A case study of involving children in the process of medical equipment design in the hospital environment
This thesis is submitted to the Auckland University of Technology for the Degree of Masters of Philosophy.

'I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person nor material which to a substantial extent has been accepted for the award of any other degree or diploma of a university or other institution of higher learning, except where due acknowledgment is made in the acknowledgments.

Attestation of Authorship
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Abstract
Pediatric hospital design is receiving growing attention internationally around the value of involving children (the users) in the process.

Many studies demonstrate the value of involvement and consultation/collaboration with children seeking their input in the design of their pediatric hospital environments. This should extend to furniture and equipment in the environment. However, little evidence suggests children are involved in the design of other medical equipment or general products found in these environments.

As a design student, I explored the feasibility of involving children alongside stakeholders in the design of medical equipment through the design of Sprout IV Pole; an Intravenous Pole produced with the intention of positively impacting the hospital experience for children.

Through an extensive process of consultation, Sprout IV Pole was trialed in hospital. While trialed, children alongside their parents and nurses were involved through a questionnaire to gain their feedback upon the design, to determine what value Sprout IV Pole offered in comparison to existing IV Poles.

This process illustrated the complexity of involving children in hospital but also demonstrates the value their involvement holds to designing medical equipment. This case study concludes by offering advice to fellow design students and researchers aiming to design medical equipment as well as hospital organizations to seek the involvement of children through the process if improving their healthcare environment, service and products.
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INTRODUCTION

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Paediatric Hospital

The paediatric hospital can be a daunting place for children (Landro, 2013; Government of Australia, 2012). They feel a range of emotion such as fear, anxiety, stress and pain (Lambert, Glacken & McCarron, 2013). These four negative emotions are commonly felt by children because of their experience in hospital and can adversely affect their physical and psychological wellbeing (Lambert, Coad, Hicks et al., 2013). Admission to hospital entails that children cooperate and interact with people, the noises and the smells (Landro, 2013; Lambert, Coad, Hicks et al., 2013). They placed considerable value on contact with their friends, as well as physical activity (Hunt, Brown, Coad et al., 2013). This lack of activity provided to children while in hospital was one factor contributing to some of the worst experiences for children in hospital (Pelander & Leino-Kilpi, 2010).

One major cause of anxiety and pain for children is associated with the admission process and the experience of waiting for treatment (Bledsoe, McPherson, Shiao & Kay, 2010; Pelander & Leino-Kilpi, 2010) as well as the treatment itself (Lambert, Coad, Hicks et al., 2013; Eislen, Ulrich, Shaylor et al., 2008). Another contributing factor relates to children’s experiences of disconnection from their usual routines, going to school, going home, playing with their toys and socialising with their friends (Hunt, Brown, Coad et al., 2013; Pelander & Leino-Kilpi, 2010). Lambert, Coad and Hicks et al. (2013) concluded that these factors also demonstrated the greatest potential to create the best experiences of children in hospital (Pelander & Leino-Kilpi, 2010).

Other influential factors contributing to children’s negative emotions related to the unfamiliar nature of the hospital physical environment, the people, the noises and the smells (Landro, 2013; Lambert, Coad, Hicks et al., 2013). Admission to hospital entails that children experience and interact with all of these new elements while enduring treatment and painful procedures (Pelander & Leino-Kilpi, 2010). Studies conducted with children about their worst experiences in hospital revealed that both the people and the environment were also factors contributing to their worst experiences. Paradoxically, these factors also demonstrated the greatest potential to create the best experiences for children in hospital (Pelander & Leino-Kilpi, 2010).

The anxiety of children is heightened because of the limited communication they provided about their health (Lambert, Glacken & McCarron, 2013). Children seek information about their health to enable them to understand what was happening. Inadequate information provision can lead children to draw inaccurate interpretations and misconceptions, resulting in unnecessarily worry, fear and anxiety (Lambert, Glacken & McCarron, 2013a). Providing children with information about their health is considered to affect positively their coping ability, reduce their stress and uncertainty as well as improve recovery times (Lambert, Glacken & McCarron, 2013a).

Evidence suggests the traditional approach of designing healthcare services and environments is medical-centred (Bledsoe & Kay, 2010). This is a leading contributor to children’s experiences of disconnection from their lives. When they experience unfamiliar environments with little ability to self-determine their care needs, they develop stress and fear. The medical-centred approach prioritises the clinical needs of healthcare professionals over the psychological needs of children and their families (Lambert, Coad, Hicks et al., 2013). This approach assumes that health professionals are the primary users of the hospital space but many would disagree (Hunt, Brown, Coad et al., 2013; Lambert, Coad, Hicks et al., 2013; Pelander & Leino-Kilpi, 2010; Robertson, Plyler & Evans, 2012; Soderback, Coyne & Harder, 2011). Child’s voices are seldom sought or heard when decisions are made about their healthcare (Coyne & Harder, 2011). This is also the case for the design of children’s healthcare. Nonetheless, a considerable number of studies demonstrate the value of children’s involvement in the design of their healthcare (Bishop, 2013; Coad & Shaw, 2008; Lambert, Coad, Hicks et al., 2013; Pelander & Leino-Kilpi, 2010).

Studies have demonstrated the benefit of involving children in the decision-making process so that their needs are placed considerably elevating their anxiety and stress levels (Lambert, Coad, Hicks et al., 2013). Children’s voices are seldom sought or heard when decisions are made about their healthcare (Coyne & Harder, 2011). This is also the case for the design of children’s healthcare. Nonetheless, a considerable number of studies demonstrate the value of children’s involvement in the design of their healthcare (Bishop, 2013; Coad & Shaw, 2008; Lambert, Coad, Hicks et al., 2013; Pelander & Leino-Kilpi, 2010).

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Design of healthcare environments and services with children

Considerable international efforts are being made to improve or simply understand what constitutes a hospital environment that doesn’t contribute to increasing the fear, anxiety, stress and pain felt by children (Hunt, Brown, Coad et al., 2013; Bishop, 2013; Coad & Coad, 2008; Lambert, Coad, Hicks et al., 2013; Landro, 2013). What these studies have found is the value children place upon supportive environments (Bishop, 2013); the appropriateness of the design for children (Hunt, Brown, Coad et al., 2013); age-appropriate spaces for children (Bishop, 2013); the value of aesthetics (Lambert, Coad, Hicks et al., 2013); as well as their colour preferences (Coad & Coad, 2008; Lambert, Coad, Hicks et al., 2013). This indicates a range of factors that need careful consideration when designing paediatric hospital environments to improve the experiences of children. For example, small elements such as incorporating natural lighting, nature, careful colour selection and quiet sound (Marschner, 1998) have been seen to positively influence how patients feel. Colour has also been identified as an emotional trigger for children, and requires careful consideration when designing hospital environments (Lambert, Coad, Hicks et al., 2013). Children’s preferences lay with pale to mid-range colours, specifically blues and greens. It is also worth noting that colour preferences differ and depend on the ages of the children (Coad & Coad, 2008).

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However, most importantly, a supportive, paediatric hospital environment encourages children to engage and manage their health instead of neglecting their perspectives (Bishop, 2013). By creating environments more focused on the users as opposed to the function of the environment, hospitals have the power to promote children’s wellbeing (Lambert, Coad, Hicks et al., 2013). The effect of carefully considering these elements can positively affect the recovery rates of children (Wittert, 2004) but to disregard these elements can have the opposite effect (Marschner, 1998). As much as children place specific value upon the hospital environment, the relationship of the environment to the service provided also requires careful consideration. Even though the physical environment may support the values of children, if there is a poor connection between the two this can lead to problems in the delivery and utilisation of the service (Dawson & Fabrice, 2010).

Considerable international efforts are being made to improve or simply understand what constitutes a hospital service that doesn’t contribute to increasing the fear, anxiety, stress and pain experienced by children (Biddiss, McPherson, Shea et al., 2013; Taylor, Haase-Casanovas, Weaver et al., 2010; Hunt, Brown, Coad et al., 2013; Landro, Naka & Johnson, 2010; Pelander & Leino-Kilpi, 2010). What these efforts illustrate are the value that children place on involvement; to be heard in decision-making about their healthcare and to have their perspectives considered equally alongside those of their parents (Taylor, Haase-Casanovas, Weaver et al., 2010). In a study presented by Taylor, Haase-Casanovas, Weaver et al., (2010), parents and children were consulted to understand their attitudes towards involving children in healthcare decisions. Aside from one family, everyone agreed that children should be involved, but to varying degrees depending on their age, cognitive ability, maturity, gender and severity of illness among other factors (Taylor, Haase-Casanovas, Weaver et al., 2010).

Paediatric hospital environments and services need to cater to children’s developmental needs to ensure that their services are supportive and constructive for children (Lindke, Naka & Johnson, 2010). While health professionals are experts in the developmental needs of children (Lindke, Naka & Johnson, 2010) the best way to really understand these needs is by actually involving children and listening to their experiences (Pelander & Leino-Kilpi, 2010). “Due to the complex needs of these children and young people, it is essential that their views, along with those of their families, are embedded into service design and provision to ensure that services are relevant and appropriate” (Hunt, Brown, Coad et al., 2013, p.3).
Barriers to children’s involvement

Common issues reported through the literature revolve around misconceptions about children, their vulnerability, adult proxy and gaining access. There are many fears and misconceptions around the ability of children to make decisions, fearful that they will make irresponsible decisions for short term gains (Coad & Shaw, 2008; Kirk, 2006). Some believe children are unable to separate “Fantasy from reality” (p.1251), making them too immature to understand their world and accurately convey their experience (Kirk, 2006). Counter arguments to this suggest that someone cannot be denied the right to make a decision on the basis that they will make irresponsible choices (Coad & Shaw, 2008).

Parents also feel that their children are dependent upon them, thus giving parents the authority to speak on behalf of their children (Children’s Hospitals Australasia & the Paediatric Society New Zealand, 2011). In a study of health professional-parent-child interactions, it was found that both the health professional and the parents displayed non-supportive behaviour towards the child’s participation in conversation and decision (Soderback, Coyne & Harder, 2011). This observation transfers to research and design, with adults inclined to speak on behalf of their children out of a sense of protection (Kodish, 2006; Kodish, 2012; Soderback, Coyne & Harder, 2011). Parents and health professionals often see the need to protect their children from exposure to research instead of allowing them to participate and share their own experience and views (Kodish, 2006; Kodish, 2012). This creates a conflict between protection and participation (Soderback, Coyne & Harder, 2011).

