a formulaic weighted domain scoring system (Grimmer et al., 2014). It is important to score the six domains independently of one another, and at no point should they be aggregated into one quality score (Graham et al., 2011). Data analysis of the guideline assessment tool was done in accordance with the recommended data analysis method suggested by the same tool.

The maximum and minimum possible scores for each domain were calculated by using two equations provided by the AGREE II tool:

Maximum Possible Score = 7 X Number of Items X Number of Appraisers

Minimum Possible Score = 1 X Number of Items X Number of Appraisers

Using both scores, each domain was then scored separately by summing up all the scores of the individual items in each separate domain and working it out as a percentage of the maximum possible score for each domain using the following equation:

$$\textbf{Scaled Domain Score} = \frac{\textbf{Obtained Score} - \textbf{Minimum Possible Score}}{\textbf{Maximum Possible Score} - \textbf{Minimum Possible Score}} \times 100$$

3.5.4 Interpreting domain scores

The results obtained by using the latter formula are given in a percentage form for each of the six domains. These scores were used to recognise the strengths and limitations of the guideline based on each separate domain. As recommended by Xie et al. (2016), the guideline was "recommended" if the overall scores of each domain was higher than 60%, "recommended with modification" if scored was between 30%-60% and finally "not recommended" if scores was less than 30%.

3.6 Conclusion

This chapter was guided by the aims and objectives of the research question which helped in choosing the methodological processes for this study. This chapter outlined a detailed description of how the prototype guideline was formulated as well as the modified Delphi methods applied to refine the finalised guideline through a FGD and a guideline assessment tool. The next chapter provides the results of the methodological processes applied.

Chapter 4
Findings

4.1 Introduction

In this chapter, the results obtained based on the study's objectives are presented. The results retrieved from both ScRs as a part of Phase 1 of this GDP are reported. These were used to complete Phase 2 (Developing the Prototype Guideline) of the GDP. The prototype guideline was used to complete Phases 3 and 5 which have been described in chapter 3 and their results are presented in this chapter. The results from these two phases were used to update the prototype guideline and formulate the finalised guideline (Phase 4).

4.2 Results from the scoping reviews

A total of six articles (Table 8) and eight guidelines (Table 9) were retrieved through the ScRs in chapter 2. The results are summarised in Tables 12 and 13.

4.2.1 Results from the retrieved articles

Patel et al. (2013) found that portacaths caused lower complications compared to PICCs for the administration of chemotherapy in patients with solid malignancies (12% and 29% respectively) with a 0.142 and 0.414 complications per 100 catheter days, (P=0.011). Time-to-complication was longer for portacaths (hazard ratio (HR): 0.25, CI 0.09-0.86, log-rank P=0.038). The most common complications were CRDVT and obstruction which was more common in PICC (25% and 0%, p=0.013). CRBSI and premature line removal were similar (20% and 15.2%). No statistical significance was noted. The study concluded that the rate of complications was not affected by age, gender or metastatic disease.

Wu et al. (2016) state that 54% of patients reported one/more complication with Hickman compared to 38% with portacaths. This shows that the Hickman pose a higher statistically significant risk of getting complications (80%CI 1.11, 3.88. P=0.068) which

included: 28 CRBSI (Hickman: 45%, portacath: 5%), exit site infections (ESI) (Hickman: 7%, portacath: 32%) and malfunction (Hickman: 3%, portacath: 15%). Overall, 20 Hickman were removed compared to one portacath. It was analysed that the median time-to-complication for Hickman was 30 weeks (80% CI:19). This was not calculated for portacaths since complication rate was <50%. Finally, although more expensive, it was concluded that portacaths are more appropriate for patients with a non-haematological malignancy with/without metastasis when compared to Hickman.

Moss et al. (2021) report a complication rate of 52% with PICC and 49% with Hickman. Overall PICCs were in situ for a shorter duration (113days and 158days respectively), however, PICCs were associated with a higher complication per catheter week with the most common complications being the inability to aspirate blood (PICC: 21%, Hickman: 16%) and mechanical failure (PICC: 15%, Hickman: 3%). CRBSI was more commonly associated with Hickman (30%) compared to PICC (11%). When Hickman was compared to portacath, the latter was found to be superior (odds ratio: 0·54 [95% CI 0·37–0·77]). Overall, portacaths were left in situ for a longer duration than Hickman (367days and 165days respectively) and whilst portacaths were linked to 0.02 (SE:0.00) complications/catheter weeks, Hickman were responsible to 0.06 complications (SE 0.01) with 14% of portacaths having to be removed earlier compared to 32%. Portacaths were also linked with lower CRBSIs (14% and 16%). Finally, with a 10% margin, it could not be concluded that PICC had a significant non-inferiority to Hickman (1.15, 95% CI 0.79-1.71).

In Alexandrou et al. (2011), thematic analysis of all 30 papers was done and three themes emerged: advantages, disadvantages and maintenance of midlines. The data collected concluded that midlines help in avoiding repetitive peripheral cannulation whilst minimising the risk of needle-stick injuries with the main use for midlines being IV infusions. They concluded that using midlines is a more cost-effective and a less

traumatic solution than PIVCs. Midlines also save time and minimise stress on caregivers for needing to repeatedly re-cannulate patients. The overall dwell-time for midlines was concluded to be between two to four weeks, however, if cared for properly, they can be left in situ for longer. Another reported advantage for midlines was the positioning of the catheter tip which does not need to be confirmed by fluoroscopy/x-ray, therefore ideal to be inserted at the bedside and midlines have lower complication rate than PICCs.

Verma et al. (2020) found that from 101,660 admissions, 3,479 had a PICC inserted. The average age was 65years (SD 18years) with 46% females. 2222 PICCs inserted for medication infusion were considered as 'appropriate' (64%, 95%CI 62%-65%) whilst 16 were 'inappropriate' (0.5%, 95%CI 0.3%-0.8%). From 389 ICU PICCs, 93 were 'appropriate' (24%, 95%CI 20%-29%) since they were needed for >15days, whilst 296 PICCs were 'inappropriate' (76%, 95%CI 71%-80%) due to the short duration of IV medication. However, from the 296 PICCs considered as 'inappropriate', 243 (62%, 95%CI 57%-67%) were later marked as 'appropriate' due to their use after being discharged into a normal ward. For bloodletting, 281 PICCs (8%, 95%CI 7%-9%) were 'appropriate' and 34 were marked as 'inappropriate' (1%, 95%CI 0.7%-1.4%). 847 PICC placements were considered as 'uncertain' since the MAGIC guidelines do not go into detail on non-frequent bloodletting for more than five 5days. For CKD, 500 PICCs (14%, 95%CI 13%-16%) were 'inappropriate'.

Overall, Verma et al. (2020) concluded that 1848 (53%, 95%CI 51%-55%) PICC placements were appropriate based on the MAGIC guidelines whilst 573 (16%, 95%CI 15%-18%) were 'inappropriate' and 1058 (30%, 95%CI 29%-32%) were 'uncertain' due to missing data in the MAGIC guidelines. They found that the most common reason for inappropriate PICC insertion was placement in patients with CKD and in patients admitted to the ICU for <15days. A common tendency was seen that

older, female patients with higher levels of co-morbidities were more likely to get an 'inappropriate' PICC.

Bertoglio et al. (2016) found that PICCs were inserted for 35.710 catheter-days with an estimated failure-free rate at one year of 73% (95%CI, 64-82%). PICCs were removed at the end of treatment without complications (186) or due to patients' death (61). Also, 72 PICCs (25%) developed complications from which 44 were removed. Complications included CRDVT (12%, after median 78days), CRBSI (2%, infection rate 0.95/1000days), ESI (5%, infection rate 1.46/1000days), dislodgement (4%) and occlusion (2%). It was concluded that the most common reasons for PICC failure included past DVT and chemotherapy use. Other borderline failures with statistical significance included using 5Fr versus 4Fr lines (P=0.052), using the basilic vein (P=0.074) and the type of chemotherapy (P=0.099). Finally, it was concluded that PICCs are safe for the administration of chemotherapy between 2-3months, with an estimated failure of 15%. Also, patients for chemotherapy with a past history of DVT needing a 5Fr PICC or larger should be considered for an alternative CVAD.

4.2.1.1 Main conclusions

From the literature retrieved, it can be concluded that:

- Portacaths are preferred over Hickmans for the administration of chemotherapy for solid, non-haematological tumours with/without metastasis due to the higher rates of complications associated with Hickman.
- Midlines help to avoid repetitive peripheral cannulation and minimise the risk of needle-stick injuries for physicians and nurses. These are also ideal to be inserted at the bedside for haemodynamically-unstable patients. The total duration that midlines can be left in situ is between two to four weeks.

- PICCs were the most devices inserted without proper indication, especially in patients with CKD and older woman. PICCs are also not recommended for long-term chemotherapy use.

Table 12

Table of Results for Articles

Authors & Publication	VAD Studied	Results
Moss et al. (2021)	PICC Hickman Portacath	• PICCs had a higher risk on complication when compared to Hickman for the administration of chemotherapy for solid tumours • PICCs were associated with a higher complication rate per catheter week • CRBSI was more commonly associated with Hickman lines compared with PICCs • Portacaths had fewer complications compared to Hickman during the administration of chemotherapy for solid tumours
Verma et al. (2020)	PICC	• Commonly used for medication infusion • Most common reason for inappropriate PICC insertion was placement in patients with CKD and the placement of PICCs in patients admitted to the ICU for <15days
Bertoglio et al. (2016)	PICC	• PICCs are safe for the administration of chemotherapy between two and three months • Most common reasons for PICC failure included past DVT and prolonged chemotherapy use • Patients for chemotherapy with a past history of DVT needing a 5Fr PICC or larger, should be considered for an alternative CVAD
Wu et al. (2016)	Hickman Portacath	• Hickman posed a higher statistically significant risk of getting complications compared to portacath, including CRBSI • Exit site infection was more common in portacath • Conclusion: Portacaths are more appropriate for patients with a non-haematological malignancy with/without metastasis when compared to Hickman.
Patel et al. (2013)	Portacath PICC	• Portacaths had lower complications compared to PICC • Time to first complication was longer for portacaths • PICC were associated with higher rates of CRDVT
Alexandrou et al. (2011)	Midline	• Midlines help in avoiding repetitive peripheral cannulation whilst minimising the risk of needle-stick injuries for physicians and nurses • Midlines are more cost-effective and a less traumatic solution to repetitive peripheral cannulation • Overall dwell-time for midlines is between 2-4weeks • Compared to PICC lines, midlines have a lower rate of complications.

CRBSI: Catheter Related Blood Stream Infection, CRDVT: Catheter Related Deep Vein Thrombosis, VAD: Venous Access Device, DVT: Deep Vein Thrombosis, PICC: Peripherally Inserted Central Catheter

4.2.2 Results from the retrieved guidelines

4.2.2.1 Peripheral intravenous catheters

All guidelines retrieved from the ScR are in agreement that PIVCs are not to be used for the infusion of vesicant/irritant infusates including Dobutamine, TPN and continuous chemotherapy infusions. Additionally, before considering a PIVC, one should take into consideration the osmolarity of the infusate. Gorski et al. (2016), Hallam et al. (2020) and RNAO (2021) agree that PIVCs are not to be used for infusates with an osmolarity >900mOsm/L whilst MOHSSE (2014) and Sou et al. (2017) recommend an osmolarity <600mOsm/L and Bodenham et al. (2016) advise an osmolarity <500mOsm/L.

Hallam et al. (2020) and Sou et al. (2017) highlight the importance that high flexion areas such as the antecubital fossa and wrist are avoided as these increase the risk of CRBSI and phlebitis. They also highlight that forearm veins are to be avoided for the infusion of peripherally compatible infusates due to the risk of complications which are pointed out by the RNAO (2021) who specifically recommend that unless necessary, PIVC insertion should be avoided in lower-extremity veins as this increases the risk of tissue damage, ulceration and thrombophlebitis. Contrarily, Chopra et al. (2015) suggest that the dorsum of the hand is the best site for PIVC insertion.

Although all guidelines suggest the use of PIVC for short-term infusions, they all provide a different recommendation on how long a PIVC can stay in situ. Chopra et al. (2015) and Hallam et al. (2020) recommend that a PIVC should be used for infusions which are not planned to take longer than five days, whilst Gorski et al. (2016) recommend PIVCs for infusions up to six days and MOHSEE (2014), RNAO (2021) and Sou et al. (2017) recommend PIVCs for infusions up to seven days. Contrarily, Bodenham et al. (2016) recommend that PIVCs are suitable for infusions planned for up

to two weeks. The recommended duration that a PIVC is left in situ is recommended to be between 72-96hours by all guidelines. Frequent PIVC change can lead to an increased risk of complications (Bodenham et al., 2016, Hallam et al., 2020, Loveday et al., 2014 and MOHSSE, 2014). Additionally, Bodenham et al. (2016), Chopra et al. (2015), Gorski et al. (2015), Hallam et al. (2020), MOHSSE (2014), RNAO (2021) and Sou et al. (2017) write that using US to insert cannulas was found to be successful to limit complications and increase PIVC dwell time.

4.2.2.2 Midlines

Since a midline catheter is not a central VAD, not all infusates can be infused through it. All guidelines agree that only peripherally-compatible infusates can be infused through midlines. Gorski et al. (2016), Hallam et al. (2020) and RNAO (2021) recommend that midlines are not used for continuous infusion of vesicant medications/solutions such as chemotherapy and TPN. They also suggest that midlines, like PIVCs, are used for infusates with an osmolarity <900mOsm/L. Sou et al. (2017) and MOHSSE (2014) recommend an osmolarity <600mOsm/L and Bodenham et al. (2016) recommend an osmolarity <500mOsm/L. MOHSSE (2014) suggests midlines over PIVCs for infusions taking longer than six days, Chopra et al. (2015) and Hallam et al. (2020) suggest that midlines can be used for up to 14days and Bodenham et al. (2016), Gorski et al. (2016), RNAO (2021) and Sou et al. (2017) suggest midlines for up to four weeks.

All the selected guidelines are in agreement that the veins in the upper arm (cephalic, median cubital and brachial veins, with the basilic vein preferred) are preferred for midline insertion. If not possible, Chopra et al. (2015), Gorski et al. (2016) and RNAO (2021) suggest using veins in the antecubital fossa. Bodenham et al. (2016), Chopra et al. (2015) and Hallam et al. (2020) suggest that the tip of the catheter should

lie outside the central veins just before the subclavian vein. The average catheter length should be between 7.5-20cm (Hallam et al.: 10-20cm, Bodenham et al. and Chopra et al.: 7.5-25cm).

4.2.2.3 Peripherally inserted central catheters

All guidelines suggest that PICCs can be used for medium-long term IV infusion of any infusate, including TPN (Gorski et al., 2016 and Sou et al., 2017), vesicant medications/solutions (Gorski et al., 2016 and Sou et al., 2017) antibiotic therapy and chemotherapy (RNAO., 2021), inotropes (Sou et al., 2017) patients with DiVA (Chopra et al., 2015 and RNAO., 2021) or outpatients requiring VA for several days (MOHSSE, 2014). The basilic and brachial veins are preferred for PICC insertion as these were shown to cause less risk of CRT. Bodenham et al. (2016), Chopra et al. (2015), Hallam et al. (2020), Loveday et al. (2014), MOHSSE (2014) and RNAO (2021) agree that the tip of the catheter should be positioned in the superior vena cava or the inferior vena cava.

RNAO (2021) suggest PICC use for long-term infusions and Bodenham et al. (2016) and Hallam et al. (2020) suggest PICC for infusions taking up to six months. Sou et al. (2017) suggest PICC for infusions of non-irritant solutions/medications taking more than six weeks or the infusion of irritant/vesicant infusates taking less than three months whilst Chopra et al. (2015) suggest PICCs for patients with DiVA requiring IV infusion for more than 15days and for infusions of non-peripherally compatible infusates taking more than 31days. MOHSSE (2014) suggest using PICCs for infusions between six days and four weeks.

4.2.2.4 Portacath and Hickman

All guidelines suggest the use of portacaths and Hickman for infusions taking up to years. Chopra et al. (2015) suggest using a portacath/Hickman for infusions taking

longer than 31days whilst Sou et al. (2017) suggests using a portacath or a Hickman for infusions longer than three months. All guidelines concluded that any infusate can be given through these lines, including chemotherapy, antineoplastic therapy (RNAO, 2021), long-term infrequent infusions (Gorski et al., 2016, Hallam et al., 2020, Loveday et al., 2014 and RNAO, 2021) and long-term frequent infusions (Bodenham et al., 2016).

Table 13

Table of Results for Guidelines

		PIVC	Midline	PICC	Portacath	Hickmann Line
RNAO (2021)	Use	Do not use for continuous vesicant therapy, TPN or infusates with an osmolarity >900mOsm/L	Peripheral compatible infusates. Do not use midlines for continuous vesicant therapy, TPN or infusates with an osmolarity >900mOsm/L	Long-term antibiotic therapy, chemotherapy or other medication administration in the presence of difficult venous access	Intermittent long-term infusion therapy	Long-term intermittent vesicant infusion
	Duration	Up to 7 days	<4 weeks	Long-term	Long-term	Long-term
Hallam et al. (2020)	Use	Do not use for continuous vesicant chemotherapy, TPN and infusates with an osmolarity >900mOsm/L	Do not use Continuous vesicant chemotherapy, TPN, Solutions with osmolarity >900mOsml/L.	Long-term IV therapy	For infrequent long-term infusion therapy	N/A
	Duration	<5 days	Up to 14 days	6 days to 6 months	4 weeks up to years	4 weeks to years
Sou et al. (2017)	Use	Infusion of non-irritant/non-vesicant infusates. Osmolarity <600mOsm/L	Infusion of non-irritant/non-vesicant infusates. Osmolarity <600mOsm/L. Do not use for TPN, vesicant medication and inotropes	For TPN, vesicants and inotropes	Infusion of TPN, irritant/vesicant infusates and inotropes	Infusion of TPN, irritant/vesicant infusates and inotropes
	Duration	Up to 7 days	Up to 4 weeks	Up to 6 weeks for non-irritant/vesicant infusates OR Up to 3 months for irritant/vesicant infusates	>3 months	> 3 months
Bodenham et al. (2016)	Use	Short-term access for the infusion of non-irritant/non-vesicant	Short to medium-term access for the infusion of non-irritant/non-vesicant medication/substance.	Medium to long-term access	Frequent long-term access	Frequent long-term access

		medication/substance. Osmolarity <500mOsm/L. Not good for low (<5) or high pH (>9)	Osmolarity <500 mOsm/L			
	Duration	Up to 2 weeks Changed every 72 to 96 hours	Up to 4 weeks	1 to 6 months and longer	Months to years	Months to years
Gorski et al. (2016)	Use	Non-irritant/vesicant infusate. Osmolarity <900mOsm/L	Medications and solutions such as antimicrobials, fluid replacement and analgesics with characteristics that are well tolerated by peripheral veins. Not suitable for continuous vesicant therapy, TPN, or infusates with an osmolarity >900 mOsm/L	Any type of infusion Therapy including irritants, vesicants and TPN	Any type of intermittent or continuous long-term infusion therapy	Any type of intermittent long-term infusion therapy
	Duration	Up to 6 days	Up to 4 weeks	N/A	Up to years	Up to years
Chopra et al. (2015)	Use	Peripherally compatible infusate	Peripherally compatible infusates	Long-term infusion of non-peripherally compatible infusates or long term venous access on patients with difficult venous access	Long term non-peripherally compatible infusates	Long term non-peripherally compatible infusates
	Duration	Up to 5 days	6 to 14 days	For infusions up to 15 days for patients with difficult venous access Up to >31 days for non-peripherally compatible infusates	>31 days	>31 days
MOHSSE (2014)	Use	Not advisable for irritants, vesicants, TPN and infusates with an osmolarity >600 mOsm/L	Not advisable for irritants, vesicants, TPN and infusates with an osmolarity >600mOsm/L	Any Infusate IV therapy >6 days Outpatients who require venous access over several days	Any infusate	Any infusate

	Duration	Up to 7 days (changed every 72-96 hours)	> 6 days	IV therapy >6 days up to 4 weeks	>4 weeks to years	>4 weeks to years
Loveday et al. (2014)	Use	N/A	N/A	Use a single-lumen catheter unless multiple ports are essential for the management of the patient	Regular or continuous access,	Long-term intermittent vascular access
	Duration	(changed every 72 hours)	N/A	N/A	>4 weeks	>4 weeks
TPN- Total Parenteral Nutrition, N/A-Not Available						

4.3 Prototype venous access guideline

As described in chapter 3, the results retrieved from the ScRs discussed above, were used to develop the prototype VA guideline (Appendix F).

4.4 Results from the focus group discussion

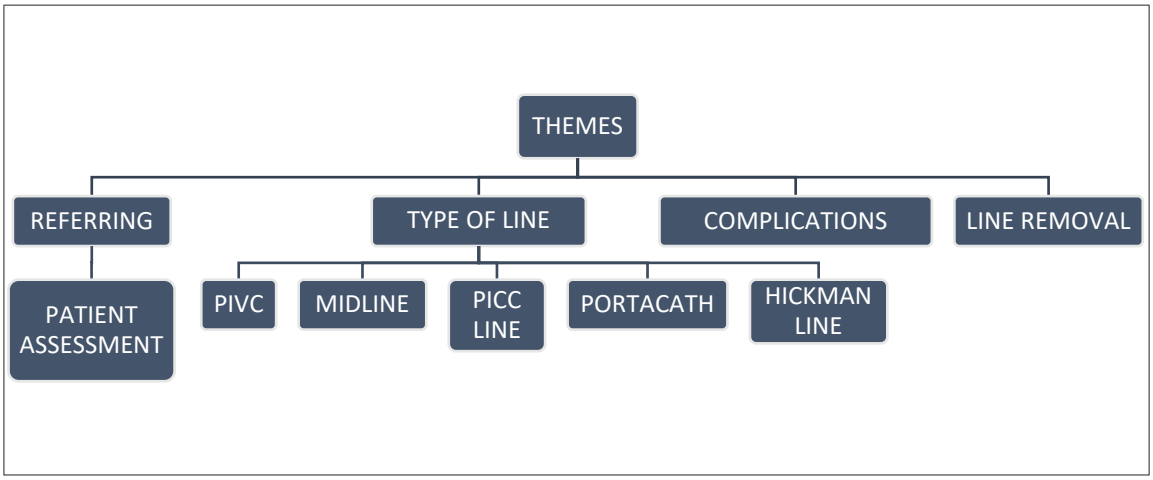
This section aims to present the findings attained from the FGD with local experts on the prototype guideline using thematic analysis. A total of five participants from 11 eligible participants attended the FGD. These were representative of all key areas identified during purposive sampling. Participants included both males and females of different age groups with multiple years of experience in the field (≥5years).

4.5 Main themes

Four main themes were identified: *Referring Patients for a VAD Insertion, Types of Lines, Complications and Line Removal* (Figure 8). A running theme highlighting the importance of having a local evidence-based VA guideline was also recognised.

Figure 7

Themes and Sub-Themes



4.5.1 Theme 1: Referring patients for a VAD insertion

4.5.1.1 When to refer

This was one of the main themes identified during the thematic analysis of the FGD. All participants agreed that that there needs to be a clarification on when and how to refer. This begins with patient assessment at the ward and not necessarily in the ED; *"What I think needs to be emphasized in the beginning of the guideline is that the patient needs to be assessed. Maybe in casualty is a bit too early for any assessment"* - Participant 7. The other participants agreed with this comment stating that the in the ED a PIVC is usually inserted and a more appropriate VAD will be discussed once the patient gets admitted to a ward; *"In casualty, they will insert the cannula, which they always do*" - Participant 2.

The expert panel then concluded that the VA guideline should be targeted towards non-urgent patients and not for urgent cases including those needing urgent surgery; *"I think this guideline is more for patients who are maybe not an emergency … You come in as an emergency with the cannula from casualty, or you have a portacath*

and you needle it. So I think operations, surgery, emergency admissions etc I think are outside this"- Participant 7.

A current problem that was discussed during the FGD is that patients needing long-term VA or frequent bloodletting are not being assessed properly for the possibility of having a more appropriate VAD inserted other than a normal PIVC, leading to failed cannulation attempts, patient discomfort, unnecessary pain and permanent vein damage:

> *"Hopefully if we catch patients earlier on, peripheral cannula won't be an issue. Cause their veins wont all be destroyed"* - Participant 5
>
> *"... Not destroyed his arms, destroyed his morale and then we go for a PICC line"* - Participant 7

One participant stated that referring should be done at the early stages of admission. All other participants agreed that this guideline should be targeted towards patients admitted to a ward and should be assessed during the first 24hours of their admission. When asked who should be the person responsible to carry out this assessment, all participants agreed that the firm consultant should be the one taking this decision based on the patient's needs and treatment plan:

> *"On the first 24 hours of admission, people, let's say not 100%, but a good 80% of patients will have been seen by their consultant and roughly know: this is an infection that will need six weeks of treatment for sure for example or this is a complicated patient that we're looking at IV access for at least three weeks as an inpatient, you know, and then things develop as you go along ... So day one we start thinking of this. Not we exhaust the cannulas and then okay, might as well have done the PICC line two weeks ago, and then continue"* - Participant 7

4.5.1.2 Who to refer to

The discussion continued on who to refer to once the best VAD is selected using the VA guideline. One participant was quick to point out that no specific person is to be mentioned as a contact because even though currently only IR physicians are inserting

VADs, this will eventually change and the guideline would no longer be accurate once this change is done; *"I wouldn't mention a specific unit. But I would leave it a little bit broad and say: dedicated specialists"*- Participant 7. It was explained how until four years ago, there was no VA service being offered by the Angiosuite Unit. They then started by procuring the equipment, setting up an IV access team which helped with educating the staff in MDH on how to appropriately use VADs and the number of referrals for VA to the Angiosuite Unit started to increase:

> *"It's not 'it might change', it will change. We took this on board four years ago, by starting procuring the equipment, then IV access team were roped in through education, education comes in, equipment comes in, number starts increasing, the service builds up, then the service stabilizes with the numbers, the numbers that it will stabilize at our way beyond us"* - Participant 7

With the increase in referrals for VAD insertion and an overall increase in workload on the Angiosuite Unit, an outreach team consisting of nurses and/or physicians going around the wards to insert US-guided PIVCs, midlines and PICCs could make the service more effective. Therefore this new concept of an VA outreach team is the next step in local VA once this VA guideline is introduced and why all participants agreed that no particular individual/s are to be mentioned as a point of referring since this is in the process to change:

> *"If there is an outreach team to go in the ward, that will become even more effective"* - Participant 6

> *"There is an IV access team doing ward-based midlines and PICC lines and radiology they only do the very complicated or difficult and obviously portacaths and Hickman lines that cannot be done …Why should a patient that needs a midline come to radiology department to have a midline done? Why does a patient needing an ultrasound guided cannula come to radiology?"*- Participant 7

> *"Once we have a guideline in place, we fill the last lacuna with the equipment that we have, then we'll sort of spread the knowledge around and then the next step will be to create an outreach team"*
>
> - Participant 7

4.5.2 Theme 2: Types of lines

4.5.2.1 Peripheral intravenous cannula

The discussion started by a participant stating that currently PIVCs can stay in situ for up to 72hours, and nurses will have to inform the patient's physician should this need to stay in situ for longer; *"Right now the policy is up to three days about the peripheral cannulas and we have to inform the firm doctors if we need to use it more in difficult patients"* - Participant 3. A counterargument by another participant was made arguing that according to evidence, in situations where the PIVC is properly assessed and the date of insertion is documented, there is no need to replace the PIVC every 72hours. However unfortunately, PIVCs are still being found without a documented date of insertion and a Visual Infusion Phlebitis (VIP) score and therefore they would need to be removed after 72hours from the date of insertion even if still functional. Consequently, if PIVCs are better cared for by nurses, patients could benefit from the same PIVC for two more days. All participants agreed that for planned IV access of not more than six days for patients admitted to a ward, PIVCs are a good first line VAD option:

> *"With regards to peripheral lines, evidence shows that in places where the lines are assessed on a daily basis, the date of insertion is documented and there are no signs of phlebitis, there is no need to institute this routine changing but unfortunately up to now, you don't find date of insertion and the VIP score is not documented. So we can't really keep them for as long as they will last because in some areas they are assessed and in others not"*
>
> - Participant 4

During the discussion, a participant brought up the argument of introducing US assisted PIVCs in the guideline because from his/her experience this has proven to be more successful in patients with DiVA. Therefore with the use of US guidance, you can limit the number of cannulation attempts on patients with a DiVA:

"Sometimes patients have difficult veins that clinically you cannot put a cannula in. Now he needs 3 days of treatment, fine. Now I cannot get the cannula in by hand, what do I do? So the same patient can be three days, five days, six days of treatment, but an ultrasound assisted like it's the purpose of this paper with ultrasound assisted cannulation. So if there is a nice vein, go usual cannula. If there is no vein and still the treatment is short, go for an ultrasound assisted cannulation" - Participant 7

One participant continued by saying that locally currently they are working on introducing such service and they started by training physicians in the ED with the use of US-guided cannulation. Three participants stated that they were unaware of this new system. One of them also mentioned that such procedures can be done at the bedside by the VA outreach team mentioned earlier. However, one participant argued that a specific type of cannula needs to be made available since the usual PIVC devices are not appropriate for US insertion and these could cause complications; "*an ultrasound assisted cannulation using a non ultrasound device will create problems"* – Participant 7. One participant remarked that as a part of the VA team in MDH, they are in the process of introducing such US compatible PIVCs; "*We were working on trying to get the four devices one for SAMOC, one for Mater Dei and one for the phlebotomy"* – Participant 3.

