

# Law, Ethics and Communication

A guide for giving information and obtaining  
informed consent for central venous access devices

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## 1. Introduction: Communication and informed consent in paediatric practice

Providing information and obtaining informed consent in paediatric clinical practice is a complex endeavour for clinicians, parents and children. Parents have legal and moral authority to make decisions on behalf of their children, although that authority is not absolute and their decisions must be in the best interests of the child.<sup>1</sup>

From a legal and ethical perspective, the paediatric health professional must consider how much information is adequate to ensure parents understand and can consent to treatment for their child; whether a child has sufficient capacity to understand and should therefore give their assent or consent to treatment and whether parents are making decisions which are in the best interests of their child.

This booklet discusses current law and ethical principles which underpin communication necessary to obtain informed consent for Central Venous Access Devices in the paediatric setting.

1. Miller, R. B. (2006). On Medicine, culture and children's basic interests: A reply to 3 critics. *Journal Of Religious Ethics*, 34(1), 177-189.

## 2. Communication and informed consent for Central Venous Access Devices (CVADs)

The typical model of informed consent for invasive procedures involves one main surgeon who is able to discuss the benefits, risks and alternatives of the proposed procedure. Communicating with parents and children about CVAD procedures is more challenging. There may be multiple specialists involved, including the referring clinician, the anaesthetist, radiologist and the surgeon. In addition, the insertion of a CVAD is often a secondary procedure or a means to treat a child's main problem.<sup>2</sup> Recent Coroner's Court findings in Australia<sup>3</sup> and New Zealand<sup>4</sup> highlight these complexities, calling for increased clarity of information about the risks of CVAD procedures and improved communication processes between health professionals and parents.

### Key factors producing of legal and ethical uncertainty for doctors when obtaining informed consent from parents and older children for CVAD procedures:

1. There is little documented information about risks of the different CVAD procedures.
2. The procedures may be performed by a range of medical specialists including an anaesthetist, a surgeon or a radiologist, and the levels of competence and credentialing for performing the surgery in each of these professions has not been delineated.
3. The decision for a child to have a CVAD maybe made by the child's physician but the procedure itself maybe conducted by an anaesthetist or a radiologist. This has implications for decisions about who should provide information and obtain informed consent.
4. The need for a CVAD procedure often occurs because the child has another condition that requires a longer term means of delivering necessary drugs. In these circumstances, there may be little obvious choice for parents to make about whether or not their child should have the CVAD procedure.
5. Although there may be little choice about having a CVAD inserted, the risks associated with CVAD procedures are separate to the risks associated with the anaesthetic.

*There is little documented information about risks of the different CVAD procedures.*

2. For example a CVAD may be used for chemotherapy, and for children requiring long term parenteral nutrition or blood products.

3. <http://www.smh.com.au/nsw/hospital-faces-scrutiny-over-heart-catheters-role-in-babys-death-20120116-1q37u.html>

4. BJA [BJA 99(3): 384-8 (2007)]

### 3. A guide for obtaining informed consent for CVADs

This guide is a tool to assist clinicians to apply the current law of consent and to understand their ethical obligations relevant to providing information and obtaining informed consent from parents and children for CVADs.

The objectives of this guide are:

1. To present current best practice principles about obtaining informed consent based on consideration of ethics and current law to guide clinicians who are involved in conducting CVADs for children.
2. To promote consistency between clinicians in the application of the law and ethical principles when informing parents and children about CVAD procedures and for obtaining their informed consent.

*“The process of informed consent is fundamental to clinical communication. It involves disclosing information, ensuring sufficient understanding and enabling a person to voluntarily give their consent to any proposed treatment.”<sup>5</sup>*

5. Faden R. and Beauchamp, T. (1986) *A history and theory of informed consent*, New York: Oxford University Press.

### 4. Principles for giving information and obtaining informed consent for Central Venous Access Devices

- Medical Context
- Legal Principles
- Ethical Principles

#### 4.1 Medical Context

**Definition:** Central Venous Access Devices (CVADs) are catheters whose tip terminates in a central vessel. They are suitable for infusions requiring central venous infusion, or therapy lasting longer than one week. They are also used for perioperative monitoring.

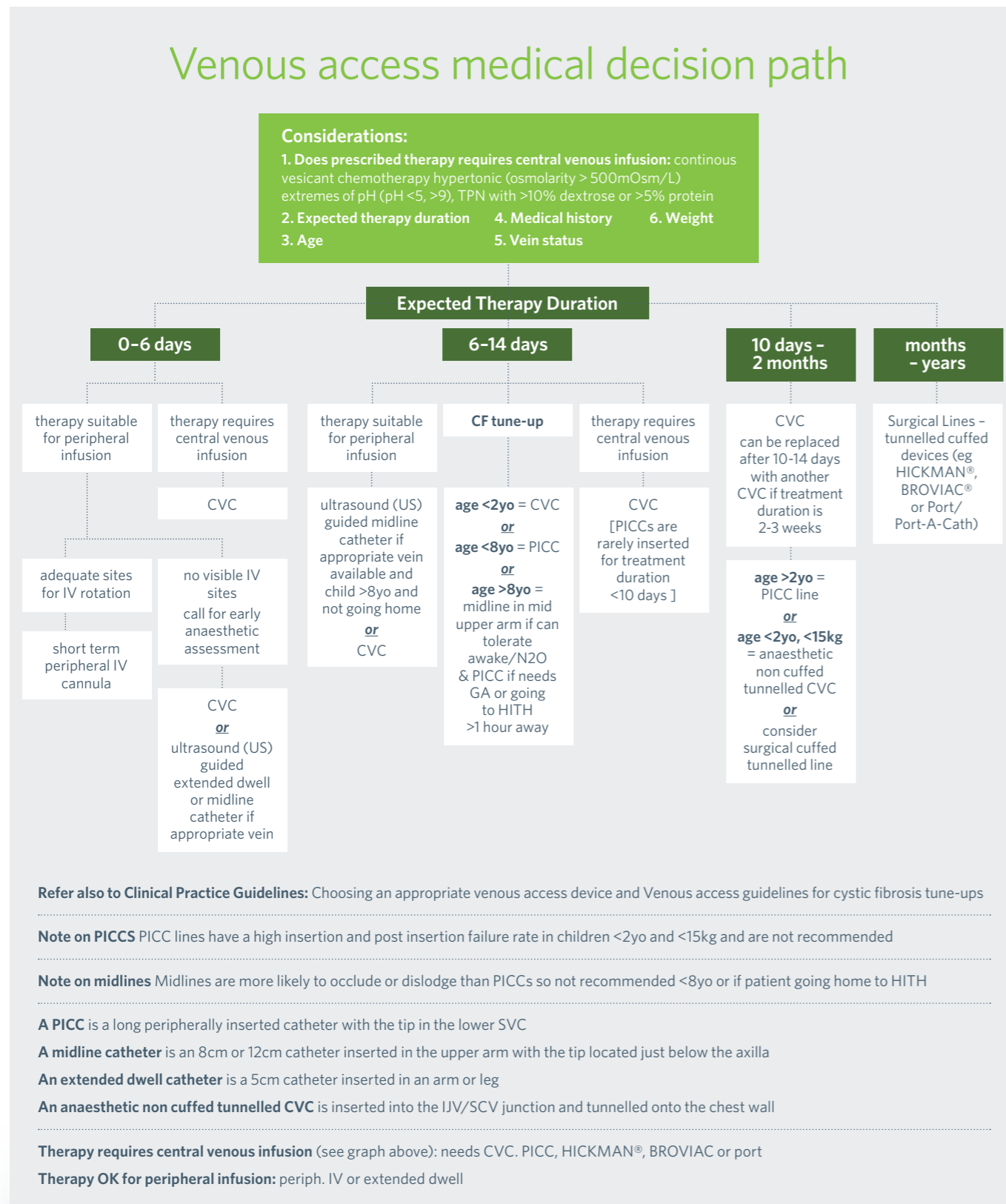
Inserting a Central Venous Access Device is a procedure which is commonly conducted in both chronic and acute conditions for children. The need for a CVAD may arise during the course of an illness, when the child requires drugs that are only suitable for central venous infusion (such as chemotherapy), or when the duration of therapy is likely to exceed 7 days, and a more permanent form of intravenous access than a peripheral IV is required. This more permanent device avoids frequent painful peripheral intravenous access procedures. A simple Central Venous Catheter “CVC” may also be inserted as part of a surgical procedure, for perioperative cardiovascular monitoring or infusion of drugs requiring central venous infusion. These perioperative CVCs are removed soon after the end of surgery, or within the first postoperative week.

**Complications:** Although necessary and common, CVAD procedures are also associated with a number of diverse complications including the development of catheter-related thrombosis, pneumothorax, arterial puncture and infection.<sup>6</sup>

*Figure 1*, developed by Dr Liz Prentice at the Royal Children’s Hospital provides an example of a flow chart for medical decision making in this area of medical practice.

6. Journeycake and Buchanan 2003, *Current Opinion in Hematology* 2003, 10:369-374

Figure 1: Venous Access Decision Path



## 4.2 Current Law

In paediatric practice, health professionals are legally obliged to obtain consent prior to any invasive medical procedure. Parents have legal authority to make medical and other decisions on behalf of their children. However, this authority is not absolute.<sup>7</sup>

The law of consent provides guidance for determining the minimum content and communication approach for giving information and obtaining informed consent. This is set out for CVADs in Table 1.

## 4.3 Ethical Principles

Paediatric health practitioners are ethically obliged to present all of the medically reasonable alternatives to parents and where a child is able to understand, to the child. These include all the 'technically possible and physically available clinical management plans that have a reliable evidence base of expected net clinical benefit'.<sup>8</sup> Presenting medically reasonable options for treatment forms part of the ethical duty to respect parents' role as their child's guardians and respect for children's developing capacities to know about and contribute to decisions about their healthcare.

Providing information and obtaining informed consent is ethically important even if there is no real choice as to whether to have the procedure, because the conversation represents a way of engaging with parents and/or their children that is respectful of them as individuals.<sup>9</sup> When decisions about what to tell children are left largely to parents and parents withhold or selectively choose what information to give, children can be left 'in a very lonely place' without the ability to 'discuss their fears or ask questions'.<sup>10</sup> As a consequence, encouraging children and their parents to be involved in decisions about their health care to the extent that they are willing and able to do so, is part of 'good clinical care'.<sup>11</sup>

There is ample evidence about the content and style of communication, which meets the needs of parents and children (see Table 3). Merely presenting information may not be enough. A review of evidence about communication in the paediatric setting indicates that parents who have been given 'very detailed information' can still feel dissatisfied with this information if their fears are not recognised or addressed and they feel that they are not being treated with respect - for instance 'being asked to consent to a new procedure while standing in the hall the night before surgery'.<sup>12</sup>

Meeting parents' and children's needs for information has also been shown to have therapeutic value, leading to 'greater compliance with treatment' and enhancing 'commitment to the chosen decision'.<sup>13</sup> Patients who are well informed about medical procedures require less pain medications, and are less anxious than patients who do not understand the medical procedures they underwent.<sup>14</sup> Ethical principles relevant to giving information and obtaining informed consent for CVADs are set out in Table 2.

*Encouraging children and their parents to be involved in decisions is part of 'good clinical care'.*

7. Discussion paper on informed consent to medical treatment (1992) WALRC 77 (11)

8. Miller, Richard B. Children, ethics, and modern medicine. *Indiana University Press*, 2003. p 18

9. Unguru Y. (2011) 'Paediatric decision-making: informed consent, parental permission, and child assent' in Diekema, D., Mercurio, M. and Adam, M., eds., *Clinical Ethics in Pediatrics. A Case - Based Textbook*, Cambridge, UK: Cambridge University Press, 1-6.

10. Wright, B., Aldridge, J., Wurr, K., Sloper, T., Tomlinson, H., & Miller, M. (2009). Clinical dilemmas in children with life-limiting illnesses: Decision making and the law. *Palliative Medicine*, 23(3), 238-247: p.245

11. British Medical Association (2001). *Consent, rights and choices in health care for children and young people*. London: BMJ Books: p.104

12. Levettown, M., & the Committee on Bioethics (May 2008). Communicating with children and families: From everyday interactions to skill in conveying distressing information. *Pediatrics*, 121(5), e1441-e1460: p.1444.

13. Popper, A. (1997-1998). Averting malpractice by information: Informed consent in the pediatric treatment environment. *DePaul Law Review*, 47, 819-836: p.826

14. Mortensen, M. G., Kiyak, H. A., & Omnell, L. (2003). Patient and parent understanding of informed consent in orthodontics. *American Journal of Orthodontics and Dentofacial Orthopedics*, 124(5), 541-550:p.542



**Table 1: Legal questions, principles and practical implications**

Questions	Answer	Current Law	What this means in practice for doctors
<b>1 Is consent always required for CVADs?</b>	Yes	<ul style="list-style-type: none"> <li>An invasive medical procedure undertaken without consent will constitute a trespass on or assault to the patient<sup>15</sup></li> <li>If a patient is advised in broad terms of the nature of the procedure to be undertaken, consent will be a valid defence to a claim of trespass or assault<sup>16</sup></li> </ul>	Inserting a CVAD is an invasive medical procedure. At a minimum, doctors should always inform parents in broad terms about the CVAD procedure even if it is part of another procedure.
<b>2 Who has responsibility to obtain and record consent?</b>	The doctor performing the procedure	<ul style="list-style-type: none"> <li>If consent is raised as an issue in a proceeding, the onus will be on the medical practitioner to prove that consent was given<sup>17</sup></li> <li>The medical practitioner who is conducting the procedure has this legal responsibility<sup>18</sup></li> </ul>	<ul style="list-style-type: none"> <li>Doctors must have documented evidence that information about the procedure was provided to the parents. The doctor who is conducting the CVAD procedure should tell the parents</li> <li>Where there are several doctors involved, there should be clear division of communication tasks</li> </ul>
<b>3 What information should be given to obtain informed consent for a CVAD?</b>	Enough information to enable the particular patient/parent to understand the procedure and risks and benefits of concern to them	<p>Failure to obtain informed consent</p> <ul style="list-style-type: none"> <li>A claim in negligence may exist if there has been a failure to adequately or properly warn of material risks of a proposed treatment</li> <li>A risk will be material (and therefore required to be disclosed) if:                             <ul style="list-style-type: none"> <li>(a) a reasonable person in the patient's position (<i>or parents of the young patient</i>) would be likely to attach significance to it; or</li> <li>(b) the medical practitioner was, or should have been, aware that the particular patient (<i>or parents of the young patient</i>) would be likely to attach significance to it.<sup>19</sup></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Doctors should provide information to parents and/or older children about what a CVAD procedure involves; risks involved in conducting the procedure; management of those risks; what to expect afterwards; likely complications and management of those complications</li> <li>The risks of the procedure should also be balanced and presented against the need for the procedure and the alternatives (if any) of not having the CVAD procedure.</li> <li>The conversation should also include an opportunity for parents to ask questions or express their concerns and the doctor should check on the extent of parents' understanding.</li> </ul>

15. Schor v Furesh (No 2) [2012] WASC 305  
 16. Dean v Phung [2012] NSWCA 223 at [61]  
 17. Dean v Phung (above) at [59] – [60], [64]  
 18. Rogers v Whitaker, at [490]  
 19. Rogers v Whitaker, at [479]

Questions	Answer	Current Law	What this means in practice for doctors
<b>4 How should information about CVADs be communicated?</b>		<ul style="list-style-type: none"> <li>The practitioner is required to communicate the relevant information in terms that the particular patient can understand<sup>20</sup></li> </ul>	<ul style="list-style-type: none"> <li>Information about CVADs should match the particular child's and/or parents' level of understanding</li> <li>Doctors need a variety of methods and tools to draw from when obtaining informed consent (see Table 3)</li> </ul>
<b>5 From whom should consent be obtained?</b>	From parents of the child and from an older child who is capable of understanding the procedure	<ul style="list-style-type: none"> <li>Until a minor achieves sufficient understanding and intelligence to enable him or her to understand fully the proposed course of treatment (is Gillick competent),<sup>21</sup> the child's parents assume decision-making responsibility and must provide any relevant consent, unless the proposed treatment is a "special medical procedure" (usually invasive and irreversible) requiring a Court order<sup>22</sup></li> <li>If a child is regarded as Gillick competent (capable of understanding the nature and consequences of the proposed treatment,<sup>23</sup> the child is considered to have legal capacity to consent to treatment</li> </ul>	<ul style="list-style-type: none"> <li>Where a child is too young to understand the CVAD procedure, doctors should gain the consent of parents. One parent is sufficient to provide consent</li> <li>Where an older child is able to understand the nature and consequences (is Gillick competent), this legal capacity must also be recognised and their consent obtained</li> </ul>
<b>6. Are there any exceptions to informed consent?</b>	Yes, if there is a medical emergency	Generally except in the case of emergency or necessity, all medical treatment is preceded by the patient's/parents choice to undergo it. <sup>24</sup>	If a CVAD is required as part of emergency treatment, informed consent is not required.

20. Rogers v Whitaker at [490]  
 21. Gillick v West Norfolk and Wisbech Area Health Authority [1986] AC 112  
 22. Marion's case (1992) 175 CLR 218  
 23. Marion's case (1992) 175 CLR 218  
 24. Rogers v Whitaker at [632]

**Table 2: Ethical Principles and Informed Consent**

Ethical Principles	What this means in practice for doctors
<b>All treatment and communication about treatment should aim to maximize benefits for children</b>	<p><b>Inserting a CVAD must be in the best clinical interests of the child.</b></p> <ul style="list-style-type: none"> <li>Be aware of and refer to relevant and evidence based guidelines when informing parents about the need for, insertion of and management of CVADs</li> <li>If you are conducting a CVAD procedure as part of a multidisciplinary team, have a plan to ensure that parents receive all the required information</li> <li>Recognise that benefits can also arise from communication about treatment procedures with parents and with children</li> </ul>
<b>Paediatric clinicians should respect parents' responsibility to be primary decision makers for their children.</b>	<p><b>Obtain informed consent</b></p> <ul style="list-style-type: none"> <li>Respect for parents' capacity to make decisions for their child means doctors need to tailor information and communication to meet their individual needs (see Table 3)</li> <li>Brochures and written information are important aids to understanding, but are not a substitute for conversation between doctor and parents<sup>25</sup></li> <li>The emphasis for informed consent should be on the 'interactive process' in which information is shared and 'joint decisions are made'<sup>26</sup></li> <li>Making your clinical thinking and reasoning transparent<sup>27</sup> is a useful way to share information with parents</li> <li>Discussing options and procedures with parents enables them to ask questions and talk about their concerns – a necessary part of the decision making process</li> </ul>
<b>Paediatric clinicians should respect a child's developing autonomy and capacity to contribute to medical decisions</b>	<p><b>Discuss the procedure with the child</b></p> <p>Providing information is 'a way of engaging with children that is respectful of them as individuals'<sup>28</sup></p> <ul style="list-style-type: none"> <li>Providing information to children models a process of respect for and enhances their future capacity to contribute to health decisions</li> <li>Children undergoing surgical procedures 'would like to know about seemingly "minor" questions' – things that are 'routine for practitioners'. These include: the expected duration of the procedure; the location and length of any incision and bandages; the location and purpose of intravenous lines and other assorted tubes, and the child's likely appearance after the procedure<sup>29</sup></li> <li>If there is no choice in having the procedure, It is important that children 'should not be given the illusion that their opinion will be a determining factor if adults have already made a final decision'<sup>30</sup></li> </ul>

25. **National Health and Medical Research Council (2004).** *Communicating with patients: Advice for medical practitioners.* Canberra: Australian Government; National Health and Medical Research Council. (2004). *General guidelines for medical practitioners on providing information to patients.* Canberra: Australian Government; Skene, L., & Milwood, S. (2001). "Informed consent" to medical procedures: The current law in Australia, doctors' knowledge of the law and their practices in informing patients. In L. Shotton (Ed.), *Health care law and ethics* (pp. 84-92). Katoomba: Social Science Press; : p.88

26. **Committee on Bioethics (1995).** Informed consent, parental permission, and assent in pediatric practice. *Pediatrics*, 95(2), 314-317: p.316;

27. **Brody H. (1989).** 'Transparency: Informed consent in primary care' in Arras, J. and Steinbock, B., eds., *Ethical issues in modern medicine 5th ed.*, Mountain View: Mayfield Publishing Company, 94-100.

28. **Unguru Y. (2011)** 'Pediatric decision-making: informed consent, parental permission, and child assent' in **Diekema, D., Mercurio, M. and Adam, M., eds.**, *Clinical Ethics in Pediatrics.* A Case - Based Textbook, Cambridge, UK: Cambridge University Press, 1-6.

29. **Levetown, M., and the Committee on Bioethics (May 2008).** *Communicating with children and families: From everyday interactions to skill in conveying distressing information.* *Pediatrics*, 121(5), e1441-e1460: p.e1444

30. **Wilfond and Diekema, 2012.** see n 27, p.3

**Table 3: Information needs of parents<sup>31</sup>**

Parents prefer...
<ul style="list-style-type: none"> <li>Information that is 'consistent, up-to-date, comprehensive, evidence based, value free and tailored to their needs and reading level'</li> <li>Information presented in comparative risk terms or using a question and answer format, rather than information presented as probabilities or using vague descriptors such as "rare"</li> <li>Information that is tailored to their individual needs, and available in a variety of formats e.g. written text, DVD, face-to-face or telephone discussion and appropriate languages</li> <li>Direction from health professionals about where to find "good" information sources</li> <li>Time to process and discuss information both during and outside the consultation'</li> <li>The opportunity to talk with other parents in the same situation as themselves to share knowledge, experience and feel reassured, to counterbalance the information received from official sources (e.g. health professionals, Government, scientific community)</li> <li>Consultations to take place in a relaxed and unhurried atmosphere where possible</li> <li>Having written information in advance of a consultation to be better prepared to ask questions'</li> <li>Information written in plain language<sup>32</sup></li> <li>A leaflet about the procedure prior to attending the unit<sup>33</sup></li> <li>The answer to: "what does it mean for me and my family and what should I do about it?"<sup>34</sup></li> </ul>

31. **Jackson, C., Cheater, F. M., & Reid, I. (2008).** A systematic review of decision support needs of parents making child health decisions. *Health Expectations*, 11(3), 232-251

32. **Mortensen, M. G., Kiyak, H. A., & Omnell, L. (2003).** Patient and parent understanding of informed consent in orthodontics. *American Journal of Orthodontics and Dentofacial Orthopedics*, 124(5), 541-550: 549

33. **Steven, M., Broadis, E., Carachi, R., & Brindley, N. (2008).** Sign on the dotted line: Parental consent. *Pediatric Surgery International*, 24, 847-849

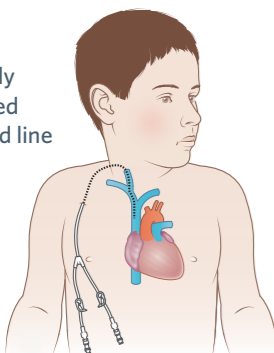
34. **Woodward, S., Franck, L., & Wilcox, D. (2004).** Consent for paediatric surgery: What are the risks. *Clinical Governance*, 9(4), 216-221: p.218)

Photocopy for use with patients.

## Sample informed consent process

(for clinicians to complete to give to parents or as a trigger to begin discussions)

Surgically implanted tunnelled line



### Central Venous Access Device: Surgically implanted port or tunnelled line

#### Information for parents and (older) children prior to obtaining informed consent.

Your child needs a surgical CVL line because .....

The benefits of this procedure for your child are.....

This procedure involves .....

The procedure is done under anaesthetic .....

The person who will do this procedure is.....

The risks of this procedure are .....

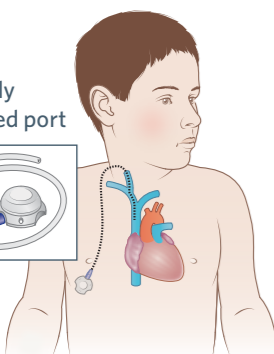
The risks of not having the procedure are.....

The likelihood of these risks or complications occurring are .....

If complications arise during this procedure, the following will be done.....

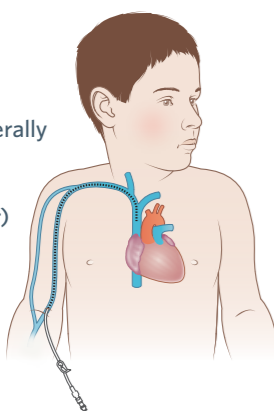
Afterwards you should expect .....

Surgically implanted port



- Peripherally inserted central catheter
- Enters a vein in the arm, ideally inner upper arm
- Tips is in lower SVC

PICC (peripherally inserted central catheter)



### Central Venous Access Device: PICC peripherally inserted central catheter

#### Information for parents and (older) children prior to obtaining informed consent.

Your child needs a (peripherally inserted central catheter) PICC line because .....

The benefits of this procedure for your child are.....

This procedure involves .....

The procedure is done under anaesthetic .....

The person who will do this procedure is.....

The risks of this procedure are .....

The risks of not having the procedure are.....

The likelihood of these risks or complications occurring are .....

If complications arise during this procedure, the following will be done.....

Afterwards you should expect .....

### Central Venous Access Device: Midline Device

#### Information for parents and children.

Your child needs a midline i/v line because .....

The benefits of this procedure are .....

This procedure involves .....

The procedure is done under anaesthetic .....

The person who will do this procedure is.....

The risks of this procedure are .....

The risks of not having the procedure are.....

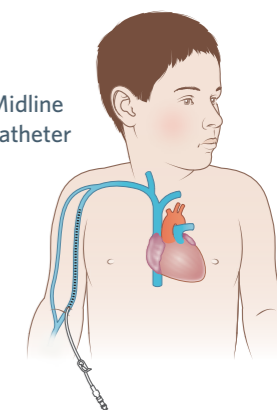
The likelihood of these risks or complications occurring are .....

If complications arise during this procedure, then.....will occur

Afterwards you should expect .....

- A 'midline' catheter is a long i/v, inserted into the arm, finishing in the axillary vein

Midline catheter





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