Another way in which protection dominates participation is when children are considered vulnerable, implying that research conducted with them is risky and inevitably could be “dangerous” (Carter, 2009, p.859). Review bodies instinctively adopt an extremely cautious approach to examining any proposals for children’s participation in research (Carter, 2009). This may deter researchers from conducting meaningful research with children as proposals are heavily scrutinised, limiting the methods of interaction and the richness of data that researchers can collect (Carter, 2009).

Children inherit this label of vulnerability through the way that society is structured (Children’s Hospitals Australasia & the Paediatric Society New Zealand, 2011). Children are negatively defined by what they lack in relation to adulthood. This position fails to recognise that childhood has its own culture (Kirk, 2006). Thus, children that are commonly involved in research are ‘adult-like’ and perceived to be less vulnerable, consequently making the research less risky (Carter, 2009). Children seen to be less vulnerable include older articulate and healthy children (Carter, 2009). Yet, in many ways this excludes a large proportion of children with complex needs from the opportunity to participate in research (Carter, 2009). Studies indicate that children with medical conditions rely on parents and health professionals to communicate information on their behalf as adult proxies because the children are seen to be too vulnerable (Stalker, Carpenter, Corrins et al., 2004).

This practice of adult proxies communicating on behalf of children rests on the assumption that adults know best and that children are unable to articulate their perspectives (Kirk, 2006). Many would suggest the poor reliability of proxies’ ability to communicate on behalf of their children (Stalker, Carpenter, Corrins et al, 2004; Coad & Coad, 2008; Pelander & Leino-Kilpi, 2010). This is due to a range of factors including the proxies and healthcare professionals’ differing priorities for children, which potentially misrepresents the needs and desires of the children in research (Pelander & Leino-Kilpi, 2010). Another factor is that children view and experience situations differently to adults, and they cannot communicate these experiences easily (Kirk, 2006; Pelander & Leino-Kilpi, 2010). First hand interaction is the best way of understanding the perspectives of children experiencing hospitalisation (Taylor, Haase-Casanova, Weaver et al., 2010; Pelander & Leino-Kilpi, 2010).
Importance of involving children

Children differ in many ways to adults, predominantly through the different cultures of childhood as well as their different healthcare needs and priorities. The culture of childhood is unique, it is not just a stepping stone to adulthood and researchers need to acknowledge this when researching with children (Kirk, 2006). Many forget that children are a completely individual population with their own cultural norms and complexities (Druin, 2002). These cultures are created by children when developing their understanding and interpretation of the adult world they live in (Freeman & Mathison, 2009). Adults can offer interpretations of the cultures of childhood, but cannot offer exact representations.

Alongside the differing cultures of childhood, this can be illustrated through the different priorities of adults in healthcare services. Hospital managers value the easy maintenance of products that are low cost, easy to install and long lasting (Marzano, 1998). Health professionals value products that are “quiet and unobtrusive” allowing them to get on with their jobs tending to patients instead of dealing with unwieldy products (Marzano, 1998, p.52). This perspective contrasts with the value that children place on products that make them feel safe, and are comfortable to use (Marzano, 1998). Children are constantly growing and developing, and environments, services and products need to be flexible enough to support them to grow (National Association of Children’s Hospitals and Related Institutions, 2007). Children require health-care services that involve their parents throughout the experience, as well as child-sized and child-friendly environments and products (National Association of Children’s Hospitals and Related Institutions, 2007).

How to empower children

To empower children to share their views and perspectives in a way that positively informs the design of medical equipment, a range of factors need to be considered. These include the mind shift of adults, children’s desire to be heard and appropriate methods. Adults working with children such as health professionals, parents, designers and researchers need to shift their view of children to support them and provide opportunities to share their perspectives. Children should no longer be considered ‘objects of research’ like species or animals that require humans to create their meaning and interpretations of what they perceive they feel but acknowledge that children have a voice as “active agents” in research (Kirk, 2006, p.1252). Research should be conducted “with” children as opposed to “on” children (Carter, 2009). This view of research with children acknowledges them as key stakeholders rather than beneficiaries or passive recipients of services (Roberson, Pyle & Evans, 2013, p.21). Adults should accept that children are the experts in their daily experiences of childhood. “If viewed in this light it is possible to frame the researcher/reviewers as vulnerable due to the lack of skills, expertise and understanding of the landscapes of childhood and the spaces in which children live their lives” (Carter, 2009, p.1252).

Alongside the need for adults to shift their perspective of children, they also need to understand children’s hunger to communicate thoughts about their healthcare experiences (Bishop, 2013; Lambert; Glacken & McCarron, 2013; Stalker; Carpenter, Cutmore et al 2004). This can be done through the careful selection of appropriate methods that enable the children to feel comfortable with the consultation process (Kirk, 2006). There is a growing body of evidence that children can effectively communicate when researchers are aware and acknowledge the best ways of facilitating their participation (Kirk, 2006; Carter, 2009). To empower children through consultation, a combination of traditional research methods (with adults) alongside novel innovative child-friendly methods are recommended (Lambert; Glacken; McCarron, 2013b).

Novel methods include arts-based methods of drawing, making, photographing and videoing – methods that lean towards qualitative research (Carter, 2009). These methods have been used in the past by researchers to collect information that reflects children’s lives through enjoyable and fun activities (Carter, 2009; Kirk, 2006). However they do have their limitations when it comes to analysis (Kirk, 2006). Overall in order to empower children to communicate their perspectives adults need to facilitate opportunities for them to share through appropriate methods.
Acknowledging children’s human rights

Finally, involving children in the design of medical equipment and healthcare not only values the voices of children and positively shapes their healthcare experiences, but also involves their rights to have a say on issues that are important in their lives. Over the past decade, emerging legislative pieces such as The United Nations Convention of the Rights of the Child created a political driver to involve children in decisions associated with their healthcare (Lambert, Clarken & McCarron, 2013a). This convention brought international attention to the involvement of children in decision-making that included healthcare decisions (Cavet & Sloper, 2004). This draws upon the Universal Declaration of Human Rights, stating that children are entitled to special care and assistance.

The convention was officially recognised in New Zealand in 1993 (The United Nations, 1989; Children’s Hospital Australasia & the Paediatric Society of New Zealand, 2011). This influenced the Care of the Child Act in 2004. The Act supports the need to provide children with opportunities to voice their perspectives in decision-making processes with their parents and health professionals, as well as giving equal value to the child’s perspective when finalising decisions.

Although these documents do not specifically stipulate the need to involve children in the “design” of their healthcare environments, services and products, the benefits of involving children are apparent. Applying the key messages that these legislative pieces offer would further the benefits offered to children by removing the barriers that disabled them from sharing their view and acknowledging the importance of involving children, as well as empowering them to competently decide what they need from their healthcare environments, services and products.
Involving children in the design of medical equipment

Considerable literature supports the involvement of children in the design of their healthcare environments and services, ensuring that their perspectives and viewpoints are heard and acknowledged. The healthcare environment includes medical equipment, which informs a part of the traditional approach of designing the paediatric hospital environment and service; to design with the functionality of equipment in mind (Hutchison, 2007) (Refer to figure 1). Designing medical equipment involves a broad range of considerations around health and safety issues, the ease of cleaning, and the need to design appropriately for specific environments (Hutchison, 2007).

Focusing on health and safety issues may lead to equipment that works efficiently but is harshly designed with little value placed on aesthetics (Hutchison, 2007). It is argued that the qualities of products people surround themselves with (such as medical equipment) and how well designed they are considerably impacts on the quality of our lives (Cross, 2006). The power of carefully considered design decisions is currently not sufficiently acknowledged in the design of medical equipment, but this is slowly starting to change (Hutchison, 2007).

Involving children in the process of medical equipment design in the hospital environment.

A design revolution is starting to take place in hospitals, affecting everything from the design of buildings to the smallest of pieces of medical equipment (Hutchison, 2007). Paediatric hospitals need to cater to children not only through the appropriateness of the environment and service, but also through the design of equipment (Children’s Hospitals Australasia & the Paediatric Society New Zealand, 2011). Hutchison (2007) argues that well-designed pieces of medical equipment have the ability to reduce fear, anxiety, stress and pain by valuing the voice of the user (children) and seeking their involvement. The case study aims to explore the process of how to gain the involvement of children in the design of a piece of medical equipment for the paediatric hospital environment, and to understand what value this can bring to the final design outcome.

The design approach taken for this project differs from the traditional process of designing medical equipment. The traditional approach consists of...
developing medical equipment within strict regulatory requirements that add constraints to the development, manufacturing, marketing and continual improvement of the equipment (Medina, Kremer & Wysk, 2012). This process is grounded in a series of five linear stage-gated steps planned to ensure that all boxes are ticked in an orderly manner; these are identified as 1 - clinical need definition and team formation, 2 - feasibility, risk assessment and conceptualisation, 3 - detailed design/verification and validation 4 - production planning and qualification and 5 - market introduction and post launch (Medina, Kremer & Wysk, 2012). The reasoning behind the addition of these constraints on the design of medical equipment is because of the impact that the success or failure of the equipment can have upon the lives of their users (Medina, Kremer & Wysk, 2012).

This contrasts with the human-centered approach for this project which values the voices of users and stakeholders throughout the design process (Marzano, 1998). There is growing evidence that suggests the value of this approach for addressing the needs of healthcare design (Uehira & Kay, 2009; Boyd, McKernon and Old, 2010; Duncan & Breslin, 2009; Marzano, 1998; Searl, Borgi & Chemali, 2010). The valuing of involving users throughout this approach also ensures that the actual needs of users is considered, as well as valuing the input of health professionals (Cavetta & Fabris, 2012). Product designers rely on users' needs to underpin the success of their design process (Park, 2012). What designers do understand is that if their designs do not properly reflect users' needs then their products can be compromised because they fail to function as required (Park, 2012).

In order to elicit the involvement of children in the design of medical equipment their level of involvement needs to be carefully considered. That said, identifying the best level is still an ambiguous process (Druin, 2002). Involving children in the design process as ‘users’ is perhaps the most common role for children in design (Druin, 2002). This is achieved by observing children in the existing environment using the existing product (Druin, 2002). Involving children in the process as “testers” consists of seeking their involvement in the testing of new products for use. This testing comes before any commercialization of the product, as they are purely in the form of prototypes (Druin, 2002). Involving children in the process as “informants” means involving children throughout the process of designing the product. Their role would also encompass the roles of ‘user’ and ‘tester’ as well as providing them with the opportunity to provide feedback on sketches and designs throughout the duration of the process (Druin, 2002). And lastly, involving children in the process as “design partners” involves considering them as an equal stakeholder (Druin, 2002). This level of involvement offers them the opportunity to participate in any stage they desire to, allowing them maximum control and influence on the process (Druin, 2002).