A participant identified a problem that most physicians including anaesthetists, do not know that they can ask IR physicians working in Angiosuite for a PIVC insertion under US guidance and instead patients are being referred for a PICC insertion even when the duration of treatment is short. Therefore through this guideline we will be able to educate referring physicians and nurses about this service.

"Sometimes they ask us to do PICC lines because they are very difficult that they're having trouble with difficult venous access. Even from the anaesthetic point of view, they only need the venous access for seven days, for example, when it doesn't really make sense to insert a PICC line for just seven days. But they don't know that we can actually try

and do the venous puncture by ultrasound, they don't ask us for them. They ask us for a PICC line" - Participant 6

Another aspect which was discussed during the FGD was PIVCs for outpatients requiring VA for a short duration. One participant argued that a cannula for seven days of home antibiotic treatment will not work whilst another participant argued against this. The reasons behind the participant's argument was that PIVCs pose a safety risk and if the person is not trained to assess for this, a PIVC can result in multiple problems; "*There is an element of safety with cannulas at home; phlebitis, infection. If the person is not trained to look for that, a cannula can be a problem"* – Participant 7. One participant replied that there is a dedicated home-antibiotic team who visits patients taking home antibiotic treatment every day; however, as argued by one participant, if the home antibiotic team needs to visit these patients daily, there is an element of cost-effectiveness; *"Putting in a midline/PICC line, and having a nurse going every second day is much more cost effective, especially considering that the human resources are a limiting factor"*- Participant 7. After hearing this argument, it was agreed by all participants that patients needing IV access for seven to 14 days on an outpatient basis, they would benefit more from a midline rather than a PIVC. A participant also added that they are teaching patients with a midline or a PICC to self-administer treatment and the home antibiotic team only visit these patients once a week and this has proven to be effective.

"With the PICC lines and midlines if we find it suitable they will go weekly" Participant 3

"We are teaching the patients to self administer treatment and it's working brilliantly, especially after COVID" Participant 3

A point identified by one participant was that locally we are slowly introducing peripherally compatible TPN which can be given through a PIVC. Therefore as agreed by all participants, this is something that needs to be added in the local VA guidelines.

4.5.2.2 Midlines

A participant immediately pointed out that locally, contrary to the recommendations given on the prototype guideline, midlines are used when the expected duration of treatment is between seven days to three weeks and not four weeks; *"As for midlines we use it up to three weeks"* - Participant 3. The other participants agreed with this statement. Two participants also noted that currently, midlines are not being requested by physicians and are not being done even when a midline would be the best VAD for their patients. For instance in 2021 only three midlines were inserted. This is mainly because as identified by one participant, there is no equipment available in MDH; *"There's actually no kit for a midline and there's no request for a midline because doctors don't know the difference"* - Participant 5. Currently PICC kits are being used and cut to a shorter length and inserted as a midline. However as another participant commented, upon introducing such a VA guideline in MDH, there will be enough education that physicians start referring their patients for midlines and eventually midline kits will be introduced locally; *"The purpose of this meeting is to develop the guideline and the midline will come"* - Participant 7. Another participant also noted that midlines are a great alternative to be used on patients who need a VAD other than a PIVC but who are not haemodynamically stable to be transferred to the Angiosuite unit or even transferred onto the theatre table as midline insertion does not require x-ray confirmation after insertion and therefore could be done at the bedside; *"We do midlines if the patient's totally unstable to be moved at all. So like it's only a desperate situation where I do midlines or for very short term"* - Participant 5.

A very good point was pointed out by a participant who said that the problem with midlines is that they stop returning blood after one week and another participant agreed with this statement; *"The thing is they stop giving blood after a week. They*

stop" - Participant 3. An explanation for this was given by a participant who said that bloodletting from a midline depends on the length of the line: if it is slightly shorter, the tip will end in the axillary vein which does not give blood return, whilst if it is slightly longer the tip will be positioned in the subclavian vein which will allow bloodletting. This would be considered as a main limitation of midlines should the patient require frequent bloodletting.

> *"It varies from the length of the midline. The average length of midline is 20 centimetres. But if you put it close to the elbow, it ends up in the axillary. If you put it higher up, it ends up in the subclavian. Subclavian will give you, axillary will not. So that's why the limitation of the device"* - Participant 7

When asked whether midlines would be appropriate for use on an outpatient basis for patients taking seven-15 days of home antibiotics, it was agreed that midlines for two weeks of home antibiotic therapy would be ideal; *"A midline for two weeks of antibiotics at home would work just fine"* - Participant 7. The only problem would be when they need frequent bloodletting as they stop returning blood after a few days. However it was concluded that patients fit to be discharged home will not need daily bloodletting. It was also discussed that peripheral compatible TPN can be transfused though a midline; *"They give five days of TPN, which can be given through midline before the operation to boost the nutrition and shortly after"* - Participant 7.

4.5.2.3 Peripherally inserted central catheters

Locally, PICCs are left in situ for six months, however, this can be accommodated to the duration that it will be needed for especially in haematology patients. Therefore it was agreed by all participants that the duration that PICCs can stay in situ can be accommodated to specific cases and usually PICCs can even stay in situ for up to 18months.

"PICC line here it says it can stay in for six months. If the patient has nine months left, you don't take it out to put a portacath for three months … can be accommodated in specific circumstances as dictated by haematology" Participant 7

One point that was mentioned was the number of lumens: single or dual lumen PICCs. A common misconception is that having a dual-lumen PICC is better than having a single-lumen PICC. Therefore all participants agreed that there needs to be a clarification on how to choose between the two. Mainly dual lumen PICCs are only inserted for continuous infusions including non-peripherally compatible TPN and continuous chemotherapy infusion during which the patient might need another VA port, for example for bloodletting or antibiotics.

"Many have this miss-belief that having two lumens is better and if you are giving IVI and antibiotics you need two lumens … double lumen devices only for continuous infusion. For example TPN and continuous chemotherapy infusion in which time they will need bloodletting, IVI or antibiotics. Otherwise, IV fluids, antibiotics and bloodletting, one lumen is enough. Less risk of infection, bigger lumen, less trouble" – Participant 7

Three participants highlighted that the number of requests for the insertion of PICCs on haematology patients has increased over the last months mainly because of the newly introduced subcutaneous metal anchor which anchors the PICC to the skin; making it safer and helps it stay in situ for a longer duration; *"Patients are also getting a subcutaneous metal anchor which is the safest way, not sutured. Before our PICC lines could not stay in for six months, because we couldn't save the line for so long because we didn't stabilise it."* - Participant 7. A participant highlighted that PICC are preferred over Hickmans in haematology patients especially when the patient's blood clotting and platelet count are not within range and it would not be safe to insert a Hickman; *"Especially in the beginning, when the patient's blood clotting and platelets are on the floor, it is safer to do a PICC line with platelets of one or two, than a Hickman line"* - Participant 7.

4.5.2.4 Portacaths

Locally, the portacath insertion service has improved drastically once this service started being offered by the Angiosuite Unit and it is now being offered as an outpatient service with approximately four portacath insertions/week whereas before there was a 4-month waiting list and insertion was done under general anaesthesia; *"to get a portacath you had to wait four months and get a general anaesthesia"* - Participant 7. This service is also gaining popularity amongst referring physicians with just 21 portacaths inserted in 2017 and over 200 in 2021; *"Portacaths as well, the service started four years ago in 2017 with 21 portcaths only, and now we are reaching 200 portacaths a year. So yes, the service is gaining popularity"* - Participant 1.

Locally patients who are started on a treatment that's expected to last up to a number of years, a portacath is inserted. This includes long-term chemotherapy and TPN; *"if we are looking at a year or two, I would start off immediately with a portacath"* - Participant 7. Another subset of patients which could benefit from a portacath insertion is patients diagnosed with cystic fibrosis (CF) of whom currently only two patients have had a portacath inserted; *"we have two of the cystic fibrosis which have portacaths which I agree totally with … "one of them she does the needle herself because we taught her how to and she's doing brilliantly"* Participant 3. Although all participants agreed that patients with CF would benefit more from a portacath, one participant commented that from experience he/she have seen that patients with CF are refusing portacaths and in certain cases, the referring physicians do not agree with portacath insertion for these patients; mainly due to a lack of education.

> *"The patients we do PICC lines on cystic fibrosis usually have refused a portacath. Two in particular, I remember actually refused a portacath. But then again, I guess with education, things will improve. And some were the referring physician that we're not keen on a*

portacath. But it was trying to convince them, education, education"- Participant 7

Other patients who would benefit from portacaths are haematology patients who are at a lower risk of getting immunosuppressed and lead an active lifestyle.

> *"Those that are less likely to get immunosuppressed and infected, are younger and more active, they are asking me to put in a portacath for them because it's more comfortable for the patient and the patient request it. To be honest with you, I have removed around eight this year. 5, 6, 8 months, nine months of good quality life, good treatment with no issues at all"* - Participant 7

4.5.2.5 Hickman

Hickmans are inserted for patients with planned treatment duration of more than one year up to a couple of years including long-term TPN; *"if we are looking at a year or two, I would start off immediately with a portacath or a Hickman line … for long term TPN, I will not put in a PICC line, I will put a Hickman line because this is something that will last longer"* - Participant 7. Locally, haematology patients are usually referred for a Hickman due to their increased risk of CRBSI and the efficiency of having it removed on the ward; *"haematology patients will usually get a Hickman line because of the higher risk of infection and the need to remove within the ward"* - Participant 7. However, haematology physicians have started to refer more patients for portacaths as these are more comfortable for patients who are less likely to get immunosuppressed and have a more active lifestyle since Hickmans have a higher risk of getting infected when compared to portacaths. Hickmans have also started being replaced by PICCs once the subcutaneous metal anchors were introduced. This can also be seen in Table 1 where the number of referrals for Hickman insertion started going down.

4.5.3 Theme 3: Complications

A running theme that was discussed throughout the discussion was 'complications'. These included bacteraemia, access site infection, CRDVT and other general complications. One participant remarked that they sometimes get referrals for a line insertion on patients with a suspected line septicaemia and who have no VA; *"we've had some instances where patients had a PICC line, it was suspected they were septic, septicaemia, a line infection was suspected, they obviously needed to remove the line and send the tip for culture, but they needed access"* - Participant 5. This was also supported by two other participants as they have experienced a similar situation with one of them stating that based on international guidelines they should leave 24hours from the time of the infected VAD removal to the time of a new VAD insertion. In this timeframe, the least possible invasive line should be inserted for those 24hours; "A*t least you have to be 24hours line free … you are off central lines for 24 hours before you insert another one"* - Participant 7. Two other participants agreed with this statement. One participant explained that even though this is what the literature has shown, sometimes this is not always possible and usually a temporary line is inserted; "*sometimes that is not possible and what we do, I do a temporary line, which is a midline for example to bridge the patients that 24, 48 hours line free"* - Participant 7. As a participant pointed, if proper and early VA assessment is done, the peripheral vein would still be healthy and a PIVC could be inserted. In the case of access site infection, the line needs to be removed; *"If the line is assessed and there's infection, it needs to be removed"* - Participant 7.

For CRDVT, a participant discussed that contrary to what should happen, the line shouldn't be removed; *"A lot of people just when they see thrombosis, they just pull it out. But you have the problem of thrombosis and no venous access then"* - Participant 5. All experts agreed that in such situations, they should contact the VA PDNs and

consider doing a Doppler US. If a CRDVT is confirmed, anticoagulation should be started. Therefore, as a baseline, whenever there is a suspected complication, the ward nurses are to contact the VA team immediately by calling or emailing them; *"step one would be to alert the vascular access specialists, consider maybe an ultrasound, in the case of confirmed thrombosis, anticoagulate"*- Participant 7.

4.5.4 Theme 4: Line removal

A participant brought up the concept of VAD removal once they are no longer needed. This includes who should be removing them and where. Another participant said that currently portacath devices are removed once treatment is finished and after a few months of surveillance have passed; *"Once you have a portacath, you finished treatment with the portacath you go through a few months of surveillance. If you are cleared from the three months of surveillance, you will put on a list for removal"* - Participant 7. These are removed in the Angiosuite unit. Hickmans are usually removed once the patient is discharged from the haematology ward, the patient feels well and blood results are good. Hickmans can also be removed in Angiosuite; *"Hickman lines are usually removed when the patient is discharged from the haematology ward. The patient is well, comes for a review, bloods okay, then we remove this"* - Participant 7. Contrary, PICCs and Midlines can be removed by nurses on the ward. All experts agreed that this is the best procedure to be followed for line removal; *"PICC lines are removed by IV team and the ward nurses"* - Participant 7.

4.6 Developing the finalised guideline

As described in chapter 3, the results from the consensus FGD were used to develop the finalised VA guideline (Appendix S).

4.7 Results from the Questionnaire

Once all responses were submitted (Table 14), the maximum and minimum possible scores and the scaled domain scores (Tables 15&16) were calculated using the equation identified in chapter 3. The results were interpreted based on the information provided in section 3.5.3.

Table 14
Respondent's Scores

	INDIVIDUAL RESPONDENTS' SCORES						
Question	**A**	**B**	**C**	**D**	**E**	**TOTAL**	**Domain**
The overall objective/s of the guideline are described	6	7	7	6	7	33	
The health question(s) covered by the guideline is (are) described	6	7	7	6	7	33	**1**
The population to whom the guideline is meant for is described	7	7	7	5	7	33	
The guideline development group includes individuals from all relevant professional groups	7	5	5	5	7	29	
The views and preferences of the target population have been sought	7	2	2	5	7	23	**2**
The target users of the guideline are clearly defined	7	7	7	6	7	34	
Systematic methods were used to search for evidence	6	7	7	6	7	33	
The criteria for selecting the evidence are clearly described	7	7	7	6	7	34	
The strengths and limitations of the body of evidence are clearly described	7	5	5	6	7	30	
The methods for formulating the recommendations are clearly described	7	7	7	5	6	32	
The health benefits, side effects, and risks have been considered	6	2	2	6	6	22	**3**
There is an explicit link between the recommendations and the evidence	7	3	3	6	7	26	
The guideline has been externally reviewed by experts	6	7	7	5	7	32	
A procedure for updating the guideline is provided	7	5	5	6	7	30	
Recommendations are specific and unambiguous	7	6	6	6	7	32	
The different options for management of the condition or health issue are presented	7	7	7	5	7	33	**4**
Key recommendations are easily identifiable	6	7	7	6	7	33	
Describes facilitators and barriers to its application	7	7	7	6	6	33	
Provides advice and/or tools on how the recommendations can be put into practice	6	7	7	6	6	32	
Potential resource implications of applying the recommendations have been considered	7	7	7	5	6	32	**5**
The guideline presents monitoring and/or auditing criteria	7	7	7	6	5	32	
The views of the funding body have not influenced the content of the guideline	7	7	7	7	7	35	
Competing interests of guideline development group members have been addressed	7	7	7	5	7	33	**6**
Overall Quality of the guideline	*7*	*6*	*6*	*5*	*7*	*31*	
Recommend for use	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*		

Note: This table shows the scores of each individual participant to each question. The scores are marked on a 7-score Likert Scale with '1' representing the least possible score and '7' representing the highest possible score. The last question asks participants whether they would recommend this guideline for use

Table 15

Minimum and Maximum Possible Scores

	MAXIMUM POSSIBLE SCORE (7 x number of items x number of appraisers)	**MINIMUM POSSIBLE SCORE** (1 x number of items x number of appraisers)
Domain 1	105	15
Domain 2	105	15
Domain 3	280	40
Domain 4	105	15
Domain 5	140	20
Domain 6	70	10

Table 16

Scaled Domain Score

	SCALED DOMAIN SCORE $\frac{\text{obtained score} - \text{minimum possible score}}{\text{maximum possible score} - \text{minimum possible score}} \times 100$
Domain 1	93.33%
Domain 2	78.88%
Domain 3	82.91%
Domain 4	92.22%
Domain 5	90.83%
Domain 6	96.66%

4.7.1 Scaled domain scores

The scaled domain scores (Table 16) were calculated using the equation given in chapter 3. The first domain (scope and purpose) scored relatively high at 93.33%. The second domain (stakeholder involvement) scored 78.88% which although still considered as a 'high' score, it is the least scoring domain of this guideline assessment tool. Domain 3 (rigor of development) scored 82.91% whilst Domain 4 (clarity of presentation) scored relatively high in all 3 questions with a scaled domain score of 92.22%. Domain 5 (applicability) scored 90.83% and the last domain (editorial independence) scored the highest scoring domain of 96.66%.

4.8 Conclusion

In this chapter, the results obtained from the ScRs, FGD and the guideline assessment questionnaire aiming to fulfil the study's aims and objectives were provided. The results from the ScRs were used to formulate the prototype guideline which was discussed and refined during a FGD. From the FGD, four themes were identified through thematic analysis of the FGD: referring patients for a VAD insertion, types of lines, complications and line removal. The prototype guideline was updated based on these results. The finalised guideline along with the AGREE II tool was sent to all participants as a Google Form link. The responses were analysed quantitatively using the recommended equations. In the next chapter, these results will be comprehensively analysed against recent evidence and research.

Chapter 5
Discussion

5.1 Introduction

This chapter aims to discuss the results presented in chapter 4 obtained from the ScRs and the two-round modified Delphi study: FGD and the guideline tool questionnaire, to help in getting a better understanding of the VA guideline based on the WHO Handbook (2014) and assess whether the study's objectives were met. This is the first local study aiming to develop a VA guideline therefore, the discussion of these findings held in view of current evidence and literature is important for a reliable and safe guideline. Finally, the strengths and limitations of this study are discussed.

5.2 Venous assessment and patient referral

A theme which was identified from the data analysis of the FGD was 'referring'. All experts present during the FGD were in consensus about the importance of including 'referring' as a part of the finalised guideline which should start with early patient assessment by the firm consultant as this is somewhat lacking in the local practice. This is consistent with the literature as Dunn and Weston (2015) write that generally, limited assessment is done to identify the best VAD and as a result a PIVC is usually inserted even when a different VAD would be more suitable. As concluded during the FGD, this will often lead to repetitive cannulations until most/all superficial veins are permanently damaged. Jackson et al. (2013) also write that PIVC insertion is very often delegated to the least experienced staff who are not able to consider a different VAD should the need arise whilst Helm et al. (2016) found that there is a 50% failure rate with PIVCs before the completion of treatment primarily due to a lack of a formal VA assessment. This is also highlighted in an article written by an IPC nurse in the Nursing Times who writes about the problems with having untrained junior staff carrying out a VAD-needs assessment which is very often informal and poorly

documented; leading to unnecessary failed cannulation attempts and device failure (Dunn & Weston, 2015).

In conclusion, during the FGD it was agreed that early assessment within the first 24hours of admission by the firm consultant needs to be carried out which is consistent with the data found in the research.

5.2.1 Venous access outreach team

A conclusion drawn during the FGD was on the importance of a 'VA outreach team' which are responsible for the insertion of bedside US-guided PIVCs, midlines and PICCs (Kelly et al., 2009). As discussed by a participant, the demand for VAD insertion is increasing worldwide; posing a strain on the IR department which could easily be addressed with the setting up of these outreach teams. Carr et al. (2018) writes that specialised VA teams have more advanced knowledge on the insertion techniques, maintenance and management of different VADs. The USA Centres for Disease Control and Prevention (CDC, 2011) also state that having a specialised VA team has proven to be unequivocally more effective in reducing complications and costs. Deutsch et al. (2014) found that bedside midline insertion by a specialised outreach team is more cost-effective when compared to midline insertion by an IR physician in patients with DiVA admitted in ITU. This led to an estimated saving of 12,588.80euro in six months. Therefore, the importance of introducing a VA outreach team, discussed during the FGD, is consistent with the findings in research.

5.3 Venous access devices

5.3.1 Peripheral intravenous cannulas

From the ScRs, Chopra et al. (2015), Gorski et al. (2016), Hallam et al. (2020), MOHSSE (2014), RNAO (2021) and Sou et al. (2017) concluded that PIVCs are ideal

for VA between five to seven days. Experts in the FGD agreed with this conclusion with a participant adding that currently locally, PIVCs are left in situ for 72hours whilst a participant stated that PIVCs can stay in situ for a longer duration; given that they are assessed daily using the VIP score criteria and an insertion date is documented. This could avoid repetitive cannulation which according to findings from both ScRs, frequent change of PIVCs could lead to increased risks of CRBSI (Bodenham et al., 2016, Hallam et al., 2020, Loveday et al., 2014 and MOHSSE, 2014). From the ScRs, the recommended duration for a PIVC was 72-96hours (Bodenham et al., 2016, Loveday et al., 2014 and MOHSSE, 2014) which is consistent with the duration given by a participant during the FGD. A search on the MDH Intranet, 'KURA', on PIVCs generated two results. A document titled 'Insertion and Maintenance of Peripheral Intravenous Cannulae' (2015) policy no: ICU 03Pol2011v02.0, written by the MDH IPC team, states that in adult patients, PIVCs can be changed every 72hours even in the absence of complications. In exceptional circumstances where the cannula needs to be left in situ for >72hours (including in patients with DiVA) a senior firm physician needs to write the clinical reason behind their decision to keep the cannula for >72hours. The NHS (2020) also agrees with the notion that cannulas are not to be left in situ for >72hours unless it is considered as an 'exceptional case'. Therefore, for the purpose of this dissertation, the recommended duration that PIVCs can be left is situ will be 72hours unless instructed otherwise by the firm or the IPC Department.

5.3.1.1 Ultrasound-guided peripheral intravenous cannula

From the ScRs, Bodenham et al. (2016), Chopra et al. (2015), Gorski et al. (2016), Hallam et al. (2020), MOHSSE (2014), RNAO (2021) and Sou et al. (2017) write that using US to insert cannulas was found to be successful to limit complications and increase PIVC dwell time. This was also brought up during the FGD by a participant and all FGD experts were in consensus that US-guided PIVCs should be

introduced as a part of the local guideline. Presley and Isenberg (2022) state that although being a rather common procedure, PIVC insertion can be complicated by multiple factors including hypovolemic shock, IV drug abuse and obesity. Another study by Blanco (2019) found that in patients with DiVA, US-guided PIVC insertion has shown a 90% success rate over blind PIVC insertion and an overall improvement in patient satisfaction. A participant highlighted that the current PIVCs available locally are not appropriate for US-guided insertion. This is confirmed by Paladini et al. (2018) who explains that US-guided PIVCs are longer than the traditional PIVCs. They also write that longer US-guided PIVCs can stay in situ for a longer duration.

5.3.2 Midlines

From the ScRs, it was concluded that midlines can stay in situ for a longer duration than a PIVC (Alexandrou et al., 2011, Bodenham et al., 2016, Chopra et al., 2015, and Gorski et al., 2016, Hallam et al., 2020, MOHSSE, 2014, RNAO, 2021 and Sou et al., 2017). However, results on the exact duration that midlines can stay in situ varied across both ScRs from six days to four weeks. During the FGD, a participant pointed out that locally, midlines are used for infusions taking between seven days to three weeks. All other participants agreed with this statement. A study by Swaminathan et al. (2022) who aimed to study the effectiveness of midlines against PICCs for patients requiring short-term VA has consistent findings with the findings from the FGD during which it was agreed that for short-term treatment durations, midlines are associated with less complications than PICCs. This multicenter study concluded that after reviewing 10,863 patients from which 5,758 had a PICC inserted and 5,105 patients had a midline inserted for short-term antibiotic therapy, midlines were associated with a lower rate of CRBSI and occlusions when compares with PICCs (HR, 0.53; 95% CI, 0.38-0.74). Therefore this is consistent with the findings from the FGD and ScRs.

When discussing the type of infusate that can be administered through midlines, all FGD experts agreed that only peripheral-compatible infusates can be transfused through a midline. This is consistent with the literature found during both ScRs where Gorski et al. (2016), Hallam et al. (2020) and RNAO (2021) recommend that midlines are not used for continuous infusion of vesicant medications/solutions such as chemotherapy. This is consistent with the literature as Masters et al. (2014) write a case report on a 77 year old woman who developed complications after one hour of staring an Oxaliplatin infusion (a type of chemotherapy) through a midline. The main complications included swelling, tenderness, erythema and extravasation in the arm which worsened and spread further down the arm by the following day and needed a Plastic Surgery review. As a conclusion from this case report written by three oncology physicians, midlines are not to be used for the transfusion of vesicant medications; which is consistent with the findings from the FGD and ScRs.

Another finding on midlines from the FGD was 'bloodletting'. A participant shared that from his/her experience with using midlines, they usually stop giving blood-return after approximately a week. This was explained by another participant who discussed that a midline is usually around 20cm. However, when it is cut too short with the tip ending in the axillary vein rather than the subclavian vein, blood return might be difficult. This is consistent with the recommended midline length found in the results during both ScRs in which the authors wrote that the average catheter length should be between 7.5-20cm (Bodenham et al., 2016, Chopra et al., 2015 and Hallam et al., 2020:10-25cm). The notion that midlines are not appropriate for frequent bloodletting is also discussed by Caprara (2017) who comments about this complication and states that midlines usually fail to return blood after some days from their insertion date.

Another finding on midlines during the FGD was that midlines are a great alternative in patients who need urgent VA but who are not haemodynamically stable to

be transferred out of their ward to the Angiosuite unit. This is also consistent with the findings from the Alexandrou et al. (2011) form the ScRs and with other literature as Moureau et al. (2015) write that midlines are an optimal alternative for haemodynamically unstable patients until they are stable enough to get a more invasive VAD since they do not require catheter tip X-ray confirmation.

During the FGD, the idea of having midlines used as a part of a home-antibiotic programme was discussed. It was also established that most patients with a midline inserted for home antibiotic therapy can self-administer their medications and home-antibiotic nurses only do weekly visits as opposed to patients taking home-antibiotic treatment through a PIVC where nurses do daily visits; making midlines more cost-effective. Similar to what was discussed, Gorski and Czaplewski (2004) report that midlines are a great alternative to PIVCs for outpatients; providing a more cost-effective option. Consequently, the findings from the FGD are consistent with the literature.

5.3.3 Peripherally inserted central catheters

From both ScRs, Bodenham et al. (2016) Hallam et al. (2020) and RNAO (2021) concluded that PICCs are ideal for infusions taking up to six months or slightly longer. During the FGD, the experts agreed with this duration, however, it was added that there can be exceptions made to this for oncology patients who are mainly haematology patients where PICCs can be left in situ for up to nine months. A study by Caris et al. (2022) showed that the risk of developing CRBSI is not directly proportional to the number of catheter indwelling time and therefore such exceptions can be made.

From the ScRs, it was concluded that PICCs are appropriate for the transfusion of TPN, vesicant infusates, antibiotic therapy, chemotherapy, inotropes, patients with DiVA and/or outpatients requiring VA for several days/months (Chopra et al., 2015,

Gorski et al., 2016, MOHSSE, 2014, RNAO, 2021 and Sou et al., 2017). All participants in the expert panel were in consensus with this statement.

During the FGD it was concluded that there has been an increase in the number of referrals for PICC insertion for oncology patients, specifically haematology patients. A study by Hashimoto et al. (2017) who studied the safety of PICCs in 95 patients with a hematologic disease requiring a VAD for bloodletting, hematopoietic stem cell transplantation, blood transfusion and medication administration, found no evidence of PICC-associated complications. Another study by Morano et al. (2009) also found that PICCs are a safe alternative to traditional VADs for haematology patients needing chemotherapy/palliative care. During the FGD, it was concluded that PICCs are preferred over Hickmans in some haematology patients due to the introduction of a metal anchoring device for PICCs (SecurAcath). This subcutaneous anchor secures the PICC at the percutaneous entry of the device to avoid line dislodgement (Macmillan et al., 2018). An External Assessment Centre: The King's Technology Evaluation Centre commissioned by the NICE critically appraised the effectiveness of the SecurAcath device and concluded that this device was the most cost-effective and appropriate device to be used for medium to long term dwelling PICCs. A retrospective review of 7,776 participants with a PICC in situ found that the use of subcutaneous metal securing devices reduced the risk of CRBSI when compared to the traditional adhesive securing devices (Rowe et al., 2020).

