



Children's Bioethics Centre

# Making law practical for families and paediatricians

Victoria Law Foundation Grant

**Project Funding Body**

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**Project Team**

Associate Professor Clare Delany  
Senior Ethics Associate, The Royal Children's Hospital, Children's Bioethics Centre

Associate Professor Lynn Gillam  
Academic Director and Clinical Ethicist, The Royal Children's Hospital, Children's Bioethics Centre

Dr Merle Spriggs  
Senior Research Fellow  
Murdoch Children's Research Institute

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## Executive Summary

The “Making Law Practical Project” was funded by the Victorian Law Foundation in 2010. The project aimed to assist in managing the interface between law and paediatric medical practice when obtaining informed consent for paediatric surgical procedures. The project involved 3 overall phases:

### Phase 1: Scoping study

This phase examined five parents’ experience of the informed consent process in situations where their child (with haemophilia) required a port-a-cath (PORT). These interviews identified the importance of the informed consent process in situations where the medical indication for their child to receive a PORT was urgent and there was little or no choice involved. Based on interviews with parents the key findings were:

1. The process of communication associated with obtaining informed consent for the insertion of a port was valuable because it provided parents with opportunities and encouragement to ask questions and be involved in decision making about their child’s port. This involvement enhanced the trust they developed with their clinician.
2. After the procedure, parents reflected that receiving information and being involved in some way in decision-making about their child’s port increased their understanding of and confidence in their ongoing role as advocates for their child.

### Phase 2: Consultation

Meetings and interviews with surgeons and anaesthetists at the Royal Children’s Hospital (RCH) were conducted. The insertion of a Central Venous Access Devices (CVAD) was identified as a procedure which although commonly conducted for children, required examination and review of processes of communication. (See Appendix 1 for a description of types of CVADs). These consultations, combined with two recent interstate Coroner’s Court findings examining deaths related to complications from CVAD procedures in children, highlighted a need to improve the consistency of communication in this area of paediatric practice to accord with required legal and ethical principles.

### Phase 3: Dissemination

This phase involved delivery of conference and workshop papers, and publication of ‘Law, Ethics and Communication: A Guide for giving information and Obtaining Informed Consent for Central Venous Access Devices CVADs’. Available as a printed booklet and online at [www.rch.org.au/bioethics](http://www.rch.org.au/bioethics)

This report provides the outcomes of these phases.

## Project objectives

The three main objectives of the project were to:

1. Increase parents’ and where appropriate older children’s knowledge and understanding of how they may participate in and share decisions about treatment.
2. Increase doctors’ understanding of legal and ethical principles relevant to providing information and obtaining informed consent in a specific area of clinical practice.
3. Enable doctors to make better decisions about what information they should give to parents and children, and how to involve them in health care decisions.

## Project Phases

### Phase 1: Scoping Study

#### Parents' experiences of Informed Consent for Ports: A pilot study<sup>1</sup>

Scoping Study objectives: To explore the types of information parents received prior to their child undergoing the insertion of a port; how, when and from whom they received such information; and how they used that information to make the decision for their child to undergo the insertion of a port. Five parents (all mothers) participated in the interviews, either by phone or in person. The interviews were transcribed and analysed thematically.

In this scoping study, all parents indicated they wanted to be part of discussions about their child's port and although they recognized the need to trust health professionals to make decisions in their child's best interests, they also expressed the desire to have some input into the decision-making process. Reflecting back, (after the procedure), parents commented that despite not making the final decision about the timing of the port, their involvement in discussing the pros and cons of the port prior to the event, had a lasting effect. In particular, being involved had increased their confidence in advocating for their child and had provided an example to them, of how they can contribute to their child's ongoing care.

#### Major Findings

There were two major findings from these interviews:

- 1. The process of informed consent for the insertion of a port was valuable to parents.** Parents recognised there was little choice or alternatives available for this procedure for their child. However they valued the information they received, the trust developed with health professionals, and the opportunities and encouragement to ask questions and be involved in decision making about their child's port.