Although involving children as ‘design partners’ may provide maximum benefit for children, there may be institutional and structural barriers that impede this happening. This case study involved children as testers for the design of one specific piece of medical equipment, Sprout IV Pole. The design of Sprout IV Pole was used as a case study to explore how this process might be undertaken in a hospital.

Sprout IV Pole
Sprout IV Pole started as the final project of my Bachelor of Design degree in 2012 (refer to figure 2). My desire to improve the paediatric hospital ex-
experience came from my personal hospital experience as a toddler. Sprout IV Pole was designed to appeal to the core values children place upon play and aesthetics (Biddiss, McPherson, Shea et al., 2013). Offering children play opportunities in the healthcare environment provides children with objects that make the environment more child-friendly (Biddiss, McPherson, Shea et al., 2013). Beautiful objects and toys in the hospital environment make children feel more at ease, alleviating their fear (Salmela, Salantera & Aronen, 2010). Positive distractions in these spaces are also known to reduce the anxiety of waiting among children (Biddiss, McPherson, Shea et al., 2013). The intention of Sprout IV Pole aims to spark this connection with children to improve their paediatric hospital experience. The involvement of children in the research process is important for understanding if these values were actually experienced by children.

Journey to consult children

When this project first started its design was supported by a few nurses within the hospital, as well as my supervisor. At the completion of my Bachelor degree, support was increased to receive funding from the Starship Foundation and their Five Stars sponsor Mercury Energy, and their Star Supporters Club. This funding supported the development of Sprout IV Pole with the intention of implementing the design in Starship Children’s Hospital (Refer to figure 6).

From this point forward, support gradually increased with many more collaborators informing and supporting the design to make it safer and stronger. This support contributed towards making the product a tangible option for hospitals. Over time, the design evolved to reach its fourth stage generation at the completion of this study (Refer to figure 1). From the onset of the project it was important to have children’s involvement. However because of the time restrictions of my degree, the ethical difficulty of gaining access to children, and the uncertainties of how to involve children in hospital, their involvement was not obtained until late 2013.

Children were involved with the evaluation of the second generation of Sprout IV Pole during a validation trial (part of my honours year) (Refer to figure 3) conducted with healthy children in a simulated hospital environment (Parbhu, 2013). In this evaluation, children had the opportunity to experience both Sprout IV Pole variations alongside a traditional IV Pole used in hospitals today. This produced a wealth of insight into the value that children place upon the aesthetics of the product, over its functionality. The evaluation also revealed differing perspectives between children that experienced hospitalisation from those that hadn’t (Parbhu, 2013).

The children involved in the simulation potentially saw the trial as an opportunity to experience these different products, with a limited understanding of how children in hospital may experience them, having had no first-hand experience of themselves. From the simulation I learnt that in order to truly understand how children would interact with Sprout IV Pole compared with existing IV Poles, I would need to conduct an evaluation in hospital with sick children. Progressing from my honours it was clear that refinements were needed at the manufacturing stages of the Sprout IV Pole design, to ensure that the product was safe for evaluation use in hospital with children, their parents and hospital staff.
METHODOLOGY

Designer's View - Social Constructivist Design Process and Human Centered Design
The personality, skills, background, culture, values and motives of the person; these factors include the colour, shape, behaviour and texture of the object; the product responds to as well as the social context (Freeman & Mathison, 2009). This experience has on varying influential factors that our sensory system recognises, that people construct through interactions with objects. Different people perceive the same things differently (Feast & Melles, 2010). The truth and meanings that people construct through interactions with objects vary (Freeman & Mathison, 2009). This perspective is shaped by my personal experiences of childhood, research, and how they are represented in the study (Freeman and Mathison, 2006). As a researcher, my perspective and assumptions about children shape the perspectives of the product based upon their own personal experiences and influential factors.

As a product designer, I hold a social constructivist perspective. This perspective acknowledges that there is truth waiting to be discovered. This perspective is shaped by my personal experiences of childhood, research, and how they are represented in the study (Freeman and Mathison, 2006). As a researcher, my perspective and assumptions about children shape the perspectives of the product based upon their own personal experiences and influential factors.

Constructivist Designer’s View - Social Constructivist

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This study aimed to explore how a designer might understand the experiences of health professionals (Nurses), children and their parents in the context of hospitalisation. This is because I am not contextually bound to the hospital environment, nor am I a health professional or user of the product. I relied on the knowledge and experiences of the children, their parents, and the health professionals to allow me to evaluate whether my design held value to them.

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This said, each individual’s experience with the product cannot be predetermined; one person’s positive experience doesn’t imply that everyone will experience it that way. This informs the value of consulting children during the evaluation of Sprout IV Pole, which was essential to understanding the value that the design held for them.

This approach acknowledges that as the designer/researcher I am not the expert in designing to cater to the needs and experiences of those experiencing Sprout IV Pole in hospital. This is because I am not contextually bound to the hospital environment, nor am I a health professional or user of the product. I relied on the knowledge and experiences of the children, their parents, and the health professionals to allow me to evaluate whether my design held value to them.

But most importantly, to value the voices of children through the social constructivist approach aligns more so with the qualitative or mixed method approach (MacKenzie & Kröge, 2006). Even though the study design resulted in a questionnaire (explained in methods chapter), which didn’t align with the social constructivist approach to research, this study still applies the values of this perspective to induce qualitative data collection questions through the questionnaire. This provided participants the option to contribute their thoughts and experiences that shaped their Likert Scale responses.
Design Process and Human Centered Design

A Human Centered methodological approach was employed to embody the social constructivist perspective. This approach is solution focused, which differs considerably from a scientific, systematic approach that is problem focused (Cross, 2006; Swann, 2002).

“Historically, design has been treated as a downstream step in the development process the point where designers, who have played no earlier role in the substantive work of invention, come along and put a beautiful wrapper around the idea” (Brown, 2008, p.86). Over time this has evolved with design- ers broadening their design scope and rediscovering their role in society. This has led to the people centered era where collaboration has encouraged a range of new practices such as human centered design (Bremer & Rodgers, 2013). The objective of a human centered design approach is not to simply produce products, instead the aim is to produce services and systems that are multifaceted to elicit certain emotional responses and physiological reactions (Brown, 2008; Deumert & Hekkert, 2007).

Process

The design process is recognised by its cyclical nature moving between three phases best described as Inspiration, Ideation, and Implementation (Brown, 2008). These stages were used in the process of designing Sprout IV Pole (Brown, 2008) offers an explanation for the non-linear process. The design process is best described metaphorically as a system of spaces rather than a predefined series of orderly steps (p.88). Designers continuously move backward and forward through the process, refining and developing the design, moving closer to equilibrium in the process (Stapleton, 2005).

Commonly, designers start with the inspiration phase of a design process, consisting of sourcing the input of users to inform the direction of the study (Cross, 2006). Gaining their input early in the process allows the designer to understand and empathise with them before designing. Because this study was iterative and cyclical, this phase was revisited to gain further information as needed to informant the refinements of the design.

The ideation phase consists of designing to address opportunities identified.
Overall, this approach can be seen as the ‘bottom up’ approach that acknowledges the humans using the service, instead of a ‘top down’ approach that fails to acknowledge the extent to which decision-makers make mistakes (Searl, Borgi & Chemali, 2010). This approach is recognised internationally for the value of direct contact with users to improve the design of healthcare environments and services (Searl Borgi & Chemali, 2010; IDEO, 2013). Literature supports the value of the human centered design approach for the design of healthcare (Jones, 2013). Employing this process and approach, enables disruptive, radical innovations (Jones, 2013). Currently, disruptive, radical design only plays a small role in healthcare services, environment and product design due to the slow adoption rates for innovation (Jones, 2013). Designers have largely disengaged with health professions until recent moves to educate designers in healthcare practices so that they can positively contribute to patients’ understandings of well being (Marzano, 1998). Good design does offer delight and amazement, but can also save money (Hutchison, 2007).

Human Centered Collaboration is a key characteristic of the human centered design approach (Gray, 2009). While collaboration has been traditionally neglected, its application alongside action research has strengthened the value of users’ voices (Koshy, Koshy & Waterman, 2011). Collaboration was fundamental in the process of designing Sprout IV Pole. This occurred through consultation with health professionals throughout the process of planning the trial and refining Sprout IV Pole and reflecting on this was important as a means of informing the next direction of exploration and movement.

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The benefits of applying an iterative process accommodates for additional requirements and needs to the design throughout the process; reducing risk associated with the design early in the process reducing errors that require fixing later on in the process as well as accommodating continuously changing healthcare policy and practice (Park, 2012; Robert and Priest, 2010). This was essential for the process of designing Sprout IV Pole, as further needs and requirements were continuously added as an outcome of consultation with different health professionals.

This process was heavily informed by the stages of Action Research methodology; plan, act, observe and reflect (Collins, 2010; Gray, 2009; Swan, 2002). Refer to figure 8. Planning the cycle, acting on this and gathering evidence, observing and analysing what this means, and reflecting on the success of the cycle to meet objectives in order to establish the focus of the next cycle of the design process (Gray, 2009). This process involved systematic enquiry into a topic to produce practical knowledge heavily focused on the ability to reflect on ones work (Koshy, Koshy & Waterman, 2011). Progressing through the design process, applying this structure to different aspects of exploration with Sprout IV Pole and reflecting on this was important as a means of informing the next direction of exploration and movement.

The third phase of the design process saw the implementation of the design, as well as development and refinements made through testing (Brown, 2008). The commercialisation path was considered pending the success of the testing and development of the product. The development of Sprout IV Pole through this year revolved around developing and refining the design in the lead up to conducting the evaluation in hospital with children. This re-considered vision of the manufacturing and the techniques of production ensuring that the product met standards so that it was safe for hospital use (Brown, 2008). This included revising the iteration phase on multiple occasions to work with new input and information from sources such as health professionals, which resulted in refinements to the design.

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METHODS

Expectation
Reality
Sprout IV Pole Development and Refinement
Evaluation of Sprout IV Pole
Expectation

Figure 3. Process Expectations based on assumptions from other studies from the literature.
Sprout IV Pole Development and Refinement Methods

The required output Sprout IV Pole Development and Refinement was the manufacturing of four Sprout IV Poles that could be approved for evaluation in hospital with children, their parents and nurses. The expectations of this process are illustrated in figure 9. It took considerably longer than expected to progress through this process (Refer to figure 10). This was due to increased functional needs introduced by new hospital stakeholders, which entailed the use of design methods explained below.