Another reason concluded from the FGD as to why PICCs are being preferred over Hickman in haematology patients was that patients with a haematological disease have altered platelet levels and an increased blood clotting time. As described by Cavanna et al. (2020), patients with a haematological condition usually have a low platelet count. Therefore patients with a low platelet count have an overall increased risk of bleeding especially when inserting CVCs in more central veins like Hickman and

portacaths (Cavanna et al., 2020). Contrarily, a study by Potet et al. (2013) found that the risk of bleeding amongst patients diagnosed with a haematological disease and having a low platelet count was minimal. Therefore as agreed during the FGD, the type of line inserted on haematology patients remains at the consultant's discretion.

From the ScRs, Verma et al. (2020) who assessed PICC placement appropriateness in 3,479 patients against the MAGIC guideline found that 573 PICCs inserted were considered as being 'inappropriate'. The main reasons for 'inappropriate' PICC insertion included old age, patients with CKD and patients requiring VA for less than 15 days. The latter was discussed during the FGD and concluded that physicians are referring their patients for PICCs even when they only need access for a short duration. This is consistent with data found in the literature. Paje et al. (2018) found that inserting PICCs for a short duration (less than five days) can cause multiple complications including CRBSI, CRT and occlusion. Another article by Swaminathan et al. (2022) also found that for shorter treatment durations, when appropriate, midlines are associated with fewer complications when compared to PICCs. Therefore this is important to be highlighted in the guideline that PICCs are only to be used in cases with a planned medium to long term treatment duration.

During the FGD, it was concluded that referrers believe that dual-lumen PICCs are better than single-lumen PICCs. All participants agreed that dual-lumen PICCs are to be inserted for patients on continuous infusions including TPN and chemotherapy. This is consistent with the literature as Lam et al. (2018) write that multi-lumen PICCs have found to be associated with a higher risk of CRBSI, occlusion and CRDVT and that multi-lumen PICCs are only to be inserted in specific cases including the infusion of two or more continuous infusions including antibiotics, chemotherapy and TPN.

5.3.4 Portacaths

During the FGD, three participants remarked that they have seen an increase in the number of referrals for portacath devices over the last couple of years. This can also be seen in Table 1 of this dissertation where one can observe that from 21 portacaths inserted in the Angiosuite Unit in 2017 this has gone up to 219 portacaths in 2021. As agreed by all experts in the FGD, locally portacaths are the preferred VAD for patients undergoing planned treatment taking from one year up to a couple of years. This is consistent with the findings from both ScRs in which Bodenham et al. (2016), Chopra et al. (2015), Gorski et al. (2016), Hallam et al. (2020), Loveday et al. (2014), MOHSSE (2014), Moss et al. (2021), Patel et al. (2013), RNAO (2021), Sou et al. (2017) and Wu et al. (2016) agree that portacaths can be used for planned treatment durations taking up to years. Samad and Ibrahim (2015) studied 250 patients with a portacath which was left in situ for an average of 22 months (range six to 60months). The average complication rate was 11.6%, resulting to be a rather reliable and safe device for long term VA access. This is consistent with the conclusions from both ScRs where Patel et al. (2013) found that for long term VA, portacaths were safer than PICCs with a lower rate of complications and a longer time to first complication. From the ScRs, Moss et al. (2021) and Wu et al. (2016) also found that portacaths were associated with fewer complications.

From both ScRs, it was concluded that that portacath devices can be used for the administration of non-peripherally-compatible infusates including chemotherapy and TPN. All experts in the FGD were in consensus with this conclusion. This is also consistent with the findings from other research in which Samad and Ibrahim (2015) write that portacaths are ideal for long term chemotherapy infusion, TPN and bloodletting.

During the FGD, it was agreed by all experts that a subset of patients who are believed to benefit from a portacath insertion are patients diagnosed with CF, yet, currently only two CF patients have a portacath; mainly due to a lack of education. Kariyawasam et al. (2000) looked at the experience of 74 patients and reports that the median duration that portacaths were left in situ was 1429 days. They concluded that portacaths offer a great VA option for patients diagnosed with CF who need frequent antibiotic therapy, which is consistent with the conclusions drawn during the FGD. Another study by Pedersen et al. (2015) found that between PICCs and Portacaths for the administration of antimicrobial therapy in CF patients, the latter showed a longer life time.

During the FGD it was also concluded that another cohort of patients who would benefit from a portacath are haematology patients. This is consistent with the findings from two studies by Hooda et al. (2008) and Li et al. (2019) who write that since these are totally implanted devices, patients can lead a normal lifestyle without having to worry about increasing their risk of CRBSI and/or their aesthetics. Consistent with West and Jin (2016), during the FGD it was concluded that portacaths are ideal for haematology patients who are young, active and less likely to get immunosuppressed.

5.3.5 Hickman

From the data retrieved through both ScRs, Bodenham et al. (2016), Chopra et al. (2015), Gorski et al. (2016), Hallam et al. (2020), Moss et al. (2021), Pratt et al. (2007), RNAO (2021), Sou et al. (2017) and Wu et al. (2016) conclude that Hickman are ideal for planned treatments taking between one year and a couple of years. During the FGD, all participants agreed with this conclusion. From the ScRs, Wu et al. (2016) concluded that Hickmans have a higher rate of complications compared with portacaths (54% and 38% respectively). This is consistent with the findings by Ng et al. (2007)

who write that Hickmans are more susceptible to getting complications when compared with portcaths due to their exposed catheter tip contrary to portacaths which are totally implanted. This study concludes that Hickmans increase the risk of getting a catheter-related complication by five times within the first four weeks of insertion.

During the FGD, it was concluded that locally Hickmans are usually only inserted in haematology patients for the treatment of non-solid tumours due to their increased risk of developing infections. Contrary to this statement, a study by Adler et al. (2006) concluded that portacaths are still preferred over Hickmans in haematology patients due to the increase in the risk of developing infections with Hickmans. Shaw et al. (1988) also concluded that portacaths pose a lower risk of sepsis in haematology patients. Therefore, choosing between portacath and Hickman for haematology patients remains subject to the haematologist's preference based on the patient's needs. Another conclusion was drawn during the FGD about the decrease in the number of Hickmans inserted which dropped from 64 Hickman insertions per year to 35 in 2021 (Table 1). Latest research shows that PICCs are being preferred over Hickmans due to a decrease in the number of complications reported (Hashimoto et al., 2017).

5.4 Complications

'Complications' were discussed during the FGD and all experts agreed that the guideline should include a section on this. The main complication discussed was CRBSI which results in the removal of the line and therefore no VA for the patient. Lee et al. (2020) conducted a retrospective review of 316 patients diagnosed with a CRBSI and who had their VAD removed. From these, 41.1% underwent a VAD insertion after ≤72hours whilst 12.4% underwent VAD re-insertion after >72hours. This study found no significant difference in the rate of persistent CRBSI in both groups indicating that catheter-free days after a confirmed CRBSI had no impact on persistent infection. On

the same concept, the British Intestinal Failure Alliance (BIFA) recommends that line re-insertion after a CRSBI should only take place after the completion of an appropriate anti-microbial treatment and a negative blood-culture result. Contrarily, another study by Chin et al. (2010) suggests that immediate catheter reinsertion after confirmed CRBSI results in re-infection. The latter is consistent with the consensus agreement amongst all FGD experts who believe that patients with a confirmed CRBSI are to stay 24hours line-free or if VA is needed, the least invasive VAD is inserted.

Another complication identified was CRT. Participants highlighted the lack of education amongst caring nurses and physicians on how to manage CRT and unfortunately these lines are being removed even when they could be treated with anti-coagulation therapy. Consistent with the conclusions drawn during the FGD, Wall et al. (2015) suggests using a duplex ultrasound to confirm CRT. However, contrast venography is considered as the gold standard to examine for CRT if US results are inconclusive. This article also states that systemic anticoagulation is the first line treatment for CRT and the device should only be removed if this gets infected, dislodged or CRT does not resolve after treatment. This is consistent with the agreement reached during the FGD.

5.5 Line removal

The final concept that was discussed during the FGD was ‘line removal’. Once All FGD experts were in consensus that line removal should be included in the guideline. This concept was brought up by a participant who stated that PIVCs, midlines and PICCs can be removed on the ward by nurses/physicians once they are no longer needed. This is consistent with the literature which states that these lines can be removed by a registered nurse/physician ("Removal of a Midline/PICC Catheter", 2020). Contrarily, a participant stated that locally portacaths are removed in the

Angiosuite MID, a few months after the treatment is finished. This is consistent with the recommendations by the American Cancer Society (2022). Finally, Hickmans are removed in the haematology ward/Angiosuite, MID once the treatment is finished.

5.6 Discussion of findings from the guideline assessment tool

From the results obtained, the domains scored 93.33%, 78.88%, 82.91%, 92.22%, 90.83% and 96.66% respectively, meaning the that guideline is of 'high quality' (Xie et al., 2016). From the high scaled domain score obtained in the first domain, it indicates that the study experts were highly satisfied with the presentation and specificity of the recommendations (Hoffmann-Eßer et al., 2018). The second domain, although being the least scoring domain, this is still considered to be of 'high quality'. The least scoring question in this domain was that regarding the views and preferences of the target population. According to Armstrong et al. (2016), this can be done through direct communication with the target population and/or through a review of the literature. The third domain scored 82.91%. This shows that the study experts were highly satisfied with the guideline development process. Castellani et al. (2015) state that this is highly important especially in clinical guidelines as these ought to encourage efficient healthcare based on unbiased and evidence-based research. The fourth domain scored 92.22%, showing high guideline quality. Yang et al. (2019) write that clear presentation of recommendations in a comprehensive and visible way is important as this directly contributes to the success in implementing the guidelines into practice. In the VA guideline developed in this dissertation, this was done through the use of a flow-diagram which makes it easier for users to follow the recommendations (Vu-Ngoc et al., 2018). The fifth domain scored 90.83%. It can be concluded that the experts were highly satisfied with the applicability tools included in the guideline. The main recommendation of how this guideline can be introduced into practice successfully was: easy access to the guideline. Some recommendations of how this could be done

included: presenting the guideline during workshops, uploading the guideline on KURA, printing the algorithm on wards and educating all healthcare staff by going around the wards to explain how and when this guideline is to be used. This is consistent with the findings of a study aiming to find ways of how junior doctors could get easier clinical guideline access (Walkden et al., 2016). This final domain scored 96.66%. The author declared that there were no funding sources and no competing interests. Yu et al. (2020) writes that disclosing any possible competing interests is crucial in decreasing the risk of bias and improving the overall quality of a study.

A question asked the experts to rate the overall quality of the guideline which scored 31/35. This shows that the experts were in consensus with the contents of the guideline and from their professional opinion, they all believed that the guideline offered good-quality and reliable recommendations. A final question asking the experts whether they would recommend this guideline for use, all the responses were 'yes', showing that they are in consensus that these guidelines could improve the overall local VA service.

5.7 Aims and objectives of the study

The aim of this study was to inform policy by developing a local evidence-based VA guideline on PIVCs, midlines, PICCs, portacaths and Hickmans for adults >18years, in tertiary and outpatient care. A set of objectives were set at the beginning of this study in section 1.6. After discussing all the results obtained through the ScRs, FGD and the guideline assessment questionnaire, it is clear that the aim and objectives of this study were met.

5.8 Strengths and limitations of the study

This is the first research study conducted locally to formulate a VA guideline based on evidence-based literature and consensus agreement amongst local clinical

experts using a modified Delphi methodology. This lays the foundation of informing local policy on VA and for future implementation studies based on the recommendations that have been withdrawn. One critical research which could be carried out is to study the effectiveness of this VA guideline in different clinical areas. Another strength is that the researcher has four years of experience working in the Angiosuite Unit, MID; enabling the author to gain complete understanding on the topic under study. This experience allows the author to have a critical reflection about current practice problems, patients' views, practice needs and subjectivity to provide a more effective and impartial analysis which would not have otherwise been possible (Dodgson, 2019).

One of the study strengths lies in the robust methodological design adopted for the formulation of evidence-based recommendations based on the WHO (2014) GDP. The researcher carried out two ScRs to identify relevant literature and guidelines. The ScRs helped the researcher to map out the available literature on VA and identify any key characteristics related to it. ScRs are also useful in identifying knowledge gaps and since this is the first local study on VA, this served as a robust process to get a deeper general understanding on the topic (Munn et al., 2018). The ScRs also helped the researcher to identify high quality, evidence-based VA guidelines which are being used by other international hospitals to formulate a good-quality local guideline.

A strength of this study lies in the robust and well-established modified Delphi method which basis it's foundations on discussion on the body of research whilst aiming to reach consensus amongst all key experts in a more time-efficient and cost-effective manner (Ozier, 1998) which was ideal to reach the study's objectives. Another strength of this study was that two intermediaries were identified before initiating the study. These were responsible to contact the study's participants through email which have been proven to increase participant autonomy (Festinger et al., 2011). Another

strength of the study was that the FGD had a representation of the key clinical areas identified as being important in VA identified through purposive sampling where the author aimed to identify all those involved in the insertion and care of VADs in MDH. A limitation of using purposive sampling to identify the study's population group lies in the risk of enhancing the possibility of sample bias. The author aimed to limit this through the reading of similar VA guidelines and their expert panel sample group and through personal communication with field experts in order to ensure that all concerned clinical experts were included. An area which might not have been well-represented is the IPC as only one participant from five eligible participants was present. Five clinicians participated in both round of the modified Delphi study. This might be considered as a small population group and saturation might not have been reached (Hennink et al., 2019). However, the author asked direct and in-depth questions during the FGD to avoid this. The author tried to overcome these limitations by sending all participants reminders to complete the questionnaire and by having two more attempts to set up a second FGD. However, this was not possible mainly due to a spike of cases during the Covid-19 pandemic which severely affected participation due to shortage of staff and quarantine challenges in the departments. Ultimately, time-constrains was another factor which limited the researcher in conducting another FGD. The researcher had to take the decision to continue with the data analysis process and use the data gathered from the first FGD which was robust and of good quality.

A possible limitation is that there was only one researcher carrying out the ScRs, which might have lead to bias and conflict of interest. Waffenschmidt et al. (2019) suggests a minimum of two independent reviewers for study selection and data synthesis in order to maximise the retrieval of most eligible studies. Since this was not possible, the researcher took a number of precautions to minimise evidence-selection bias. First, the research question and PICO elements were identified before the initiation

of the ScRs (Drucker et al., 2016). Secondly, the PRISMA-P guidance was used. Drucker et al. (2016) suggests that this helps to minimise evidence-selection bias. Also, a number of databases and search engines were used to search for the evidence. The author also searched for gray literature and the reference lists of the selected articles and guidelines to minimise publication bias (Drucker et al., 2016).

This is also the first time for the author to carry out a FGD. The author tried to overcome this limitation by following the Krueger (2002) and Nyumba et al. (2018) guidelines to guide the FGD and FGD guide. The author also prepared a PowerPoint presentation to introduce the study to the FGD experts including a brief welcoming, a short introduction on the topic and some ground rules. The author also prepared a pre-structured discussion guide based on Krueger (2002) and Nyumba et al. (2018) consisting of probing and trigger questions which consisted of both open-ended and focused questions to helped guide the FGD.

A final strength identified in this study was the use of the AGREE II tool which has undergone validity and reliability testing which have concluded that this tool is both a reliable and a valid instrument with sufficient inter-rater reliability (The AGREE Research Trust, 2014). This phase was also done anonymously by sending the offline Google Form link to the questionnaire to all experts as a part of the final consensus agreement process.

5.9 Conclusion

This chapter provided a discussion of the findings obtained from the ScRs and the modified Delphi consensus agreement based on the FGD and guideline assessment questionnaire presented in chapter 4 which allowed the researcher to reach the study's objectives. A number of strengths and limitations of this study were also presented. In

the next chapter, the main study conclusions along with recommendations for future practice, education and research are provided.

Chapter 6
Conclusion

6.1 Introduction

This research study aimed to formulate a local VA guideline for adult patients (>18years) based on recent evidence-based literature and consensus agreement amongst local experts. A comprehensive understanding of the topic was possible by conducting two ScRs of articles and guidelines to map out the literature on the topic. The search engines and databases HyDi, Google Scholar, BMJ Journals, PubMed, EBSCO host interface and ProQuest were searched using the formulated key terms. The PRISMA flow diagram was used and a total of six articles and eight guidelines were retrieved and critically appraised using the respective critical appraisal tools. The WHO Handbook for Guideline Development (2014) was used to compile a prototype VA guideline based on the findings from the ScRs. A two-round modified Delphi method was then applied to review and refine the prototype guideline by reaching consensus agreement amongst local VA experts. The first modified Delphi round consisted of a FGD to reach consensus on the prototype guideline. Data was analysed using thematic analysis and four main themes were identified: referring patients for a VAD insertion, types of VADs, complications and line removal. The second round of the modified Delphi method consisted of an online guideline assessment questionnaire using the AGREE II tool. This aimed to assess the quality of the guideline whilst aiming to reach consensus amongst the study experts on the finalised guideline. Data analysis of the tool was done using quantitative analysis. A finalised VA guideline document was produced.

This chapter aims to discuss the synthesis of the findings in relation to the research question and study objectives. A discussion of the findings' implications on practice, education and research and a set of recommendations are given.

6.2 Synthesis of research findings

6.2.1 Patient assessment and referral

During the FGD it was established that the guideline should be aimed towards non-urgent patients, >18years, admitted in tertiary care hospitals and/or outpatients who do not need urgent critical care admission. The importance of an early VA assessment within the first 24hours of admission by the firm consultant was highlighted during the FGD. A decision for the possibility of a VAD insertion should be taken at this stage. Findings from both ScRs and from the FGD suggest that failing to undertake a proper VA assessment could lead CRBSI, patient discomfort, failed cannulation attempts, permanent vein damage and pain. During the FGD, it was concluded that should a patient need a VAD insertion, the respective dedicated specialist should be contacted.

6.2.2 Peripheral intravenous cannulas

From the ScRs and the FGD, it was concluded that PIVCs are the preferred VADs for the infusion of peripherally-compatible infusates taking up to six days and should be changed every 72hours. During the FGD, a remark on the lack of proper PIVC assessment on the wards was made; leading to early PIVC removal and unnecessary re-cannulation. During the FGD, it was highlighted that the IR team was not being consulted in cases where patients have DiVA which could help with minimising failed cannulation attempts. US-guided cannulas were discussed during the FGD. It was concluded that these types of cannulas are ideal for patients with DiVA, however, specific US-compatible cannulas need to be procured as the current devices could cause more harm if inserted under US.

The concept of PIVCs for home-antibiotic therapy was also discussed during the FGD. It was concluded that contrary to what is currently being done, PIVCs are not a

cost-effective and efficient way for patients needing more than six days of antibiotics due to their high risk of getting complications including dislodgement. This could also lead to multiple complications since the patients are not well-trained to identify such complications.

6.2.3 Midlines

From the ScRs and the FGD, it was concluded that midlines are ideal for the infusion of peripherally-compatible infusates taking between seven days to three weeks. A current local problem with midlines is that referring physicians do not know about this service and patients are getting referred for PICC lines instead. One of the main factors resulting in this is that currently there are no midline kits available and these are not being recommended to referrers. During the FGD, midlines were also recommended to be used on haemodynamically-unstable patients requiring VA as midlines can be inserted at the bedside. A drawback with midlines was highlighted in both ScRs and the FGD stating that midlines should not be used on patients needing frequent bloodletting as slightly shorter midlines usually stop blood return after a couple of days.

During the FGD, midlines were also suggested as a great VAD for home-antibiotic therapy between seven days and three weeks. Patients can be taught how to self-administer their medication and the home-antibiotic team only needs to do weekly home-visits; making it more cost-effective.

6.2.4 Peripherally inserted central catheters

From the ScRs and the FGD, it was concluded that PICCs can stay in situ up to six months, however, during the FGD, it was agreed that exceptions can be made for haematology patients where PICCs can stay in situ for longer based on particular individual needs. PICCs are being requested more for haematology patients over

Hickman as the former is safer to insert in patients were the platelet count and blood-clotting results are deranged. During the FGD, it was recognised that PICCs became safer with the introduction of a subcutaneous metal anchor which anchors the PICC line to the skin, which also preserves the line for a longer duration. It was also explained that choosing between single and dual-lumen PICCs should be based on the type of treatment that will be infused; dual-lumen are only inserted for continuous infusions including TPN and continuous chemotherapy. From the ScRs it was determined that a PICC with the least possible number of lumens should be chosen as this lowers the risk of line-associated complications.

6.2.5 Portacaths

Locally, the portacath service has improved drastically after it started being offered by the Angiosuite Unit, MID. Results from the ScRs and the FGD concluded that portacaths are preferred for treatment durations taking up to a couple of years, including long-term chemotherapy for solid tumours and TPN. CF patients could also benefit from this device, yet, there is resistance from patients and some physicians. From the FGD it was concluded that haematology patients who are young, active and have a lower risk of getting immunosuppressed could also benefit from a portacath due to it being totally implanted.

6.2.6 Hickman

From the ScRs and the FGD, it was concluded that Hickman are ideal for treatment durations taking up to a couple of years; including TPN. They have traditionally been preferred for the treatment of haematological tumours due to the high risk of haematology patients getting CRBSI. However, these are starting to get replaced with PICCs and portacaths.

6.2.7 Complications

During the FGD, it was concluded that in the case of line septicaemia, the patient should stay 24hours line-free before a new VAD is inserted. In the meantime, the least invasive VAD, preferably a PIVC is used. In the case of a line occlusion, the line should not be removed but a Doppler US should be done and if thrombosis is confirmed, anticoagulation is prescribed. In the case of any complications, the VA team should be contacted.

6.2.8 Line removal

During the FGD, it was agreed that PIVCs, midlines and PICCs are to be removed by ward nurses/physicians whilst portacath devices should be removed once treatment is finished and after a few months of surveillance have passed. These are removed in the Angiosuite unit, MDH. Hickman lines are removed once the patient is discharged from the haematology ward. These can be removed on the ward or in the Angiosuite unit.

6.3 Recommendations

Recommendations for improving the current practice and education as well as recommendations to conduct new research to enhance current evidence are given based on the findings obtained in the study.

6.3.1 Recommendations for practice

6.3.1.1 Recommendations for guideline implementation

VA guidelines have proven to be useful in improving the overall VA service within an institution (Shaw, 2017). Therefore, the finalised VA guideline will be recommended to the clinical practice guideline committee, MDH, for implementation to

inform policy. As agreed during the FGD, this will not be recommended to be introduced in the ED. For a successful implementation of these guidelines, guideline-implementation and dissemination strategies need to be used (Fischer et al., 2016). Facilitators which could lead to a successful guideline implementation include:

- **Guidelines are short and user-friendly** (Fischer et al., 2016): A summary of the recommendations together with a flow diagram to allow for easier use and visualisation was formulated (Appendix T).

- **Easily accessible guidelines to healthcare staff** (Fischer et al., 2016):

    - The guideline could be made easily accessible to staff by sending the guideline by email to all nurses and physicians, having printed copies on each ward in MDH and the home-antibiotic team office and also making it available on the hospital intranet: KURA. These could also be sent to referring physicians by the Angiosuite radiographers receiving VAD insertion requests and presented during the weekly IR multi-disciplinary team meetings to physicians from different areas. The guideline could also be presented to charge nurses by ward managers.

    - This study could be published in the Malta Medical Journal and/or Malta Journal of Health Sciences for easier access to the systematic methodological processes applied.

- **Using technological advancements** (Fischer et al., 2016): Setting up an easily-accessible mobile application with the pathway for choosing the best VAD for patients.

- **Monitoring and updating** (Martínez García et al., 2012): Scientific research is constantly being updated, therefore, these guidelines need to be updated every three-five years to ensure safety and guideline adherence.

6.3.1.2 Other recommendations for practice

- **Procuring midline kits:** These have shown to be more cost-effective for infusions taking between seven days-three weeks, including home-antibiotic treatment which helps in lowering hospitalisation.

- **Procuring US-guided PIVCs:** These have shown to be successful in decreasing cannulation attempts in patients with DiVA, reducing the risk of complications and increasing staff and patient satisfaction.

- **Setting up a VA outreach team:** A VA team consisting of nurses and/or physicians who are trained in inserting bedside US-guided PIVCs, midlines and PICCs has proven to be effective in lowering VAD-related complications, reduce the workload on IR physicians and increase patient satisfaction.

6.3.2 Recommendations for education

- Educating nurses and physicians about:

    - The importance of proper **VA assessment** which has shown to aid in vein preservation, reduce VAD-associated complications and reduce repetitive cannulation attempts.

    - The **US-guided PIVC insertion service** being offered by the Angiosuite unit for patients with a DiVA.

- Educating patients and physicians about:
    - The advantages of **portacaths in patients with CF.**

6.3.3 Recommendations for future studies:

- Similar studies on the paediatric population.
- The conduction of a **qualitative study** through a FGD and/or interviews to get a deeper understanding of the views and perceptions of healthcare workers and patients on VA. A larger population sample than this study is recommended.
- **Pre and post-test studies** comparing the behaviour, attitude and knowledge on VA amongst nurses and physicians before and after introducing the proposed VA guideline which could help with guideline adherence.

6.4 Conclusion

This was the first research study aiming to compile a local evidence-based VA guideline for adult patients in Malta through two ScRs of recent literature and guidelines which helped to formulate a prototype VA guideline that was further refined through consensus agreement amongst local experts using a two-round modified Delphi method. The findings of this study were used to formulate a high-quality evidence-based VA guideline for PIVCs, US-guided PIVCs, midlines, PICCs, portacaths and Hickman lines based on the type and expected treatment duration which will be recommended for local practice to inform policy. A list of recommendations for practice, education and research which were brought out from the findings of this study were also provided.

References

"Delphi Method". *Delphi Method*. Rand.org. Retrieved September 14, 2021 from https://www.rand.org/topics/delphi-method.html.

Abraham, A., Ahn, R., Woodbridge, A., Madden, E., Keyhani, S., & Korenstein, D. (2018). What constitutes an independent statistical analysis?. *Journal of General Internal Medicine*, *33*(6), 786-788. https://doi.org/10.1007/s11606-018-4399-5

Abrahamson, K., Fox, R., & Doebbeling, B. (2012). Original research. *AJN, American Journal of Nursing*, *112*(7), 26-35. https://doi.org/10.1097/01.naj.0000415957.46932.bf

Acocella, I. (2011). The focus groups in social research: advantages and disadvantages. *Quality & Amp; Quantity*, *46*(4), 1125-1136. https://doi.org/10.1007/s11135-011-9600-4

Adams, J., Hillier, B. F., Moore, H., Lake, A., Araujo, S. V., White, M., & Summerbell, C. (2016). Searching and synthesising 'grey literature' and 'grey information' in public health: critical reflections on three case studies. *Systematic Reviews*, *5*(1). https://doi.org/10.1186/s13643-016-0337-y

Adebiyi, B., Mukumbang, F., Okop, K., & Beytell, A. (2018). A modified Delphi study towards developing a guideline to inform policy on foetal alcohol spectrum disorders in South Africa: a study protocol. *BMJ Open*, *8*(4), e019907. https://doi.org/10.1136/bmjopen-2017-019907

Adler, A., Yaniv, I., Steinberg, R., Solter, E., Samra, Z., Stein, J., & Levy, I. (2006). Infectious complications of implantable ports and hickman catheters in

paediatric haematology–oncology patients. *Journal of Hospital Infection*, *62*(3), 358-365. https://doi.org/10.1016/j.jhin.2005.08.019

Ajidahun, A. (2011). *Guidelines in designing a warm up program for the prevention of playing related musculoskeletal disorder among instrumentalists* [Masters Degree in Physiotherapy]. Department of Physiotherapy, University of the Western Cape.

Alexandrou, E., Ramjan, L., Spencer, T., Frost, S., Salamonson, Y., Davidson, P., & Hillman, K. (2011). The use of midline catheters in the adult acute care setting – clinical implications and recommendations for practice. *Journal of the Association for Vascular Access*, *16*(1), 35-41. https://doi.org/10.2309/java.16-1-5

Alexandrou, E., Ray-Barruel, G., Carr, P., Frost, S., Inwood, S., Higgins, N., Lin, F., Alberto, L., Mermel, L., & Rickard, C. (2015). International prevalence of the use of peripheral intravenous catheters. *Journal of Hospital Medicine*, *10*(8), 530-533. https://doi.org/10.1002/jhm.2389

Altman, D., & Bland, J. (2005). Treatment allocation by minimisation. *BMJ*, *330*(7495), 843. doi: 10.1136/bmj.330.7495.843

Alsense, Inc. (2021, December 9). *Otter Voice Meeting Notes*. Otter. https://otter.ai/

American Cancer Society. (2022). *Tubes, Lines, Ports, and Catheters Used in Cancer Treatment*. Cancer.org. Retrieved March 14, 2022 from https://www.cancer.org/treatment/treatments-and-side-effects/planning-managing/tubes-lines-ports-catheters.html.

Ames, H., Glenton, C., & Lewin, S. (2019). Purposive sampling in a qualitative evidence synthesis: a worked example from a synthesis on parental

perceptions of vaccination communication. *BMC Medical Research Methodology*, *19*(1). https://doi.org/10.1186/s12874-019-0665-4

Armstrong, M., Rueda, J., Gronseth, G., & Mullins, C. (2016). Framework for enhancing clinical practice guidelines through continuous patient engagement. *Health Expectations*, *20*(1), 3-10. https://doi.org/10.1111/hex.12467

Avella, J. (2016). Delphi Panels: Research Design, Procedures, Advantages, and Challenges. *International Journal of Doctoral Studies*, *11*, 305-321. https://doi.org/10.28945/3561

Bailey, J. (2008). First steps in qualitative data analysis: transcribing. *Family Practice*, *25*(2), 127-131. https://doi.org/10.1093/fampra/cmn003

Basnet, H. (2018). Focus Group Discussion: A Tool for Qualitative Inquiry. *Researcher: A Research Journal of Culture and Society*, *3*(3), 81-88. https://doi.org/10.3126/researcher.v3i3.21553

Beecham, G., & Tackling, G. (2022). *Peripheral Line Placement*. Ncbi.nlm.nih.gov. Retrieved May 3, 2022 from https://www.ncbi.nlm.nih.gov/books/NBK539795/.

Beheshti, M. (2011). A Concise History of Central Venous Access. *Techniques in Vascular and Interventional Radiology*, *14*(4), 184-185. https://doi.org/10.1053/j.tvir.2011.05.002

Bertoglio, S., Faccini, B., Lalli, L., Cafiero, F., & Bruzzi, P. (2016). Peripherally inserted central catheters (PICCs) in cancer patients under chemotherapy: a prospective study on the incidence of complications and overall

failures. *Journal of Surgical Oncology*, *113*(6), 708-714. https://doi.org/10.1002/jso.24220

Bewick, V., Cheek, L., & Ball, J. (2004). *Critical Care*, *8*(5), 389. https://doi.org/10.1186/cc2955

Blanco, P. (2016). Ultrasound-Guided Vascular Cannulation in Critical Care Patients: A Practical Review. *Medicina Intensiva (English Edition)*, *40*(9), 560-571. https://doi.org/10.1016/j.medine.2016.07.002

Blanco, P. (2019). Ultrasound-Guided Peripheral Venous Cannulation in Critically Ill Patients: A Practical Guideline. *The Ultrasound Journal*, *11*(1). https://doi.org/10.1186/s13089-019-0144-5

Bodenham Chair, A., Babu, S., Bennett, J., Binks, R., Fee, P., Fox, B. Johnston, A., Klein, A., Langton, J., Mclure, H. & Tighe, S. (2016). Association of anaesthetists of Great Britain and Ireland: safe vascular access 2016. *Anaesthesia*, *71*(5), 573-585. https://doi.org/10.1111/anae.13360

Boutron, I., Estellat, C., Guittet, L., Dechartres, A., Sackett, D., Hróbjartsson, A., & Ravaud, P. (2006). Methods of Blinding in Reports of Randomized Controlled Trials Assessing Pharmacologic Treatments: A Systematic Review. *Plos Medicine*, *3*(10), e425. doi: 10.1371/journal.pmed.0030425

Bradburn, M., Clark, T., Love, S., & Altman, D. (2003). Survival Analysis Part II: Multivariate Data Analysis – An Introduction to Concepts and Methods. *British Journal of Cancer*, *89*(3), 431-436. https://doi.org/10.1038/sj.bjc.6601119

Brouwers, M., Kho, M., Browman, G., Burgers, J., Cluzeau, F., & Feder, G., Fervers, B., Graham, I., Grimshaw, J., Hanna, S., Littlejohns, P., Makarski, J. & Zitzelsberger, L. (2010). AGREE II: Advancing Guideline Development,

Reporting and Evaluation in Health Care. *Canadian Medical Association Journal*, *182*(18), E839-E842. https://doi.org/10.1503/cmaj.090449

Brown, j. (2018). Interviews, focus groups, and delphi techniques. *Advanced Research Methods for Applied Psychology* (1st ed., pp. 7-9). Routledge.

Byrne, D. (2021). A Worked Example of Braun and Clarke's Approach to Reflexive Thematic Analysis. *Quality & Amp; Quantity*, *56*(3), 1391-1412. https://doi.org/10.1007/s11135-021-01182-y

Caprara, J. (2017). PICC versus Midline. *Home Healthcare Now*, *35*(10), 575-576.

Caris, M., de Jonge, N., Punt, H., Salet, D., de Jong, V., Lissenberg-Witte, B., Zweegman, S., Vandenbroucke-Grauls, C., Van Agtmael, M. & Janssen, J. (2022). Indwelling time of peripherally inserted central catheters and incidence of bloodstream infections in haematology patients: a cohort study. *Antimicrobial Resistance & Amp; Infection Control*, *11*(1). https://doi.org/10.1186/s13756-022-01069-z

Carr, P., Higgins, N., Cooke, M., Mihala, G., & Rickard, C. (2018). Vascular access specialist teams for device insertion and prevention of failure. *Cochrane Database of Systematic Reviews*, *2019*(1). https://doi.org/10.1002/14651858.cd011429.pub2

Carter, P., O'Donoghue, K., Dworzynski, K., O'Shea, L., Roberts, V., Reeves, T., Bastounis, A., Mugglestone, M., Fawke, J. & Pilling, S. (2021). A demonstration of using formal consensus methods within guideline development; a case study. *BMC Medical Research Methodology*, *21*(1). https://doi.org/10.1186/s12874-021-01267-0

Castellani, A., Girlanda, F., & Barbui, C. (2015). Rigour of development of clinical practice guidelines for the pharmacological treatment of bipolar disorder: systematic review. *Journal of Affective Disorders*, *174*, 45-50. https://doi.org/10.1016/j.jad.2014.11.032

Cavanna, L., Citterio, C., Di Nunzio, C., Orlandi, E., Toscani, I., & Ambroggi, M. (2020). Central venous catheterization in cancer patients with severe thrombocytopenia: ultrasound guide improves safety avoiding prophylactic platelet transfusion. *Molecular and Clinical Oncology*. https://doi.org/10.3892/mco.2020.2010

Charlson, M., Carrozzino, D., Guidi, J., & Patierno, C. (2022). Charlson comorbidity index: a critical review of clinimetric properties. *Psychotherapy and Psychosomatics*, *91*(1), 8-35. doi: 10.1159/000521288

Cheung, E., Baerlocher, M. O., Asch, M., & Myers, A. (2009). Venous access: a practical review for 2009. *Canadian Family Physician Medecin de Famille Canadien*, *55*(5), 494–496.

Chin, B., Han, S., Lee, H., Jeong, S., Choi, H., Kim, C., Choi, J., Song, Y. & Kim, J. (2010). Risk factors for recurrent catheter-related infections after catheter-related bloodstream infections. *International Journal of Infectious Diseases*, *14*(1), 16-21. https://doi.org/10.1016/j.ijid.2009.01.016

Choi, J., Jun, J., Kang, B., Kim, K., & Lee, M. (2014). Endorsement for improving the quality of reports on randomized controlled trials of traditional medicine journals in Korea: a systematic review. *Trials*, *15*(1). https://doi.org/10.1186/1745-6215-15-429

Chopra, V., Flanders, S., Saint, S., Woller, S., O'Grady, N., Safdar, N., Trerotola, S., Saran, R., Moureau, N., Wiseman, S., Pittiruti, M., Akl, E., Lee, A., Courey, A., Swaminathan, L., LeDonne, J., Becker, C., Krein, S. & Bernstein, S. (2015). The Michigan appropriateness guide for intravenous catheters (MAGIC): results from a multispecialty panel using the RAND/UCLA appropriateness method. *Annals of Internal Medicine*, *163*(Supplement), 1-40. https://doi.org/10.7326/m15-0744

Clark, E., Donovan, E., & Schoettker, P. (2006). From outdated to updated, keeping clinical guidelines valid. *International Journal for Quality in Health Care*, *18*(3), 165-166. https://doi.org/10.1093/intqhc/mzl007

Cooke, M., Ullman, A., Ray-Barruel, G., Wallis, M., Corley, A., & Rickard, C. (2018). Not "just" an intravenous line: consumer perspectives on peripheral intravenous cannulation (PIVC). An international cross-sectional survey of 25 countries. *PLOS ONE*, *13*(2). https://doi.org/10.1371/journal.pone.0193436

Cooper, C., Booth, A., Varley-Campbell, J., Britten, N., & Garside, R. (2018). Defining the process to literature searching in systematic reviews: a literature review of guidance and supporting studies. *BMC Medical Research Methodology*, *18*(1). doi: 10.1186/s12874-018-0545-3

Coulter, I., Elfenbaum, P., Jain, S., & Jonas, W. (2016). SEaRCH™ expert panel process: streamlining the link between evidence and practice. *BMC Research Notes*, *9*(1). https://doi.org/10.1186/s13104-015-1802-8

Critical Appraisal Skills Programme UK. (2019). CASP checklists. Retrieved November 18, 2021 from https://casp-uk.net/casp-tools-checklists/

De Chesnay, M. (2014). Chapter 11: Using focus group discussion. *Nursing research using data analysis* (174-175). Springer Publishing Company.

Deutsch, G., Sathyanarayana, S., Singh, N., & Nicastro, J. (2014). Ultrasound-guided placement of midline catheters in the surgical intensive care unit: a cost-effective proposal for timely central line removal. *Journal of Surgical Research*, *191*(1), 1-5. https://doi.org/10.1016/j.jss.2013.03.047

Dickson, M., & Baird, D. (2011). Significance testing. *Philosophy of Statistics*, 199-229. https://doi.org/10.1016/b978-0-444-51862-0.50006-x

Dodgson, J. (2019). Reflexivity in qualitative research. *Journal of Human Lactation*, *35*(2), 220-222. https://doi.org/10.1177/0890334419830990

Drucker, A., Fleming, P., & Chan, A. (2016). Research techniques made simple: assessing risk of bias in systematic reviews. *Journal of Investigative Dermatology*, *136*(11), 109-114. https://doi.org/10.1016/j.jid.2016.08.021

Dunn, H., & Weston, V. (2015). A framework for selection of vascular access devices. *Nursing Times*, *112*(35/36), 16-19.

Eccles, M., Grimshaw, J., Shekelle, P., Schünemann, H., & Woolf, S. (2012). Developing clinical practice guidelines: target audiences, identifying topics for guidelines, guideline group composition and functioning and conflicts of interest. *Implementation Science*, *7*(1). https://doi.org/10.1186/1748-5908-7-60

Edwards, S. (2000). Can unequal be more fair? A response to Andrew Avins. *Journal of Medical Ethics*, *26*(3), 179-182. https://doi.org/10.1136/jme.26.3.179

Eikermann, M., Holzmann, N., Siering, U., & Rüther, A. (2014). Tools for assessing the content of guidelines are needed to enable their effective use – a

systematic comparison. *BMC Research Notes*, *7*(1), 853. https://doi.org/10.1186/1756-0500-7-853

Eubank, B., Mohtadi, N., Lafave, M., Wiley, J., Bois, A., Boorman, R., & Sheps, D. (2016). Using the modified Delphi method to establish clinical consensus for the diagnosis and treatment of patients with rotator cuff pathology. *BMC Medical Research Methodology*, *16*(1). https://doi.org/10.1186/s12874-016-0165-8

Festinger, D., Dugosh, K., Croft, J., Arabia, P., & Marlowe, D. (2011). Do research intermediaries reduce perceived coercion to enter research trials among criminally involved substance abusers?. *Ethics & Amp; Behavior*, *21*(3), 252-259. https://doi.org/10.1080/10508422.2011.570167

Firstenberg, M., Kornbau, C., Lee, K., & Hughes, G. (2015). Central line complications. *International Journal of Critical Illness and Injury Science*, *5*(3), 170. https://doi.org/10.4103/2229-5151.164940

Fischer, F., Lange, K., Klose, K., Greiner, W., & Kraemer, A. (2016). Barriers and strategies in guideline implementation- a scoping review. *Healthcare*, *4*(3), 36. https://doi.org/10.3390/healthcare4030036

Galloway, S., & Bodenham, A. (2004). Long-term central venous access. *British Journal of Anaesthesia*, *92*(5), 722-734. https://doi.org/10.1093/bja/aeh109

Gonzalez, R., & Cassaro, S. (2021). Percutaneous central catheter. Retrieved 21 September 2022, from https://www.ncbi.nlm.nih.gov/books/NBK459338/

Gorski, L., & Czaplewski, L. (2004). Peripherally inserted central catheters and midline catheters for the homecare nurse. *Journal of Infusion Nursing*, *27*(6), 399-409. https://doi.org/10.1097/00129804-200411000-00005

Gorski, L., Hadaway, L., Hagle, M., McGoldrick, M., Orr, M., & Doellman, D. (2016). *Journal of Infusion Nursing*, *39*(1S).

Govender, B. (2016). *The Development of Guidelines for Social Workers Involved in Early Childhood Development within the Department of Social Development*. Hdl.handle.net. Retrieved May 9, 2022 from http://hdl.handle.net/11394/4972.

Graham, R., Mancher, M., Wolman, D., Greenfield, S., & Steinberg, E. (2011). *Clinical Practice Guideline Appraisal Tool*s. National Academy of Sciences. Washington (US). Retrieved September 12, 2021 from https://www.ncbi.nlm.nih.gov/books/NBK209533/.

Grewal, A., Kataria, H., & Dhawan, I. (2016). Literature search for research planning and identification of research problem. *Indian Journal of Anaesthesia*, *60*(9), 635. https://doi.org/10.4103/0019-5049.190618

Grimmer, K., Dizon, J., Milanese, S., King, E., Beaton, K., Thorpe, O., Lizarondo, L., Luker, J., Machotka, Z. & Kumar, S. (2014). Efficient clinical evaluation of guideline quality: development and testing of a new tool. *BMC Medical Research Methodology*, *14*(1). https://doi.org/10.1186/1471-2288-14-63

Hadaway, L. (2002). Choosing the right vascular access device, part I. *Nursing*, *32*(9), 75. https://doi.org/10.1097/00152193-200209000-00051

Hallam, C., Denton, A., Weston, V., Dunn, H., Jackson, T., Keeling, S., & Hill, S. (2020). UK vessel health and preservation (VHP) framework: a commentary on the updated VHP 2020. *Journal of Infection Prevention*, *22*(4), 147-155. https://doi.org/10.1177/1757177420976806

Hallam, C., Weston, V., Denton, A., Hill, S., Bodenham, A., Dunn, H., & Jackson, T. (2016). Development of the UK vessel health and preservation (VHP) framework: a multi-organisational collaborative. *Journal of Infection Prevention*, *17*(2), 65-72. doi: 10.1177/1757177415624752

Hashimoto, Y., Fukuta, T., Maruyama, J., Omura, H., & Tanaka, T. (2017). Experience of peripherally inserted central venous catheter in patients with hematologic diseases. *Internal Medicine*, *56*(4), 389-393. https://doi.org/10.2169/internalmedicine.56.7625

Hasson, F., Keeney, S., & McKenna, H. (2000). Research guidelines for the Delphi survey technique. *Journal of Advanced Nursing*, *32*(4), 1008-1015. https://doi.org/10.1046/j.1365-2648.2000.t01-1-01567.x

Helm, R., Klausner, J., Klemperer, J., Flint, L., & Huang, E. (2015). Accepted but unacceptable. *Journal of Infusion Nursing*, *38*(3), 189-203. https://doi.org/10.1097/nan.0000000000000100

Hennink, M., Kaiser, B., & Weber, M. (2019). What influences saturation? estimating sample sizes in focus group research. *Qualitative Health Research*, *29*(10), 1483-1496. https://doi.org/10.1177/1049732318821692

Hoffmann-Eßer, W., Siering, U., Neugebauer, E., Brockhaus, A., McGauran, N., & Eikermann, M. (2018). Guideline appraisal with AGREE II: online survey of the potential influence of AGREE II items on overall assessment of guideline quality and recommendation for use. *BMC Health Services Research*, *18*(1). https://doi.org/10.1186/s12913-018-2954-8

Hooda, B., Lalani, G., Fadoo, Z., & Billoo, G. (2008). Implantable port devices are catheters of choice for administration of chemotherapy in paediatric oncology

patients-a clinical experience in Pakistan. *Annals of the New York Academy of Sciences*, *1138*(1), 43-46. https://doi.org/10.1196/annals.1414.007

Hsu, C., & Sandford, B. (2007). The Delphi technique: making sense of consensus. *Practical Assessment, Research and Evaluation*, *12*.

Ives, J., Dunn, M., Molewijk, B., Schildmann, J., Bærøe, K., Frith, L., Huxtable, R., Landeweer, E., Mertz, M., Provoost, V., Rid, A., Salloch, S., Sheehan, M., Strech, D., de Vries, M. & Widdershoven, G. (2018). Standards of practice in empirical bioethics research: towards a consensus. *BMC Medical Ethics*, *19*(1). https://doi.org/10.1186/s12910-018-0304-3

Jackson, T., Hallam, C., Corner, T., & Hill, S. (2013). Right line, right patient, right time: every choice matters. *British Journal of Nursing*, *22*, 24-28. https://doi.org/10.12968/bjon.2013.22.sup5.s24

Joanna Briggs Institute. (2020). Checklist for cohort studies. *Critical Appraisal Tools for Use in JBI Systematic Reviews.* (1-6). Retrieved November 21, 2021 from https://jbi.global/critical-appraisal-tools

Kariyawasam, H., Pepper, J., Hodson, M., & Geddes, D. (2000). Experience of totally implantable venous access devices (TIV ADs) in adults with cystic fibrosis over a 13-year period. *Respiratory Medicine*, *94*(12), 1161-1165. https://doi.org/10.1053/rmed.2000.0943

Kelly, L., Buchan, E., Brown, A., Tehrani, Y., & Cowan, D. (2009). Exploring how the development of a nurse-led vascular access service has benefited patients. *Nursing Times*, *105*(24), 16-18.

Khamis, A., Bou-Karroum, L., Hakoum, M., Al-Gibbawi, M., Habib, J., El-Jardali, F., & Akl, E. (2018). The reporting of funding in health policy and systems

research: a cross-sectional study. *Health Research Policy and Systems*, *16*(1). https://doi.org/10.1186/s12961-018-0356-3

Kishore, J., Goel, M., & Khanna, P. (2010). Understanding survival analysis: Kaplan-Meier estimate. *International Journal of Ayurveda Research*, *1*(4), 274. https://doi.org/10.4103/0974-7788.76794

Krueger, R. (2002). Focus group interviewing. *Designing and Conducting Focus Group Interviews*. Retrieved November 17, 2021 from https://www.eiu.edu/ihec/Krueger-FocusGroupInterviews.pdf.

Krueger, R., & Casey, M. (2014). *Focus Groups* (5th ed.). SAGE.

Lal, S., Chadwick, P., Nightingale, J., & BIFA Committee. (2019). Management of catheter related blood stream infections (CRBSIs). *British Intestinal Failure Alliance (BIFA) Recommendation*.

Lam, P., Volling, C., Chan, T., Wiggers, J., Castellani, L., & Wright, J. Peckham, K., Shadowitz, S., Tasker, S., MacFadden, D., Daneman, N., Gold, W., Pugash, R., & Leis, J. (2018). Impact of defaulting to single-lumen peripherally inserted central catheters on patient outcomes: an interrupted time series study. *Clinical Infectious Diseases*, *67*(6), 954-957. https://doi.org/10.1093/cid/ciy301

Lari, F. (2014). The impact of using powerpoint presentations on students' learning and motivation in secondary schools. *Procedia - Social and Behavioral Sciences*, *98*, 1672-1677. https://doi.org/10.1016/j.sbspro.2014.03.592

Lee, Y., Ryu, B., Hong, S., Cho, O., Hong, K., Bae, I., Kwack, W., Kim, Y., Chung, E., Kim, D., Lee, M., & Park, K. (2020). Clinical impact of early reinsertion of a central venous catheter after catheter removal in patients with catheter-

related bloodstream infections. *Infection Control & Amp; Hospital Epidemiology*, *42*(2), 162-168. https://doi.org/10.1017/ice.2020.405

Lewin, S., Glenton, C., Lawrie, T., Downe, S., Finlayson, K., Rosenbaum, S., Barreix, M., & Tunçalp, Ö. (2019). Qualitative evidence synthesis (QES) for guidelines: paper 2 – using qualitative evidence synthesis findings to inform evidence-to-decision frameworks and recommendations. *Health Research Policy and Systems*, *17*(1). https://doi.org/10.1186/s12961-019-0468-4

Li, G., Zhang, Y., Ma, H., & Zheng, J. (2019). Arm port vs chest port: a systematic review and meta-analysis. *Cancer Management and Research*, (*11)*, 6099-6112. https://doi.org/10.2147/cmar.s205988

Lok, C., & Foley, R. (2013). Vascular access morbidity and mortality: trends of the last decade. *Clinical Journal of the American Society of Nephrology*, *8*(7), 1213-1219. doi: 10.2215/cjn.01690213

Loveday, H., Wilson, J., Pratt, R., Golsorkhi, M., Tingle, A., Bak, A., Browne, J., Prieto, J., & Wilcox, M. (2014). Epic: national evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England. *Journal of Hospital Infection*, *86*, 1-70. https://doi.org/10.1016/s0195-6701(13)60012-2

Macmillan, T., Pennington, M., Summers, J., Goddard, K., Zala, D., Herz, N., MacmillanN., Peacock, J., Keevil, S., & Chalkidou, A. (2018). SecurAcath for securing peripherally inserted central catheters: a nice medical technology guidance. *Applied Health Economics and Health Policy*, *16*(6), 779-791. https://doi.org/10.1007/s40258-018-0427-1

Madabhavi, I., Patel, A., Sarkar, M., Anand, A., Panchal, H., & Parikh, S. (2017). A study of use of "PORT" catheter in patients with cancer: a single-center experience. *Clinical Medicine Insights: Oncology*, *11*. https://doi.org/10.1177/1179554917691031

Manti, S., & Licari, A. (2018). How to obtain informed consent for research. *Breathe*, *14*(2), 145-152. doi: 10.1183/20734735.001918

Martínez García, L., Arévalo-Rodríguez, I., Solà, I., Haynes, R., Vandvik, P., & Alonso-Coello, P. (2012). Strategies for monitoring and updating clinical practice guidelines: a systematic review. *Implementation Science*, *7*(1). https://doi.org/10.1186/1748-5908-7-109

Masters, B., Hickish, T., & Una Cidon, E. (2014). A midline for Oxaliplatin infusion: the myth of safety devices. *Case Reports*, (6). https://doi.org/10.1136/bcr-2014-204360

Matey, L., & Camp-Sorrell, D. (2016). Venous access devices: clinical rounds. *Asia-Pacific Journal of Oncology Nursing*, *3*(4), 357-364. https://doi.org/10.4103/2347-5625.196480

Mercy, T. (2018). *Peripheral intravenous (IV) device management*. The Royal Children's Hospital Melbourne. Retrieved October 11, 2021 from https://www.rch.org.au/rchcpg/hospital_clinical_guideline_index/Peripheral_Intravenous_IV_Device_Management/.

Middleton, F. (2022). Reliability vs. validity: what's the difference?. Retrieved February 8, 2022 from https://www.scribbr.com/methodology/reliability-vs-validity/#:~:text=Reliability%20refers%20to%20how%20consistently,several%20times%20under%20identical%20conditions

Ministry of Health, Social Services and Equality. (2014). Development group of the clinical practice guideline on intravenous therapy with temporary devices in adults. Clinical practice guidelines in the SNS. Health Technologies Assessment Agency of Andalucía (AETSA).

Morano, G., Mercanti, C., Federico, V., Matturro, A., Micozzi, A., Latagliata, R., Breccia, M., Girmenia, C., Brunetti, G., Berneschi, P., Giampaoletti, M., Foà, R. & Alimena, G. (2009). Clinical usefulness and safety of peripherally-inserted central catethers (PICC) in hematological patients. *Blood*, *114*(22), 4545-4545. https://doi.org/10.1182/blood.v114.22.4545.4545

Morgan, D. (1997). *Focus Groups as Qualitative Research* (2nd ed., pp. 34). SAGE.

Morrell, E. (2020). Reducing risks and improving vascular access outcomes. *Journal of Infusion Nursing*, *43*(4), 222-228. https://doi.org/10.1097/nan.0000000000000377

Moss, J., Wu, O., Bodenham, A., Agarwal, R., Menne, T., Jones, B., Heggie, R., Hill, S., Dixon-Hughes, J., Soulis, E., Germeni, E., Dillon, S. & McCartney, E. (2021). Central venous access devices for the delivery of systemic anticancer therapy (CAVA): a randomised controlled trial. *The Lancet*, *398*(10298), 403-415. https://doi.org/10.1016/s0140-6736(21)00766-2

Moureau, N. (2020). Establishing vascular access teams for patient safety. *Infection Control Today*, *24*(4).

Moureau, N., & Alexandrou, E. (2019). Device selection. *Vessel Health and Preservation: the Right Approach for Vascular Access*, 23-41. https://doi.org/10.1007/978-3-030-03149-7_3

Moureau, N., Sigl, G., & Hill, M. (2015). How to establish an effective midline program: a case study of 2 hospitals. *Journal of the Association for Vascular Access*, *20*(3), 179-188. https://doi.org/10.1016/j.java.2015.05.001

Munn, Z., Peters, M., Stern, C., Tufanaru, C., McArthur, A., & Aromataris, E. (2018). Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Medical Research Methodology*, *18*(1). https://doi.org/10.1186/s12874-018-0611-x

National Institute for Health and Care Excellence. (2014). *Developing NICE guidelines: the manual.* Retrieved on September 17, 2020 from https://www.nice.org.uk/process/pmg20/resources/developing-nice-guidelines-the-manual-pdf-72286708700869

Ng, F., Mastoroudes, H., Paul, E., Davies, N., Tibballs, J., Hochhauser, D., Mayer, A., Begent, R., & Meyer, T. (2007). A comparison of hickman line- and port-a-cath-associated complications in patients with solid tumours undergoing chemotherapy. *Clinical Oncology*, *19*(7), 551-556. https://doi.org/10.1016/j.clon.2007.04.003

NHS. (2020). *Your Intravenous Cannula*. Retrieved April 9, 2022 from https://nhsforthvalley.com/wp-content/uploads/2014/01/Your-Intravenous-Cannula.pdf.

Nowell, L., Norris, J., White, D., & Moules, N. (2017). Thematic analysis. *International Journal of Qualitative Methods*, *16*(1). https://doi.org/10.1177/1609406917733847

Nyumba, T., Wilson, K., Derrick, C., & Mukherjee, N. (2018). The use of focus group discussion methodology: insights from two decades of application in

conservation. *Methods in Ecology and Evolution*, *9*(1), 20-32. https://doi.org/10.1111/2041-210x.12860

Omar, D. (2018). Focus group discussion in built environment qualitative research practice. *IOP Conference Series: Earth and Environmental Science*, *117*(1). https://doi.org/10.1088/1755-1315/117/1/012050

Osti, C., Khadka, M., Wosti, D., Gurung, G., & Zhao, Q. (2019). Knowledge and practice towards care and maintenance of peripheral intravenous cannula among nurses in Chitwan medical college teaching hospital, Nepal. *Nursing Open*, *6*(3), 1006-1012. https://doi.org/10.1002/nop2.288

Ozier, W. (1998). 85-10-10 The Delphi / modified Delphi technique : a consensus approach to information valuation. Retrieved on October 17, 2021 from The Delphi/Modified Delphi Technique: A Consensus Approach to Information Valuation (ittoday.info)

Page, M., McKenzie, J., Bossuyt, P., Boutron, I., Hoffmann, T., Mulrow, C., Shamseer, L., Tetzlaff, J., Akl, E., Brennan, S., Chou, R., Glanville, J., Grimshaw, J., Hróbjartsson, A., Lalu, M., Li, T., Loder, E., Mayo-Wilson, E., McDonald, S., McGuinness, L., Stewart, L., Thomas, J., Tricco, A., Welch, V., Whiting, P., & Moher, D. (2021). The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. https://doi.org/10.1136/bmj.n71

Paje, D., Conlon, A., Kaatz, S., Swaminathan, L., Boldenow, T., Bernstein., Flanders, S., & Chopra, V. (2018). Patterns and predictors of short-term peripherally inserted central catheter use: a multicenter prospective cohort study. *Journal of Hospital Medicine*, *13*(2), 76-82. https://doi.org/10.12788/jhm.2847

Paladini, A., Chiaretti, A., Sellasie, K., Pittiruti, M., & Vento, G. (2018). Ultrasound-guided placement of long peripheral cannulas in children over the age of 10 years admitted to the emergency department: a pilot study. *BMJ Paediatrics Open*, *2*(1). https://doi.org/10.1136/bmjpo-2017-000244

Patel, G., Jain, K., Kumar, R., Strickland, A., Pellegrini, L., Slavotinek, J., Eaton, M., McLeay, W., Price, T., Ly, M., Ullah, S., Koczwara, B., Kichenadasse, G. & Karapetis, C. (2013). Comparison of peripherally inserted central venous catheters (PICC) versus subcutaneously implanted port-chamber catheters by complication and cost for patients receiving chemotherapy for non-haematological malignancies. *Supportive Care in Cancer*, *22*(1), 121-128. https://doi.org/10.1007/s00520-013-1941-1

Patino, C., & Ferreira, J. (2018a). Inclusion and exclusion criteria in research studies: definitions and why they matter. *Jornal Brasileiro De Pneumologia*, *44*(2), 84-84. https://doi.org/10.1590/s1806-37562018000000088

Patino, C., & Ferreira, J. (2018b). Internal and external validity: can you apply research study results to your patients?. *Jornal Brasileiro De Pneumologia*, *44*(3), 183-183. doi: 10.1590/s1806-37562018000000164

Patton, M. (2009). *Qualitative Research & Evaluation Methods* (3rd ed., pp. 377-378). SAGE.

Pautasso, M. (2013). Ten simple rules for writing a literature review. *Plos Computational Biology*, *9*(7). doi: 10.1371/journal.pcbi.1003149

Pedersen, M., Jensen-Fangel, S., Olesen, H., Tambe, S., & Petersen, E. (2015). Outpatient parenteral antimicrobial therapy (OPAT) in patients with cystic

fibrosis. *BMC Infectious Diseases*, *15*(1). https://doi.org/10.1186/s12879-015-1019-4

Pharaoh, H. (2014). *Development, implementation and evaluation of youth development programmes to address health risk behaviour among grade 8 to grade 10 learners in selected schools in the Paarl area* [Degree of Doctor Philosophiae, Department of Physiotherapy, University of the Western Cape]. pharaoh_h_phd_chs_2014.pdf (uwc.ac.za)

Pitman, A., & Jones, D. (2006). Radiologist workloads in teaching hospital departments: Measuring the workload. *Australasian Radiology*, *50*(1), 12-20. https://doi.org/10.1111/j.1440-1673.2005.01524.x

Potet, J., Thome, A., Curis, E., Arnaud, F., Weber-Donat, G., Valbousquet., Peroux, E., Flor, E., Dody, C., Konopacki, J., Malfuson, J., Cartry, C., Lahutte, M., de Revel, T., Baccialone, J., & Teriitehau, C. (2013). Peripherally inserted central catheter placement in cancer patients with profound thrombocytopaenia: a prospective analysis. *European Radiology*, *23*(7), 2042-2048. https://doi.org/10.1007/s00330-013-2778-1

Presley, B., & Isenberg, J. (2022). *Ultrasound Guided Intravenous Access*. Retrieved May 12, 2022 from https://www.ncbi.nlm.nih.gov/books/NBK525988/.

R Avella, J. (2016). Delphi panels: Research design, procedures, advantages, and challenges. *International Journal of Doctoral Studies*, *11*, 305-321. https://doi.org/10.28945/3561

Rahman, M. (2016). The advantages and disadvantages of using qualitative and quantitative approaches and methods in language “testing and assessment”

research: a literature review. *Journal of Education and Learning*, *6*(1), 102. https://doi.org/10.5539/jel.v6n1p102

Ramirez-Santana, M. (2018). Limitations and Biases in Cohort Studies. *Cohort Studies in Health Sciences*. https://doi.org/10.5772/intechopen.74324

Registered Nurses' Association of Ontario (RNAO). (2021) *Vascular Access 2nd edition*. Toronto (ON). RNAO.

Removal of a Midline/PICC Catheter. (2020). Retrieved February 12, 2022 from https://www.careprohs.com/handlers/secure-document-handler.php?file=694d2ba51277d531b3aa846c02516030.pdf.

Robinson-Reilly, M., Paliadelis, P., & Cruickshank, M. (2015). Venous access: the patient experience. *Supportive Care in Cancer*, *24*(3), 1181-1187. https://doi.org/10.1007/s00520-015-2900-9

Rowe, M., Arnold, K., & Spencer, T. (2020). Catheter securement impact on PICC-related CLABSI: A university hospital perspective. *American Journal of Infection Control*, *48*(12), 1497-1500. https://doi.org/10.1016/j.ajic.2020.06.178

Salkind, N. (2010). Follow-Up. *Encyclopedia of Research Design*. doi: 10.4135/9781412961288.n157

Samad, A., & Ibrahim, Y. (2015). Complications of port a cath implantation: A single institution experience. *The Egyptian Journal of Radiology and Nuclear Medicine*, *46*(4), 907-911. https://doi.org/10.1016/j.ejrnm.2015.06.004

Schardt, C., Adams, M., Owens, T., Keitz, S., & Fontelo, P. (2007). Utilization of the PICO framework to improve searching PubMed for clinical questions. *BMC*

Medical Informatics and Decision Making, *7*(1). https://doi.org/10.1186/1472-6947-7-16

Schneider, P., Evaniew, N., Rendon, J., McKay, P., Randall, R., & Turcotte, R., Vélez, R., Bhandari, M. & Ghert, M. (2016). *Moving forward through consensus: protocol for a modified Delphi approach to determine the top research priorities in the field of orthopaedic oncology*. *BMJ Open*, *6*(5). https://doi.org/10.1136/bmjopen-2016-011780

Schober, P., & Vetter, T. (2019). Clear study aims and hypotheses in a research paper. *Anesthesia & Amp; Analgesia*, *129*(1), 3. doi: 10.1213/ane.0000000000004230

Scott, N., McPherson, G., Ramsay, C., & Campbell, M. (2002). The method of minimization for allocation to clinical trials. *Controlled Clinical Trials*, *23*(6), 662-674. https://doi.org/10.1016/s0197-2456(02)00242-8

Sedgwick, P. (2014). Retrospective cohort studies: Advantages and disadvantages. *BMJ*, *348*(jan24 1), g1072-g1072. https://doi.org/10.1136/bmj.g1072

Shanja-Grabarz, X., Santoriello, L., Ritter, G., Nicastro, J., Patel, V., Coppa, G., & Barrera, R. (2020). Midline catheters: an underutilized means of decreasing central venous catheter use. *International Journal of Surgery: Global Health*, *3*(2). https://doi.org/10.1097/gh9.0000000000000014

Shaw, J., Douglas, R., & Wilson, T. (1988). Clinical performance of hickman and portacath atrial catheters. *ANZ Journal of Surgery*, *58*(8), 657-659. https://doi.org/10.1111/j.1445-2197.1988.tb07578.x

Shaw, S. (2017). Using the vessel health and preservation framework to enhance vein assessment and vascular access device selection. *Nursing Standard*, *31*(46), 50-63. https://doi.org/10.7748/ns.2017.e10741

Shekelle, P., Woolf, S., Grimshaw, J., Schünemann, H., & Eccles, M. (2012). Developing clinical practice guidelines: reviewing, reporting, and publishing guidelines; updating guidelines; and the emerging issues of enhancing guideline implementability and accounting for comorbid conditions in guideline development. *Implementation Science*, *7*(1). https://doi.org/10.1186/1748-5908-7-62

Siering, U., Eikermann, M., Hausner, E., Hoffmann-Eßer, W., & Neugebauer, E. (2013). Appraisal tools for clinical practice guidelines: A systematic review. *Plos ONE*, *8*(12). https://doi.org/10.1371/journal.pone.0082915

Sou, V., McManus, C., Mifflin, N., Frost, S., Ale, J., & Alexandrou, E. (2017). A clinical pathway for the management of difficult venous access. *BMC Nursing*, *16*(1). https://doi.org/10.1186/s12912-017-0261-z

Strategic Management Services, LLC. (2018). *Health Care Auditing & Monitoring Tools for an Effective Compliance Program*. Strategic Management Services, LLC. Retrieved February 10, 2022 from https://www.compliance.com/resources/health-care-auditing-and-monitoring-tools-for-an-effective-compliance-program/.

Sucharew, H. (2019). Methods for Research evidence synthesis: the scoping review approach. *Journal of Hospital Medicine*, *14*(7), 416. https://doi.org/10.12788/jhm.3248

Swaminathan, L., Flanders, S., Horowitz, J., Zhang, Q., O'Malley, M., & Chopra, V. (2022). Safety and outcomes of midline catheters vs peripherally inserted central catheters for patients with short-term indications. *JAMA Internal Medicine*, *182*(1), 50. https://doi.org/10.1001/jamainternmed.2021.6844

Tarsi, K., & Tuff, T. (2012). *Introduction to Population Demographics | Learn Science at Scitable*. Nature.com. Retrieved September 2, 2021 from https://www.nature.com/scitable/knowledge/library/introduction-to-population-demographics-83032908/.

Tempe, D., & Hasija, S. (2017). Quest to determine the ideal position of the central venous catheter tip. *British Journal of Anaesthesia*, *118*(2), 148-150. https://doi.org/10.1093/bja/aew443

The AGREE Research Trust. (2014). *AGREE II FAQ - AGREE Enterprise Website*. Agreetrust.org. Retrieved 16 October 2022, from https://www.agreetrust.org/resource-centre/agree-ii/faq-agree-ii-2/#:~:text=Answer%3A%20The%20AGREE%20II%20has,with%20sufficient%20inter%2Drater%20reliability.

Thomas, L. (2022). *Understanding confounding variables*. Scribbr. Retrieved February 6, 2022 from https://www.scribbr.com/methodology/confounding-variables/#:~:text=There%20are%20several%20methods%20you,values%20of%20potential%20confounding%20variables.

Tianjing, L., Higgins, J., & Deeks, J. (2022). Chapter 5: Collecting data. Retrieved February 15, 2022 from https://training.cochrane.org/handbook/current/chapter-05

Tomaszewski, L., Zarestky, J., & Gonzalez, E. (2020). Planning qualitative research: Design and decision making for new researchers. *International Journal of Qualitative Methods*, *19*, 160940692096717. https://doi.org/10.1177/1609406920967174

Tomlin, G., & Borgetto, B. (2011). Research pyramid: A new evidence-based practice model for occupational therapy. *The American Journal of Occupational Therapy*, *65*(2), 189-196. https://doi.org/10.5014/ajot.2011.000828

Tricco, A., Lillie, E., Zarin, W., O'Brien, K., Colquhoun, H., Levac, D., Moher, D., Peters, M., Horsley, T., Weeks, L., Hempel, S., Akl, E., Chang, C., McGowan, J., Stewart, L., Hartling, L., Aldcroft, A., Wilson, M., Garritty, C., Lewin, S., Godfrey, C., Macdonald, M., Langlois, E., Soares-Weiser, K., Moriarty, J., Clifford, T., Tunçalp, Ö. & Straus, S.. (2018). PRISMA Extension for scoping reviews (PRISMA-ScR): Checklist and explanation. *Annals of Internal Medicine*, *169*(7), 467-473. doi: 10.7326/m18-0850

Vaughn, S., Schumm, J., & Shinagub, J. (1996). Preparing for the focus group. *Focus Group Interviews in Education and Psychology*, 36-55. https://doi.org/10.4135/9781452243641.n4

Verma, A., Kumachev, A., Shah, S., Guo, Y., Jung, H., Rawal, S., Lapointe-Shaw, L., Kwan, J., Weinerman, A., Tang, T. & Razak, F. (2020). Appropriateness of peripherally inserted central catheter use among general medical inpatients: an observational study using routinely collected data. *BMJ Quality & Safety*, *29*(11), 905-911. https://doi.org/10.1136/bmjqs-2019-010463

Vieira, R., Sousa-Pinto, B., & Figueira, L. (2021). *Beware of word truncation in PubMed: unexpected problems and potential solutions*. *BMJ Evidence-Based Medicine*, *26*(1), 34-36. https://doi.org/10.1136/bmjebm-2019-111286

Vu-Ngoc, H., Elawady, S., Mehyar, G., Abdelhamid, A., Mattar, O., Halhouli, O., Vuong, N., Ali, C., Hassan, U., Kien, N., Hirayama, K. & Huy, N. (2018). Quality of flow diagram in systematic review and/or meta-analysis. *PLOS ONE*, *13*(6). https://doi.org/10.1371/journal.pone.0195955

Waffenschmidt, S., Knelangen, M., Sieben, W., Bühn, S., & Pieper, D. (2019). Single screening versus conventional double screening for study selection in systematic reviews: a methodological systematic review. *BMC Medical Research Methodology*, *19*(1). https://doi.org/10.1186/s12874-019-0782-0

Walkden, G., Millwood, S., & Cavanagh, A. (2016). Improving access to clinical guidance: Redevelopment of a junior doctor intranet page. *BMJ Quality Improvement Reports*, *4*(1). https://doi.org/10.1136/bmjquality.u208197.w3938

Wall, C., Moore, J., & Thachil, J. (2015). Catheter-related thrombosis: A practical approach. *Journal of the Intensive Care Society*, *17*(2), 160-167. https://doi.org/10.1177/1751143715618683

Woolf, S., Grol, R., Hutchinson, A., Eccles, M., & Grimshaw, J. (1999). Clinical guidelines: Potential benefits, limitations, and harms of clinical guidelines. *BMJ*, *318*(7182), 527-530. https://doi.org/10.1136/bmj.318.7182.527

World Health Organization. (2012). *WHO Handbook for Guideline Development*. World Health Organization. Retrieved November 2, 2021, from

https://apps.who.int/iris/bitstream/handle/10665/75146/9789241548441_eng.pdf?sequence=1

World Health Organization. (2014). *WHO Handbook for Guideline Development, 2nd Edition*. Who.int. Retrieved September 10, 2021, from https://www.who.int/publications-detail-redirect/9789241548960.

World Health Organization. (2019). *Using Qualitative Research to Strengthen Guideline Development*. Who.int. Retrieved October 4, 2021, from https://www.who.int/news/item/08-08-2019-using-qualitative-research-to-strengthen-guideline-development.

Wu, O., Boyd, K., Paul, J., McCartney, E., Ritchie, M., Mellon, D., Kelly, L., Dixon-Hughes, J. & Moss, J. (2016). Hickman catheter and implantable port devices for the delivery of chemotherapy: a phase II randomised controlled trial and economic evaluation. *British Journal of Cancer*, *114*(9), 979-985. https://doi.org/10.1038/bjc.2016.76

Xie, Z., Wang, X., Sun, L., Liu, J., Guo, Y., Xu, B., Zhao, L. & Shen, A. (2016). Appraisal of clinical practice guidelines on community-acquired pneumonia in children with AGREE II instrument. *BMC Pediatrics*, *16*(1). https://doi.org/10.1186/s12887-016-0651-5

Yang, N., Yu, Y., Zhang, A., Estill, J., Wang, X., Zheng, M., Zhou, Q., Zhang, J., Luo, X., Qian, C., Mao, Y., Wang, Q., Yang, Y. & Chen, Y. (2019). Reporting, presentation and wording of recommendations in clinical practice guideline for gout: a systematic analysis. *BMJ Open*, *9*(1), e024315. https://doi.org/10.1136/bmjopen-2018-024315

Yu, J., Su, G., Hirst, A., Yang, Z., Zhang, Y., & Li, Y. (2020). Identifying competing interest disclosures in systematic reviews of surgical interventions and devices: a cross-sectional survey. *BMC Medical Research Methodology*, *20*(1). https://doi.org/10.1186/s12874-020-01144-2

Appendix A - CASP Tool for Randomised Controlled Trials

CASP Randomised Controlled Trial Standard Checklist:
11 questions to help you make sense of a randomised controlled trial (RCT)

Main issues for consideration: Several aspects need to be considered when appraising a randomised controlled trial:

- Is the basic study design valid for a randomised controlled trial? (Section A)
- Was the study methodologically sound? (Section B)
- What are the results? (Section C)
- Will the results help locally? (Section D)

The 11 questions in the checklist are designed to help you think about these aspects systematically.

How to use this appraisal tool: The first three questions (Section A) are screening questions about the validity of the basic study design and can be answered quickly. If, in light of your responses to Section A, you think the study design is valid, continue to Section B to assess whether the study was methodologically sound and if it is worth continuing with the appraisal by answering the remaining questions in Sections C and D.

Record 'Yes', 'No' or 'Can't tell' in response to the questions. Prompts below all but one of the questions highlight the issues it is important to consider. Record the reasons for your answers in the space provided. As CASP checklists were designed to be used as educational/teaching tools in a workshop setting, we do not recommend using a scoring system.

About CASP Checklists: The CASP RCT checklist was originally based on JAMA Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL and Cook DJ), and piloted with healthcare practitioners. This version has been updated taking into account the CONSORT 2010 guideline (http://www.consort-statement.org/consort-2010, accessed 16 September 2020).

Citation: CASP recommends using the Harvard style, i.e. *Critical Appraisal Skills Programme (2020). CASP (insert name of checklist i.e. Randomised Controlled Trial) Checklist. [online] Available at: insert URL. Accessed: insert date accessed.*

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Study and citation:

Section A: Is the basic study design valid for a randomised controlled trial?			
1. Did the study address a clearly focused research question? *CONSIDER:* *Was the study designed to assess the outcomes of an intervention?* *Is the research question 'focused' in terms of:* • *Population studied* • *Intervention given* • *Comparator chosen* • *Outcomes measured?*	Yes ☐	No ☐	Can't tell ☐
2. Was the assignment of participants to interventions randomised? *CONSIDER:* • *How was randomisation carried out? Was the method appropriate?* • *Was randomisation sufficient to eliminate systematic bias?* • *Was the allocation sequence concealed from investigators and participants?*	Yes ☐	No ☐	Can't tell ☐
3. Were all participants who entered the study accounted for at its conclusion? *CONSIDER:* • *Were losses to follow-up and exclusions after randomisation accounted for?* • *Were participants analysed in the study groups to which they were randomised (intention-to-treat analysis)?* • *Was the study stopped early? If so, what was the reason?*	Yes ☐	No ☐	Can't tell ☐

Section B: Was the study methodologically sound?			
4. • Were the participants 'blind' to intervention they were given? • Were the investigators 'blind' to the intervention they were giving to participants? • Were the people assessing/analysing outcome/s 'blinded'?	Yes ☐ ☐ ☐	No ☐ ☐ ☐	Can't tell ☐ ☐ ☐
5. Were the study groups similar at the start of the randomised controlled trial? *CONSIDER:* • *Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly set out?* • *Were there any differences between the study groups that could affect the outcome/s?*	Yes ☐	No ☐	Can't tell ☐

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6. Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)? *CONSIDER:* • *Was there a clearly defined study protocol?* • *If any additional interventions were given (e.g. tests or treatments), were they similar between the study groups?* • *Were the follow-up intervals the same for each study group?*	Yes ☐	No ☐	Can't tell ☐

Section C: What are the results?

7. Were the effects of intervention reported comprehensively? *CONSIDER:* • *Was a power calculation undertaken?* • *What outcomes were measured, and were they clearly specified?* • *How were the results expressed? For binary outcomes, were relative and absolute effects reported?* • *Were the results reported for each outcome in each study group at each follow-up interval?* • *Was there any missing or incomplete data?* • *Was there differential drop-out between the study groups that could affect the results?* • *Were potential sources of bias identified?* • *Which statistical tests were used?* • *Were p values reported?*	Yes ☐	No ☐	Can't tell ☐
8. Was the precision of the estimate of the intervention or treatment effect reported? *CONSIDER:* • *Were confidence intervals (CIs) reported?*	Yes ☐	No ☐	Can't tell ☐
9. Do the benefits of the experimental intervention outweigh the harms and costs? *CONSIDER:* • *What was the size of the intervention or treatment effect?* • *Were harms or unintended effects reported for each study group?* • *Was a cost-effectiveness analysis undertaken? (Cost-effectiveness analysis allows a comparison to be made between different interventions used in the care of the same condition or problem.)*	Yes ☐	No ☐	Can't tell ☐

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Section D: Will the results help locally?		
10. Can the results be applied to your local population/in your context? *CONSIDER:* • *Are the study participants similar to the people in your care?* • *Would any differences between your population and the study participants alter the outcomes reported in the study?* • *Are the outcomes important to your population?* • *Are there any outcomes you would have wanted information on that have not been studied or reported?* • *Are there any limitations of the study that would affect your decision?*	Yes ☐	No ☐ Can't tell ☐
11. Would the experimental intervention provide greater value to the people in your care than any of the existing interventions? *CONSIDER:* • *What resources are needed to introduce this intervention taking into account time, finances, and skills development or training needs?* • *Are you able to disinvest resources in one or more existing interventions in order to be able to re-invest in the new intervention?*	Yes ☐	No ☐ Can't tell ☐

APPRAISAL SUMMARY: *Record key points from your critical appraisal in this box. What is your conclusion about the paper? Would you use it to change your practice or to recommend changes to care/interventions used by your organisation? Could you judiciously implement this intervention without delay?*

Appendix B - CASP Tool for Systematic Reviews

CASP Checklist: 10 questions to help you make sense of a Systematic Review

How to use this appraisal tool: Three broad issues need to be considered when appraising a systematic review study:

- Are the results of the study valid? (Section A)
- What are the results? (Section B)
- Will the results help locally? (Section C)

The 10 questions on the following pages are designed to help you think about these issues systematically. The first two questions are screening questions and can be answered quickly. If the answer to both is "yes", it is worth proceeding with the remaining questions. There is some degree of overlap between the questions, you are asked to record a "yes", "no" or "can't tell" to most of the questions. A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

About: These checklists were designed to be used as educational pedagogic tools, as part of a workshop setting, therefore we do not suggest a scoring system. The core CASP checklists (randomised controlled trial & systematic review) were based on JAMA 'Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL, and Cook DJ), and piloted with health care practitioners.

For each new checklist, a group of experts were assembled to develop and pilot the checklist and the workshop format with which it would be used. Over the years overall adjustments have been made to the format, but a recent survey of checklist users reiterated that the basic format continues to be useful and appropriate.

Referencing: we recommend using the Harvard style citation, i.e.: *Critical Appraisal Skills Programme (2018). CASP (insert name of checklist i.e. Systematic Review) Checklist. [online] Available at: URL. Accessed: Date Accessed.*

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Paper for appraisal and reference:

Section A: Are the results of the review valid?

1. Did the review address a clearly focused question?

Yes ☐
Can't Tell ☐
No ☐

HINT: An issue can be 'focused' In terms of
- the population studied
- the intervention given
- the outcome considered

Comments:

2. Did the authors look for the right type of papers?

Yes ☐
Can't Tell ☐
No ☐

HINT: 'The best sort of studies' would
- address the review's question
- have an appropriate study design (usually RCTs for papers evaluating interventions)

Comments:

Is it worth continuing?

3. Do you think all the important, relevant studies were included?

Yes ☐
Can't Tell ☐
No ☐

HINT: Look for
- which bibliographic databases were used
- follow up from reference lists
- personal contact with experts
- unpublished as well as published studies
- non-English language studies

Comments:

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4. Did the review's authors do enough to assess quality of the included studies?

Yes ☐
Can't Tell ☐
No ☐

HINT: The authors need to consider the rigour of the studies they have identified. Lack of rigour may affect the studies' results ("All that glisters is not gold" Merchant of Venice – Act II Scene 7)

Comments:

5. If the results of the review have been combined, was it reasonable to do so?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider whether
- results were similar from study to study
- results of all the included studies are clearly displayed
- results of different studies are similar
- reasons for any variations in results are discussed

Comments:

Section B: What are the results?

6. What are the overall results of the review?

HINT: Consider
- If you are clear about the review's 'bottom line' results
- what these are (numerically if appropriate)
- how were the results expressed (NNT, odds ratio etc.)

Comments:

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7. How precise are the results?

HINT: Look at the confidence intervals, if given

Comments:	

Section C: Will the results help locally?

8. Can the results be applied to the local population?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider whether
- the patients covered by the review could be sufficiently different to your population to cause concern
- your local setting is likely to differ much from that of the review

Comments:	

9. Were all important outcomes considered?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider whether
- there is other information you would like to have seen

Comments:	

10. Are the benefits worth the harms and costs?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- even if this is not addressed by the review, what do you think?

Comments:	

Appendix C - CASP Tool for Cohort Studies

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CASP Checklist: 12 questions to help you make sense of a Cohort Study

How to use this appraisal tool: Three broad issues need to be considered when appraising a cohort study:

- Are the results of the study valid? (Section A)
- What are the results? (Section B)
- Will the results help locally? (Section C)

The 12 questions on the following pages are designed to help you think about these issues systematically. The first two questions are screening questions and can be answered quickly. If the answer to both is "yes", it is worth proceeding with the remaining questions. There is some degree of overlap between the questions, you are asked to record a "yes", "no" or "can't tell" to most of the questions. A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

About: These checklists were designed to be used as educational pedagogic tools, as part of a workshop setting, therefore we do not suggest a scoring system. The core CASP checklists (randomised controlled trial & systematic review) were based on JAMA 'Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL, and Cook DJ), and piloted with health care practitioners.

For each new checklist, a group of experts were assembled to develop and pilot the checklist and the workshop format with which it would be used. Over the years overall adjustments have been made to the format, but a recent survey of checklist users reiterated that the basic format continues to be useful and appropriate.

Referencing: we recommend using the Harvard style citation, i.e.: *Critical Appraisal Skills Programme (2018). CASP (insert name of checklist i.e. Cohort Study) Checklist. [online] Available at: URL. Accessed: Date Accessed.*

CASP
Critical Appraisal Skills Programme

Paper for appraisal and reference:

Section A: Are the results of the study valid?

1. Did the study address a clearly focused issue?

Yes ☐
Can't Tell ☐
No ☐

HINT: A question can be 'focused' in terms of
- the population studied
- the risk factors studied
- is it clear whether the study tried to detect a beneficial or harmful effect
- the outcomes considered

Comments:

2. Was the cohort recruited in an acceptable way?

Yes ☐
Can't Tell ☐
No ☐

HINT: Look for selection bias which might compromise the generalisability of the findings:
- was the cohort representative of a defined population
- was there something special about the cohort
- was everybody included who should have been

Comments:

Is it worth continuing?

CASP
Critical Appraisal Skills Programme

3. Was the exposure accurately measured to minimise bias?

Yes ☐
Can't Tell ☐
No ☐

HINT: Look for measurement or classification bias:

- did they use subjective or objective measurements
- do the measurements truly reflect what you want them to (have they been validated)
- were all the subjects classified into exposure groups using the same procedure

Comments:

4. Was the outcome accurately measured to minimise bias?

Yes ☐
Can't Tell ☐
No ☐

HINT: Look for measurement or classification bias:

- did they use subjective or objective measurements
- do the measurements truly reflect what you want them to (have they been validated)
- has a reliable system been established for detecting all the cases (for measuring disease occurrence)
- were the measurement methods similar in the different groups
- were the subjects and/or the outcome assessor blinded to exposure (does this matter)

Comments:

CASP
Critical Appraisal Skills Programme

5. (a) Have the authors identified all important confounding factors?

Yes ☐
Can't Tell ☐
No ☐

HINT:
- list the ones you think might be important, and ones the author missed

Comments:

5. (b) Have they taken account of the confounding factors in the design and/or analysis?

Yes ☐
Can't Tell ☐
No ☐

HINT:
- look for restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors

Comments:

6. (a) Was the follow up of subjects complete enough?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- the good or bad effects should have had long enough to reveal themselves
- the persons that are lost to follow-up may have different outcomes than those available for assessment
- in an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort

6. (b) Was the follow up of subjects long enough?

Yes ☐
Can't Tell ☐
No ☐

CASP
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Comments:	

Section B: What are the results?

7. What are the results of this study?

HINT: Consider
- what are the bottom line results
- have they reported the rate or the proportion between the exposed/unexposed, the ratio/rate difference
- how strong is the association between exposure and outcome (RR)
- what is the absolute risk reduction (ARR)

Comments:	

8. How precise are the results?

HINT:
- look for the range of the confidence intervals, if given

Comments:	

9. Do you believe the results?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- big effect is hard to ignore
- can it be due to bias, chance or confounding
- are the design and methods of this study sufficiently flawed to make the results unreliable
- Bradford Hills criteria (e.g. time sequence, dose-response gradient, biological plausibility, consistency)

Comments:

Section C: Will the results help locally?

10. Can the results be applied to the local population?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider whether
- a cohort study was the appropriate method to answer this question
- the subjects covered in this study could be sufficiently different from your population to cause concern
- your local setting is likely to differ much from that of the study
- you can quantify the local benefits and harms

Comments:

11. Do the results of this study fit with other available evidence?

Yes ☐
Can't Tell ☐
No ☐

Comments:

CASP
Critical Appraisal Skills Programme

12. What are the implications of this study for practice?

Yes	
Can't Tell	
No	

HINT: Consider

- one observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making
- for certain questions, observational studies provide the only evidence
- recommendations from observational studies are always stronger when supported by other evidence

Comments:	

Appendix D – The Joanna Briggs Institute for Cross- Sectional Studies

Introduction

JBI is an JBI is an international research organisation based in the Faculty of Health and Medical Sciences at the University of Adelaide, South Australia. JBI develops and delivers unique evidence-based information, software, education and training designed to improve healthcare practice and health outcomes.With over 70Collaborating Entities, servicing over 90 countries, JBI is a recognised global leader in evidence-based healthcare.

JBI Review Systems

The core of evidence synthesis is the systematic review of literature of a particular intervention, condition or issue. The systematic review is essentially an analysis of the available literature (that is, evidence) and a judgment of the effectiveness or otherwise of a practice, involving a series of complex steps. JBI takes a particular view on what counts as evidence and the methods utilised to synthesise those different types of evidence. In line with this broader view of evidence, JBI has developed theories, methodologies and rigorous processes for the critical appraisal and synthesis of these diverse forms of evidence in order to aid in clinical decision-making in healthcare. There now exists JBI guidance for conducting reviews of effectiveness research, qualitative research, prevalence/incidence, aetiology/risk, economic evaluations, text/opinion, diagnostic test accuracy, mixed-methods, umbrella reviews and scoping reviews. Further information regarding JBI systematic reviews can be found in the JBI Evidence Synthesis Manual.

JBI Critical Appraisal Tools

All systematic reviews incorporate a process of critique or appraisal of the research evidence. The purpose of this appraisal is to assess the methodological quality of a study and to determine the extent to which a study has addressed the possibility of bias in its design, conduct and analysis. All papers selected for inclusion in the systematic review (that is – those that meet the inclusion criteria described in the protocol) need to be subjected to rigorous appraisal by two critical appraisers. The results of this appraisal can then be used to inform synthesis and interpretation of the results of the study. JBI Critical appraisal tools have been developed by the JBI and collaborators and approved by the JBI Scientific Committee following extensive peer review. Although designed for use in systematic reviews, JBI critical appraisal tools can also be used when creating Critically Appraised Topics (CAT), in journal clubs and as an educational tool.

JBI Critical Appraisal Checklist for
analytical cross sectional studies

Reviewer_____
Date_____

Author_____Year_____ Record Number_____

	Yes	No	Unclear	Not applicable
1. Were the criteria for inclusion in the sample clearly defined?	☐	☐	☐	☐
2. Were the study subjects and the setting described in detail?	☐	☐	☐	☐
3. Was the exposure measured in a valid and reliable way?	☐	☐	☐	☐
4. Were objective, standard criteria used for measurement of the condition?	☐	☐	☐	☐
5. Were confounding factors identified?	☐	☐	☐	☐
6. Were strategies to deal with confounding factors stated?	☐	☐	☐	☐
7. Were the outcomes measured in a valid and reliable way?	☐	☐	☐	☐
8. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

Appendix E – AGREE II Tool

DOMAIN 1. SCOPE AND PURPOSE

1. The overall objective(s) of the guideline is (are) specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

2. The health question(s) covered by the guideline is (are) specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 2. STAKEHOLDER INVOLVEMENT

4. The guideline development group includes individuals from all relevant professional groups.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

5. The views and preferences of the target population (patients, public, etc.) have been sought.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

6. The target users of the guideline are clearly defined.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 3. RIGOUR OF DEVELOPMENT

7. Systematic methods were used to search for evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

8. The criteria for selecting the evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

9. The strengths and limitations of the body of evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 3. RIGOUR OF DEVELOPMENT continued

10. The methods for formulating the recommendations are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

12. There is an explicit link between the recommendations and the supporting evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 3. RIGOUR OF DEVELOPMENT continued

13. The guideline has been externally reviewed by experts prior to its publication.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

14. A procedure for updating the guideline is provided.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 4. CLARITY OF PRESENTATION

15. The recommendations are specific and unambiguous.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

16. The different options for management of the condition or health issue are clearly presented.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

17. Key recommendations are easily identifiable.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 5. APPLICABILITY

18. The guideline describes facilitators and barriers to its application.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

20. The potential resource implications of applying the recommendations have been considered.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 5. APPLICABILITY continued

21. The guideline presents monitoring and/or auditing criteria.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 6. EDITORIAL INDEPENDENCE

22. The views of the funding body have not influenced the content of the guideline.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

23. Competing interests of guideline development group members have been recorded and addressed.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

OVERALL GUIDELINE ASSESSMENT

For each question, please choose the response which best characterizes the guideline assessed:

1. Rate the overall quality of this guideline.

1 Lowest possible quality	2	3	4	5	6	7 Highest possible quality

2. I would recommend this guideline for use.

Yes	
Yes, with modifications	
No	

NOTES

Appendix F – Prototype Guideline Summary

Recommendations

Peripheral Intravenous Cannula (PIVC)

- Infusate osmolarity must be between 900mOsm/L and 500mOsm/L.
- PIVCs are to be inserted into a peripheral vein in the upper extremity of the arm, including veins in the forearm, ventral and dorsal surfaces in the upper extremities (basilic, median, metacarpal and the cephalic vein), avoiding high flexion areas such as the antecubital fossa and wrist as these increase the risk of CRBSI, phlebitis and thrombosis.
- Forearm veins are to be avoided for the infusion of peripherally compatible infusates due to the risk of complications such as tissue damage, ulceration and thrombophlebitis.
- The recommended duration for PIVC use is for infusion taking up to 6 days.
- For normal infusions, a 20-24gauge PIVC is to be used whilst for rapid fluid replacement therapy, vesicant or irritant infusates, a 16-20 gauge is ideal.
- Not to be used for:
    - The infusion of vesicant/irritant infusates including Dobutamine and continuous chemotherapy infusions
    - Total parenteral nutrition (TPN)

Notes

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Midlines

- Midlines help in avoiding repetitive peripheral cannulation whilst minimising the risk of needle-stick injuries for physicians and nurses. They are also more cost-effective and a less traumatic solution to repetitive peripheral cannulation.
- Can be used for the infusion of peripherally compatible infusates including antibiotic treatment.
- Recommended for infusions taking between 7 days up to 4 weeks.

- Veins in the upper arm (cephalic, median cubital and brachial veins, with the basilic vein preferred) are preferred for midline insertion. If not possible, the antecubital fossa can be used.
- Infusate osmolarity must be between <500mOsm/L and <900mOsm/L.
- Not to be used for:
    - TPN
    - Vesicant medications/solutions such as long-term chemotherapy

Notes

_____

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_____

Peripherally Inserted Central Catheters

- To be used for medium-long term IV infusion of any infusate, including:
    - TPN
    - Vesicant medication/solutions
    - Antibiotic therapy
    - Chemotherapy
    - Inotropes
    - Non-peripherally compatible infusates
    - Blood-letting
- Ideal for inpatients and/or outpatients requiring intravenous access between 4 weeks and 6 months.
- Recommended PICC insertion sites are the veins of the upper arm (basilic, cephalic and brachial veins) with the basilic and brachial veins being preferred as these were shown to cause less risk of thrombosis.
- Not recommended to be used for:
    - Long-term (>6months) chemotherapy infusions in patients with a haematological or non-haematological tumours.
    - Patients for chemotherapy with a past history of DVT needing a 5Fr PICC or larger, should be considered for an alternative CVAD.

- Data shows that the most common reason for inappropriate PICC insertion is placement in patients with CKD and the placement of PICC lines in patients admitted to the ICU for less than 15 days. A common thread was seen that older, female patients with higher levels of co-morbidities were more likely to get an 'inappropriate' PICC.

Notes

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Portacaths

- Portacaths have a lower complication rate compared to PICC in patients with a non-haematological/solid tumour.
- They also have a lower time to first complication rate and line dislodgement rate.
- Overall, the data suggests portacath devices for infusions taking between 4 weeks to 4 years for the infusion of any infusate including:
    - Chemotherapy
    - Antineoplastic therapy
    - Long-term infrequent infusions
    - Long-term frequent infusions

Notes

_____

_____

_____

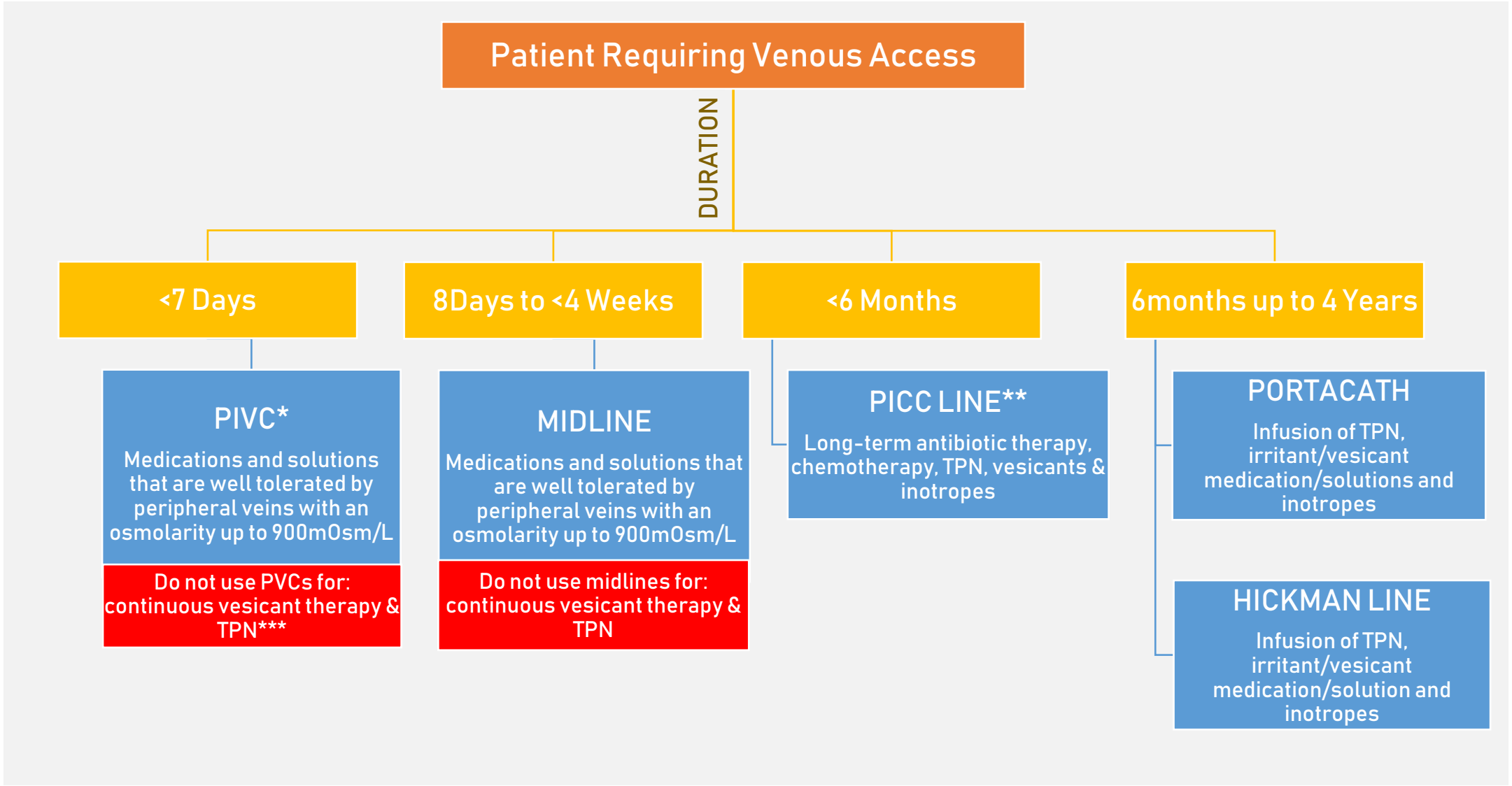
_____

Hickman Lines

- Hickman lines can be used for infusions taking between 4 weeks to 4 years.
- Any infusate can be given through these lines, including:

- Chemotherapy
- Antineoplastic therapy
- Long-term infrequent infusions
- Long-term frequent infusions

Notes


Patient Requiring Venous Access
DURATION
<7 Days
8Days to <4 Weeks
<6 Months
6months up to 4 Years
PIVC*
Medications and solutions that are well tolerated by peripheral veins with an osmolarity up to 900mOsm/L
Do not use PVCs for: continuous vesicant therapy & TPN***
MIDLINE
Medications and solutions that are well tolerated by peripheral veins with an osmolarity up to 900mOsm/L
Do not use midlines for: continuous vesicant therapy & TPN
PICC LINE**
Long-term antibiotic therapy, chemotherapy, TPN, vesicants & inotropes
PORTACATH
Infusion of TPN, irritant/vesicant medication/solutions and inotropes
HICKMAN LINE
Infusion of TPN, irritant/vesicant medication/solution and inotropes

Appendix G – Focus Group Discussion Guide

PowerPoint Presentation: So good afternoon. Thank you all for being here and welcome to this FGD which is a part of my Masters dissertation titled: 'Developing a Venous Access Guideline in Malta – A Modified Delphi Study'. I am also a nurse in Angiosuite and have been working there for the past 3 years. Hence why I chose to write my dissertation on this particular topic.

Disclaimer* This session is being audio recorded. This will be saved in a password-protected file and any names will be coded. Something else before we start, please state your name before every each time you speak because of transcribing purposes.

Some ground rules

- As I said this session is being recorded so please don't speak over each other
- Allow everyone to share their opinion
- And feel free to help yourself to any tea/coffee

So what is the current Problem on venous access?

So currently only physicians and practice development nurses who know about this service are referring patients to Angiosuite for VAD insertion by **contacting** one of the radiology physicians.

But still, even though as you can see this service is **gaining popularity**, and there is an increase in demand, device selection is still not yet guided by any sort of guideline/algorithm and patients are unfortunately not being referred or being referred late and as you know we start having problems like these**. Therefore this is why we need these guidelines.

Aim

So the aim of my dissertation is to develop a venous access guideline to be used by all healthcare professionals who provide direct care to adult patients both on an inpatient and outpatient service.

**Now the guideline development followed a strict systematic process. We first started by submitting the proposal …

**So why are we here?

So after we analysed the results of both reviews, their conclusions were used to develop a prototype guideline **which I will present to you shortly**. So we are here to discuss these guidelines as a part of a **modified Delphi method** and get your opinions and expertise of what can be changed and included so as to make them more adaptable to the local setting. So for this discussion we decided that the main stakeholders for this guideline development were the radiology department, infection prevention and control nurses, and the vascular access team.

The Delphi method also includes a second round of data collection, where after the prototype guideline is updated based on the outcomes of this FGD, a guideline

assessment tool along with the updated guideline will be sent by email in the form of a google document were you can rate the quality and add any further suggestions.

Should this guideline be published or introduced in this hospital, you will be **acknowledged** as a part of this guideline development team.

So now can you all **introduce yourself** please including your name and area of your work.

**Here is a copy of a proposed clinical guideline and pathway for Venous Access.

This guideline identifies a venous access clinical pathway based on vascular access devices to be considered such as: peripheral intravenous cannulas, Midlines, peripherally inserted central catheters (PICC) lines, Hickman lines and Portacath devices. This is a clinical pathway to inform the right decision on the device to be inserted based on a thorough patient evaluation.

Please take some time (5 minutes) to review the guideline provided

General

1. What are your initial thoughts on the proposed guideline?
2. Is the pathway for venous access recommended here easy to follow?
3. Do you think that the flow diagram here actually helps rather than just giving the bullet form?

PIVCs

So let's start with peripheral IV cannulas

a. Would you like to add anything to it? Do you agree with what is written?
b. Do you agree that 6 days is the maximum duration that a patient should be left with a PIVC?
c. From your experience, is there anything else you would not recommend giving through a midline or PIVC?

Midline

d. Would you like to add anything to it? Do you agree with what's written?
e. Do you agree that 4 weeks is the maximum duration that a patient should be left with a midline?
f. Data is not clear when it comes to bloodletting through a midline. Would you use a midline for bloodletting?

PICC

g. Would you like to add anything to it?
h. Do you agree with what's written?
i. What do you think about PICC lines for chemotherapy/TPN?
j. Maximum duration to use it for?

Portacath/hickman

k. How do you think we should tackle the issue with late portacath referral for patients on chemo?
l. Hickman for TPN?
m. Hickman Vs Portacath for chemotherapy?
n. Haematology patients and VADs

General

4. Do you agree that this is the best device for patients presenting with these specific needs?
5. Would you change anything from this?
6. Do you think there are exceptions that need to be made for patients presenting with certain characteristics? Ex. Intravenous drug users
7. Do you think that locally, this is feasible?
8. Would you like to make any further comments?

Overall/closing question

9. Is there anything else that you would like to comment on the guideline overall?

Prompts

- Is there anything else you would like to say about venous access?
- Some have said that if we change this particular section, the guideline would be better, what do you think Mr/Ms X?
- How can this department (ex. Radiology, infection prevention and control practice nurses or vascular access practice nurses) help in this process?

Other questions:

Blood products could be added?

To discuss with radiology how to refer… email etc.

Who should follow them in outpatients?

Bedside access?

Appendix H – Chairperson of the Medical Imaging Department

L-Università ta' Malta

Date Tuesday 22nd June 2021

Request for permission to conduct research in Mater Dei Hospital.

Dear Dr. Saliba,

My name is Maria Gauci and I am a student at the University of Malta, presently reading for a Master of Science in Nursing (by Taught and Research). As part of my course requirements I am conducting a research study entitled, "Developing a Venous Access Guideline in Malta – A Modified Delphi Study". This aims to develop a local venous access guideline which provides nurses and physicians with guidance on how to choose the best type of venous access device for their patients based on their needs. The research will be conducted in four stages; Stage 1: A scoping literature review of the evidence that is available to date on the topic of interest, Stage 2: Developing a prototype guideline based on the current evidence, Stage 3: A Modified Delphi Approach using a focus group discussion (approximate duration of 1 hour) amongst participants to reach consensus on the proposed prototype guideline from all experts invited to participate in this study, Stage 4: A guideline assessment tool and guideline will be distributed for a final Delphi round to each individual participant to assess the quality of the finalized guideline. Participants will include Interventional Consultant Radiologists, Radiology Trainees, Infection Prevention and Control Practice Nurses and Vascular Access Nurses.

This project is being conducted under the supervision of Dr. Ermira Tartari Bonnici, Department of Nursing, Faculty of Health Sciences.

I am hereby seeking your permission to recruit Interventional Consultant Radiologists and Radiology Trainees who have been offering a venous access service for at least two years.

Participation in this study is completely voluntary and participants are free to accept or refuse to take part without giving a reason. As participants, they have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning them to be erased. Once the study is completed and the results are published, the data will be retained in anonymous form. Any personal details will be destroyed.

Furthermore, withdrawal from the study will not have any negative repercussions on the participants and any data collected will be erased. Data will be stored anonymously if it is

impossible to delete (e.g. if it has already been anonymised). I can assure you that confidentiality will be maintained throughout the study and that participants' identity and personal information will not be revealed in any publications, reports or presentations arising from this research. All data collected will be pseudonymised meaning that the transcripts will be assigned codes and that this data will be stored securely and separately from any codes and personal data. This data may only be accessed by the researcher. The academic supervisor and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes. The coded audio-recordings, and transcripts will be stored on the researcher's personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard.

Should you require further information, please do not hesitate to contact me or my supervisor; both our contact details are provided below.

Thank you for your kind consideration of this request.

Yours Sincerely,

M. Gauci

Maria Gauci

Researcher

Contact on 79580034 or by e-mail
maria.gauci.15@um.edu.mt

Dr. Ermira Tartari Bonnici

Research Supervisor

Re: MARIA GAUCI - RESEARCH REQUEST 22/06/24

I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I give permission to proceed with the study.

Name & Surname Dr Kenneth Refalo MD, MSc, MRCR, FRCR
Clinical Chairman – Medical Imaging Department
Mater Dei Hospital Malta, Malta

Signature: _____

Date: 24/06/2024

Appendix I – Permission from the Chief Executive Officer in MDH

6/25/2021 University of Malta Mail - Permission Letter

L-Università ta' Malta

Maria Gauci <maria.gauci.15@um.edu.mt>

Permission Letter

CEO at Health-MDH <ceo.mdh@gov.mt> 25 June 2021 at 13:05
To: Maria Gauci <maria.gauci.15@um.edu.mt>

Dear Ms Gauci,

Kindly note that approval has been given by Ms Celia Falzon for you to conduct this study in line with applicable hospital protocols.

Please also be reminded that approval from Ms Marsette Portelli our Legal Advisor on behalf of the CEO has to be sought before any data being published outside of hospital locally or abroad.

Regards

Carmen Farrugia
Personal Assistant To CEO

SPTAR MATER DEI

T +356 +356 25454102

E carmen.farrugia@gov.mt

Mater Dei Hospital, Triq id-Donaturi tad-Demm, l-Imsida, Malta MSD 2090 | Tel +356 2545 0000 | https://deputyprimeminister.gov.mt/en/MDH/Pages/Home.aspx | https://www.facebook.com/materdeihospital/

Appendix J – Permission from the Chief Medical Officer in MDH

L-Università ta' Malta

Date Tuesday 22nd June 2021

Request for permission to conduct research in Mater Dei Hospital.

Dear Mr. Busuttil,

My name is Maria Gauci and I am a student at the University of Malta, presently reading for a Master of Science in Nursing (by Taught and Research). As part of my course requirements I am conducting a research study entitled, **"Developing a Venous Access Guideline in Malta – A Modified Delphi Study"**. This aims to develop a local venous access guideline which provides nurses and physicians with guidance on how to choose the best type of venous access device for their patients based on their needs. The research will be conducted in four stages; Stage 1: A scoping literature review of the evidence that is available to date on the topic of interest, Stage 2: Developing a prototype guideline based on the current evidence, Stage 3: A Modified Delphi Approach using a focus group discussion (approximate duration of 1 hour) amongst participants to reach consensus on the proposed prototype guideline from all experts invited to participate in this study, Stage 4: A guideline assessment tool and guideline will be distributed for a final Delphi round to each individual participant to assess the quality of the finalized guideline. Participants will include Interventional Consultant Radiologists, Radiology Trainees, Infection Prevention and Control Practice Nurses and Vascular Access Nurses.

This project is being conducted under the supervision of Dr. Ermira Tartari Bonnici, Department of Nursing, Faculty of Health Sciences.

I am hereby seeking your permission to recruit Interventional Consultant Radiologists, Radiology Trainees, Infection Prevention and Control Practice Nurses and Vascular Access Nurses for this study.

Participation in this study is completely voluntary and participants are free to accept or refuse to take part without giving a reason. As participants, they have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning them to be erased. Once the study is completed and the results are published, the data will be retained in anonymous form. Any personal details will be destroyed.

Furthermore, withdrawal from the study will not have any negative repercussions on the participants and any data collected will be erased. Data will be stored anonymously if it is

impossible to delete (e.g. if it has already been anonymised). I can assure you that confidentiality will be maintained throughout the study and that participants' identity and personal information will not be revealed in any publications, reports or presentations arising from this research. All data collected will be pseudonymised meaning that the transcripts will be assigned codes and that this data will be stored securely and separately from any codes and personal data. This data may only be accessed by the researcher. The academic supervisor and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes. The coded audio-recordings, and transcripts will be stored on the researcher's personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard.

Should you require further information, please do not hesitate to contact me or my supervisor; both our contact details are provided below.

Thank you for your kind consideration of this request.

Yours Sincerely,

M. Gauci

Maria Gauci

Researcher

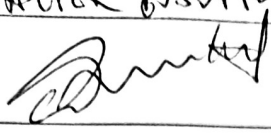
Contact on 79580034 or by e-mail
maria.gauci.15@um.edu.mt]

Dr. Ermira Tartari Bonnici

Research Supervisor

I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I give permission to proceed with the study.

Name & Surname WALTER OSSWALD

Signature: 

Date: 23/6/2021

Appendix K – Permission from the Data Protection Officer

SPTAR MATER DEI

Data Protection Clearance Declaration Form

REF: 169/2021

I hereby declare that I will respect the confidentiality and privacy of any personal data or information that I will come across at Mater Dei and will in no circumstance disclose any such information to third parties.

I confirm that information submitted for Data Protection Clearance is correct and that I will abide with conditions issued in same clearance notice.

- **This clearance does not cover ethical approval.**
- **All the documents presented to your potential participants must include UOM's logo.**
- **Your submitted documentation must remain unchanged.**
- **What was declared during this clearance process is what you will abide to.**
- **You must abide with all the articles of the GDPR (EU) 2016 / 679 throughout the data collection process and thereafter.**
- **You are requested to submit a copy of your findings to this office at the end of your study.**
- **Please communicate with Mr Mark Pullicino and Ms Josianne Portelli to present this clearance email.**

I also declare that I am aware of the provisions of the:

General Data Protection Regulation (2016)
(ref: https://idpc.org.mt/en/Pages/gdpr.aspx),
Computer misuse provisions of the Criminal Code
(ref: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8574),
and, the Professional Secrecy Act
(ref: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8844&l=1)

and that I will abide by all Government and Hospital regulations related to data, information and use of IT Systems and services (ref: http://ictpolicies.gov.mt , http://www.kura.gov.mt).

Full Name: Maria Gauci

ID/ Passport: 0352497M

Approval Date from DPO: 25th June 2021

Approval Date from CEO: 25th June 2021

Data Collection Period (From – To): August 2021 – October 2021

MDH Official Approval Names: Dr K Saliba, Mr W Busuttil, Ms C D'Amato

Name of Study / Audit: Developing a Venous Access Guideline in Malta – A Modified Delphi Study

Applicant's Signature: M Gauci
Maria Gauci (Jun 25, 2021 14:42 GMT+2)

L-Università ta' Malta

Maria Gauci <maria.gauci.15@um.edu.mt>

Request for Permission Form

Data Protection at MDH <datapro.mdh@gov.mt> 25 June 2021 at 12:22
To: Maria Gauci <maria.gauci.15@um.edu.mt>
Cc: Young Sharon at Health-MDH <sharon.young@gov.mt>, Data Protection Approval Form at Health-MDH <dpaform.mdh@gov.mt>

Dear Ms Gauci

On the basis of the documentation you submitted, from the MDH data protection point of view you have been cleared to proceed with your study titled ***Developing a Venous Access Guideline in Malta – A Modified Delphi Study*** provided that you obtain approval from MDH CEO (ceo.mdh@gov.mt - please provide the relevant documents including Mr Walter Busuttil's, Ms Carmen Damato's and Dr Kenneth Saliba's approval with this email).

-

- Your intermediaries to reach potential participants on your behalf are Mr Mark Pullicino Staff Nurse who works at the Medical Imaging Department and Ms Josianne Portelli Secretary at the Directorate of Nursing and Midwifery
- Your potential participants are Practice Nurses and Radiologists at MDH

-

Focus Group Interviews: Potential participants will be reached for invitation through Mr Mark Pullicino and Ms Josianne Portelli via email; if potential participants are interested they will communicate with you for an interview to take place.

-

All data stored must be anonymized and in no way should you retain any personal details you obtain from your research and these should be destroyed at the end of your study and /or if any of your participants decides to withdraw. Remember that participants reserve the right to be forgotten.

Anonymisation and Data minimisation

Participant consent forms must be separated from the answered questionnaires / interview answers at source meaning that there will be no correlation between one and the other that will indicate how participants replied.

-

ALL data presented to your supervisors / tutors or examiners or any other personnel from UOM or anyone else must be already anonymized; meaning that you must not divulge to anyone the identity of your participants and / or how they replied. If the Data Subject wants to enquire who accessed personal data for verification purposes, Dr Tartari Bonnici can be contacted through the details included with the information letter and consent form.

Consent Criteria

This clearance does not allow viewing of medical records nor access to Health Information Systems.

Since you haven't declared otherwise, all your participants must be reached and approached through email invitation by your declared intermediaries and not via telephone or any other means. You cannot be handed any contact details of potential participants, otherwise consent would be bypassed and breach GDPR.

Potential participants must be approached by your Mr Mark Pullicino and Ms Josianne Portelli for invitation and not directly by you. If potential participants are interested they will reach in.

Personal identifiable data such as signed consent forms or pseudonym lists are not to be sent via email (not even relayed to yourself), replicated and/or uploaded in any server, cloud storage, site or any other media since participants did not consent any service provider to store their personal identifiable data.

Audio recordings must be strictly accessed and listened only by you (not even by your tutors, supervisors or any personnel from UOM/ FHS) and that all data (including transcripts) presented to UOM / FHS must be completely anonymised. Such recordings are not to be sent via email, replicated and/or uploaded in any server, cloud storage, site or any other media. Audio recordings must be destroyed after the conversation will be transcribed or if the participant decides to withdraw from the study.

Online Questionnaire: Potential participants will be reached for invitation through Mr Mark Pullicino and Ms Josianne Portelli via email; if potential participants are interested they will reply the questionnaire.

All data will be provided to you already anonymized since MDH staff (Radiologists and Practice Nurses) will reply to the anonymous online questionnaire through the hyperlink.

-

Anonymisation

-

The identity of your participants cannot be divulged to anyone by your intermediaries not even to academic staff at the UOM.

Consent Criteria

For this study, consent is implied with affirmative action meaning that if participants click on the hyperlink, they will be consenting.

Since you haven't declared otherwise, all your participants must be reached and approached through email invitation by your declared intermediaries and not via telephone or any other means. You cannot be handed any contact details of potential participants, otherwise consent would be bypassed and breach GDPR.

Your intermediaries cannot feed Google Forms with a list of email addresses otherwise consent would be bypassed. Only a hyperlink through an invitation email can be used.

This clearance does not allow you to communicate with participants since these will only be approached by Mr Mark Pullicino and Ms Josianne Portelli through the gov email.

Your intermediaries must approach potential participants only through the gov mail since they will be representing MDH on your behalf. Personal email accounts must not be used.

This clearance does not cover your intermediaries to approach potential participants through social media or any other means. MDH clearance is applicable for MDH grounds and not for public domains or any other spheres that are not under MDH's responsibility.

Potential participants for this questionnaire are staff working at MDH (Radiologists and Practice Nurses); not staff or any other public servant who is not under the responsibility of MDH's Data Controller.

Clarifications

This clearance does not cover ethical approval.

All the documents presented to your potential participants must include UOM's logo.

Your submitted documentation must remain unchanged.

What was declared during this clearance process is what you will abide to.

You must abide with all the articles of the GDPR (EU) 2016 / 679 throughout the data collection process and thereafter.

You are requested to submit a copy of your findings to this office at the end of your study.

Please communicate with Mr Mark Pullicino and Ms Joslanne Portelli to present this clearance email.

To sign the data protection form, please contact Ms Aquilina through dpaform.mdh@gov.mt and provide the following:

1. *This clearance email in PDF format – to provide in PDF*
2. *CEO's approval in PDF format – pending*
3. *Name of the Chairpersons and Director who approved your study – Dr Kenneth Saliba, Mr Walter Busuttil and Ms Carmen Dar*
4. *State the period of data collection – August 2021 – October 2021*
5. *Title of your research - Developing a Venous Access Guideline in Malta – A Modified Delphi Study*
6. *Your ID Number - pending*

NB: you must sign this form before you start

In summary – next step

1. Approval from MDH CEO through ceo.mdh@gov.mt
2. Sign the Data Protection form at Ms Graziella Aquilina through dpaform.mdh@gov.mt ; please provide her the above six points

Regards

Simon Caruana

Senior Manager (Compliance)

SPTAR MATER DEI

Mater Dei Hospital, Triq id-Donaturi tad-Demm, l-Imsida, Malta MSD 2090 | Tel +356 2545 0000 | https://deputyprimeminister.gov.mt/en/MDH/Pages/Home.aspx | https://www.facebook.com/materdeihospital/

Appendix L – Permission from the Director of Nursing Services

L-Università ta' Malta

Date Tuesday 22nd June 2021

Request for permission to conduct research in Mater Dei Hospital.

Dear Ms. D'Amato,

My name is Maria Gauci and I am a student at the University of Malta, presently reading for a Master of Science in Nursing (by Taught and Research). As part of my course requirements I am conducting a research study entitled, **"Developing a Venous Access Guideline in Malta - A Modified Delphi Study"**. This aims to develop a local venous access guideline which provides nurses and physicians with guidance on how to choose the best type of venous access device for their patients based on their needs. The research will be conducted in four stages; Stage 1: A scoping literature review of the evidence that is available to date on the topic of interest, Stage 2: Developing a prototype guideline based on the current evidence, Stage 3: A Modified Delphi Approach using a focus group discussion (approximate duration of 1 hour) amongst participants to reach consensus on the proposed prototype guideline from all experts invited to participate in this study, Stage 4: A guideline assessment tool and guideline will be distributed for a final Delphi round to each individual participant to assess the quality of the finalized guideline. Participants will include Interventional Consultant Radiologists, Radiology Trainees, Infection Prevention and Control Practice Nurses and Vascular Access Nurses.

This project is being conducted under the supervision of Dr. Ermira Tartari Bonnici, Department of Nursing, Faculty of Health Sciences.

I am hereby seeking your permission to recruit Infection Prevention and Control Practice Nurses and Vascular Access Nurses for this study.

Participation in this study is completely voluntary and participants are free to accept or refuse to take part without giving a reason. As participants, they have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning them to be erased. Once the study is completed and the results are published, the data will be retained in anonymous form. Any personal details will be destroyed.

Furthermore, withdrawal from the study will not have any negative repercussions on the participants and any data collected will be erased. Data will be stored anonymously if it is

impossible to delete (e.g. if it has already been anonymised). I can assure you that confidentiality will be maintained throughout the study and that participants' identity and personal information will not be revealed in any publications, reports or presentations arising from this research. All data collected will be pseudonymised meaning that the transcripts will be assigned codes and that this data will be stored securely and separately from any codes and personal data. This data may only be accessed by the researcher. The academic supervisor and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes. The coded audio-recordings, and transcripts will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard.

Should you require further information, please do not hesitate to contact me or my supervisor; both our contact details are provided below.

Thank you for your kind consideration of this request.

Yours Sincerely,

M. Gauci

Maria Gauci

Researcher

Contact on 79580034 or by e-mail
maria.gauci.15@um.edu.mt]

Dr. Ermira Tartari Bonnici

Research Supervisor

I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I give permission to proceed with the study.

Name & Surname CD'Amato

Signature: Ms. Carmen D'amato
Director Nursing & Midwifery Services
Mater Dei Hospital
Tel. 25454202

Date: _____

Appendix M – Permission from the Chief Nursing Manager in MDH

L-Università ta' Malta

Date Tuesday 22nd June 2021

Request for permission to conduct research in Mater Dei Hospital.

Dear Mr. Cini,

My name is Maria Gauci and I am a student at the University of Malta, presently reading for a Master of Science in Nursing (by Taught and Research). As part of my course requirements I am conducting a research study entitled, **"Developing a Venous Access Guideline in Malta – A Modified Delphi Study"**. This aims to develop a local venous access guideline which provides nurses and physicians with guidance on how to choose the best type of venous access device for their patients based on their needs. The research will be conducted in four stages; Stage 1: A scoping literature review of the evidence that is available to date on the topic of interest, Stage 2: Developing a prototype guideline based on the current evidence, Stage 3: A Modified Delphi Approach using a focus group discussion (approximate duration of 1 hour) amongst participants to reach consensus on the proposed prototype guideline from all experts invited to participate in this study, Stage 4: A guideline assessment tool and guideline will be distributed for a final Delphi round to each individual participant to assess the quality of the finalized guideline. Participants will include Interventional Consultant Radiologists, Radiology Trainees, Infection Prevention and Control Practice Nurses and Vascular Access Nurses.

This project is being conducted under the supervision of Dr. Ermira Tartari Bonnici, Department of Nursing, Faculty of Health Sciences.

I am hereby seeking your permission to recruit Infection Prevention and Control Practice Nurses and Vascular Access Nurses for this study.

Participation in this study is completely voluntary and participants are free to accept or refuse to take part without giving a reason. As participants, they have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning them to be erased. Once the study is completed and the results are published, the data will be retained in anonymous form. Any personal details will be destroyed.

impossible to delete (e.g. if it has already been anonymised). I can assure you that confidentiality will be maintained throughout the study and that participants' identity and personal information will not be revealed in any publications, reports or presentations arising from this research. All data collected will be pseudonymised meaning that the transcripts will be assigned codes and that this data will be stored securely and separately from any codes and personal data. This data may only be accessed by the researcher. The academic supervisor and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes. The coded audio-recordings, and transcripts will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard.

Should you require further information, please do not hesitate to contact me or my supervisor; both our contact details are provided below.

Thank you for your kind consideration of this request.

Yours Sincerely,

M. Gauci

Maria Gauci

Researcher

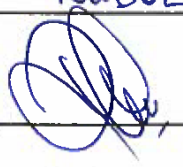
Contact on 79580034 or by e-mail
maria.gauci.15@um.edu.mt]

Dr. Ermira Tartari Bonnici

Research Supervisor

I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I give permission to proceed with the study.

Name & Surname RUDOLPH CINI

Signature: 

Mr. Rudolph Cini
Chief Nursing Manager
Mater Dei Hospital

Date: 23/6/21

Appendix N – Permission from the Head of the Department of Infection Control

L-Università ta' Malta

Date Tuesday 22nd June 2021

Request for permission to conduct research in Mater Dei Hospital.

Dear Prof. Borg,

My name is Maria Gauci and I am a student at the University of Malta, presently reading for a Master of Science in Nursing (by Taught and Research). As part of my course requirements I am conducting a research study entitled, **"Developing a Venous Access Guideline in Malta – A Modified Delphi Study"**. This aims to develop a local venous access guideline which provides nurses and physicians with guidance on how to choose the best type of venous access device for their patients based on their needs. The research will be conducted in four stages; Stage 1: A scoping literature review of the evidence that is available to date on the topic of interest, Stage 2: Developing a prototype guideline based on the current evidence, Stage 3: A Modified Delphi Approach using a focus group discussion (approximate duration of 1 hour) amongst participants to reach consensus on the proposed prototype guideline from all experts invited to participate in this study, Stage 4: A guideline assessment tool and guideline will be distributed for a final Delphi round to each individual participant to assess the quality of the finalized guideline. Participants will include Interventional Consultant Radiologists, Radiology Trainees, Infection Prevention and Control Practice Nurses and Vascular Access Nurses.

This project is being conducted under the supervision of Dr. Ermira Tartari Bonnici, Department of Nursing, Faculty of Health Sciences.

I am hereby seeking your permission to recruit Infection Prevention and Control doctor/s and Infection Prevention and Control Practice Nurses as a part of my study.

Participation in this study is completely voluntary and participants are free to accept or refuse to take part without giving a reason. As participants, they have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning them to be erased. Once the study is completed and the results are published, the data will be retained in anonymous form. Any personal details will be destroyed.

Furthermore, withdrawal from the study will not have any negative repercussions on the participants and any data collected will be erased. Data will be stored anonymously if it is

impossible to delete (e.g. if it has already been anonymised). I can assure you that confidentiality will be maintained throughout the study and that participants' identity and personal information will not be revealed in any publications, reports or presentations arising from this research. All data collected will be pseudonymised meaning that the transcripts will be assigned codes and that this data will be stored securely and separately from any codes and personal data. This data may only be accessed by the researcher. The academic supervisor and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes. The coded audio-recordings, and transcripts will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard.

Should you require further information, please do not hesitate to contact me or my supervisor; both our contact details are provided below.

Thank you for your kind consideration of this request.

Yours Sincerely,

M. Gauci

Maria Gauci

Researcher

Contact on 79580034 or by e-mail
maria.gauci.15@um.edu.mt]

Dr. Ermira Tartari Bonnici

Research Supervisor

I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I give permission to proceed with the study.

Name & Surname _____

Prof. Michael A. Borg
Head: Infection Control Department
Mater Dei Hospital

Signature: _____

Date: 23/6/2021

Appendix O – UREC and FREC Submission

L-Università ta' Malta

ETHICS & DATA PROTECTION

PART 1: APPLICANT AND PROJECT DETAILS

1. Name and surname: Maria Gauci
Email Address: maria.gauci.15@um.edu.mt
2. Applicant status: UM student
3. Faculty: Health Sciences
4. Department: Nursing

If applicable

5. Principal supervisor's name: Dr. Ermira Tartari Bonnici
6. Co-supervisor's name:
7. Name of Degree and Study-unit code: Master of Science (by Taught and Research) in Nursing. NUR5020
8. Student number: 0352497M

9. Title of research project: Developing a Venous Access Guideline in Malta – A Modified Delphi Study
10. Research question/statement & method: Research Problem: There are no guidelines available locally to indicate which patients should be referred for which venous device. The introduction of such guideline aims to provide nurses and physicians with guidance on how to choose the best type of vascular access device for their patients, increasing the reliability and longevity of the device whilst improving patient comfort by limiting complications

Research Question: How can we formulate a venous access guideline in Malta?

Subjects: Subjects will be recruited through a non-probabilistic, purposeful sample and shall include intervention consultant radiologists and radiology trainees who have been providing a venous access service for at least two years, Infection Prevention and Control (IPC) consultant, IPC Practice Nurses and Venous Access Practice Nurses. An invitation to participate along with an information letter and consent form will be sent out to all eligible subjects by email through Mr. Rudolph Cini's office (Chief Nursing Manager) for IPC consultant, IPC Practice Nurses and Venous Access Practice Nurses and Mr. Mark Pullicino (Charge Nurse in Angiosuite Unit - Medical Imaging Department) for consultant interventional radiologists and radiology trainees. A reply to the invitation will imply consent to participate.

The guideline will include the following venous devices: peripheral cannulas, Midlines, central venous catheters, peripherally inserted central catheters (PICC lines), Hickmann lines and totally implantable devices (Portacath).

Methodology: An adopted approach of the WHO Handbook for Guideline Development (2014) will be used to develop a guideline for venous access in Malta. The development of the guideline will follow 4 phases.

Phase 1: A scoping literature review of available international guidelines and recommendations will be carried out. Data sources used will include HyDi search engine, databases accessed through HyDi and non-profit and Governmental websites. Data analysis will be done through a narrative analysis.

UNIQUE FORM ID: 9195_28262021_Maria Gauci

No self-assessment issues ticked. Submitting to FREC for records.

Phase 2: A prototype guideline based on the data gained in phase 1, will be formulated.
Phase 3: The prototype guideline will be distributed to the expert panel using a Modified Delphi method; aiming to potentially reach a formal consensus through a focus group discussion using a pre-formulated discussion guide and cues. A second researcher will be present during the discussion to take notes. Primary data gained though discussion will be analysed using thematic analysis and any outcomes proposing changes to the prototype guideline will be made.
Phase 4: The finalised version of the guideline along with a guideline assessment tool will be distributed to each individual in the expert panel. This will collect expert opinion on the quality of the finalised guideline. This will help the author to provide recommendations for future guideline amendments.
11. Collection of primary data from human participants?
Yes/Unsure (PLEASE ANSWER NEXT QUESTION)
12. If applicable, explain: 6 to 10 healthcare professionals will be recruited using purposive sampling. These will include radiology trainees and intervention consultant radiologists who have been providing a venous access service for at least 1 year, infection prevention and control practice nurses and vascular access practice nurses. Participants will participate in a focus group discussion with the aim to reach consensus on the proposed prototype guideline from all experts invited to participate in this study. This focus group discussion will take approximately 1 hour. In a second data collection round, the same participants will be asked to participate in an online questionnaire which will be sent out individually to all participants by intermediaries. This AGREE II questionnaire is a validated questionnaire which will assess the quality of the finalised guideline and consists of 25 Likert scale type questions, which should take approximately 25 minutes to be completed.

PART 2: SELF-ASSESSMENT

Human Participants

1. Risk of harm to participants:
2. Physical intervention:
3. Vulnerable participants:
4. Identifiable participants:
5. Special Categories of Personal Data (SCPD):
6. Human tissue/samples:
7. Withheld info assent/consent:
8. Opt-out consent/assent:
9. Deception in data generation:
10. Incidental findings:

Unpublished secondary data

11. Was the data collected from human participants?
12. Was the data collected from animals?
13. Is written permission from the data controller still to be obtained?

Animals

14. Live animals out of habitat:

UNIQUE FORM ID: 9195_28262021_Maria Gauci

No self-assessment issues ticked. Submitting to FREC for records.

15. Live animals, risk of harm:
16. Dead animals, illegal:

General considerations

17. Cooperating institution:
18. Risk to researcher/s:
19. Risk to environment:
20. Commercial sensitivity
21. Other potential risks:

Self-assessment outcome: No self-assessment issues ticked. Submitting to FREC for records.

PART 3: DETAILED ASSESSMENT

1. Risk of harm to participants:
2. Physical intervention on participants:
3. Vulnerable participants:
4. Identifiable participants:
5. Special Categories of Personal Data (sensitive personal data):
6. Collection of human tissue/samples:
7. Withholding information at consent/assent:
8. Opt-out consent/assent:
9. Deception in data generation:
10. Incidental findings:
11. Unpublished secondary data - human participants :
12. Unpublished secondary data - animals:
13. Unpublished secondary data - no written permission from data controller:
14. Lasting harm to animals out of natural habitat:
15. Risk of harm to live animals :
16. Use of non legal animals/tissue:
17. Permission from cooperating institution:
18. Risk to researcher/team:
19. Risk of harm to environment:
20. Commercial sensitivity:
21. Other issues
    - 21a. Dual use and/or misuse:
    - 21b. Conflict of Interest:
    - 21c. Dual role:
    - 21d. Use research tools:
    - 21e. Collaboration/data/material collection in low/lower-middle income country:
    - 21f. Import/export of records/data/materials/specimens:
    - 21g. Harvest of data from social media:
    - 21h. Other considerations:

UNIQUE FORM ID: 9195_28262021_Maria Gauci

No self-assessment issues ticked. Submitting to FREC for records.

PART 4: SUBMISSION

1. Which FREC are you submitting to? : Health Sciences
2. Attachments: Information and recruitment letter*, Consent forms (adult participants)*, Data collection tools (interview questions, questionnaire etc.), Licence/permission to use research tools (e.g. constructs/tests), Letter granting institutional approval for access to participants, Letter granting institutional approval from person directly responsible for participants, Other (please specify in remarks below)
3. Cover note for FREC : Kindly also find attached Intermediary letters from Mr Mark Pullicino and Ms Josianne Portelli. Permission from data protection officer, Prof. Michael Borg, Mr Walter Busuttil and Ms Carmen D'Amato
4. Declarations: I hereby confirm having read the University of Malta Research Code of Practice and the University of Malta Research Ethics Review Procedures., I hereby confirm that the answers to the questions above reflect the contents of the research proposal and that the information provided above is truthful., I hereby give consent to the University Research Ethics Committee to process my personal data for the purpose of evaluating my request, audit and other matters related to this application. I understand that I have a right of access to my personal data and to obtain the rectification, erasure or restriction of processing in accordance with data protection law and in particular the General Data Protection Regulation (EU 2016/679, repealing Directive 95/46/EC) and national legislation that implements and further specifies the relevant provisions of said Regulation.
5. Applicant Signature: Maria Gauci
6. Date of submission: 28262021
7. If applicable data collection start date: 15092021
8. E-mail address (Applicant): maria.gauci.15@um.edu.mt
9. E-mail address (Principal supervisor): ermira-tartari.bonnici@um.edu.mt
10. Conclude: Proceed to Submission

Research Ethics HEALTHSCI <research-ethics.healthsci@um.edu.mt> 7 Jul 2021, 09:26

to Rita, me, Ermira

Dear Maria,

Your REDP Form and supervisor's endorsement were received with thanks.

As indicated in the UM Research Ethics Review Procedures, REDP forms having no self-assessment issues are kept for record and audit purposes and the **research may commence.**

Please note that FREC will not issue any form of approval as the responsibility for the self-assessment part lies exclusively with the principal investigator (PI).

Sincere Regards,
Christabel

Christabel Vella
FREC Secretary

University of Malta
Faculty of Health Sciences
Room 76, Block A, Level 1
Mater Dei Hospital

Appendix P – Participants' Information Sheet

L-Università ta' Malta

Participants` Information Sheet

Dear Participant,

My name is Maria Gauci and I am currently reading for a Master of Science in Nursing (by Taught and Research) at the University of Malta. As part of my course requirements I am conducting a research study entitled, **"Developing a Venous Access Guideline in Malta – A Modified Delphi Study"**.The aim of this study is to develop a venous access guideline which provides nurses and physicians with guidance on how to choose the best type of venous access device for their patients based on their needs.This will be done in four stages; Stage 1: A scoping literature review by the researcher of available venous access guidelines, Stage 2: Developing a prototype guideline, Stage 3: A Modified Delphi Approach using a focus group discussion amongst participants to collect data on how to improve the prototype guideline, Stage 4: The finalized guideline along with a guideline assessment tool will be distributed to each individual participant to assess the quality of the finalized guideline. Your participation in this study would help us formulate a venous access guideline. Furthermore, all data collected from this research shall be used solely for the purpose of this study.

You are being invited to participate in a focus group discussion exploring your expertise on venous access devices. The discussion will take approximately 1 hour. In stage 4, an online questionnaire assessing the quality of the finalized guideline will be sent out individually. This will consist of 25 Likert scale type questions, which should take approximately 25 minutes to complete. Throughout the duration of the study, you are not obliged to answer all the questions and may withdraw from the study at any time without giving a reason. Furthermore, withdrawal from the study will not have any negative repercussions on you and any data collected will be erased. Data will be stored anonymously if it is impossible to delete (e.g. if it has already been anonymised). Unless you have any objections, this discussion will be audio-recorded. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be revealed in any publications, reports or presentations arising from this research. All data collected will be pseudonymised meaning that

the transcripts will be assigned codes and that this data will be stored securely and separately from any codes and personal data. This data may only be accessed by the researcher. The academic supervisor and the examiners will typically have access to coded data only.There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes. If you want to enquire who accessed your data, kindly contact Dr. Ermira Tartari Bonnici, Lecturer at the University of Malta and Supervisor for this study on ermira-tartari.bonnici@um.edu.mt.The coded audio-recordings, and transcripts will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard.

Participation in this study is completely voluntary and you are free to accept or refuse to take part without giving a reason. A copy of the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning you to be erased. Once the study is completed and the results are published, the data will be retained in anonymous form. Any personal details will be destroyed.

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me 79580034 or by e-mail maria.gauci.15@um.edu.mtor my supervisor Dr. Ermira Tartari Bonnici on ermira-tartari.bonnici@um.edu.mt or 23401168.

Yours Sincerely,

M. Gauci

Maria Gauci

Researcher

Dr. Ermira Tartari Bonnici

Research Supervisor

Any material in hard-copy form will be placed in a locked cupboard and kept until results are published.

8. I am aware that my identity and personal information will not be revealed in any publications, reports or presentations arising from this research.
9. I also understand that I am free to accept, refuse or stop participation at any time without giving any reason. This will have no negative repercussions on myself and that any data collected from me will be erased. Data will be stored anonymously if it is impossible to delete (e.g. if it has already been anonymised).
10. I also understand that my contribution will serve to help formulate a local venous access guideline.
11. I understand that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.
12. I also understand that once the study is completed and results are published the data will be retained in anonymous form. Any personal details will be destroyed.
13. I will be provided with a copy of the information letter and consent form for future reference.
14. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: _____

Signature: _____

Date: _____

Yours Sincerely,

Maria Gauci
Researcher
Contact on 79580034 or by e-mail
maria.gauci.15@um.edu.mt

Dr. Ermira Tartari Bonnici
Research Supervisor
Contact on23401168 or by e-mail
ermira-tartari.bonnici@um.edu.mt

Appendix Q – Intermediaries Consent Forms

L-Università ta' Malta

Dear Mr.Pullicino,

My name is Maria Gauci and I am a student at the University of Malta, presently reading for a Master of Science in Nursing (by Taught and Research). As part of my course requirements I am conducting a research study entitled, "Developing a Venous Access Guideline in Malta – A Modified Delphi Study". This aims to develop a local venous access guideline which provides nurses and physicians with guidance on how to choose the best type of venous access device for their patients based on their needs. The research will be conducted in four stages; Stage 1: A scoping literature review of the evidence that is available to date on the topic of interest, Stage 2: Developing a prototype guideline based on the current evidence, Stage 3: A Modified Delphi Approach using a focus group discussion (approximate duration of 1 hour) amongst participants to reach consensus on the proposed prototype guideline from all experts invited to participate in this study, Stage 4: A guideline assessment tool and guideline will be distributed for a final Delphi round to each individual participant to assess the quality of the finalized guideline. Participants will include Interventional Consultant Radiologists, Radiology Trainees, Infection Prevention and Control Practice Nurses and Vascular Access Practice Nurses.

This project is being conducted under the supervision of Dr. Ermira Tartari Bonnici, lecturer, Department of Nursing, Faculty of Health Sciences.

I am hereby seeking your permission for you to act as an intermediary to send out an email invitation to all eligible Interventional Radiology Consultants and Radiology Trainees in conformity with Data Protection Policy.

Yours Sincerely,

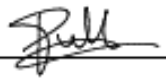
M. Gauci

Maria Gauci
Researcher
Contact: 79580034
maria.gauci.15@um.edu.mt

Dr.ErmiraTaratriBonnici
Research Supervisor
Contact: 99873798
ermira-tartari.bonnici@um.edu.mt

I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I give permission to proceed with the study.

Name & Surname Mark Pullicino

Signature: 

Date: 24 June, 2021

L-Università ta' Malta

Dear Ms. Portelli,

My name is Maria Gauci and I am a student at the University of Malta, presently reading for a Master of Science in Nursing (by Taught and Research). As part of my course requirements I am conducting a research study entitled, "Developing a Venous Access Guideline in Malta – A Modified Delphi Study". This aims to develop a local venous access guideline which provides nurses and physicians with guidance on how to choose the best type of venous access device for their patients based on their needs. The research will be conducted in four stages; Stage 1: A scoping literature review of the evidence that is available to date on the topic of interest, Stage 2: Developing a prototype guideline based on the current evidence, Stage 3: A Modified Delphi Approach using a focus group discussion (approximate duration of 1 hour) amongst participants to reach consensus on the proposed prototype guideline from all experts invited to participate in this study, Stage 4: A guideline assessment tool and guideline will be distributed for a final Delphi round to each individual participant to assess the quality of the finalized guideline. Participants will include Interventional Consultant Radiologists, Radiology Trainees, Infection Prevention and Control Practice Nurses and Vascular Access Practice Nurses.

This project is being conducted under the supervision of Dr.Ermira Tartari Bonnici, lecturer, Department of Nursing, Faculty of Health Sciences.

I am hereby seeking your permission for you to act as an intermediary to send out an email invitation to all eligible practice nurses in conformity with Data Protection Policy.

Yours Sincerely,

M. Gauci

Maria Gauci
Researcher
Contact: 79580034
maria.gauci.15@um.edu.mt

Dr.ErmiraTaratriBonnici
Research Supervisor
Contact: 99873798
ermira-tartari.bonnici@um.edu.mt

I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I give permission to proceed with the study.

Name & Surname Josanne Postelli

Signature: J. Postelli

Date: 25/06/21

Appendix R – AGREE II Permission

AGREE Enterprise Research Office
McMaster University – Juravinski Hospital
G Wing, 2nd Floor
711 Concession Street
Hamilton, ON, L8V 1C3
Phone: 905-527-4322 ext. 42851
Fax: 905-526-6775

Jun 21, 2021

To Maria Gauci,

We, the AGREE Enterprise Research Office, give permission to ***Maria Gauci*** to use the AGREE II tool, in the project "**Developing a Venous Access Guideline in Malta – A Modified Delphi Study**".

This permission provided that the authors properly cite the AGREE II tool in the mentioned article.

If any clarification of the conditions is needed, please contact the AGREE office at agree@mcmaster.ca

Sincerely,

Iván D. Flórez MD, MSc
Leader
AGREE Enterprise Research Office
McMaster University
Hamilton, Ontario, Canada
www.agreetrust.org

Appendix S – Finalised Guideline

Venous Access Guideline for Acute and Non-Acute Care Settings

Last Updated: May 2022

List of Abbreviations

CASP	Critical Appraisal Skills Programme
FGD	Focus Group Discussion
HyDi	Hybrid Discovery
IV	Intravenous
M.Sc.	Master of Science
MDH	Mater Dei Hospital
MeSH	Medical Subject Headings
MID	Medical Imaging Department
PDN	Practice Development Nurse
Ph.D	Doctor of Philosophy
PICC	Peripherally Inserted Central Catheter
PICO	Population, Intervention, Comparison, Outcome
PIVC	Peripheral Intravenous Cannula
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
RCT	Randomised Controlled Trial
SAMOC	Sir Anthony Mamo Oncology Centre
SR	Systematic Review
VAD	Venous Access Device
WHO	World Health Organisation

1.0 Aim

This guideline aims to provide nurses and physicians with evidence-based recommendations on how to choose the best venous access device (VAD) for non-critically ill patients requiring venous access in both acute and non-acute care settings in order to ensure good quality care whilst minimising the risk of complications and improving patient safety. These guidelines include recommendations on the following VADs:

- Peripheral Intravenous Cannulas (PIVC)
- Midlines
- Peripherally Inserted Central Catheters (PICC)
- Portacath devices
- Hickman lines

2.0 Health Question

After identifying the aims and objectives of this dissertation, the research question was formulated. The PICO Framework was used to identify the main elements; Population: Adult patients (>18 years) in acute, non-acute or outpatients care, Intervention: venous access, Outcome: A local evidence-based VA guideline. This led to the development of the PICO question: 'How to develop a local evidence-based venous access guideline for adults (>18 years) who are in acute, non-acute or outpatient care settings?'

3.0 Target Users

These guidelines are needed by nurses and physicians when trying to identify the best VAD for their patients based on the type and duration of the IV infusion and who currently have no guidelines available to indicate when patients are to be referred and which patients should be referred for which device. Therefore, the guidelines will be recommended for use to inform policy and reform the service organisation.

4.0 Guideline Development Process

The guideline development process followed a thorough systematic process based on the World Health Organisation (WHO) Handbook for Guideline Development (2014) (WHO, 2014). The process consisted of five phases:

- **Phase 1:** Mapping the literature - Two ScRs of the most recent evidence-based literature and available guidelines on the topic.
- **Phase 2:** Developing the prototype guideline- The data collected from both ScRs in Phase 1 was used to develop a prototype guideline.
- **Phase 3:** Refining the prototype guideline - A two-round modified Delphi approach was taken in which a FGD was held to discuss the prototype guideline with members of the expert panel and data was analysed using Thematic Analysis.
- **Phase 4:** Developing the finalised guideline - The finalised guideline was formulated based on the results from the FGD.
- **Phase 5:** Guideline assessment - The updated guideline along with a guideline assessment tool was sent to all participating experts for the second round of the modified Delphi method. The data on the quality of the guideline was analysed and any recommendations to update the finalised guideline were considered.

5.0 Main Key Terms and Synonyms

The main key concepts were identified through the research statement being studied: 'Developing a Venous Access Guideline in Malta – A Modified Delphi Study'. These were translated into key words and their respective synonyms were established through personal communication with experts in the field, the thesaurus, Medical Subject Headings (MeSH) generator, through personal clinical experience and through reading of research studies (Tables 1 and 2).

Table 1: *The Main Key Terms and Synonyms to Identify Relevant Articles*

Key Term	Synonym
venous access	vascular access
peripheral intravenous cannula	PIVC, peripheral cannula, PIVC, peripheral line
midline	*N/A*
peripherally inserted central catheter	peripheral line, PICC,
portacath	port-a-cath, port, totally implanted,
hickman line	*N/A*

**N/A Not Available*

Table 2: *The Main Key Terms and Synonyms to Identify Relevant Guidelines*

Key Term	Synonyms
venous access	vascular access
guideline	protocol, algorithm, pathway, standard operating procedure, SOP

6.0 Formulating Search Phrases

Search phrases were formulated by combining the key terms and synonyms using Boolean operators "AND" and "OR". The former operator is used to find articles/guidelines including all key terms in the search term whilst the latter will be used to generate results which include at least one of the key terms. Once all 5 terms were formulated, the asterisk symbol "*" was used for the Truncation of all terms (Tables 3 and 4).

Table 3: *Formulating Search Phrases using Boolean operators and Truncation to Find Relevant Articles*

Phrase	Main Key Terms/Synonyms/MeSH	Search Phrase with Boolean Operators and Truncation
1	venous access, vascular access, peripheral intravenous cannula, PIVC, peripheral line, PIVC, peripheral cannula, use, duration	(venous access) OR (vascular access) AND (peripheral intravenous cannula*) OR (PIVC) OR (peripheral line*) OR (PIVC*) OR (peripheral cannula*) AND (use) or (duration)
2	venous access, vascular access, midline, use, duration	(venous access) OR (vascular access) AND (midline*) AND (duration) OR (use)
3	venous access, vascular access, peripherally inserted central catheter, PICC, peripheral line, use, duration	(venous access) OR (vascular access) AND (peripherally inserted central catheter*) OR (PICC) OR (peripheral line*) AND (duration) OR (use)
4	venous access, vascular access, portacath, port-a-cath, port, totally implanted, use, duration	(venous access) OR (vascular access) AND (portacath*) OR (port-a-cath) OR (port*) OR (totally implant*) AND (use*) OR (duration)
5	venous access, vascular access, hickman, use, duration	(venous access) OR (vascular access) AND (hickman*) AND (use) OR (duration)

Table 4: *Formulating Search Phrases Using Boolean Operators and Truncation to Find Relevant Guidelines*

Main Key Terms/Synonyms/MeSH	Search Phrase with Boolean Operators and Truncation
venous access, vascular access, guideline, protocol, pathway, algorithm, standard operating procedure, SOP	(venous access*) OR (vascular access) AND (guideline*) OR (protocol) OR (pathway*) OR (algorithm) OR (standard operating procedure*) OR (SOP)

7.0 Study Selection Criteria

For a more comprehensive search, a set of inclusion and exclusion criteria were established before initiating the search process (Table 2). The articles and guidelines included were peer-reviewed, published/translated in English/Maltese and performed on human adults (>18years) from any ethnic group. No exclusion on the year of publication was done. The guidelines/articles needed to include information on the insertion, duration, purpose and/or maintenance on at least one of the following: PIVCs, PICCs, midlines, portacaths and/or Hickman with the following study design: meta-analyses, systematic review (SR), randomised/non-randomised controlled trial (RCT) or observational studies. The guidelines included were accepted on the basis of their systematic methodology used to search for evidence: the search sources and search strategy, the tool/s used for classifying levels of evidence and the method used for formulating the recommendations. Exclusion on the year of publication was made for guidelines published before 2014.

8.0 Search Trail for Articles and Guidelines

This section provides a detailed description of the search strategy that was followed to identify the main key articles and guidelines using Google Scholar, Hybrid Discovery (HyDi), BMJ Journals, PubMed, EBSCO Host and ProQuest. The respective filters were selected according to the inclusion and exclusion criteria set for this study.

8. 1 Data Management for Relevant Articles

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) (Moher et al., 2009) was followed. A total of 543,707,777 articles were retrieved, which were filtered down to 19,426,849 results. These were imported to RefWorks and duplicate results were removed (n=19,223,689). A total of 203,160 records were screened by their title and 198,556 articles were excluded. 4,604 full-text articles and their reference lists were read and 4,169 articles were eliminated. A total of 6 articles were considered as being eligible for the review.

8.2 Data Management for Relevant Guidelines

The guidelines identified through the search strategy (n=335,235) were imported to RefWorks. 298,358 duplicate guidelines were removed. The titles of the remaining guidelines (n=36,877) were read and compared against the inclusion and exclusion criteria. Any papers which did not meet these criteria were eliminated (n=34,965). After reading all titles, the

abstracts of the remaining articles were read and after checking them against the inclusion and exclusion criteria, 98 papers were left. The full text and the reference lists of the remaining 98 papers were screened. 21 possible eligible papers were found through the skimming of their reference lists. Finally, after comparing them against the inclusion and exclusion criteria of this scoping review, 8 guidelines were considered to be eligible.

8.3 Data Collection Process

The selected articles and guidelines were read and data was extracted. The outcomes recorded were those which provide information on PIVC, midlines, PICCs, portacaths and Hickman lines. This was done using a pre-structured template for data collection on Excel Spreadsheet.

9.0 Strengths and Limitations of the Body

9.1 Critical Appraisal of the Selected Articles and Guidelines

A total of 6 articles (3 RCTs, 1 SR, 1 cross-sectional study and 1 cohort study) and 8 guidelines were identified. The RCTs, cohort study and SR were critically appraised using the respective Critical Appraisal Skills Programme (CASP) Tool (Critical Appraisal Skills Programme, 2019). The cross-sectional study was appraised using the Joanna Briggs Critical Appraisal Tool (Joanna Briggs Institute, 2017). Guideline appraisal was done using the Advancing the Science of Practice Guidelines second edition (AGREE II) (Brouwers et al., 2010).

10.1 Developing the Prototype Guideline

Results from the scoping reviews were used to develop the prototype guideline. Since there is only one researcher in this study, consensus cannot be reached at this stage, therefore, the prototype guideline process was done by identifying the most common recommendations found through the scoping reviews, and used them as recommendations in the prototype guideline.

10.2 Modified Delphi Method

The modified Delphi method as suggested by the WHO handbook for guideline development (2014) was used to update the prototype guideline through the use of multiple rounds of data collection using the expertise of local field experts.

10.2.1 Data Collection

It was decided that since clear discussion among key experts on their personal experience of having met similar situations and having dealt with different outcomes in their professional working experience, face-to-face discussion for the first round of data collection as a part of the modified Delphi method was the best data collection instrument option.

10.2.2 Identifying the Expert Panel

The researcher identified the disciplines that have a professional interest in achieving the aim of this study and thus these were invited to the expert panel. Since this study aims to inform policy on the service provided in the Angiosuite Unit in MDH, radiology physicians were included. Infection Prevention and Control PDNs together with Venous Access PDNs can provide useful insight on the best VAD based on the duration of intravenous therapy backed by their expertise and experience in the field with using different VADs hence, these were also included in the study's population group. Therefore, for this dissertation, purposive sampling was used to identify the participants which formed the expert panel. The sample size was calculated to include between five to ten participants as suggested by Krueger and Casey (2014). In order to reduce bias, the eligibility criterion for participation was identified a priori.

For the purpose of this dissertation two intermediaries were asked to participate in this study. The intermediaries' responsibility was to contact the eligible experts through email and provide them with a brief explanation of the study. They also asked the participants if they were willing to participate in this study. A consent form indicating that they understood the purpose of this dissertation and their rights and responsibilities in the study was signed by all participants. Upon their acceptance to participate and signing of the consent form, the first data collection process was initiated.

10.2.3 Setting

The focus group discussion was carried out at the MID conference room. Refreshments were available and seating was arranged in a way that each individual was able to see the projector screen and all other participants clearly and comfortably. The FGD was held on the 9th December 2021 between 14:00 and 15:00.

10.2.4 Ethics Approval

The proposal was submitted to the Ethics Committee and the Data Protection Officer in MDH.

10.2.5 The Moderator and Moderator Assistant

The moderator was identified as the researcher carrying out this research. During the discussion, the moderator took field notes in which quotes, body language, new ideas, themes and key points were recorded. The whole FGD session was audio-recorded using the moderator's mobile phone and laptop computer and stored together with the coded transcripts on the moderator's personal computer in a password-protected file. This data is only accessible to the moderator. A moderator assistant previously identified as Dr. Ermira Tartari Bonnici, B.Sc. (Hons) (Melit.), M.Sc. HSM (Melit.), Ph.D. Global Health (Geneva) was assisting the moderator with the preparation of the room, setting up and operating recording equipment, welcoming participants, writing notes during the discussion, debriefing with the moderator and providing feedback.

10.3 Data Analysis of the Focus Group Discussion

The audio-recording was transcribed by the researcher the day after the discussion. This took the researcher a total of approximately 4 hours. The document was then printed and the author read the text several times whilst taking initial notes to familiarise herself with the text. It was decided that thematic analysis was the best way to analyse the data. This decision was based on the possibility of dividing wide emerging ideas/themes into smaller categories which could be analysed better and more systematically. These themes were mainly based on subjective information backed by participants' experience, opinion and expertise. Therefore, a semantic approach was taken rather than a latent one. Analysis was not deductive based on pre-formulated themes but rather an inductive approach by which themes were formed based on the data gathered from the transcript. Using thematic analysis, the transcript was read and common themes and patterns were identified and annotated/coded based on the concept of the research question being studied. Due to the nature of the data and information being gathered, a reflexive thematic analysis was used since this is a more flexible approach to coding as it allowed the researcher to change the codes at any point of the analysis process. Any emerging themes which had no relevance to the research question were discarded. The relevant emerging themes were then categorised into common themes (segmented). Four themes were identified: *Referring, Types of Lines, Complications and Removal.*

10.4 Formulating the Finalised Guideline

After the analysis was complete, the results from the FGD were used to update the prototype guideline and formulate the following finalised guideline.

Venous Access Guideline

Aim

This guideline aims to provide clinicians with evidence-based recommendations on how to choose the best venous access device (VAD) for non-critically ill adult patients (>18years) requiring venous access in the community, acute and/or non-acute care settings in order to ensure good quality care whilst minimising the risk of complications and improving patient safety. The recommendations were formulated through two scoping reviews of available literature and international guidelines, a focus group discussion (FGD) amongst local clinical experts in the field and a guideline assessment questionnaire. Recommendations will be based on two main criteria: (1) the expected duration of treatment and (2) the type of infusate being given. These guidelines include recommendations on the following VADs:

- Peripheral Intravenous Cannulas (PIVC)
- Midlines
- Peripherally Inserted Central Catheters (PICC)
- Portacath devices
- Hickman lines

Authors

This guideline was formulated by Ms. Maria Gauci – Staff Nurse working in the Angiosuite Unit, MDH as a part of a Master dissertation submitted to the University of Malta and supervised by Dr. Ermira Tartari Bonnici, B.Sc. (Hons) (Melit.), M.Sc. HM (Melit.), Ph.D. Global Health (Geneva). A group of clinical experts working as Infection Prevention and Control Practice Development Nurses (PDNs), Interventional Radiology Consultant and Physicians and Venous Access PDNs working in Mater Dei Hospital, Malta were also involved in the process of formulating these recommendations.

Target Population

These guidelines are targeted towards non-critically ill adult patients (>18years) requiring venous access in the community, acute and/or non-acute care settings (including Mater Dei Hospital, Sir Anthony Mamo Oncology Centre, Karin Grech Rehabilitation Hospital, outpatients and St. Vincent de Paul Residence) for the infusion of irritant/vesicant and/or non-irritant intravenous infusates/medications, blood-letting, chemotherapy infusion (for haematological and/or non-haematological/solid tumours) and total parenteral nutrition.

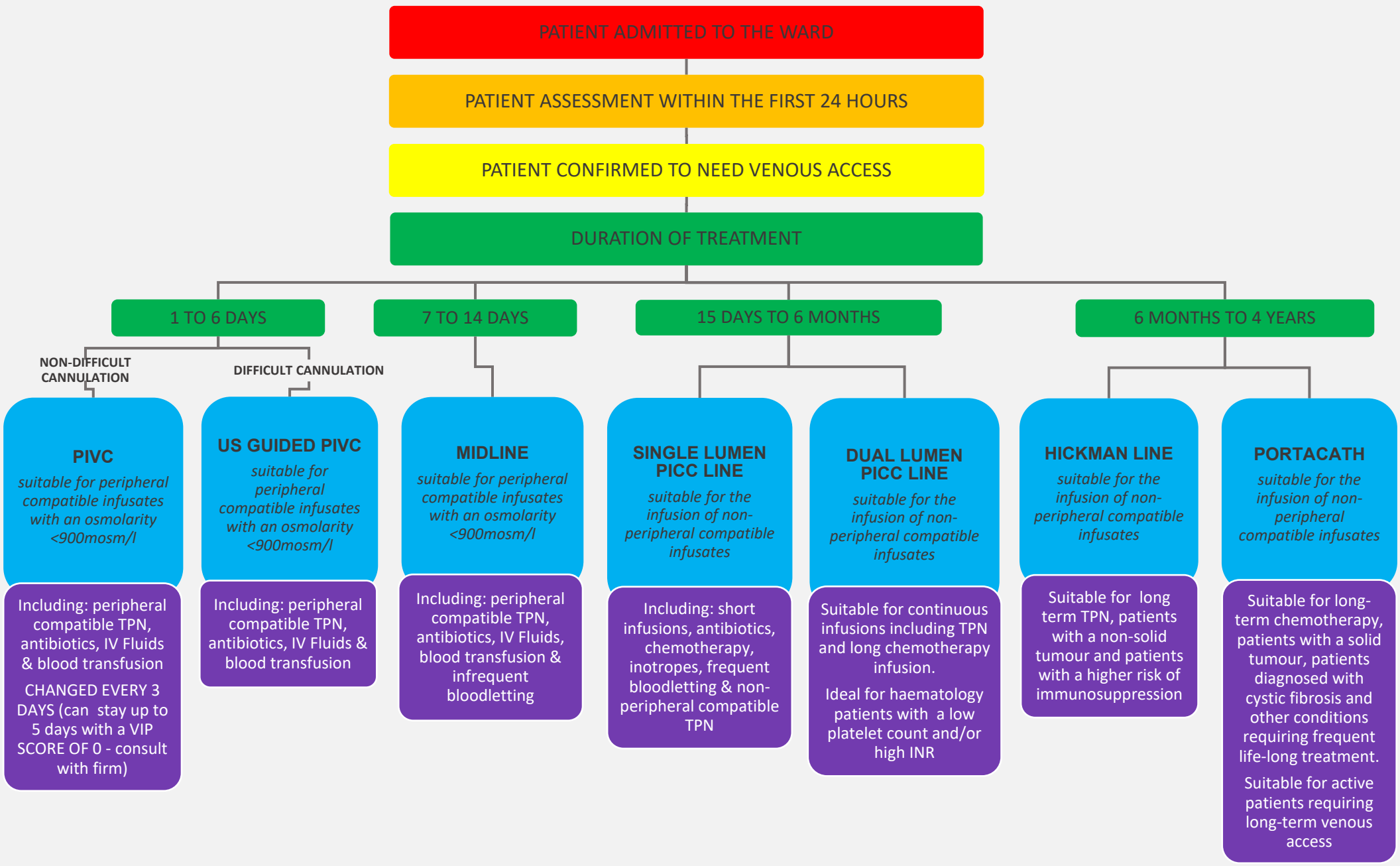
Intended Users

These guidelines aim to inform policy and provide comprehensive recommendations for nurses, physicians, healthcare providers, educators, policy-makers and health-service organisations that provide direct care to patients who are in acute/non-acute care settings and/or community care.

Referring Patients for a Venous Access Device Insertion

- Patients are to be assessed by the firm consultant within the first 24 hours of admission or prior to initiating any intravenous treatment. A risk evaluation and a peripheral vein assessment should be carried out before referring patients for a VAD insertion. When possible, patient preferences and lifestyle are considered.
- Once the need for a VAD is confirmed, follow the venous access algorithm to select the appropriate venous access device based on the type and duration of treatment.
- Contact the appropriate specialist to organise device insertion.

VENOUS ACCESS ALGORITHM



PIVC – Peripheral Intravenous Cannula, VIP – Visual Infusion Phlebitis, US – Ultrasound, PICC – Peripherally Inserted Central Catheter, INR – International Normalised Ratio

Device Maintenance

- The nurse caring for the patient has the responsibility to educate the patient, assess, maintain and document line care.
- In cases where patients are discharged home with the device, contact the respective Community Care Nursing Team.
- If any complication is suspected (including infection, line occlusion and thrombosis), do not remove the line and contact the firm or Venous Access PDNs immediately.

Line Removal

- Midlines and PICC lines can be removed on the ward by a nurse.
- Contact an interventional radiologist for the removal of Portacaths and Hickman Lines.

11.0 Updating the Guideline

The guideline will be reviewed and updated accordingly after 1 year.

12.0 Tools for Application

This guideline is planned to be introduced in MDH and SAMOC to update policy and be used as recommendations by nurses and physicians. Upon the introduction of this guideline, nurses and physicians need to have an easy access to the guideline. This can be done by presenting the guideline during workshops, uploading the guideline on KURA, printing the algorithm on wards and educating all healthcare staff by going around the wards to explain how and when this guideline is to be used. This guideline can also be presented to Charge Nurses and Nursing Managers who are in direct managerial positions in patient care. Education can be done by the Angiosuite Unit to referring physicians and nurses by introducing them to the algorithm, Venous Access PDNs and Infection Prevention and Control PDNs by direct monitoring and education on the wards.

13.0 Potential Barriers and Facilitators

- Since there are currently no guidelines on venous access in place, this is not simply an update of a guideline, but this needs to change the patient admission process and admission planning. Therefore there might be a resistance to change by referring physicians.
- Another potential barrier is that not all healthcare workers are comfortable with using all mentioned venous access devices. Therefore more training by the Venous Access PDNs needs to be held on the wards. However, this service is already being used to its full potential and other training programmes might need to be set up.
- With the introduction of these guidelines there will be an increase in workload on the Angiosuite Unit due to the increase in referrals. Therefore planning and discussion on setting up an outreach team who are trained to insert Ultrasound Guided Cannulas, midlines and PICC lines at the bedside need to be held before the introduction of this guideline in MDH.

14.0 Resource Implications

With the introduction of this guideline into practice, there will be an expected increase in the number of referrals for line insertion. This could potentially have two resource implications: i) human resources and ii) physical resources.

15.0 Monitoring and Auditing

Monitoring and auditing can be done by venous access PDNs and infection prevention and control PDNs by carrying out witness audits. These reports will be sent to the respective clinical and nursing stakeholders for the required actions. Such audits can also be done by the Angiosuite Unit by keeping record of the number of referrals and assessing them at 6 months and 1 year after introducing the guideline.

16.0 Funding and Conflict of Interest

This guideline received no funding and declares no conflicts of interests.

17.0 Plagiarism

These guidelines were done as a part of a dissertation submitted by the same author to the University of Malta as a part of a Master in Nursing by Taught and Research programme (2019-2022).

References

Alexandrou, E., Ramjan, L., Spencer, T., Frost, S., Salamonson, Y., Davidson, P., & Hillman, K. (2011). The use of midline catheters in the adult acute care setting – clinical implications and recommendations for practice. *Journal of the Association For Vascular Access*, *16*(1), 35-41. https://doi.org/10.2309/java.16-1-5

Bertoglio, S., Faccini, B., Lalli, L., Cafiero, F., & Bruzzi, P. (2016). Peripherally inserted central catheters (PICCs) in cancer patients under chemotherapy: a prospective study on the incidence of complications and overall failures. *Journal of Surgical Oncology*, *113*(6), 708-714. https://doi.org/10.1002/jso.24220

Bodenham Chair, A., Babu, S., Bennett, J., Binks, R., Fee, P., Fox, B. Johnston, A., Klein, A., Langton, J., Mclure, H. & Tighe, S. (2016). Association of anaesthetists of Great Britain and Ireland: safe vascular access 2016. *Anaesthesia*, *71*(5), 573-585. https://doi.org/10.1111/anae.13360

Brouwers, M., Kho, M., Browman, G., Burgers, J., Cluzeau, F., & Feder, G., Fervers, B., Graham, I., Grimshaw, J., Hanna, S., Littlejohns, P., Makarski, J. & Zitzelsberger, L. (2010). AGREE II: Advancing Guideline Development, Reporting and Evaluation In Health Care. *Canadian Medical Association Journal*, *182*(18), E839-E842. https://doi.org/10.1503/cmaj.090449

Chopra, V., Flanders, S., Saint, S., Woller, S., O'Grady, N., Safdar, N., Trerotola, S., Saran, R., Moureau, N., Wiseman, S., Pittiruti, M., Akl, E., Lee, A., Courey, A., Swaminathan, L., LeDonne, J., Becker, C., Krein, S. & Bernstein, S. (2015). The Michigan appropriateness guide for intravenous catheters (MAGIC): results from a multispecialty panel using the RAND/UCLA

appropriateness method. *Annals of Internal Medicine*, *163*(Supplement), 1-40. https://doi.org/10.7326/m15-0744

Critical Appraisal Skills Programme. (2019). *CASP Randomised Controlled Trial Standard Checklist*. Casp-uk.b-cdn.net. Retrieved 18 November 2021, from https://casp-uk.b-cdn.net/wp-content/uploads/2020/10/CASP_RCT_Checklist_PDF_Fillable_Form.pdf.

Ministry of Health, Social Services and Equality. (2014). Development group of the clinical practice guideline on intravenous therapy with temporary devices in adults. Clinical practice guidelines in the SNS. Health Technologies Assessment Agency of Andalucía (AETSA).

Gorski, L., Hadaway, L., Hagle, M., McGoldrick, M., Orr, M., & Doellman, D. (2016). *Journal of Infusion Nursing*, *39*(1S).

Hallam, C., Denton, A., Weston, V., Dunn, H., Jackson, T., Keeling, S., & Hill, S. (2020). UK vessel health and preservation (VHP) framework: a commentary on the updated VHP 2020. *Journal of Infection Prevention*, *22*(4), 147-155. https://doi.org/10.1177/1757177420976806

Joanna Briggs Institute. (2020). Checklist for cohort studies. *Critical Appraisal Tools for Use in JBI Systematic Reviews.* (1-6). Retrieved November 21, 2021 from https://jbi.global/critical-appraisal-tools

Krueger, R. (2002). Focus group interviewing. *Designing and Conducting Focus Group Interviews*. Retrieved November 17, 2021 from https://www.eiu.edu/ihec/Krueger-FocusGroupInterviews.pdf.

Krueger, R., & Casey, M. (2014). *Focus Groups* (5th ed.). SAGE.

Loveday, H., Wilson, J., Pratt, R., Golsorkhi, M., Tingle, A., Bak, A., Browne, J., Prieto, J., & Wilcox, M. (2014). Epic: national evidence-based guidelines for

preventing healthcare-associated infections in NHS hospitals in England. *Journal of Hospital Infection*, *86*, 1-70. https://doi.org/10.1016/s0195-6701(13)60012-2

Moss, J., Wu, O., Bodenham, A., Agarwal, R., Menne, T., Jones, B., Heggie, R., Hill, S., Dixon-Hughes, J., Soulis, E., Germeni, E., Dillon, S. & McCartney, E. (2021). Central venous access devices for the delivery of systemic anticancer therapy (CAVA): a randomised controlled trial. *The Lancet*, *398*(10298), 403-415. https://doi.org/10.1016/s0140-6736(21)00766-2

Patel, G., Jain, K., Kumar, R., Strickland, A., Pellegrini, L., Slavotinek, J., Eaton, M., McLeay, W., Price, T., Ly, M., Ullah, S., Koczwara, B., Kichenadasse, G. & Karapetis, C. (2013). Comparison of peripherally inserted central venous catheters (PICC) versus subcutaneously implanted port-chamber catheters by complication and cost for patients receiving chemotherapy for non-haematological malignancies. *Supportive Care in Cancer*, *22*(1), 121-128. https://doi.org/10.1007/s00520-013-1941-1

Registered Nurses' Association of Ontario (RNAO). (2021) *Vascular Access 2nd edition*. Toronto (ON). RNAO.

Sou, V., McManus, C., Mifflin, N., Frost, S., Ale, J., & Alexandrou, E. (2017). A clinical pathway for the management of difficult venous access. *BMC Nursing*, *16*(1). https://doi.org/10.1186/s12912-017-0261-z

Verma, A., Kumachev, A., Shah, S., Guo, Y., Jung, H., Rawal, S., Lapointe-Shaw, L., Kwan, J., Weinerman, A., Tang, T. & Razak, F. (2020). Appropriateness of peripherally inserted central catheter use among general medical

inpatients: an observational study using routinely collected data. *BMJ Quality & Safety*, *29*(11), 905-911. https://doi.org/10.1136/bmjqs-2019-010463

World Health Organization. (2014). *WHO handbook for guideline development, 2nd Edition*. Who.int. Retrieved 10 September 2021, from https://www.who.int/publications-detail-redirect/9789241548960.

Wu, O., Boyd, K., Paul, J., McCartney, E., Ritchie, M., Mellon, D., Kelly, L., Dixon-Hughes, J. & Moss, J. (2016). Hickman catheter and implantable port devices for the delivery of chemotherapy: a phase II randomised controlled trial and economic evaluation. *British Journal of Cancer*, *114*(9), 979-985. https://doi.org/10.1038/bjc.2016.76