*"I feel I understand this whole process very well but...I have no idea what to ask and I'm not really sure whether I'm getting the full information and I'm fully compliant like I do have a belief medicine is good...but...I do think doctors have a lot to learn about what informed consent is and there's no ideal patient who knows everything to ask you to make you do informed consent in a good way."*

*So even if there were massive signs in the emergency when you walk in, that said please feel free to ask any questions there is no stupid question, lots of parents still won't know and they still won't ask the question. (P1)*

1. The pilot study was conducted by five Master of Nursing Science students from The University of Melbourne, supervised by Associate Professors Clare Delany and Lynn Gillam, RCH Children's Bioethics Centre. Nursing students: Kathleen Byrne, Kristina Kolcakovski, I-Sen Lai, Wan Li, Lin-Wei Chen.

The communication process was particularly significant because the final decision to have the port was often urgent. Parents recalled that the decision felt rushed and dependent on their child's changing health needs and/or the availability of surgery.

*"To have the doctors or nurses whoever just discuss with us what's the next stage of plan just so we know for ourselves and get ourselves organised and prepared for the next stage you know and even if it means then that not only get ourselves organised but we get our child organised and get him mentally prepared for the next stage." (P5)*

- 2. Receiving information and being involved in decision-making about the port had an ongoing impact on parents.** Parents reflected on how their experience in both the lead up to the decision and the operation itself had a lasting effect. From a clinical perspective, the port improved their ability to control their child's bleeds and care for their child. From a more holistic perspective, the information received and the experience of learning, choosing and being involved in the decision to have the procedure, resulted in increased understanding of and confidence in their role as advocates for their child.

*"I think it's a journey you go on as a parent as well with a child with a chronic illness. You learn to become more of an advocate and you become more aware of your position within their medical care and that you do have a say in certain things within a boundary of safety for your child but there are things that you can that you can direct more than you thought... maybe." (P2)*

Appendix 2 provides further supporting quotes for the 2 main findings.

Figure 1 summarises these 2 main findings and demonstrates via the funnel shape that the pre-port experience for parents was one of inevitability, leading towards the single option of their child undergoing a port procedure. The decision and procedure was then followed by a period described by parents as one in which they achieved some growth or expanded control and confidence in caring and advocating for their child.

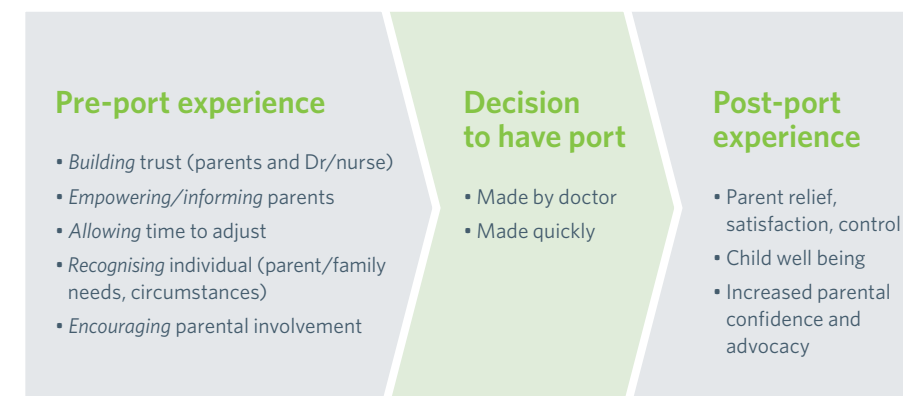


Figure 1: The process of informed consent, decision-making and outcomes for parents making decisions about ports.

*"To have the doctors or nurses whoever just discuss with us what's the next stage of plan...and get him mentally prepared for the next stage."*

*"I think it's a journey you go on as a parent as well with a child with a chronic illness."*

## Phase 2: Consultation

In June 2011, meetings were held with Associate Professor Leo Donnan (Chief of Surgery at the RCH, and anaesthetists, Dr Liz Prentice, Dr Rob McDougall and Dr Michael Nightingale) to identify an area of paediatric surgery where informed consent processes required review.

**Medical context:** The insertion of Central Venous Access Devices was identified as a procedure which is commonly conducted for children with both chronic and acute conditions. 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 going 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 “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.

Although necessary and common, more permanent CVAD devices are also associated with a number of diverse complications including the development of catheter-related thrombosis, pneumothorax, arterial puncture, leakage, line failure and infection.<sup>2</sup> A recent study of complications arising from Peripherally Inserted Central Catheters, known as PICC line reported a 30% rate of a child experiencing at least one complication.<sup>3</sup> The context was a large paediatric hospital in the USA.

**Legal issues:** There is some literature,<sup>4</sup> and case law<sup>5</sup> examining anaesthetists' legal and ethical responsibilities in gaining informed consent for anaesthesia (see also Appendix 3). In the more specific area of inserting a CVAD two recent Coroners' Court findings (discussed below), highlight the need for a review of the processes of communication and informed consent.

### Coroner's Court Findings

In 2012, in NSW, Maurice Blackburn represented the family of 10-month-old Tama Galiere at his Coronial inquest. Tama died in the Sydney Children's hospital in June 2008. He was a happy, healthy baby who was admitted to the hospital to receive antibiotics for an eye infection. A percutaneous intravenous central catheter (PICC) was inserted under general anesthetic to administer the antibiotics. Tama died two days later. The post-mortem report for Tama revealed myocarditis (inflammation of the heart) with a distinct possibility of physical trauma due to placement of the PICC line.

Tama's death raises issues about the insertion and management of PICC lines in babies and whether the hospital had appropriate clinical guidelines in place to guide good practice. His parents are keen to understand the circumstances of their son's death.

Maurice Blackburn also represented the family of one-month-old Joshua Elliott at a Coronial Inquest into his death at Sydney Children's Hospital following a central catheter insertion in September 2009. Joshua had been born with a gastric disorder of gastrochisis which was surgically corrected at birth. He required the central line so he could receive additional nutrition and the plan was for a PICC line to be attempted and if this failed for a surgical central line to be inserted the next day.

Joshua was consented for a PICC line and/or a percutaneous line which is another option. However, there was no mention in the consent form of a surgical central line option. The hospital did not have readily available the particular central line the doctor required and he used a radial arterial catheter instead. The catheter which was found to be shorter and stiffer than the central venous line that should have been used, was placed in a position that was not optimal. At some stage during the night, the catheter perforated the walls of the vessel causing the nutrition Joshua was receiving to flood his lungs. He suffered a cardio respiratory arrest and died the next morning.

The Coroner's findings focused on the serious miscommunication between the doctors looking after Joshua and his mother, who was adamant she had not consented to a percutaneous line being inserted. The Coroner made a broad recommendation that there be an information pamphlet that is clear and easy to read, listing the pros and cons of the procedure or operation to be set out and that the document be signed by the parent or patient.

These findings demonstrate that obtaining informed consent for CVADs is complex. It does not fit the usual model of consent for invasive procedures where there is one main surgeon involved who is able to discuss the pros and cons and alternatives of the procedure. In the case of CVADs, there may be multiple specialists involved, including the referring clinician, the anaesthetist and the surgeon.

Phase 2 identified key areas 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 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 may be made by the child's physician but the procedure itself may be 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. The risks associated with the CVAD procedure are separate to the risks associated with the anaesthetic.

2. **Journeycake, J. M. and G. R. Buchanan (2003).** *Thrombotic complications of central venous catheters in children.* Current opinion in hematology 10(5): 369; Beck, S., J. Dubois, et al. (1998). *Incidence and risk factors of catheter-related deep vein thrombosis in pediatric intensive care unit: a prospective study.* Journal of Pediatrics 133: 237-241.

3. **Barrier A., Williams, D., Connelly, M. and Creech, B. 2012.** *Frequency of peripherally inserted central catheter complications in children.* The Pediatric Infectious Disease Journal, 31(5), 519-521.

4. **Mavroforou A., Stamatiou, G., Koutsias, S., Michalodimitrakis, E., Vretzakis, G. and Giannoukas, A. 2007.** *Malpractice issues in modern anaesthesiology.* European journal of Anaesthesiology, 24, 903-911. White and Baldwin 2003; Davidson, A., & O'Brien, M. (2009). *Ethics and medical research in children.* Paediatric Anaesthesia, 19(10), 994-1004

5. *Kerr v Minister for Health* [2009] WASCA 32.

## Phase 3: Dissemination

1. Production of a booklet *"Law, Ethics and Communication: A Guide for giving Information and Obtaining Informed Consent for Central Venous Access Devices CVADs"*
2. Delivery of workshop on informed consent at Society for Paediatric Anaesthesia in New Zealand and Australasia, Melbourne, 2012
3. Conference presentation *"Obtaining informed consent for paediatric surgery – more complex than it seems"* Communication, Medicine and Ethics July 2013, The University of Melbourne.

## Appendix 1

### Definition: central venous access devices (CVADs)

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.

#### There are several types of CVADs including:

- **"Simple CVC"** most commonly inserted into the internal jugular neck vein, but the femoral vein in the groin can also be used. Commonly used for the perioperative period, but can remain insitu up to 14 days.
- **'Tunneled' cuffed CVCs** include HICKMAN™, BROVIAC™, permacaths, infusaports. These can stay in place for several years, and are commonly used for chemotherapy, and patients requiring long term parenteral nutrition or blood products. They are usually inserted by a surgeon.
- **Percutaneously Inserted Central Catheters (PICCs):** A long catheter inserted into an upper arm vein, with the tip ending just above the heart. They are most commonly used when antibiotics are required for more than a week for severe infection, can stay in place up to a few months. In patients less than two years of age, a variation of these ('Tunneled' non cuffed CVCs) are inserted in the neck and tunneled onto the chest wall.
- **Midline catheter:** although not truly a CVAD, as the catheter tip ends at the axilla (arm pit) this is a catheter inserted into the same location as PICC (the upper arm) and used for a 2 week course of antibiotics as an alternative to a PICC line in older children with cystic fibrosis. The use of these negates the need for x-ray, and is simpler and quicker for this patient group.



## Appendix 2

### Interview transcripts and themes

**Theme 1:** The process of informed consent for the insertion of a port was valuable to parents for building trust with their doctor especially when the decision for surgery may be rushed.

#### Examples from interviews:

##### Building Trust

*"We trusted the doctor, we were completely and utterly overwhelmed and exhausted we were very sick of seeing our little baby being poked and prodded by all sorts of people in emergency trying to access veins and we felt that putting a port in and beginning port treatment gave us a glimmer of hope that we could have a more normal life at some point." (P3)*

*"We've worked with the Dr long enough that I actually trust his judgement and he has taken us ways that have only been beneficial to us. He may have an idea of what he thinks is best and he will present that and he will also present what else there is and if you ask again and if you're still not sure he will be happy to lead you to more information so you can work it out for yourself." (P2)*

*"We had quickly developed a very trustworthy relationship with the Dr where we really took his guidance and his advice we felt he had our child's best interests at heart he was the expert in the field and he said look I think it's time to put in a port." (P3)*

##### Time to adjust

*"They (doctor and nurse) sort of just laid all the information out on the table and explained that there was a possibility that within the first couple years of our child's life a port may be required and we sort of went away thinking that sounds all high end I'm sure that's not going to be the case for our family our son. But we very quickly found that we were frequently going to the royal children's hospital in the first year of his life we travelled thousands of kilometres." (P3)*

*"We had no options it had to be done it was either that or another few weeks down the track he would have had another bleed in that knee and all we were doing were prolonging it and making the arthritis earlier and a young age and that's something we don't want we want to try to prevent all that as much as we can so he can have a normal happy walking kid life..." (P5)*

##### Making the decision

*"...we didn't really have much more time to think about it we had to really get onto it straight away and yeah do it and that was good for us because we didn't have to ponder over it or think oh its 2 months away 6 weeks away 4 weeks away it was within days and it was over and done with before we knew it." (P5)*

*"It happened so quickly if we had one more week I think then that would have been different it just happened so fast that we didn't have time to get all of the information that I would have liked but that might be me being particularly pedantic." (P3)*

*"The timing, I look back and I feel I could have controlled that better then, I didn't have to be swept up in the 'quick we booked it in come down tomorrow it's all happening'. I could have said hold on I need another week or I need another month I could have done that but at the time I didn't think I could. I felt that [haematologist] had gone to great lengths to make this happen and to make this happen fast...In hind site you look back and you realise you could have said no you could have asked for more time but I don't know he still would have ended up with a port at the end of the day so I don't feel at all as if we made the wrong decision." (P1)*

**Theme 2:** Receiving information and being involved in decision-making about the port had an ongoing impact on parents.

##### Afterwards

*"You become a stronger person. In the beginning when my child was born we felt very vulnerable I think emotionally I didn't deal with it very well I was constantly frightened feeling his whole life was going to be very different to what I imagined what my child's life would be ...so I felt I was educated and a professional person and I was on maternity leave at the time but I really felt once you're in the hospital system that you know there were times where you have to be you have to be very careful how you are advocating for your child and there were times where in the beginning I let doctors or nurses do things in a way that there's no way now I would, I would feel that I knew what the right thing to do in some cases was and I'm not going to let you make 5 attempts to hit a vein go and get someone who is more experienced than you. Whereas in the beginning I felt this is a doctor not knowing that interns and residents-- and they all have different levels of experience and I think sometimes they are excited to meet a child with haemophilia because it's a new learning opportunity for them and I completely understand that but...now I feel that no this is my child and I will talk to you and I want you to learn and become more experienced and not at the disadvantage of my child.. So your voice and your courage in that sense grow..." (T3)*

## Appendix 3: Cases dealing with CVAD use

**16** GWW and CMW (1997) 21 Fam LR 612 involved an application for an order permitting the harvesting of bone marrow from a child. It touches on the risks associated with CVADs:

*“The insertion of a central venous catheter is associated with a risk of complications such as bruising, thrombosis or if one of the veins in the chest is used, pneumothorax. These risks were described as small while recovery is very rapid.”*

**17** Re *BABY D (No 2)* (2011) 45 Fam LR 313 involved an application for an order to extubate a child. It discusses procedures related to intubation/extubation:

*“Although the procedure of extubation may be invasive, it was very clear from the evidence of Dr X and Dr Y that both practitioners considered extubation a routine medical procedure as opposed to a procedure involving major or irreversible surgery. Further, both practitioners strongly emphasised that they did not consider extubation to be a “special medical procedure” as defined in the Family Law Rules 2004 (Cth) (the Rules).”<sup>17</sup>*

The Court also reviewed recent cases concerning the division between parental and court responsibility. A decision to extubate was held to be within the realm of parental responsibility.

**18** In *Leheste v The Minister for Health* [2012] WADC 92, the Court considered the use of peripheral intravenous catheters. The case involved an adult patient and consent was not an issue. The following expert evidence was accepted:

*“Peripheral intravenous cannulation is among the commonest of medical procedures and is performed thousands of times each day in Australia hospitals. It is a procedure by which a fine plastic tube is inserted into a superficial peripheral vein so that fluid and medications can be given directly into the vein. When properly performed for appropriate indications, it is considered to be a safe procedure whose benefits outweigh its potential complications.”<sup>18</sup>*

**16** In *Metropolitan Health Service v King* [1999] WASCA 236 an adult patient had undergone an investigative procedure and subsequently had an intravenous drip line inserted, which ran into a peripheral intravenous cannula from a fluid bag. Intravenous lines are a known cause of infection. The cannula provided a pathway by which an organism could enter the bloodstream, but it was held that this could occur with or without negligent conduct. The issue in the case was whether any negligent act caused the patient’s enterobacter cloacae infection. The patient was an adult and consent was not in issue.

**17** *Wilsher v Essex Area Health Authority* [1988] 2 WLR 557 is an older case in which consent was not in issue. In this case a catheter had been inserted into a premature baby’s vein instead of an artery, resulting in low oxygen readings and treatment with excess oxygen. The issue for determination by the Court was whether the mistake caused particular injuries suffered by the child.

**18** *Kerr v Minister for Health* [2009] WASCA 32 dealt with warnings of risk of complications associated with the administration of pethidine by an anaesthetist. The Court of Appeal held that there was a material risk inherent in administering pethidine, being a small risk of causing seizures or other adverse complications. The risk was held to be material because a reasonable person in the patient’s position, if warned of the risk, would be likely to attach significance to it. It should therefore have been disclosed to the patient. The patient’s claim failed on the basis that the Court could not be satisfied that the pethidine in fact caused the seizure suffered by the patient.



**Children's Bioethics Centre**

The Royal Children's Hospital Melbourne  
50 Flemington Road Parkville  
Victoria 3052 Australia

TELEPHONE +61 3 9345 4086

[www.rch.org.au](http://www.rch.org.au)

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