Drawing/Sketching
Drawing/sketching is one of the oldest tools of design (Cross, 2006). This method can be used to visualize ideas early on in the process, as sketching an idea is often quicker than making a model (Bridge, 2008). This method was used sparingly throughout the process to creatively respond to new constraints discovered through consultation and applied to the design of Sprout IV Pole. In particular, the Sprout top was redesigned in order to meet hospital functional requirements for evaluation in hospital with children.

Model Making/Prototyping
Model making/prototyping is a tool commonly used to transform 2D into 3D ideas (Cross, 2006; Institute of Design at Stanford, 2012). As well as testing, it can be used to assist the design process through an exploration of empathy gained through role playing (Institute of Design at Stanford, 2012). Models of the Sprout top were developed and refined through low-resolution 3D printing. Throughout the process prototyping was outsourced to commercial manufacturers to produce samples for testing before hospital in situ testing (Cross, 2006). These prototypes were high resolution as a means of accurately testing the design (Institute of Design at Stanford, 2012).

Role Playing
Role-playing is a method utilised by designers to gain empathy for their users by stepping into their shoes to experience the product (Design Council, 2014). The act of role-playing can prompt intuitive responses for the designer to refine the design (Design Council, 2014). Role playing with pumps and fluid bags was used in the Starship Children’s Hospital and conducted in consultation with health professionals to provide feedback on Sprout IV Pole. The purpose was to simulate how Sprout IV Pole would be used in hospital as well as understanding how well it moved around (i.e. how easy it was to manoeuvre the accessibility of the handle the ease of wheel rotation).

Computer Aided Development (CAD)
Computer Aided Development (CAD) is a tool commonly used to build products to simulate them through geometrical parameters (Inc, 2005). CAD systems allow designers to view their designs in a range of representations digitally in order to test them before real world simulations (Inc, 2005). CAD was selectively used throughout the process of developing and refining Sprout IV Pole. This included the production of files for 3D printing and communication with manufacturers. This method of communication with manufacturers is quickly becoming commonplace almost completely eliminating the need for conventional drawings (Cross, 2006). CAD allowed quick alterations to designs and the testing of 3D printing prototypes without having to rebuild designs thus reducing the costs of physical prototypes.

Expert Consultation
Expert consultation was vital for the progression of the project as their approval was required of Sprout IV Pole in order to evaluate the design with children in hospital. A range of different stakeholders within the healthcare organisation (as well as external organisations) were consulted in the process (Refer to figure 8 and appendix 2). This consultation occurred informally through email, phone calls and meetings, underpinning many turning points and alterations to the design. External organisations informed the manufacturing and regulation of medical equipment design, whereas healthcare organisation stakeholders informed the functional needs of Sprout IV Pole.

Approval to conduct the evaluation of Sprout IV Pole centred on meeting these functional needs. Heavily influencing the timing and progression of the study. Although these experts and professionals dictated the progression of the project, without their input and collaboration children could not have been involved in the hospital evaluation of Sprout IV Pole.
practices that lend themselves better to research with children to produce able (Cavet & Sloper, 2004). The literature acknowledges that there isn’t one to involve them and seek their views in a manner they would feel comfort the decision to involve children through semi-structured interviews in order

Evaluation of Sprout IV Pole Methods

The output of the Evaluation of Sprout IV Pole sourced the responses of children, their parents and nurses in relation to the design of Sprout IV Pole in comparison to an existing IV Pole used in hospital. Literature had informed the decision to involve children through semi-structured interviews in order to involve them and seek their views in a manner they would feel comfort-

a richer and more in-depth responses from participants (Koshy, Koshy & Wa-
terman, 2011) as they provided a balance between allowing children to engage more freely as well as fulfilling an adult agenda to gain an understanding of children’s values (Jones, 2013). Some argue for the need to establish novel methods of seeking children’s involvement in research and identifying the best methods for eliciting children’s responses (Kirk, 2006). Because of the nature of the study, conversation was the method selected to provide this feedback. The level of involvement children would have in this study would be the status of Testers.

As part of the process for gaining access to children in hospital to conduct these semi-structured interviews, an application was submitted to the Re-

search Review Office Manager of the ADHB. The study was initially denied access because of bias, as it was perceived to favour Sprout IV Pole through leading questions (Scott and Mazhindu, 2005b). Through further consultation with the research office, the nurse advisor and the New Zealand Health In-

novation Hub, it was discovered that the issue was a consequence of the nature of the study, conversation was the method selected to provide this feedback. The level of involvement children would have in this study would be the status of Testers.

Considerable literature reporting on studies aiming to access children (Jones, 2013), which contrasts with the social constructivist view of a design

innovation Hub, it was discovered that the issue was a consequence of the

requirements; 9:00am – 5:00pm, five days a week, for three to four weeks.

paediatric experience to conduct the study. Recruiting an appropriately quali-
dered person proved difficult because of the nature of the work and availability

Consultation

To involve children in the evaluation of Sprout IV Pole alongside their parents and nurses, consultation was required in preparation. This took place with selected healthcare organisation senior management representatives such as the nurse advisor and nurse manager. A senior manager within the hospital was selected as my in-hospital liaison, and she informed many of the decisions around the evaluation trial. Her in-

the study before it took place, as well as reducing the amount of problems encountered when complying with hospital regulations (Haboub, 2010). Stak-
er Carpenter, Connors et al. (2006) One of her key recommendations was the need for a research assistant with nursing qualifications and, preferably, an experienced paediatric nurse. The need for an experienced paediatric nurse served to make the study more feasible and helped ensure the study’s feasibility.

Informed Consent

Informed consent is one of the key principles in research. It involves the processes of informing all potential participants of the risks and benefits asso-
ciated with the study so that they can make an informed decision about whether they would like to participate (Widmer & Morris, 2011). Participants were provided with information about the study in simple language and legi-

sional tone to ensure that they understood what their involvement in the study entailed (Haboub, 2010). When researching with children, it is important to recognize their varying ages and provide them with information they can understand (Kirk, 2006). This was done by providing young children (5-11) with

Ethics

As the evaluation of Sprout IV Pole took place in Starship Children’s Hospital with children, their parents and nurses, ethical approval was needed. Through consultation, the national ethics committee HDEC (Health and Disability Ethics Committee) had stated that AUTEC (Auckland University of Technology Ethics Committee) approval was appropriate for my study. AUTEC was consulted before seeking approval to highlight areas that may need clarification; no issues were flagged. This process was straightforward as AUTEC had been previously consulted for ethical approval of the evaluation of Sprout IV Pole in a simulated hospital environment as a part of my honours year (Parbhu, 2013). Ethical approval was sought for the evaluation trial of Sprout IV Pole from AUTEC and granted on the 2 July 2014, application number 14/180 (Refer to appendix 5 for the approval letter).
Privacy and Confidentiality
Privacy and confidentiality was assured for all participants in the study. Identifiable details were not collected during the process of face-to-face recruitment. The research assistant, charge nurse and ward nurses knew the identities of the children and their parents involved in the evaluation of Sprout IV Pole by observing their usage of Sprout IV Pole. Any information they possessed through the study was only discussed with the researcher (myself) and my supervisors. Participants were assured that no identifiable information was provided through the study was only discussed with the researcher (myself) and my supervisors. Participants were assured that no identifiable information was communicated through the findings of the study.

Minimisation of Risk
An assessment of the risks and benefits of participating in a study needs to be completed early on in the planning to establish whether the research is worthwhile, as well as mitigating any potential risk that could arise (Alderson & Morrow, 2011). Defining the possible risk to participants when researching with children can be difficult as risks perceived by adults may be different to risk felt by children (Alderson & Morrow, 2011). The ethical design also needed to consider the long-term benefits to a population as well as the direct benefits to participants that chose to take part (Alderson & Morrow, 2011). Long-term benefits included shedding light on the perspectives of children to shape further studies involving the consultation of children about hospital design (Lambert, Coad, Hicks et al., 2013), as well as encouraging changes to policies and professional opinion to better cater to children (Alderson & Morrow, 2011). Privacy and confidentiality was assured for all participants in the study. Identifiable details were not collected during the process of face-to-face recruitment. The research assistant, charge nurse and ward nurses knew the identities of the children and their parents involved in the evaluation of Sprout IV Pole by observing their usage of Sprout IV Pole. Any information they possessed through the study was only discussed with the researcher (myself) and my supervisors. Participants were assured that no identifiable information was communicated through the findings of the study.

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product trials in hospital would take out insurance, which was a condition of their access to the hospital. Taking out insurance wasn’t a possibility for me (the student).

Children, their parents and nurses were involved using a questionnaire designed to evaluate Sprout IV Pole in comparison to an existing IV Pole. Questionnaires are often considered a measuring tool, commonly used at the onset of projects to gather thoughts and perceptions cost effectively. They can then be supplemented through other methods of collecting data (Koshy, Kristy & Waterman, 2011; Scott and Mathindu, 2009). These questions allowed children, their parents and nurses to elaborate on how they would like the IV Pole to be placed on these factors (movement, safety, look and function) as a test, depending on what they perceive to be the ‘correct’ answer, instead of their gut response and perspective (Darlington & Scott, 2002; Lambert, Glacken & McCarron, 2013b). This was the method required to involve children in the evaluation of Sprout IV Pole.

Children, their parents and nurses were each given different questions with comparable questions to allow comparisons between the user groups. The questionnaire itself consisted of quantitative and qualitative questions to elicit explanations from the participants. Quantitative data was collected using Likert Scale (Scott and Mathindu, 2009). Likert scales measure the extent to which a participant agrees or disagrees with a question and commonly consists of a scale from 1-5 alongside text phrases ranging from 'not important to extremely important' (Scott and Mathindu, 2009b). Refer to Appendix 3.

The questionnaire began with the aim of understanding the value all participants placed on these factors (Movement, Safety, Look and Function). This was supplemented with open-ended questions allowing participants to distinguish whether the Sprout IV Pole provided benefit over the existing IV Poles used in hospital (Fisher & Mathison, 2009). This has been a common path for children’s choices and is sometimes seen as a sub-optimal method of data collection (Koshy, Kristy & Waterman, 2011).

Using questionnaires also pushed back the date of the evaluation trial by two months. This delay gaining access is a consistent issue faced by researchers aiming to involve children with research in hospitals (James, 2013; Stalker, Carpenter, Connon et al., 2004). However, in order to involve children, these changes were required.

Location

Two wards within Starship Children’s Hospital were selected for the evaluation trial. Initially, the Day Stay Unit was chosen to provide the highest number of participants for the study over the shortest period. Approximately four new children requiring an IV Pole are admitted each day to the Day Stay Unit (four Sprout IV Poles were manufactured on the basis of these admissions). Because there were low admissions of children requiring an IV Pole to the Day Stay Unit during the first week of the trial, a second location (the Oncology Day Stay) was added during the second week. These locations were selected by the nurses advisor.
The evaluation of Sprout IV Pole in two Starship Children’s Hospital wards was planned to take place over a three-week period. Our aim was to solicit responses from 60 children based on four admissions each day, 60 parents, and as many nurses as possible. The nurse advisor thought this would provide adequate time for the evaluation to take place before testing becoming a hindrance to the nurses. Because of the low admissions to the Day Stay Unit and the inclusion of the Oncology Day Stay, the evaluation trial was extended to a fourth week to recruit a greater number of participants.

Participants

The participants in the research were children, their parents, and health professionals/nurses in the selected locations of Starship Children’s Hospital. Thirty-two children, forty-five parents, and twelve nurses were recruited to the study (Refer to figure 11, 12 and 13).

Children between the ages of five and eighteen requiring an IV pole for IV infusion and who were able to provide informed voluntary assent and parental consent were invited to participate in the evaluation of Sprout IV Pole. Children under the age of five and those unable to read English were excluded from the study, as they weren’t able to give informed assent.

The ADHB required a minimum age limit despite literature suggesting that children should not be marginalised by their age on the assumption they won’t provide useful data (Kirk, 2006). Carter (2009) and Kirk (2006) suggest that children’s ability to participate should be based on acknowledging their situational context as well as their ability to comprehend and communicate. Parents or guardians of children participating in the evaluation were also invited to evaluate Sprout IV Pole. If children required an IV pole, but didn’t fit the criteria because they were too young, their parents were still invited to participate in the study. However, these younger children were not approached for feedback.

Children and parents were invited by the research assistant to participate in the research on arrival at either of the two wards selected for the evaluation of Sprout IV Pole. Literature suggests that there is a higher uptake of participation from face to face personalized recruitment strategies (Haboush, 2010). The research assistant provided children and their parents with a brief overview of the study information sheets and consent/assent forms and...
would require three or more independent variables to compare but t-tests are used to compare two variables (Lund Research, 2013). It allowed the quick determination of the preferred design between Sprout IV Pole and the existing IV Pole in relation to the three user groups. This was done for all three users groups combined and then each individual user group distinguished their preferences in relation to the specific factor associated with the IV Pole. The significance values is measured through a P value; < 0.05 is significant; < 0.01 strongly significant, and < 0.001 highly significant.

Qualitative
The qualitative data generated from open-ended questions were analysed using two methods, content analysis and thematic analysis. A content analysis provides a simple word frequency count in order to study textual data in most cases from different media (Stepchenkova, Kirilenko & Morrison, 2007). This style of analysis revealed patterns and structures within the data to establish categories that constructed meaning (Stepchenkova, Kirilenko & Morrison, 2007). This method is similar to a quantitative analysis method applied to qualitative data in order to provide a complete picture of the information. These systematic enquiry characteristics enabled exploration of the qualitative data in a manner that is rarely found in other qualitative analysis methods (Stepchenkova, Kirilenko & Morrison, 2007).

Alongside the content analysis, thematic analysis of the qualitative data was conducted to highlight themes in the written material (Gavin, 2008). Themes were drawn out from re-emerging ideas, emotions and feelings to enable deeper meaning and insight into people’s responses (Gavin, 2008) and to understand the reasoning behind children’s, their parents and nurses’ qualitative answers in the questionnaire. This form of analysis welcomes the subjective view of the researcher and their interpretation as well as acknowledging their need to manage their own bias (Gavin, 2008). I then explored and discussed comments with my supervisors to ensure that my bias and interpretation were representative of the data collected through the questionnaires.

Figure 14. Sprout IV Pole trialled with children during the evaluation trial
4.0 DOCUMENTATION OF RESEARCH

4.1 Sprout IV Pole Development and Refinement

4.2 Evaluation of Sprout IV Pole with children, their parents and nurses findings
4.1 SPROUT IV POLE DEVELOPMENT AND REFINEMENT

2013 REFLECTION: Simulation Trial
Design for Mass Production
Regulations
Top Form Redesign
Base/Pole Refinements 1
Construction Prototype 1
Base/Pole Refinements 2 and Construction Prototype 2
Clinical Engineering (CE) Testing
2013 REFLECTION: Simulation Trial

The simulation trial for this project was conducted as part of my honours year. This involved consulting healthy children in a simulated hospital environment to provide feedback on variations of Sprout IV Pole and to communicate their preferences (Parbhu, 2013). This was to inform my understanding of what children actually needed and elements of the design that required improvement.

The findings illustrated the preference that children had for elements of fun such as riding the base and the colour and form of both handles. Findings also gave insight about the children’s view of the simulation trial, which was included by the researcher as a play opportunity that only enabled a limited understanding of how children in hospital might experience these products.

These findings were presented to charge nurses at Starship Children’s Hospital to determine which variation should be developed further. Although this project focuses on catering to the needs of the children in hospital, it was also important to balance the needs of the nurses with those of the children (Alterman, 2004). Through discussions with the nurses about safety, a consensus was reached to remove the ride-on platform in favour of the dipped base design. Their thoughts were initially divided between the handle designs, but settled on the twisting design as the safer option because it wouldn’t catch on IV tubing (Refer to figure 15).

These findings were presented to Oncology nurses as a test case with pumps and fluid bags to reveal the further refinements that were required. These included the need for Sprout IV Pole to be taller as the twisting handle reduced the available space to attach pumps, as well as the need to redesign the top form to cater to all of the fluid bags and bottles that the hospital needed to fit. In order to address these issues a clear indication of height was required, as well as access to all of the bottles and bags that the Sprout IV Pole needed to cater for.

The most significant issue came from the lean that this Sprout IV Pole prototype (alongside other prototypes) presented when bags and pumps were fitted. This was because of the manual fabrication of the pole, which enabled imperfection and variation between prototypes (Refer to figure 16). In order to mass-produce Sprout IV Pole, new processes were needed to ensure consistency between prototypes.

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The most significant issue came from the lean that this Sprout IV Pole prototype (alongside other prototypes) presented when bags and pumps were fitted. This was because of the manual fabrication of the pole, which enabled imperfection and variation between prototypes (Refer to figure 16). In order to mass-produce Sprout IV Pole, new processes were needed to ensure consistency between prototypes.
In order to design for the manufacturing of multiple Sprout IV Poles, minor changes were required to Sprout IV Pole to ensure consistency between prototypes, as well as to improve the strength of the product joins. This was achieved through exploring techniques for long term efficiency, less manual labour to reduce the costs per unit through consultation with designers and manufacturers. They provided insight into different techniques to manufacture runs of Sprout IV Pole to ensure consistency as well as to reduce costs through careful selection (Hutchison, 2007). This included the ability to bend the central pole through programmed machines, thus eliminating the need for manual labour and fabrication. They also introduced different fabrication techniques to strengthen the joins in the pole, such as the base to the pole. This included using a nipple socket joint, bolting the pole to the base, and screwing the pole through the base into a fixed weight below (Refer to figure 17, 18, and 19).

A variety of different manufacturers in the North Island of New Zealand (predominantly Auckland), were contacted to source their knowledge of production techniques and processes as well as quotes for producing the Sprout IV Pole. Priority was placed on manufacturers that were capable of producing all Sprout IV Pole parts, and their ability to coordinate these processes. This was important because previous experiences constructing Sprout IV Pole with multiple manufacturers had resulted in some discrepancies between the parts.

As the process of producing the Sprout top (plastic moulding) differed considerably to the rest of the design (metal work) two different manufacturers were required (Refer to figure 20). The only process for top manufacturing here in New Zealand was injection moulding. This process is extremely expensive when producing small product runs (below 1000 units), as the set up costs are large (SS50,000 estimation). Through the recommendations of designers a manufacturing process of silicon moulding was identified in China at a fraction of the cost (SS100 – SS200).

Seeking this guidance from manufacturers and designers enabled me to resolve the issues raised by nurses and progress closer to gaining their approval for involving children in the evaluation of Sprout IV Pole in the hospital. Manufacturers capable of producing Sprout IV Pole were organised ready for the final drawings and designs for manufacture. Before these changes were required to the top form as well as finalising height details.
Regulations

WAND

Consultation with a Health Alliance representative was required to understand the process of implementing a product in the hospital for evaluation, long-term use and sale. The representative introduced me to the “WAND” registration of medical equipment. All medical products used in New Zealand legally require registration in the WAND database run by Medsafe. This process is not an endorsement of the product’s safety or suitability, but a registry allowing the Director-General of Health to hold information on all medical products and equipment used within New Zealand (Medsafe, 2012). If issues should arise with any product, the appropriate sponsor may be easily identified and contacted through the database.

A sponsor is accountable for a product while in use in hospitals. In the event of product faults, they can be contacted and held legally responsible (Medsafe, 2012). Through different discussions with my supervisors, ADHB and New Zealand Health Innovation Hub representatives, it was felt that as a design student it would be unreasonable for me to be legally responsible for Sprout IV Pole.

Through further discussions with the New Zealand Health Innovation Hub representatives and experts from Medsafe, it was established that in order to trial a product in hospital, WAND registration was not required. Medsafe simply required notification that a product trial was taking place in a hospital. Although WAND registration was ultimately not required for this study, these discussions explained the process of implementing a product within a hospital. If Sprout IV Pole were to be implemented into the hospital for long-term use, WAND registration will be required.

Here in New Zealand, there is no mechanism for a pre-market approval system. Products used in New Zealand do not require regulatory approvals from other markets such as the European CE Mark, Australian inclusion on the ARTG, or FDA approval prior to implementation in New Zealand — although, these approvals are preferable (Medicines Act 1981). There is then a need for these regulatory approvals to inform the design of Sprout IV Pole.

FDA

The U.S Food and Drug Administration (FDA) regulations were also consulted to understand what implication these have for the design of Sprout IV Pole. Their role in relation to medical devices is best explained as “risk assessment” (U.S. Food and Drug Administration, 2015).

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“FDA has exempted almost all class I devices [with the exception of reserved devices] from the premarket notification requirement, including those devices that were exempted by final regulation published in the Federal Registers of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.”

“If a manufacturer’s device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and FDA clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information” (U.S. Food and Drug Administration, 2015).
Top Form Redesign

The top Sprout form required redesign to cater to the different bags and bottles used throughout Starship Children’s Hospital. Industry designers were consulted as a means of creatively responding to the needs of the form while maintaining the current aesthetic of the top form. Trying to hold true to the original design aesthetic provided some constraint, as Brown (2009) states, “Without constraints, design cannot happen” (p.17). Thus, both incremental and radical solutions were explored.

The incremental idea included utilizing a clip that would secure the bags and bottles to allow them to hang vertically (Refer to figure 21). This solution was discarded after consultation because of the frequency with which these bottles and bags are used and the potential to lose the clip.

Moving prongs were introduced as a more radical idea (Refer to figure 22). The prongs would remain upright until weight from the bottle or the bag was applied to lower the prongs. This idea was potentially viable, but would introduce higher production costs and increase the potential for breakage.

The third idea consisted of enhancing the organic aesthetic of the top through the splay of the prongs (Refer to figure 23). This involved experimenting with the splay of one prong, then all prongs to provide a consistent aesthetic (Refer to figure 24 and 25). I presented the new design to the charge nurse and nurse advisor who were happy with the changes and the ability of this form to cater to the bottles and bags utilised in hospital. After consultation with the nurses of the Day Stay Unit where Sprout IV Pole was trialled, intended to strike a balance between assuring the complete safety and effectiveness of products and rushing a product to market (Medina, Kremer & Wyck, 2012, p.84).

The FDA database consists of product classifications relating to individual pieces of medical equipment that inform the process of gaining approval for product use in the U.S. An Intravenous (IV) pole is referred to as an “infusion stand” in the U.S (U.S. Food and Drug Administration, 2015). The standard provides general information about the class of the product, which is Class I and deemed low risk (U.S. Food and Drug Administration, 2015). In essence, this implies that approval from the FDA is not required prior to implementing a product in the U.S. market. Thus, FDA standards didn’t inform the product specifications for Sprout IV Pole.

ISO

The International Organization for Standardization (ISO) creates and publishes standards that constitute regulatory requirements for medical products internationally. These standards provide optional guidelines that engineers and designers can employ to enhance the credibility of their designs (International Organization for Standardisation, n.d.).

More than 10,000 ISO standards are available, providing very specific regulations to medical equipment design. The cost is around $90-$220 for each standard. An exploration of the standards library as well as consultation with ISO representatives and standards New Zealand found no clear standards that could inform the design of Sprout IV Pole. Sixty standards apply to intravenous infiltrated products, but none specifically to IV Poles.

Overall, sourcing the correct ISO standard proved difficult because of the lack of information provided by standards descriptors. As the cost of purchasing the recommended standards was considerably expensive, this was not justifiable as a means of simply finding information. Although consulting these regulations is not a requirement for implementing the use of a product in New Zealand hospitals, to ensure that Sprout IV Pole was as safe as it could be these regulatory bodies were important to consult and understand.
Overall, nurses’ feedback suggested that to function as required in hospital, the design needed to be changed for Sprout IV Pole. It was important to maintain the aesthetic of the design as children from the simulation trial corroborated findings in the literature that indicated the value of this form (Bishop, 2013; Coad & Coad, 2008; Lindeke, Nakai & Johnson, 2006).
Aside from the top form, Sprout IV Pole required minor alterations to the height to ensure that approval could be gained from the nurse advisor for the evaluation of Sprout IV Pole to take place in hospital. It was important to provide enough physical space on the pole to attach pumps. This feedback also entailed the need to reposition the handle higher, catering to the taller nurses and parents who would be moving these IV Poles around. However, this change also had the potential to make it harder for children to reach the handle (Refer to figure 27).

A Health Alliance representative introduced me to three hospital departments that were important to consult in order to ensure that Sprout IV Pole could be used in Starship Children’s Hospital. These departments were Occupational Health and Safety, Infection Control and Clinical Engineering. It is important to acknowledge the extent to which evidence to support the design of Sprout IV Pole must come from stakeholders to ensure the viability of the product (Uehira & Kay, 2009).

Occupational Health and Safety and Infection Control were also consulted about the safety and cleanability of the product. Generally, OHS sign off was only required on products purchased for the hospital over the cost value of $1,000. Since Sprout IV Pole fell below this price, their formal review was not required. To ensure that the product was easy to clean, there couldn’t be any cracks and ridges for dirt to accumulate in. The primary cleaning product used in the hospital is Sodium Hypochlorite (bleach) diluted in water. All materials used to construct Sprout IV Pole would need to withstand this product.

The Clinical Engineering department is responsible for the maintenance and repair of clinical products that require repair in the hospital. They confirmed the functioning safety of Sprout IV Pole and observed that the design was robust, providing one recommendation to remove the uneven splay of legs, as this created a tipping point if pulled in a particular direction (Refer to figure 28). The purpose of this gap was to allow children to walk closer to the pole, but observations of children using the pole during the simulation trial indicated that this gap would not be utilised.
Construction Prototype 1

Following iterative improvements based on feedback, one prototype (excluding the top) was produced by the selected manufacturer. Even though the trial required four Sprout IV Poles, one sample was produced to ensure all details were correct before committing to the full run.

Colour Selection

Sprout IV Pole had been coloured using custom made spray paint. However, in order to colour the prototype for hospital use, short-term solutions (such as spray paint) would not withstand the cleaning products. This informed the need for powder coating (the metal components) and ingraining colour (the plastic components). Powder coating came in a set range of colours for small and one-off projects. Custom-made colours were possible but entailed a minimum order quantity well in excess of the needs for the evaluation trial. This required a minor compromise in the colouring of Sprout IV Pole (Refer to Figure 29). It is known that children present strong preferences towards colour (Lambert, Coad, Hicks et al., 2013), but the extent to which this affected the appeal of Sprout IV Pole during the trial is unknown.

Manufacturing

Minor issues arose with the construction of Sprout IV Pole, as it exceeded the estimated time to produce the sample. Through a communication error, manufacturers had formed the base in a manner that was inconsistent with drawings. This resulted in the need to add three nuts between the base and the wheel to provide the wheel with enough clearance to spin (Refer to Figure 30). However, adding these spacers (the nuts made Sprout IV Pole “tippy” as the wheels weren’t fixed directly to the base). The nurse advisor was unhappy with the tippy nature of this sample, requiring alterations to the design to remove it before hospital evaluations. She suggested exploring different wheels to resolve the issue. In contrast, Clinical Engineering shared my perspective that the tippy nature was a result of the spacers. Overall, to involve children in the evaluation of Sprout IV Pole, the issue needed to be pinpointed and resolved to gain approval.
I consulted different wheel manufacturers to understand the construction of castors (wheels) and quickly learnt that the majority of wheels were made the same with bearing balls. These bearing balls require space to move which entailed a slight wiggle. Although this could contribute to the issue, it was not the source of the issue.

Consultation with Sprout IV Pole manufacturers indicated their belief that spacers were the issue. The spacers were needed to allow the wheel to rotate around the axis of the attachment without hitting the base. To mitigate this movement the castor needed to be directly fixed to the underside of the base to remove the lever. To do this there were three options.

Option 1 - different wheels
Experimentation with other wheels suggested that all wheels of comparative size would hit the base if directly fixed onto the base. The wheels could not be any smaller, otherwise they would trigger issues with movement around the hospital such as transitioning from carpet to tile floor coverings, as well as entering the elevator (Refer to figure 31 and 32).

Option 2 - extending the legs
Another viable option was to extend the legs further out horizontally. This would require the production of new tooling to form the base that would alter the shape of the legs to protrude further horizontally. This would have increased the base radius by roughly 50mm, which was not desirable as this would have made it potentially difficult for children to reach the handle and they would need to walk further away from their IV Pole (Refer to figure 33).

Option 3 - reforming the base
The last option entailed the most cost as it involved remaking the forming tools. However, it was required because option 1 and 2 were undesirable. New drawings were provided to the manufacturer for the construction of this sample. Considerable time was invested to produce this shape so that it would be consistent with the drawings, but there were limitations with the manufacturer’s moulding processes resulting in failed attempts with forming (Refer to figure 34, 35 and 36). This resulted in a need to compromise the form of the base to fit within the limitations of the moulding process (Refer to figure 33). This design was undesirable as it took away from the overall subtlety of the curved aesthetic form of Sprout IV Pole. Other moulding processes existed that could have produced the desired form (large metal stamps), but the cost of this tooling was unjustifiable for a run of four prototypes. Although the final base did not mirror the desired form, it was understood that this compromise was required because of the limitations of time and budget to explore other possibilities.

Figure 32. Option 1, wheel exploration and understanding
Figure 33. Option 1, wheel exploration and understanding
Figure 34. Option 3, wheel exploration and understanding
Figure 34. Option 2: extending the legs further horizontally.

Figure 35. Option 3: pressing machine tool.

Figure 36. Option 3: reforming the base and the tooling required.

Figure 37. Failed attempts at reforming the base.

Figure 38. Compromised base form.
Clinical Engineering (CE) Testing

The Clinical Engineering department was required to provide approval of Sprout IV Pole to receive the ADHB Research office institutional approval letter. Before this, an engineer was consulted to conduct digital simulations testing Sprout IV Pole’s strength and stability. For accuracy purposes, it is common to evaluate a product before implementation (Cross, 2006; Jones, 2013). These simulations mirrored the stability of the Sprout IV Pole when pumps were attached as well as assisting to determine how product the product was. The results illustrated ways in which the design could withstand being knocked over because of its low centre of gravity. This report provided a basis from which the Clinical Engineering department could perform their physical tests (Refer to figure 38).

Physical tests mirrored the functions and obstacles Sprout IV Pole would need to overcome in comparison to existing IV Poles. As no ISO standards existed to inform the design of IV Poles, these tests were informed by departmental knowledge (Refer to figure 39). The results proved that Sprout IV Pole was of comparable safety to existing IV Poles (without the addition of weight to the base to lower both the centre of gravity and the required knocking force (Refer to figure 40 and 41).

Following this evaluation, Sprout IV Pole was confirmed safe by Clinical Engineering and ready for the in hospital evaluation (Refer to figure 42). Considerable design compromises were required throughout the variety of consultations that took place. Without this consultation and compromise the approval of the nurse advisor as well as the formal evaluation and endorsement of the Clinical Engineering department could not have been gained.
1. Wheelbase radius (cm)
   - Sprout: 26
   - DCCM: 29
   - Amtech: 27
   - Plastic: 29

2. Weight (kg)
   - Sprout: 6.1
   - DCCM: 6.9
   - Amtech: 10.3
   - Plastic: 4.2

3. Centre of Mass (cm above floor)
   - Sprout: 55
   - DCCM: 63
   - Amtech: 50
   - Plastic: 83

4. Rolling force on lino (N)
   - Sprout: 1.5-2
   - DCCM: 1.5-9
   - Amtech: 5.5-7
   - Plastic: 6.4

5. Rolling force on carpet (N)
   - Sprout: 4.4-4.9
   - DCCM: 7.9-6
   - Amtech: 10.8

6. Force to mount 5mm thick carpet (N)
   - Sprout: 6-7.6
   - DCCM: 7
   - Amtech: 22
   - Plastic: 13.7

7. Force required to tip stand (N)
   - Sprout: 8.8
   - DCCM: 13.7
   - Amtech: 19
   - Plastic: 8

Figure 42. Clinical Engineering IV Pole safety evaluation results

Figure 43. IV Poles evaluated along Sprout IV Pole by Clinical Engineering
Figure 44. Fourth generation Sprout IV Pole evaluated with children in Starship Children’s Hospital.

Fourth Generation Sprout IV Pole
4.2 EVALUATION OF SPROUT IV POLE WITH CHILDREN, THEIR PARENTS AND NURSES FINDINGS

Quantitative Findings
Content Analysis
Qualitative Findings
Value of Aesthetics
Importance of Form
Value of Listening to Children
Quantitative Findings

The general statistics suggested overall that safety was the most important factor (x = 4.56) and the aesthetics were least important (x = 2.26). This aligned with comments made predominantly by parents and nurses, one parent stating, "Child's safety is always very important, the look might attract kids but is not so important." Some children also agreed with this, one stating, "The look isn't as important as safety." (Refer to figure 43).

There was a significant difference (F (2,83) = 5.74, P<0.05) between groups about the value of being able to move the IV Pole. A post hoc Tukey test showed that children's (x = 4.00) responses were different from nurses (x = 4.18), but not parents (x = 4.29), and parents and nurses did not differ.

There was a significant difference (F (2,81) = 4.31, P<0.05) between groups about the value of the function of the IV Pole. A post hoc Tukey test showed that children's (x = 4.00) responses were different from nurses (x = 4.18), but not parents (x = 4.29), and parents and nurses did not differ.

There was no significant difference between groups about the safety of the IV Pole (F (2,83) = 1.60, P>0.05) or the aesthetic of the IV Pole (F (2,83) = 0.86, P>0.05).

Movement

Concerning the value of the movement of an IV Pole, a reliability analysis revealed a co-efficiency value of 0.695 for the existing IV Pole and 0.596 for Sprout IV Pole, so questions were analysed together.

Overall, Sprout IV Pole (x = 4.6) moved significantly better than the existing IV Pole (x = 3.31) (t (83) = -12.10, P<0.001). Children reported that Sprout IV Pole (x = 4.71) moved significantly better than the existing IV Pole (x = 2.93) (t (29) = -9.76, P<0.001). Parents reported that Sprout IV Pole (x=4.6) moved significantly better than the existing IV Pole (x = 3.58) (t (42) = 2.56, P<0.05) (Refer to figure 44).

This demonstrated no significant different between the user groups. Children, parents and nurses were in consensus about this factor of the design.

Safety

A reliability analysis of all the participants' responses to safety questions revealed a co-efficiency value of 0.695 for the existing IV Pole and 0.596 for Sprout IV Pole. These findings excluded the last question as this was distinct compared to the other questions, reducing the reliability.

Overall Sprout IV Pole (x = 4.6) was significantly safer than the existing IV Pole (x = 3.86) (t (83) = 5.74, P<0.001). Children reported that Sprout IV Pole (x = 4.6) was significantly safer than the existing IV Pole (x = 3.48) (t (27) = 5.19, P<0.001).
Parents reported that Sprout IV Pole (x = 4.56) was significantly safer than the existing IV Pole (x = 3.97) (t (42) = 5.00, P<0.001). No significant difference was reported by nurses between the safety of Sprout IV Pole (x = 4.15) and the existing IV Pole (x = 4.03) (t (10) = 0.29, P>0.001) (Refer to figure 45).

No significant difference was reported by nurses between the ease of storing Sprout IV Pole and the existing IV Pole (t (9) = 1.5, P>0.001).

Overall, Sprout IV Pole’s aesthetics (x = 4.65) was significantly better than the existing IV Pole (x =2.83) (t (85) = 12.101, P<0.001). Children reported that Sprout IV Pole’s aesthetic (x = 4.65) was significantly better than the existing IV Pole (x = 2.55) (t (40) = 9.99, P<0.001). Nurses reported that Sprout IV Pole’s aesthetics (x = 4.70) was significantly better than the existing IV Pole (x = 3.64) (t (10) = 4.35, P<0.001) (Refer to figure 46). While aesthetics were a less important factor, all user groups considered the different look of Sprout IV Pole a positive factor, making it “inviting for little kids” (child), “refreshing” (parent), and “quirky” (nurse).

There was no significant difference in how easy it was to attach pumps between Sprout IV Pole (x = 4.36) and the existing IV Pole (x = 4.27) (t (11) = 0.29, P>0.05). There was no significant difference in how easy it was to hang fluid bags between Sprout IV Pole (x = 3.7) and the existing IV Pole (x = 4.3) (t (10) = 1.20, P>0.05). There was no significant difference between the ease of keeping Sprout IV Pole (x = 4.73) and the existing IV Pole (x = 4.45) stationary (t (11) = 1.15, P>0.05) (Refer to figure 47).

A reliability analysis revealed a low co-efficiency value between the questions, so they were analysed separately.

There was no significant difference in the importance of the Sprout IV Pole to children compared to the existing IV Pole (x = 3.85) (t (79) = 3.82, P<0.001). They all indicated that children liked using the Sprout IV Pole (x = 4.22) significantly more than the existing IV Pole (x = 2.84) (t (78) = 7.76, P<0.001). They all indicated that children were able to move the Sprout IV Pole (x = 4.66) significantly more than the existing IV Pole (x = 1.71) (t (75) = 7.37, P<0.001). No significant difference was reported between Sprout IV Pole (x = 1.86) and the existing IV Pole (x = 1.70) (t (76) = 0.17, P>0.001) (Refer to figure 49).

Interactivity
A reliability analysis revealed a low co-efficiency value between the questions, so they were analysed separately.

Nurses alone responded to questions about functionality. A reliability analysis revealed a low co-efficiency value between the questions, so they were analysed separately.

All user groups indicated that Sprout IV Pole (x = 4.45) was significantly more important to children than the existing IV Pole (x = 3.49) (t (76) = 3.82, P<0.001). They all indicated that children liked using the Sprout IV Pole (x = 4.26) significantly more than the existing IV Pole (x = 2.94) (t (75) = 7.76, P<0.001). They all indicated that children were able to move the Sprout IV Pole (x = 4.63) significantly more than the existing IV Pole (x = 1.70) (t (75) = 7.37, P<0.001). No significant difference was reported between Sprout IV Pole (x = 1.86) and the existing IV Pole (x = 1.70) (t (76) = 0.17, P>0.001) (Refer to figure 49).
Comparisons of the different user group responses revealed that children thought Sprout IV Pole (x = 3.81) was significantly more important to them than the existing IV Pole (x = 2.93) (t (26) = 3.52, P < 0.01). Parents (t (41) = 1.78, P > 0.05) and nurses (t (10) = 1.00 (10), P > 0.05) did not report that one IV Pole was significantly more important than the other for children (Refer to figure 49).

Children enjoyed using Sprout IV Pole (x = 4.41) significantly more than the existing IV Pole (x = 2.28) (t (28) = 7.53, P < 0.001). From the perspective of parents, their children enjoyed using Sprout IV Pole (x = 4.38) more than the existing IV Pole (x = 4.08) (t (39) = 4.20, P < 0.001). No significant difference was reported between the enjoyment children had with Sprout IV Pole (x = 4.20) and the existing IV Pole (x = 3.60) (t (9) = 1.96, P > 0.05) from the perspective of the nurses (Refer to figure 50).

All of these responses were collected through Likert scale questions that demonstrated clear preferences for the Sprout IV Pole among children and parents in all sections. No clear preference was demonstrated by the nurses towards either IV Pole, and there was no significant difference for three of the sections (Sprout IV Pole being significantly better in only two sections). This provides a snapshot of the perspective of children, their parents and nurses which was explored further through the qualitative data.

The main themes that emerged from children’s responses were how the aesthetics made Sprout IV Pole child-friendly, its power to elicit positive emotions as well as allowing children to feel comfortable with Sprout IV Pole in the hospital environment. Thematic analysis also revealed that the form made Sprout IV Pole easier to use, giving the children confidence and independence as well as encouraging play. Overall, this research illustrated the value of listening to children as their views differed considerably from their adult counterparts.

Qualitative Findings

Figure 52 Interaction section - enjoyment of children

Figure 53 Interaction section - used in ways unintended
One child stated that Sprout IV Pole was more important to them because of the design and colour. Children described that Sprout IV Poles is aesthetic, suggested that it was designed for children to use.

The aesthetic also provided direct indications to the parents and nurses that Sprout IV Pole was designed with children in mind. This was evident through comments by parents: ‘Definitely more appealing to children’ and ‘looked like it was created for children’. ‘Children want things to be easy, colourful + funky to make hospital less scary’. The new IV Pole is well balanced and is a bit funky for the kids with regards to colour etc.’ ‘I liked the pole better. Easy to move around, wheels don’t lock up while moving, quiet and nice bright colours for kids.’ Parents saw that the aesthetics benefited their children, and identified the widespread benefit of the aesthetic being carried throughout the hospital. ‘Children were quite inspired, stating: “contemporary design was quite inspiring, if the hospital were revamped too, overall the environment would be fantastic.”

- Easy to move around, wheels don’t lock up while moving, quiet, and nice bright colours for kids.
- Parents liked “the colour of the handle, it is kid friendly, better wheels, four hooks at the top.”

Other comments by parents: “Definitely more appealing to children” and “looked like something they can relate to or distract them.” Illustrating Sprout IV Pole’s ability to help children feel more comfortable in their environment.

**Child-Friendly nature**

In a hospital environment where children search for aspects of familiarity and comfort, the child-friendly nature of a product is very important (National Association of Children’s Hospitals and Related Institutions, 2007). Providing children with products they are familiar with and can identify as ‘theirs’ to use can lessen any fears associated with hospital (Paediatric society of New Zealand & Starship Foundation, 2007). Providing comfort with the form of products was another key theme illustrated in the trial of Sprout IV Pole in hospital through the use of colour and aesthetic. Consequently this resulted in creating a product children were comfortable with, suited to their needs.

- The approval and appreciation of the use of colour in Sprout IV Pole was indicated by children’s comments. ‘Common answers to the question, “What do you like about the IV Pole?” were: ‘the colour’, ‘My favourite colour’, ‘the green’. ‘Green is a cool colour’, ‘I liked the green colour’ ‘good colour’ ‘like the green colour’. Very few children stated that they didn’t like the green colour of Sprout IV Pole. This approval of the colour was also provided by the parents stating: ‘Looks modern and has colour’. The colour green was selected for the design because it has commonly been associated with its ability to add warmth (Coad & Coad, 2008); bring peace, hope and calm to people (Resene, n.d.) The appreciation of the use of green in the design was important as it was a key element of the design of Sprout IV Pole that distinguished it from existing IV Poles, and was an outcome of listening to the strong preferences of children towards design (Coad & Coad, 2008).

- Another emotion triggered by the use of colour was excitement about its appeal. This was indicated through comments from children stating, “appeal. This was indicated through comments from children stating, “appeal. It gives hope, the features of it are cool and the way it’s a sprout.” For some children colour looks like hope; ‘starship [Hospital] has a lot of colour in it, it fits more into the theme’. “It looks different, exciting and appealing. Take one look and say wise that’s cool to look at”. Providing children with a product that they approved of, appreciated and made them excited towards the product, building a connection, and value for it (Distel & Hakkar, 2017).

**Comfort**

Comfort with the form of products was another key theme illustrated in the findings. Children stated that making the form more comforting, colourful and modern was existing for little kids. A few children stated: ‘Good colour looks modern – not scary and metal’. More existing for little kids. ‘For young children having an IV pole can’t be scary, so the look of the pole becomes important as a tool to help the patient.”

Parents also stated the value of children feeling comfortable ‘children want things to make hospital less scary’ and ‘the parents want “Safety and anything that will make this process less intrusive and easier for their children.” Any medical device that looks too functional says “scary” and creates an impression of function over the patient.” One parent described the existing IV Poles as “Too industrial and intimidating.” Whereas in comparison, parents stated Sprout IV Pole to be “Child friendly.” The children like the idea to look something they can relate to or distract them.” Illustrating Sprout IV Pole’s ability to help children feel more comfortable in their environment.

Overall positive emotions and feelings of comfort were provided to children throughout the trial of Sprout IV Pole in hospital through the use of colour and aesthetic. Consequently this resulted in creating a product children were comfortable with, suited to their needs.
“It Makes it Easier”

Aside from valuing the aesthetic colour and form of Sprout IV Pole, the form also provided some important benefits to children by giving them confidence, independence and play opportunities.

Confidence

The form of Sprout IV Pole provided children with trust-based confidence. Children and parents listed a range of issues with existing products, such as: “It was a nightmare and made life difficult while we were here” (parent), “I wouldn’t trust the old pole because its not very stable” (parent) and “they wobble all the time” (parent). In comparison to comments made about Sprout IV Pole, “The children like the green pole. They were able to move it, the bigger the legs are shorter so good for storage, designated hand held is good, easier to push,” “Older easier making it more quiet. It didn’t move on its own” and “Designated hand held is good.” These factors made Sprout IV Pole easier for children to use on their own, helping them to be more independent.

One parent stated, “My child was frustrated that she couldn't push around the hospital pole.” In comparison to “My son is nine, he needs some independence and being able to move around by himself safely is very important.” This was supported by the nurses, stating “The children like the green pole. They were able to move it, the bigger the cold easier to move the pole.” This independence provided through the mobile ease of using Sprout IV Pole enabled children to exercise self-determination. The ability to move as they pleased independently is a huge priority of children in hospital and is seen to decrease their stress and anxiety (Lambert, Coal, Hicks et al. 2013; Eisen, Urrich, Shepley et al. 2008; Soderback, Coyne & Harder, 2011).

Independence

Independence was a theme present in the responses from children, parents and nurses. Children found Sprout IV Pole easier to use for a range of reasons. “The new pole was easier to hold making it easier to move around.” From previous research, children had illustrated the value of improving their hospital experience by including play (Salama, Salamrin & Aronen 2010; Landen, 2013; Lindkle, Hake & Johnsen 2016). This was related back to factors that allowed children to feel comfortable as it provided them with some control over their experience and independence, which many children referred to small elements in the design that improved their play opportunities, such as “Sprout has rubber wheels which make it go faster.” “Like to run with the Sprout IV Pole, easier to run with Sprout.”

Play

Another theme present in the findings was children’s desire to play. Children referred to small elements in the design that improved their play opportunities with the product. “Sprout has rubber wheels which make it go faster.” “Like to run with the Sprout IV Pole, easier to run with Sprout.” “The new pole was easier to hold making it easier to move around.” Play is seen as a method of keeping all of their IV lines securely together when moving essentially making it safer. With younger children, the only emotional attachment they may have to their IV Pole may be how they play one parent stated, “He is only old enough to view the pole as a novelty item to ride on to the bathroom.” Overall confidence, independence and play were all elements that Sprout IV Pole had provided for children in the trial. Collectively, these elements contributed to improving the experience of hospitalisation for children by reducing feelings of anxiety, stress, and fear. These examples illustrated the children’s view in combination with their parents and nurses but this study also illustrated the value of listening to children independently.

Although safety was the main priority for the parents and nurses as well as for many of the children, efforts should not be made to deny children controlled play opportunities, such as playing with the IV Pole while their parent pushes them. One nurse explained how parents generally got their younger children to ride their IV Poles as a method of keeping all of their IV lines securely together when moving essentially making it safer. With younger children, the only emotional attachment they may have to their IV Pole may be how they play one parent stated, “He is only old enough to view the pole as a novelty item to ride on to the bathroom.”

Overall confidence, independence and play were all elements that Sprout IV Pole had provided for children in the trial. Collectively, these elements contributed to improving the experience of hospitalisation for children by reducing feelings of anxiety, stress, and fear. These examples illustrated the children’s view in combination with their parents and nurses but this study also illustrated the value of listening to children independently.
Children have different values

The qualitative findings show similarities between the views of children and their parents about the value of aesthetics and the importance of form that Sprout IV Pole exemplifies. However, comparing a child’s feedback directly with their parent provided some clear differences. This can be illustrated by three examples where parents were satisfied with both IV Poles. They both moved well, they were both equal in safety.” Would change nothing about either pole.” In comparison to their children’s comments “Sprout is safer to use. Old IV pole feels like it might jam sometimes.” The sprout stronger and safer.” “The green one is bumpy so you know where to hold it.” Concluding that Sprout IV Pole was better because it was easier to move, safer and sturdier.

Another example illustrates a parent explaining what they believe children want. “Children want things to be easy, colourful + funky to make hospitals less scary.” Whereas their child held strong values towards the usability, functionality and mobility of the product. The pole just holds the medicine for you to move around, a little bit important, but not the end of the world.” “It needs to be easy to move so small kids can move it. Toddlers aren’t good at staying still so it needs to move easily.” The child also stated that Sprout more childish and that the existing IV Poles made her feel older.

These examples suggest that even though parents may think they know what their child likes and dislikes, this isn’t always the case. This understanding can be gained by providing children with an opportunity to communicate their views alongside those of their parents.
DISCUSSION

Complexity of involving Children
Navigating Hierarchy
Importance of consulting Children
Limitations
Recommendations
Conclusion
Complexity of Involving Children

Through this study of involving children in the evaluation of Sprout IV Pole, some key insights and understanding were gained. Even though children were involved in the testing of the product in hospital rather than the design/development/refinement of Sprout IV Pole, this process still revealed the complexity of involving children in a design process in hospital. The need to appeal to the senior management of healthcare organisations, as well as navigating the hierarchy of the healthcare organisation were the two biggest complexities encountered through the project. This process also revealed the importance of consulting children, and how their needs differ from those of their parents and nurses.

Designing for the healthcare context can be difficult without aiming to involve children (Jones, 2013). Seeking children’s involvement in the healthcare context through this study presented an array of complexities such as gaining access requirements as well as navigating the healthcare organisation hierarchy.

Gaining access requirements

Research with children is constantly faced with a clash of interests around whether to involve children versus their need for protection (Soderback, Coyne & Harder, 2011; Kirk, 2006). Giving children the opportunity to participate in research in order to make their voice heard can empower them (Soderback, Coyne & Harder, 2011; Kirk, 2006). Giving children the opportunity to participate in research in order to make their voice heard can empower them (Soderback, Coyne & Harder, 2011). This provides children with the opportunity to exercise their autonomy, as well as form and communicate their opinions (Lambert, Glacken, McCarron, 2013a).

On the other hand, children need protection as they are a vulnerable population, inherently smaller with little to no social-economic or political power making them increasingly vulnerable to manipulative adults (Freeman & Mathison, 2009). Within healthcare organisations it is the role of senior management to act as protectors of children, giving them the ability to block children’s participation in research (Kirk, 2006; Stalker, Carpenter, Connors et al., 2004). This was corroborated through the process of involving children in the evaluation of Sprout IV Pole. A range of senior management presented concerns that affected the involvement of children through the criteria applied to the design of Sprout IV Pole and the implications of the study design for gaining access approval.

Discussion

Children were not consulted for the original design and subsequent development and refinement of Sprout IV Pole as well as the study design. This was because of the need for ethical approval and access permissions required in order to involve them in the process (Bishop, 2013). This essentially placed children in a place of inaccessibility (Freeman & Mathison, 2009). Senior management specified criteria that Sprout IV Pole had to meet to prioritise their needs before access would be granted for the evaluation of Sprout IV Pole in hospital. When Sprout IV Pole did not meet these criteria, the project stalled until changes were made to the design, essentially pushing the evaluation trial back two months. This indicated that even though children’s voices were given the highest of importance in relation to informing the design that the voices of the health professionals granting access to these children had ultim
mass authority over the form of the design. It is uncertain whether children involved in the evaluation trial would have responded differently to the design before these changes. This issue is commonly faced by service and experience designers in healthcare as the end user of the product (the children) have a lot to gain from design-led changes (Jones, 2013).

Alongside changes to the design of Sprout IV Pole working with senior management during the planning of research with children is acknowledged as a fundamental aspect of the process. Yet this does require the designer or researcher to adapt to the schedules of health organisations and potentially alter the research design (Freeman & Mathison, 2009). This was the case with the design of the evaluation trial, which required a change from semi-structured informal interviews to a questionnaire. