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The Michigan Appropriateness Guide for Intravenous Catheters in Pediatrics: miniMAGIC

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Abbreviations:

CVAD:	Central venous access device
ECG:	Electrocardiogram
ICU:	Intensive care unit
IO:	Intraosseous
IQR:	Interquartile range
MAGIC:	Michigan Appropriateness Guide for Intravenous Catheters
PICC:	Peripherally inserted central catheter
PIVC:	Peripheral intravenous catheter
RAND/UCLA:	RAND Corporation/ University of California, Los Angeles
TIVD:	Totally implanted venous device
US:	United States
VAD:	Vascular access device

Table of Contents Summary

We outline criteria for appropriate intravenous device selection and insertion in pediatric patients, developed using the RAND/UCLA Appropriateness method.

What's Known on This Subject

Vascular access decision-making in pediatric patients remains a complex, highly variable process. To date, evidence-based criteria to inform these choices do not exist. Consequently, over- and under-use of available devices is common, frequently resulting in harm to patients.

What This Study Adds

This study provides evidence-based criteria for intravenous catheter selection— from umbilical catheters to totally implanted venous devices – in pediatric patients, across a range of clinical indication.

Contributors' Statement Page

Dr. Ullman and Dr. Chopra conceptualized and designed the study, drafted the initial manuscript, reviewed the data, and reviewed and revised the manuscript.

Dr. Bernstein assisted with designing the study, protocol development and reviewed and revised the manuscript.

Dr. Brown, designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript.

Dr. Aiyagari provided expertise for vascular access devices in pediatric cardiology patients, and reviewed and revised of the final manuscript.

Dr. Cooper provided expertise for vascular access devices in critically ill neonatal and pediatric patients, and reviewed and revised of the final manuscript.

Ms. Doellman provided expertise for vascular access devices in the neonatal and pediatric patient, and reviewed and revised of the final manuscript.

Dr. Gore provided patient and caregiver perspective, and reviewed and revised of the final manuscript.

Dr. Jacobs provided expertise for vascular access devices in pediatric cardiac surgery patients, and reviewed and revised of the final manuscript.

Dr. Jaffray provided expertise for vascular access devices in pediatric hematology, oncology and bone marrow transplant patients, and reviewed and revised of the final manuscript.

Ms. Kleidon assisted in drafting case scenarios, funding applications, protocol development and revision of the final manuscript.

Dr. Mahajan provided expertise for vascular access devices in critically ill neonatal and pediatric patients, and reviewed and revised of the final manuscript.

Dr. McBride provided content expertise in pediatric surgery and surgically inserted devices, assistance in drafting case scenarios, and reviewed and revised of the final manuscript.

Dr. Morton and Dr. Shaughnessy provided expertise in pediatric hospital medicine, and reviewed and revised the manuscript.

Ms. Pitts supported the protocol development and review, case scenario review and panel recruitment, and reviewed and revised of the final manuscript.

Dr. Prentice provided content expertise in pediatric surgery and surgically inserted devices, and reviewed and revised of the final manuscript.

Dr. Stranz provided content expertise in pediatric pharmacology, and reviewed and revised of the final manuscript.

Dr. Wolf provided expertise in pediatric infectious diseases, and pediatric hematology and oncology, and reviewed and revised the manuscript.

Dr. Rivard provided expertise in pediatric interventional radiology and image guided insertion of vascular access devices in the neonatal and pediatric patient, and reviewed and revised of the final manuscript.

Prof. Rickard and Prof. Cooke assisted with funding applications, protocol development and revision of the final manuscript.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

ABSTRACT

Objective

Vascular access device (VAD) decision-making in pediatric patients remains a complex, highly variable process. To date, evidence-based criteria to inform these choices do not exist. The objective of miniMAGIC (Michigan Appropriateness Guide for Intravenous Catheters in pediatrics) was to provide guidance on device selection, device characteristics and insertion technique for clinicians, balancing and contextualizing evidence with current practice through a multi-disciplinary panel of experts.

Methods

The RAND/UCLA Appropriateness Method was used to develop miniMAGIC, including sequential phases: definition of scope and key terms; information synthesis and literature review; expert multi-disciplinary panel selection and engagement; case scenario development; and appropriateness ratings by expert panel via two rounds.

Results

The appropriateness of the selection, characteristics and insertion technique of intravenous catheters commonly used in pediatric healthcare across age populations (neonates, infants, children and adolescents), settings, diagnoses, clinical indications, insertion locations, and vessel visualization devices and techniques was defined. Core concepts emphasized included vessel preservation, insertion and post-insertion harm minimization (e.g., infection, thrombosis), uninterrupted treatment provision and inclusion of patient preferences.

Conclusion

This study provides evidence-based criteria for intravenous catheter selection– from umbilical catheters to totally implanted venous devices – in pediatric patients, across a range of clinical indications. miniMAGIC also highlights core vascular access practices in need of collaborative research and innovation.

INTRODUCTION

The majority of all hospitalized children require placement of a vascular access device (VAD) to receive medications, for life-saving therapies and to facilitate blood tests.¹ In addition, many chronically ill children are VAD-dependent for much of their lives. These devices are required across a continuum of age, and across acute, subacute, and home care settings.² While vital for treatment, VADs have well recognized insertion morbidity risks (e.g., pneumothorax), are costly,³ and can lead to lethal complications such as thrombosis and bloodstream infection.⁴ Even minor VAD-associated adverse events, such as occlusion or dislodgement, can have significant negative sequelae and lead to delays in treatment during acute and chronic illness.^{2,5}

When clinicians select a VAD, a number of aspects are used to determine which device may be optimal for their patient. For example, anticipated duration and frequency of use, complication risk, previous vascular access history, infusate characteristics, vessel health, course and size, and operator availability and skill are factors weighed when making VAD decisions.⁴ However, this process is highly variable and often defaults to institutional culture and practice – the way things are done, rather than the way they should be done.⁶ Despite the fact that VADs have varying adverse event profiles and treatment capabilities, an evidence-driven, standardized process does not exist for the selection of the most appropriate VAD in pediatrics. This uncoordinated approach to VAD decision-making can result in inappropriate device selection. For example, peripheral VADs may be inappropriately chosen for complex, long-term therapy,⁷ and peripherally inserted central catheters (PICCs) may be unnecessarily used for short term, peripherally compatible therapies.⁶ These device selection decisions potentiate patient harm and inefficient treatment outcomes, adding to healthcare costs.

In 2015, Chopra and colleagues⁸ developed the Michigan Appropriateness Guide for Intravenous Catheters (MAGIC), to aid appropriate VAD decision making for hospitalized adults. Since publication, MAGIC has been implemented in many in many hospitals worldwide, but particularly in the US, with evidence suggesting significant reductions in inappropriate VAD use, patient harm and costs.⁹⁻¹¹ Similar evidence-based VAD appropriateness criteria have not been developed for pediatrics. Therefore, we sought to develop miniMAGIC – a pediatric-focused version of its adult counterpart – using the RAND Corporation / University of California, Los Angeles (RAND/UCLA) Appropriateness Method¹² to address this knowledge gap.

PATIENTS AND METHODS

Design

The “Michigan Appropriateness Guide for Intravenous Catheters in pediatrics” (miniMAGIC) was developed in accordance with the RAND/UCLA Appropriateness Method.¹² A detailed protocol is available.¹³ The study received ethics approval from Griffith University (2018/207) and was deemed exempt from review by the University of Michigan Institutional Review Board (HUMM00144945).

In the RAND/UCLA method a procedure is considered appropriate when the expected health benefits exceed the expected negative consequences (e.g., mortality, morbidity, anxiety, pain) by a sufficiently wide margin such that the procedure is worth doing, exclusive of cost.¹² The method balances the best available evidence with expert judgement, to form a statement regarding the appropriateness of individual procedures.¹² Within miniMAGIC, we sought to develop appropriateness criteria for the selection and insertion of VADs for specific populations and indications within pediatrics, regardless of cost.

Following the RAND/UCLA Appropriateness Method, sequential phases were performed to meet this aim.

These phases included:

- 1) Definition of scope and key terms;
- 2) Information synthesis and literature review;
- 3) Expert panel selection and engagement;
- 4) Case scenario development;
- 5) Appropriateness ratings by expert panel via two rounds

Definition of scope and key terms

miniMAGIC defined the appropriateness of VADs commonly used across pediatric health systems (hospitalized and ambulatory care) including management from maternity hospitals or equivalent discharge, until 18 years of age.¹⁴ The objective of miniMAGIC was to provide guidance on important clinical questions (i.e., device selection, device characteristics and insertion technique) for clinicians primarily making decisions regarding VADs in pediatrics (e.g., vascular access teams, interventional radiology, anesthesiologists, infectious disease, surgery, nephrology), contextualizing evidence-based data with current practice with the assistance of a multi-disciplinary panel of experts.

Comprehensive definitions of key terms are provided here.¹³ These include VAD and infusion catheter types (intraosseous [IO] catheter, peripheral intravenous catheter [PIVC], midline catheter, umbilical catheter, non-tunneled central vascular access device [CVAD], peripherally inserted central catheter [PICC], tunneled, cuffed CVAD, and totally implanted venous device),^{8, 15, 16} insertion locations, population categories (age [neonates, infants, children, adolescents],¹⁷ setting and diagnosis (general hospitalized patients, congenital cardiac disease, critically ill, oncology and hematology, long-term VAD-dependent conditions),^{8, 18-21} clinical indications (peripherally compatible and non-peripherally compatible therapy, difficult vascular access, blood sampling),^{8, 15, 22} and vessel visualization devices and techniques (near infra-red light, ultrasound, electrocardiogram tip guidance, fluoroscopy, surgical cut-down, catheter to vessel ratio).^{15, 19, 23}

Information synthesis and literature review

As recommended by the RAND/UCLA Appropriateness Method,¹² we conducted a synthesis of the literature to summarize the evidence regarding pediatric VAD selection, insertion practice and risk of complications. The methods and results of the literature review are available.²⁴ The final 133 studies and guidelines included were of variable quality, with many focusing on device performance in specialty populations (e.g., hematology and oncology, critical care), and single interventions (e.g., vessel visualization technology, device insertion location). Important gaps in the pediatric literature, especially surrounding neonatal device selection (outside of the NICU), catheter-to-vein ratio and long-term vascular access dependent conditions were observed. To bridge these gaps, additional studies from populations outside of pediatrics (e.g., NICU, adults) were included to inform appropriateness discussions. Prior to the appropriateness ratings, the literature review was provided to the expert panel. Findings from the review were also used during the in-person ratings process to inform discussions.

Expert panel selection and engagement

Fourteen clinicians and researchers, representing pediatric healthcare disciplines typically responsible for decisions about VAD choice, were invited to serve on the panel. Full details on panel members are available.¹³ To ensure rigor and inclusion of the patient's voice (especially when the evidence was unclear), we included non-voting panelists who joined for the meeting and discussions but did not rate or vote on individual scenarios. These panelists included a patient representative and three facilitators (including a methodologist).

Case scenario development

The clinical scenarios for miniMAGIC were based on the original MAGIC document,⁸ but restructured and rewritten to align with the results of the systematic review and panelist expert opinion. We included areas of controversy or ambiguity, even if there was limited evidence available, as we recognized clinicians may need guidance when making these decisions. With this framework, the clinical scenarios were divided into: a) device selection (across VAD types); b) device characteristics (including lumen number, size, insertion location); and c) insertion technique (attempts, image guidance). Device selection was further categorized into chapters for age, and for specific clinical populations.

Appropriateness ratings by expert panel

As per the RAND/UCLA Appropriateness Method, two rounds of appropriateness rating of the clinical scenarios were completed. The first round rating was done independently and performed via paper copy. Individual panelist results were returned electronically (e.g., scanned and sent via email) and centrally inputted to create a master ratings document incorporating all panelist responses. The second round rating occurred after all panelists travelled to Ann Arbor, Michigan and participated in a group discussion that included a review of all panelist ratings.¹² Appropriateness for each clinical scenario was rated on a scale of 1 to 9, where 1 indicates harm outweighs benefit (highly inappropriate), and 9 signifies benefit outweighs harm (highly appropriate). As previously described, the panelists were provided the literature review, and instructed to rate each clinical scenario using their best clinical judgement and the evidence in the literature review.¹³

As recommended by the RAND/UCLA method, indications were classified into three levels of appropriateness:

1. Appropriate: panel median score of 7 to 9, without disagreement;
2. Uncertain: panel median score of 4 to 6, or with disagreement regardless of median; and
3. Inappropriate: panel median score of 1 to 3, without disagreement.

Disagreement existed if 5 or more panelists rated in each extreme (1-3 and 7-9).¹²

RESULTS

A total of 1,234 clinical scenarios were created for review by the panelists. In the first round, panelists rated 424 scenarios as appropriate (34.4%), 492 as inappropriate (39.9%), and 266 as uncertain (21.6%). The panel

disagreed on 52 clinical scenarios (4.2%). During the second round discussion, the panelists removed 481 scenarios, as they were considered duplicative (e.g., similarity in recommendations for children and adolescents led to a revised category of children and adolescents aged 1–18 years old rather than two distinct populations), leaving 753 scenarios to review. In the second round, the panel rated 284 scenarios as appropriate (37.7%), 314 as inappropriate (41.7%), 137 as uncertain (18.2%) and disagreed on 18 clinical scenarios (2.4%). Thus, discussions and clarifications in round two reduced the proportion of clinical scenarios rated as uncertain and those with disagreement.

1. The appropriateness of VAD selection in specific populations

Pediatrics encompasses a heterogeneous population, with diverse conditions and includes patients across a range of ages. The venous network matures significantly throughout the first year of life after term delivery.²⁵ The developing vein structure has smaller luminal diameter, requiring clinicians to use smaller catheters for both peripheral and central devices, impacting catheter insertion and function.²⁶ In order to ensure accuracy, device selection was divided into the following categories for age which include neonates, infants, and children and adolescents, and specific clinical subspecialties (e.g., critical illness, cardiac surgery).

A. The appropriateness of VAD selection in hospitalized pediatric patients

Neonates (Birth to 30 days)

Within this population the panel considered full-term neonates who, in the first 30 days of life are admitted to a pediatric, or mixed pediatric-adult facilities. Infection and newly diagnosed congenital abnormalities, including cardiac conditions, are a common source of early hospital admission for this population. Reliable access to the vascular system is thus necessary for diagnosis and treatment.

For approximately the first week of life, the umbilical vein is a viable means of venous access. The panel determined selection of an umbilical catheter should be influenced by the infusate characteristics, therapy duration, and the age of the neonate. The panel rated use of the umbilical catheter appropriate, up to 2 days after birth, for peripherally compatible infusates, for therapy duration of 14 days or less. Inserting an umbilical catheter 5 or more days after birth (no matter the therapy duration), was rated as inappropriate. There was disagreement regarding the appropriateness of umbilical catheters for longer therapy duration (15 or more days),

as it was unclear whether the umbilical vascular system, and catheter, would remain patent for the predicted clinical need.^{16, 27}

The panel rated umbilical catheters as appropriate for administering non-peripherally compatible infusates (with placement occurring up to 5 days after birth). Central tip positioning of umbilical catheters is frequently problematic, with the catheter tip often moving during treatment, related to a small target of safe positioning (due to patient size), and difficult securement.^{4, 27, 28} The panel therefore endorsed frequent assessment of umbilical catheter tip positioning, in order to safely administer non-peripherally compatible infusates. The panel rated it appropriate to transition to alternative vascular access, from a functioning umbilical catheter, from 8 days after umbilical catheter placement, but rated transition before 5-7 days after placement as uncertain rather than appropriate.

The miniMAGIC recommendations for appropriate device selection for hospitalized, full-term neonates are summarized in Figure 1, across clinical indications and therapy durations. PIVC and midlines were rated appropriate for 7 or fewer days of peripherally-compatible therapy, however the panel rated them as uncertain or inappropriate for more prolonged therapies, due to concerns regarding the device reliability. In agreement with the National Association for Neonatal Nurses (NANN), PICCs were rated as appropriate for non-peripherally compatible therapies, and peripherally compatible therapies of 8 or more days of therapy.¹⁶ Tunneled cuffed CVADs were rated as appropriate for administration of infusates where therapy was projected to last 31 days or more. The panel deliberated extensively on the selection of an appropriate device for frequent blood draws (more than once per day), due to risk of catheter occlusion. Ultimately, midline catheters were rated as appropriate for short durations (7 or fewer days), and PICCs > 3Fr, or ≤20G rated as appropriate for 8 or more days of therapy. Tunneled cuffed CVADs were rated appropriate for all long-term therapy (31 days or more). Totally implanted venous devices were rated inappropriate for all clinical scenarios for hospitalized neonates, regardless of therapy duration, reflecting difficulty in implanting these devices below the skin, and rapid growth impacting tip position, in neonates.

Infants (31 days to one year)

Infants require hospitalization for a range of conditions, with respiratory conditions such as bronchiolitis being highly prevalent. miniMAGIC recommendations for the selection of VAD for hospitalized infants are presented in Figure 2.

For hospitalized infants, PIVCs were rated as appropriate for 14 or fewer days of therapy; however, robust evidence with which to rate the appropriate use of midline catheters in this population was lacking. Panelists reported successful use of these devices at some individual hospitals but stressed the necessity for high-quality insertion and maintenance practices to promote safety. Thus, ratings for midlines for peripherally compatible infusates lasting ≤ 7 days were uncertain.

As with hospitalized neonates, PICCs were rated as appropriate for administering non-peripherally compatible infusates, with non-tunneled CVADs rated appropriate for therapy duration of 14 or fewer days. The panelists again deliberated extensively regarding the appropriateness of device selection for frequent blood draws (more than once per day). The panel rated the appropriateness of PIVCs and midline catheters for 7 or fewer days uncertain, and PICCs appropriate for 8 or more days, if greater than 3Fr, or $\leq 20G$). The panel discussed the risk-benefit ratio of VADs for this indication, including infection, thrombosis and repeated procedures.⁴ Longer term devices, including tunneled, cuffed CVAD and totally implanted venous devices were rated appropriate for 31 or more days of non-peripherally compatible therapy, but as uncertain for other indications.

Children (Greater than one year to 12 years) and adolescents (greater than 12 years to less than 18 years)

While hospitalized children and adolescents represent a heterogeneous group, overall, the panelists determined physiological differences between children and adolescents do not make a clinically meaningful difference when it comes to VAD appropriateness. Thus, these sections were combined when ratings were performed. As displayed in Figure 3, consistent with the adult literature (including MAGIC) midline catheters and PIVCs were rated appropriate for peripherally compatible infusates for 14 or fewer days.^{8, 11} Consequently, PICCs were rated as appropriate for use when 15 or more days of peripherally compatible therapy is planned. PICCs remained appropriate for all durations when non-peripherally compatible infusates are planned. Non-tunneled CVADs were rated as appropriate by the panel for non-peripherally compatible therapies of up to 14 days duration, with the panel rating non-tunneled CVAD as uncertain in appropriateness for frequent blood draws of between 8-30

days duration. Tunneled, cuffed CVAD and totally implanted venous devices were rated as appropriate for most indications of 31 or more days.

B. The appropriateness of VAD selection in special pediatric populations

Malignant hematological and oncological conditions

Compared with general hospitalized pediatric patients, patients with malignant hematological and oncological conditions are at increased risk of infection and thrombotic complications, and adverse sequelae from treatment disruption.^{4, 5, 29} In addition, treatments and supportive therapies are complex and diverse, and often require cycles of peripherally and non-peripherally compatible infusates, frequent blood draws, and management across home and healthcare settings. In agreement with international guidelines,³⁰ the panel rated tunneled, cuffed CVADs as appropriate across this indication, with totally implanted venous devices also rated appropriate for patients $\geq 10\text{kg}$. The panel rated the appropriateness of PICCs (all ages/weights) and totally implanted venous devices (for patients $< 10\text{kg}$) as uncertain, citing concerns regarding procedural and post-insertion complications such as infection and thrombosis.³⁰

The panel rated it appropriate to place a PICC to commence urgent, non-peripherally compatible therapy for cancer, and replace this with a definitive device. However, the appropriateness of routinely using this approach was rated as uncertain. When comparing the appropriateness of PICCS vs. tunneled, cuffed CVADs, the panel rated it inappropriate to insert a PICC rather than a tunneled, cuffed CVAD, for all aged populations undergoing bone marrow transplant, or other treatment for cancer. Similarly, the panel rated insertion of a PICC, rather than a totally implanted venous device for children and adolescents receiving treatment for active cancer as inappropriate. The panel rated the same comparison as appropriate for neonates and uncertain for infants.

Critically ill patients

For critically ill pediatric patients, miniMAGIC panelists recommended VAD selection based on illness severity (i.e., physiologically unstable vs. stable), rather than setting of care (i.e., ICU vs. emergency department) or other patient/clinical characteristics. Ratings for critically ill patients were consistent with existing guidelines³¹ with respect to timeliness and importance of early venous access. Displayed in Figure 4, recommendations for a stable, but critically ill pediatric patient varied based on infusate characteristics and monitoring requirements.

Non-tunneled CVADs were rated appropriate for up to 14 days of non-peripherally compatible therapy, and for hemodynamic monitoring. Consistent with prior recommendations, PICCs were rated as appropriate for 8 or more days of peripherally compatible therapies, and all durations of non-peripherally compatible therapies. Despite minimal data, midline catheters were rated by the panel as appropriate for all durations of peripherally-compatible therapies. For stable, critically ill pediatric patients requiring peripherally compatible therapy for 14 or fewer days, panelists preferred PIVCs over IOs. Panelists disagreed on the appropriateness of IO use for managing pediatric patients without hemodynamic compromise without reliable vascular access for 7 or fewer days.

Also displayed in Figure 4, (and in agreement with the American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care),³¹ for an unstable pediatric patient, speed of access was first priority. For scenarios with hemodynamic compromise, panelists rated it inappropriate to attempt for PIVC access for ≥ 120 seconds, or \geq two attempts; instead recommending an IO device to gain IV access, citing how rapidly this can be inserted by clinicians with varying levels of training.³¹

Congenital cardiac conditions

For pediatric patients with congenital cardiac conditions, inappropriate VAD selection can directly impact both short and long-term survival. Damage (thrombotic or stenotic) to key vessels can prevent or complicate future life-saving procedures, including catheterization interventions, palliation of patients with a functionally univentricular heart, and cardiac transplantation.³² Because the implications of vascular access and route of access are highly relevant in decision-making, clinical scenarios for this population were divided into underlying cardiac physiology: univentricular vs. biventricular circulation. Across all scenarios there were two common recommendations. First, the panel rated totally implanted venous devices as inappropriate regardless of indication, due to concerns regarding irreparable vessel damage. Second, the panel rated umbilical catheters as an appropriate access option for neonates, as these do not typically result in significant vessel compromise for future procedures.³²

Congenital cardiac procedures are primarily performed in highly specialized pediatric facilities. miniMAGIC does not include recommendations surrounding the selection of transthoracic intracardiac lines, or other specialty cardiac devices (e.g., extracorporeal membrane oxygenation catheters). However, the panel recognized

placement of transthoracic intracardiac lines can minimize the need for other types of VADs, and thereby, minimize the risks associated with percutaneous devices.³³

For patients with univentricular physiology, miniMAGIC recommendations were based on the patient's stage of cardiac repair (Stage 1, 2 or 3),¹⁷ and duration of therapy (Figure 5). Lower-extremity PICCs, umbilical catheters and femoral CVADs (tunneled, uncuffed and non-tunneled) were rated by the panel as appropriate for Stage 1 and 2 patients, to preserve upper-extremity vein patency for Stage 2 and 3 palliation.³² To facilitate preservation of upper extremity veins, a slightly varied CVAD insertion technique was included; the tunneled, non-cuffed CVAD placed in the femoral vein.³⁴ After Stage 3 repair, appropriateness was similar to critically ill patient recommendations. For patients with highly complex functionally univentricular physiology at any stage of repair, the panel discussed the potential necessity to consider alternatives, and recommended such cases have coordinated, interdisciplinary device planning, and consideration of specialist devices (e.g., transhepatic CVAD).

For congenital cardiac conditions with biventricular circulation, miniMAGIC recommendations were based on patient age and duration of therapy. Appropriateness ratings were similar to those of stable, critically ill pediatric patients, owing to similar physiology and associated risk. The panel rated jugular-placed, non-tunneled CVADs, and upper extremity placed PICCs, as appropriate. Non-tunneled CVADs placed in femoral and subclavian veins were rated as uncertain by the panel, reflecting the insertion-related complications associated with subclavian placement (which vary based on operator experience and the use of ultrasound), and infection and thrombotic risk associated with femoral placement.³² Additionally, femoral vessel preservation was cited as being important for patients with conditions likely to require future transcatheter interventions (e.g., tetralogy of Fallot/Pulmonary Atresia and cardiac transplant patients who will need multiple myocardial biopsies).

Long-term vascular access dependent

With evolution in medical therapies, long- (>2 months) and very long- (>1 year) term vascular access dependency in pediatrics is increasingly common.² This prolonged reliance on VADs includes pediatric patients receiving treatment for non-malignant hematological (e.g., sickle cell), respiratory (e.g., cystic fibrosis), gastrointestinal, metabolic, and immunological conditions. Navigating VAD insertion decisions for children with chronic illness is vital, but complex. To this end, our non-voting patient representative was instrumental in providing context for these ratings. With her input and insight, the panel agreed that defining the appropriateness

of basic principles to enable vessel preservation and complication prevention in chronic conditions was necessary. The panel strongly recommended clinicians partner with the child and their family/caregivers when selecting devices, to ensure their immediate and evolving clinical and lifestyle needs are met.

In contrast to MAGIC, the panel did not believe frequency of hospitalization should be used as a proxy for illness severity or a defining criterion in pediatric VAD selection. This distinction was made because acute hospitalization was considered an unreliable proxy of disease in pediatric populations with chronic conditions, where an emphasis is placed on avoiding hospitalization.⁸ Instead, each of the clinical scenarios recognized children with long term vascular access dependency spend time receiving treatment across home and healthcare facilities. The scenarios also considered most long-term vascular access dependent children are likely to have difficult vascular access, related to previous vessel damage and procedural fear.²

The criteria influencing the selection of VADs for this heterogenous population focused on infusate characteristics (peripheral vs non-peripheral compatibility [including parenteral nutrition or PN]), continuous or intermittent therapies, and treatment duration. Specific recommendations are provided for children requiring long term PN; and, in accordance with the European Society for Parenteral and Enteral Nutrition (ESPEN), the panel rated use of tunneled, cuffed CVADs for all age groups as appropriate. However, the appropriateness of totally implanted venous devices for children and adolescents was rated as uncertain, and there was disagreement regarding the appropriateness of PICCs.³⁵

Recommendations for non-PN infusates are displayed in Figure 6. For continuous infusates, appropriateness mirrored PN recommendations, including tunneled, cuffed CVADs for all populations. The panel also rated use of PICCs in infants and children, and totally implanted venous devices for children and adolescents, as appropriate for this indication. For intermittent access, panelists rated PICCs and totally implanted venous devices in neonates and infants as uncertain; but rated the use of tunneled, cuffed CVADs for all populations, and totally implanted venous devices in children and adolescents, as appropriate. Peripheral devices including PIVCs and midlines were rated as being inappropriate across all long-term, complex therapies.

For children and adolescents requiring regular, peripherally compatible, intermittent treatments (e.g., steroids, antibiotics), for short durations (<7 days), the panel rated PIVC and totally implanted venous devices as appropriate. The panel rated the use of midline catheters and PICCs as uncertain owing largely to lack of

credible evidence supporting this practice. Although some panelists had substantial experience in using midline catheters for this purpose and reported few untoward events, lack of evidence to support this practice and the potential risk of complications limited recommendations. When considering medium duration (8-14 days) treatment, PICCs, tunneled, cuffed CVAD, and totally implanted venous devices were rated as appropriate.

Difficult venous access

Difficult venous access is caused by a variety of factors in pediatrics, including physiology, pathology, VAD damage, and clinician procedural skill.³⁶ Appropriateness criteria for difficult venous access focused on the number of insertion attempts, intramuscular (IM) therapy substitution, and escalation of VAD types. Each of these criteria provided a pathway to minimize vessel damage and patient distress, without impacting treatment provision.

In agreement with the Infusion Nurses Society (INS) guidelines, the panel rated ≥ 3 attempts at PIVC insertion by a single clinician as inappropriate.¹⁵ In parallel, the panel rated zero to two attempts by one individual as appropriate, but recommended early escalation to a more experienced PIVC inserter for children with difficult venous access.

It is not uncommon in pediatrics for a child to need an additional day of IV treatment, only to lose reliable IV access. In such situations, the panel rated it appropriate to substitute an antibiotic that may be delivered via alternative routes (e.g., IM ceftriaxone) with a non-intravenous injection on the final day of therapy, when advanced insertion staff are not available, or after two or more insertion attempts are unsuccessful. The panel rated this approach as uncertain with 0-1 attempts, but also indicated it was reasonable to attempt to insert a PIV for completion of intravenous therapy. Underlying the panel's recommendation was the understanding that (a) the efficacy of IV and IM administration for the antibiotic in question is similar, and (b) IM injections can be painful and often multiple doses are required, thus making it less ideal.³⁷ When transitioning from IV to IM treatment, consultation with an Infectious Diseases specialist was recommended. As well, the panel advised considering oral antibiotic therapy in all such situations, including before IV therapy is commenced with a VAD.³⁸

The panel rated placement of a PICC as appropriate for a child who does not need central access or access for extended periods but who, despite appropriate escalation with skilled inserters and technology (e.g., ultrasound), has required ≥ 2 PIVC insertion attempts. For this indication, the panel balanced the risk associated with delays to treatment and distressing repeated PIVC insertion procedures, with device complications and sequelae.

2. The appropriateness of device characteristics

The appropriateness of device characteristics such as size and number of lumens, risk of complications, device performance and successful completion of intended therapy was also rated. The panel considered these aspects broadly and across all indications, rather than for specific populations or clinical factors driving treatment.

Catheter-to-vein ratio

While thrombosis risk is generally considered to be lower in pediatrics than adults, the size of the vessel should be considered carefully when choosing the size of a catheter.¹⁶ In agreement with the INS guidelines, and adult literature, the panel rated a catheter-to-vein ratio of $\leq 45\%$ as appropriate for PIVC and PICC. The panel rated a catheter-to-vein ratio of 50% as uncertain, and a ratio $\geq 60\%$ as inappropriate.^{15, 23} For non-tunneled CVADs, tunneled CVADs and totally implanted venous device, the panel's catheter-to-vessel ratio appropriateness ratings were more conservative, with $\leq 40\%$ appropriate, 45-50% uncertain and $\geq 60\%$ inappropriate. Although the panel recognized the lack of pediatric-specific literature in this area of practice, these ratings were an instance where findings from the adult literature were felt applicable to pediatric patients. The panel did recommend this as an area of priority for future enquiry.

Device lumens

In agreement with MAGIC,⁸ and multiple national and international guidelines,^{15, 30, 39} the panel rated it appropriate to routinely place a single lumen device, unless there were specific reasons for a multi-lumen device (e.g., incompatible infusions that could not be separated in time).^{8, 30} Within this domain, the panel also rated it inappropriate to place a multi-lumen device with dedicated lumens for blood transfusions and sampling. However, the appropriateness of dedicating lumens for lipid emulsions and PN was rated as uncertain. This rating reflected lack of evidence regarding risks and benefits with respect to infectious complications from PN and lipid emulsions vs. those with a multi-lumen device. Therefore, the panel recommended collaboration with a

pharmacist and/or VAD-insertion clinician, to ensure device characteristic suitability (i.e., lumen number and size), as appropriate.

3. The appropriateness of the insertion procedure

Insertion locations

The locations into which VADs are inserted directly impacts the success of the procedure and risk of complications.^{15, 39, 40 41} Vessels suitable for VAD insertion as a neonate may become difficult and/or inappropriate to access, (e.g., scalp vessels), or lead to an increased risk of complications (e.g., lower body PICCs in a mobilizing patient) later in life. Devices inserted into areas of flexion are associated with increased risk of post-insertion complications, including infiltration, phlebitis and thrombosis.⁴² Recommendations for the appropriateness of VAD insertion vessels and sites are described in Table 1.

Table 1: miniMAGIC recommendation for the appropriate VAD insertion vessel and/or site in Pediatric Patients

Device	Clinical indication	Population	Appropriateness		
			Appropriate	Uncertain	Inappropriate
PIVC	Not difficult or urgent	Neonates	Forearm, hand, foot, scalp	Antecubital	-
		Infants	Forearm, hand, foot	Antecubital, scalp	-
		Children and adolescents	Forearm, hand	Antecubital	Scalp, foot
	Difficult	Neonates	Forearm, hand, foot, scalp, antecubital	-	-
		Infants	Forearm, hand, foot, antecubital	Scalp	-
		Children and adolescents	Forearm, hand, foot, antecubital	Scalp	Foot
	Urgent	Neonates	Forearm, hand, foot, scalp, antecubital	-	-
		Infants	Forearm, hand, foot, scalp, antecubital	-	-

	Children and adolescents	Forearm, hand, foot, antecubital	-	Scalp
PICC	Neonates	Vessel: Basilic, brachial, cephalic, greater saphenous, axillary, mid-thigh femoral Location: Above the antecubital	-	Location: At the antecubital
	Infants	Vessel: Basilic, brachial, cephalic, greater saphenous, axillary Location: Above the antecubital	Vessel: Mid-thigh femoral	Location: At the antecubital
	Children and adolescents	Vessel: Basilic, brachial, cephalic Location:	Vessel: Greater saphenous, axillary Location:	

			Above the antecubital	At the antecubital	
Non-tunneled CVAD	Not urgent	Neonates and infants	Femoral, internal jugular	Subclavian*	
		Children and adolescents	Internal jugular	Femoral, subclavian*	

PICC: Peripherally inserted central catheter; PIVC: Peripheral intravenous catheter; CVAD: Central venous access device

*Disagreement

Vessel visualization

Vessel visualization technologies, such as ultrasound, near infra-red light, and fluoroscopy are used with increasing frequency in pediatric clinical practice.⁴³ High-quality evidence is available to support the use of vessel visualization techniques during the insertion of several devices, including PIVCs, PICCs, and non-tunneled CVADs, to promote insertion success and prevent insertion-, and post-insertion complications.⁴³⁻⁴⁶ In agreement with previous guidelines,^{15,43} panelists rated it appropriate to insert all devices using ultrasound guidance. Similarly, panelists rated placement of PIVCs in patients with difficult venous access and non-emergent central devices without image guidance as inappropriate. The appropriateness of near infra-red light to guide PIVCs and midline catheter insertion was rated as uncertain due to limited evidence. Similarly, electrocardiographically-guided insertion of PICCs across populations was rated as uncertain because (unlike the adult population), the evidence in pediatrics for benefit of this technology is limited. Evaluation of the venous anatomy using ultrasound prior to placement of all VADs was rated as appropriate for neonates and pediatric patients with long term vascular access dependent conditions, and for all central devices.

DISCUSSION

Appropriate VAD selection and insertion influences a child's clinical management and outcome – reducing pain, complications, length of stay and costs, and increasing overall safety and treatment success.^{4, 5, 36} Following the RAND/UCLA Appropriateness Method,¹² the miniMAGIC recommendations from a panel of interdisciplinary clinicians provide guidance to improve everyday VAD selection and insertion decisions. The method balances contemporary literature with the pragmatic clinical experience of the expert panelists, ensuring the recommendations are realistic and reliable.

miniMAGIC is the first time the breadth of pediatric VAD selection and insertion practices have been thoroughly evaluated and critiqued. It also includes recommendations encompassing the broad and unique populations within pediatrics. Findings from this work stand to improve decisions for clinically challenging patients across a broad range of VADs. As many recommendations were grounded in evidence aimed at reducing harm, these appropriateness criteria should also help reduce complications related to poor device selection decisions. Evidence of inappropriate use of VADs and consequential harm in pediatrics and other populations is rising,^{47, 48} including inappropriate PICC use for short duration, peripherally-compatible therapy.⁶ miniMAGIC fills this evidence-practice gap and offers a pragmatic and novel way to reduce patient harm.

As is common in pediatric healthcare, many aspects of VAD practice had not been evaluated rigorously, so the panel recommendations were necessarily conservative. Consequently, important differences between miniMAGIC, and MAGIC for hospitalized adults, were observed. These included uncertainty regarding the role of midlines, the inappropriateness of totally implanted devices in neonates, and the appropriateness of PICCs in sub-specialty populations. Scenarios classified as uncertain and with disagreement demonstrate opportunity for research and innovation. For example, midline catheter use, device selection for blood sampling, the use of PICCs in malignant hematology, oncology and PN, totally implanted venous devices for children and adolescents requiring long-term PN, and insertion locations for PIVCs and non-tunneled CVAD are areas in dire need of more evidence. Because these gaps span many health disciplines, collaborative and interdisciplinary research that includes intensivists, infectious disease physicians, hospitalists, nurses, oncologists, surgeons, anesthesiologists, interventional radiologists and cardiologists, and pharmacists is necessary. To improve

pediatric health outcomes and healthcare services, funding for these research questions from foundations, national institutes and invested stakeholders is needed.

miniMAGIC aims to broadly support the current diverse clinician inserter workforce but does not diminish the need for vascular access experts, especially for complex cases. In this context, processes and recommendations to improve VAD selection for patients with long- and very long-term VAD dependency, including those with congenital cardiac conditions relying on intact vessels for procedures, are especially important. A siloed approach without a dedicated expert can result in poor decisions regarding device selection, placement, and management without consideration of long term vessel health and preservation.⁴⁹ Coordination, communication, and planning across disciplines within the art and science of vascular access are necessary to ensure that vessel damage does not occur and that the patient's and family's health goals are considered.

The implementation of miniMAGIC into practice will require further collaboration and innovation. Like its adult counterpart, the study team plans to develop a mobile health (mHealth) application to operationalize the panel recommendations for use at point of care. Following the RAND/UCLA Appropriateness Method,¹² miniMAGIC should also be used to evaluate historical, current, and planned VAD selection and insertion decisions in pediatric healthcare. The recommendations can be used to first motivate practice change, and then as a benchmark, with retrospective and prospective audits to monitor adoption. With implementation, healthcare institutions can examine and celebrate corresponding improvements in patient and health services outcomes, such as reductions in central line-associated bloodstream infections, thrombosis, re-admissions, and length of stay.

Our study has limitations. First, the recommendations largely rely on the quality of the evidence on which they have been generated. Many aspects of pediatric vascular access have poor quality evidence, which means the recommendations were often reliant upon clinical practice guidelines and the expert opinion of the panel.

However, the recommendations of miniMAGIC are not permanent. As new evidence is generated, miniMAGIC recommendations should be revised. Second, the panel members were from the United States and Australia.

Health services in other countries can be vastly different, including practitioner training and resource availability. As with MAGIC, we strongly recommend local contextualization of the recommendations, prior to wide implementation. Finally, not all sub-specialty populations were considered when creating miniMAGIC.

This limitation is most evident for children with long term vascular access-dependent conditions. For this population we have provided appropriateness criteria for practice principles; however, coordinated case management, and patient- and family-centered care are vital.

CONCLUSION

Coordinated, appropriate VAD selection and insertion decisions can change a child's life. miniMAGIC provides robust appropriateness criteria for VADs in commonly occurring, sometimes complex, pediatric clinical indications. Interdisciplinary clinicians with a range of expertise and training can use this resource to reduce VAD-associated harm and accompanying healthcare resources, and to improve treatment. miniMAGIC has also drawn attention to priority areas for research, innovation, and patient safety, across pediatric disciplines. The findings stand to challenge and improve current pediatric vascular access practice and outcomes.

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Figure Legend

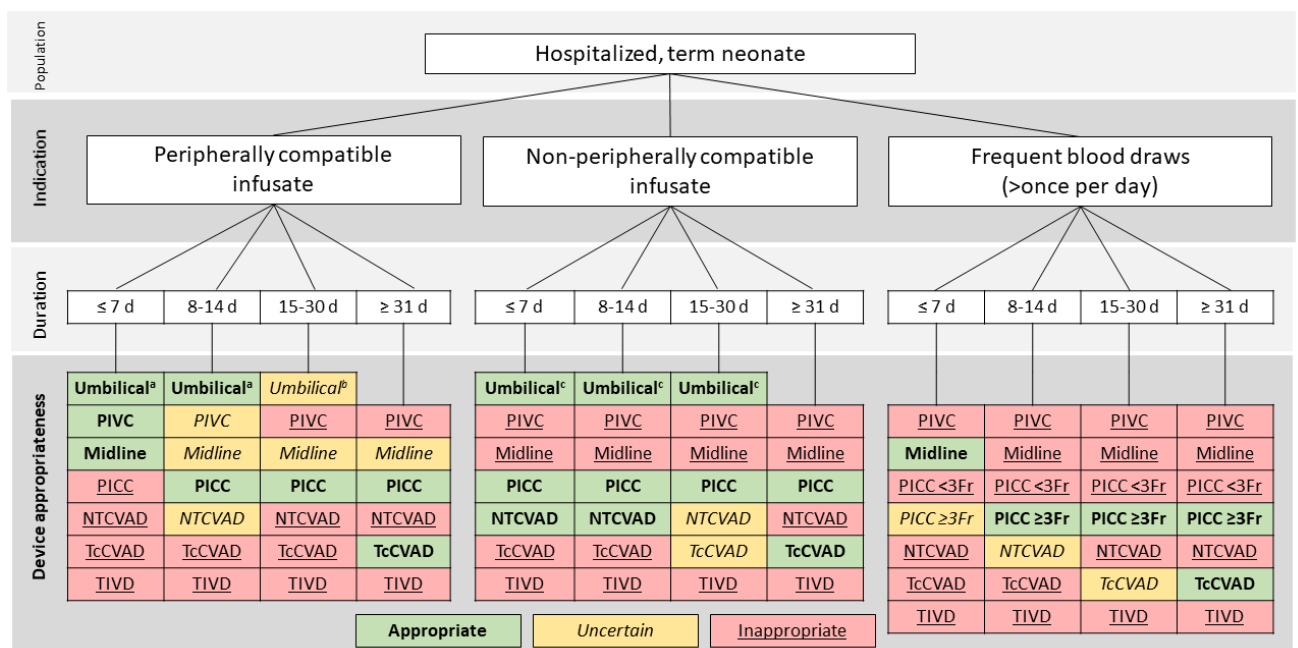


Figure 1. miniMAGIC recommendations for appropriate device selection for hospitalized, term neonates

Fr: French; NTCVAD: Non-tunneled central venous access device; PICC: Peripherally inserted central catheter; PIVC: Peripheral intravenous catheter; TcCVAD: Tunneled cuffed central venous access device; TIVD: Totally implanted venous device ^a≤2 days after birth; ^ball neonatal ages; ^c≤5 days after birth

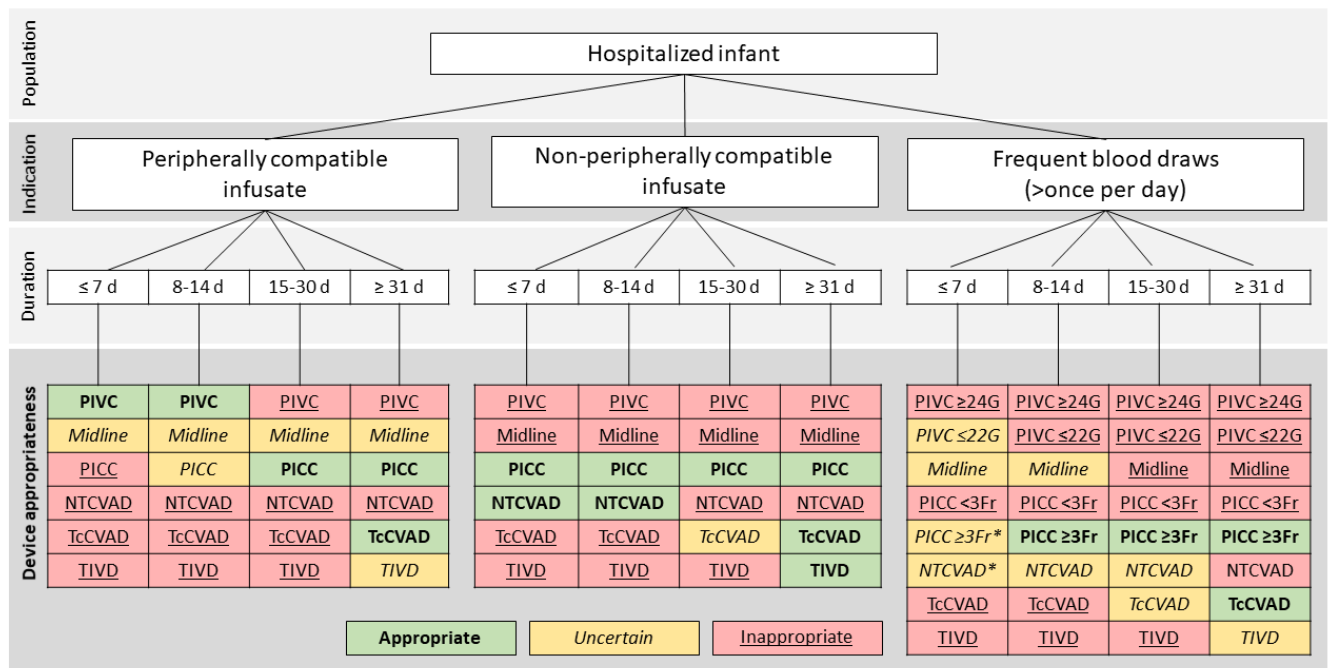


Figure 2. miniMAGIC recommendations for appropriate device selection for hospitalized infants

Fr: French; G: Gauge; NTCVAD: Non-tunneled central venous access device; PICC: Peripherally inserted central catheter; PIVC: Peripheral intravenous catheter; TcCVAD: Tunneled cuffed central venous access device; TIVD: Totally implanted venous device *indicates disagreement

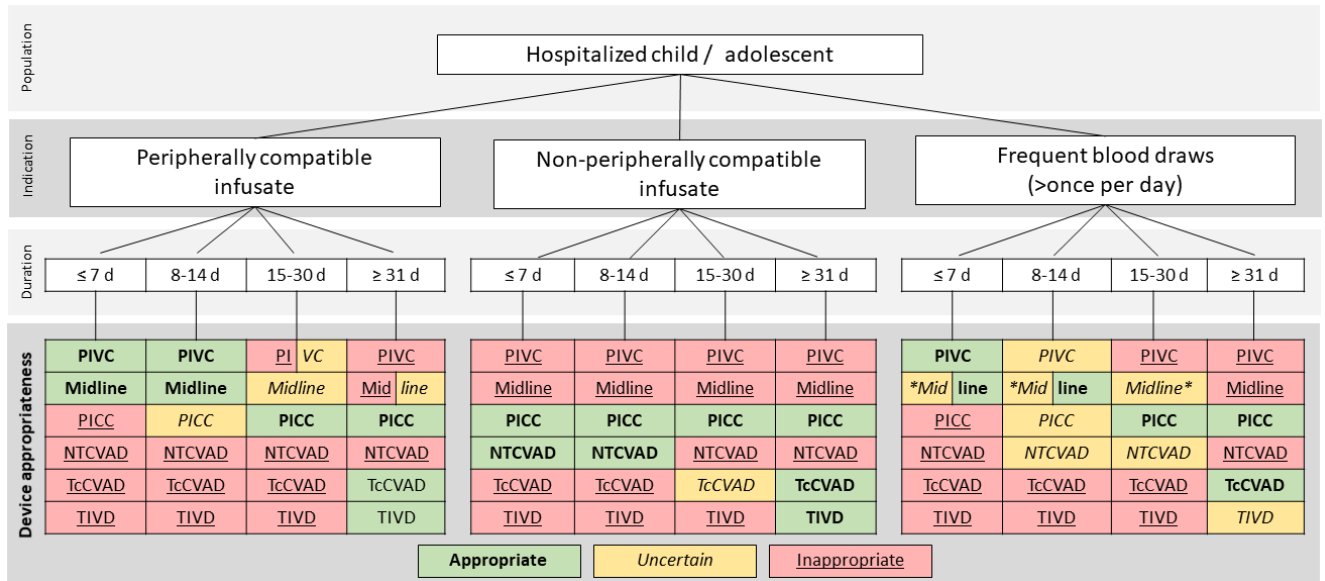


Figure 3. miniMAGIC recommendations for appropriate device selection for hospitalized children and adolescents NTCVAD: Non-tunneled central venous access device; PICC: Peripherally inserted central catheter; PIVC: Peripheral intravenous catheter; TcCVAD: Tunneled cuffed central venous access device; TIVD: Totally implanted venous device *indicates disagreement; For boxes with two colors; left: child (> One year to 12 years), right: adolescent (> 12 years to < 18 years)

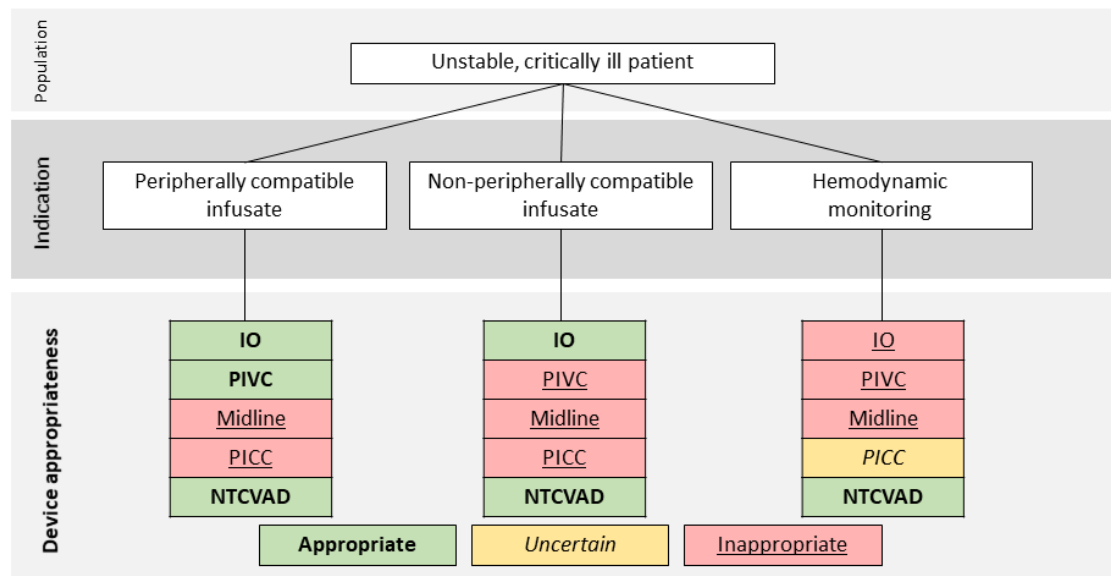
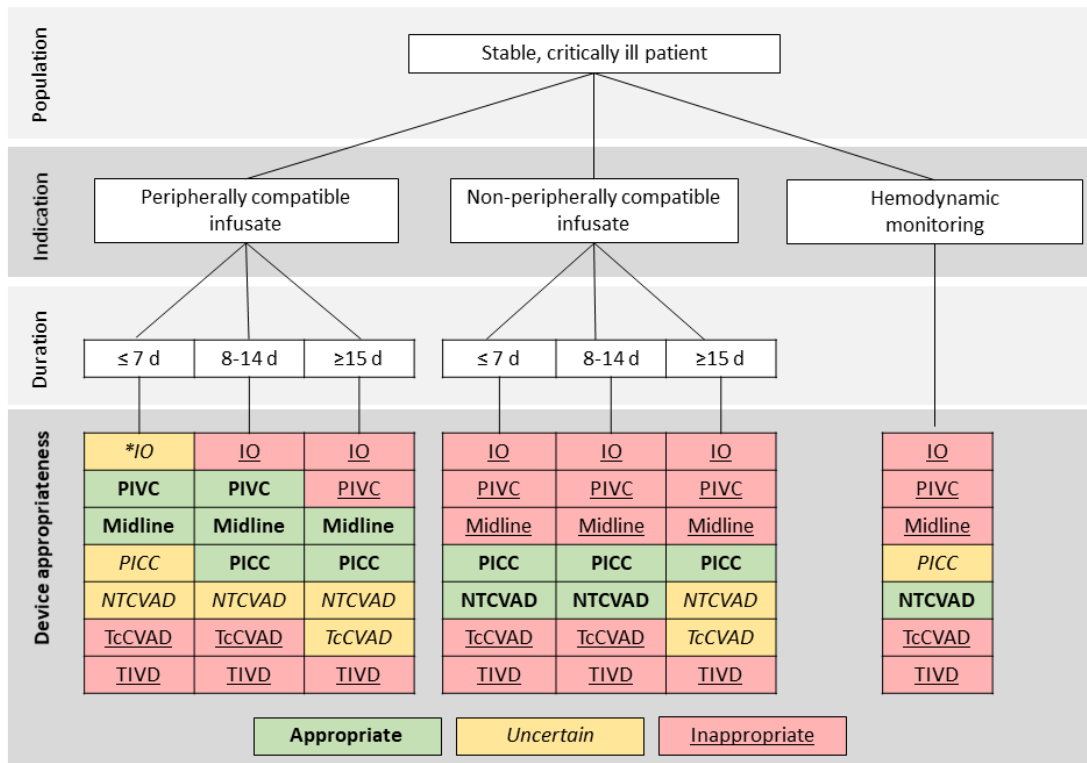
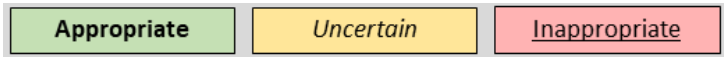
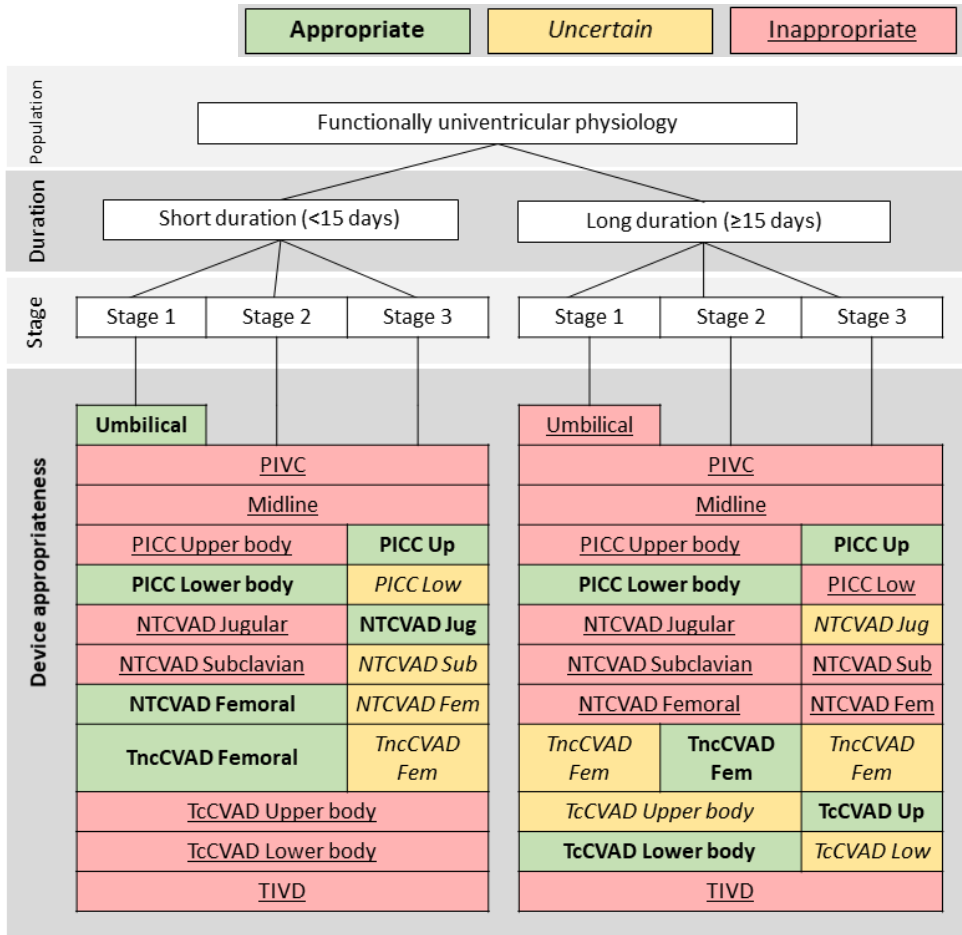


Figure 4. miniMAGIC recommendations for (a) stable and (b) unstable critically ill pediatric patients

NTCVAD: Non-tunneled central venous access device; PICC: Peripherally inserted central catheter; PIVC: Peripheral intravenous catheter; TcCVAD: Tunneled cuffed central venous access device; TIVD: Totally implanted venous device *indicates disagreement



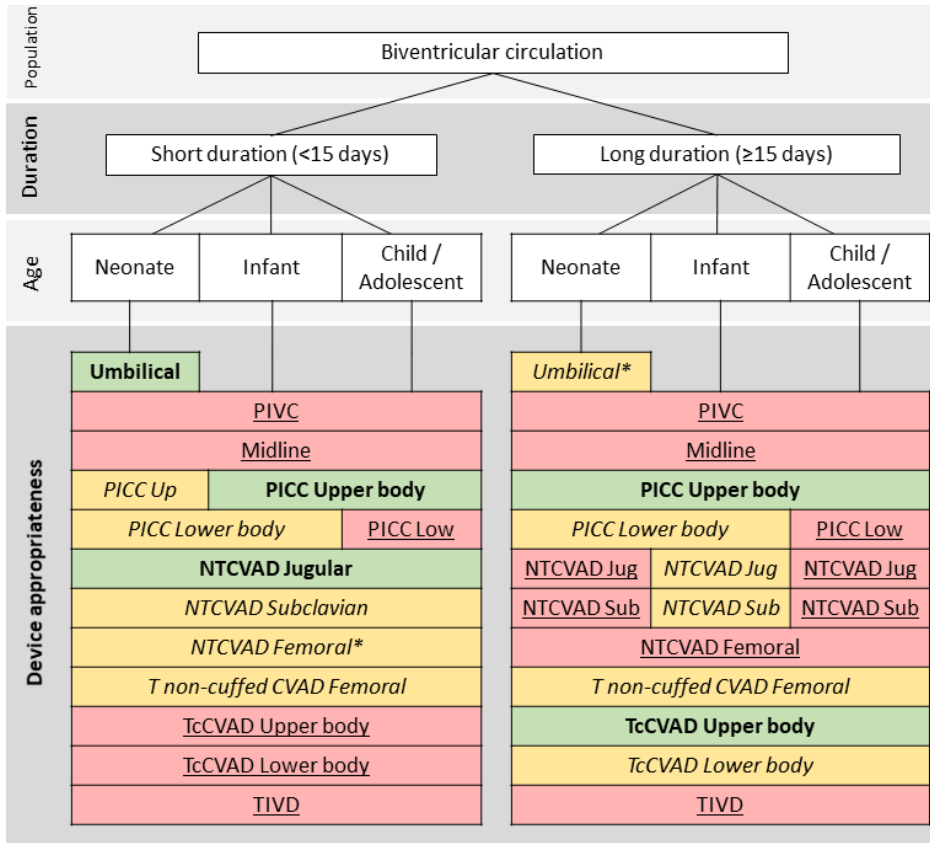


Figure 5. miniMAGIC recommendations for congenital cardiac conditions in pediatric patients Fem:

Femoral; Jug: Jugular Low: Lower body NTCVAD: Non-tunneled central venous access device; PICC:

Peripherally inserted central catheter; PIVC: Peripheral intravenous catheter; Sub: Subclavian; TcCVAD:

Tunneled cuffed central venous access device; TncCVAD: Tunneled non-cuffed central venous access device;

TIVD: Totally implanted venous device; Up: Upper body *indicates disagreement

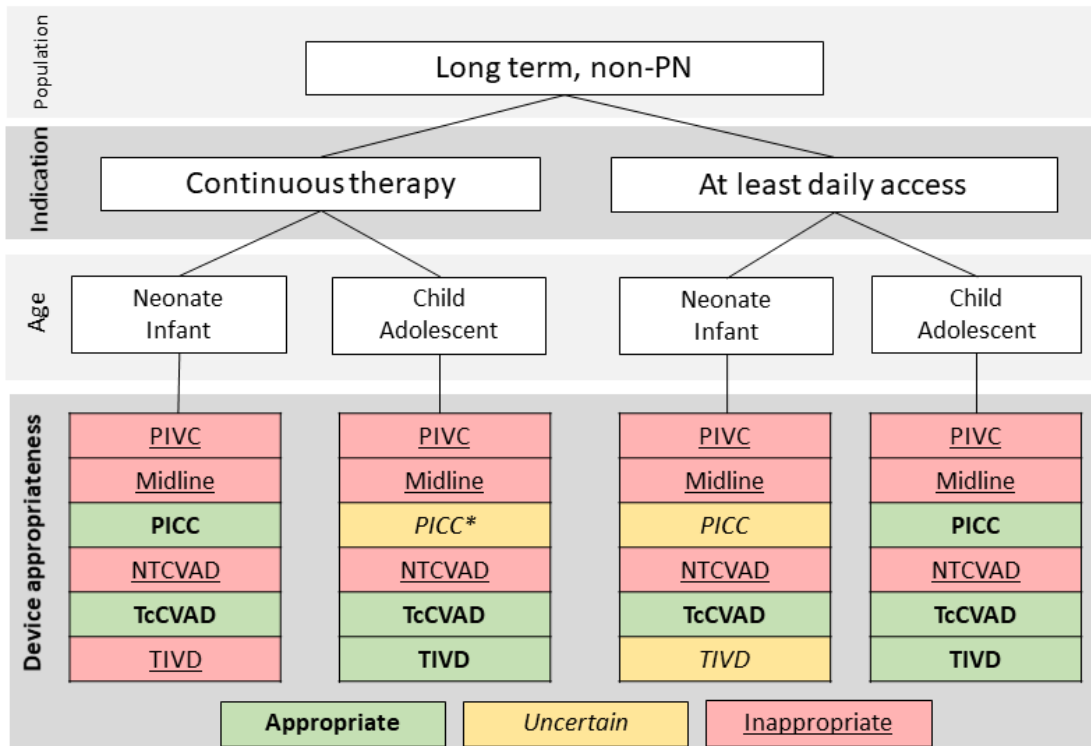


Figure 6. miniMAGIC recommendations for pediatric patients with non-PN related long-term, VAD dependency

NTCVAD: Non-tunneled central venous access device; PICC: Peripherally inserted central catheter; PIVC: Peripheral intravenous catheter; TcCVAD: Tunneled cuffed central venous access device; TIVD: Totally implanted venous device *indicates disagreement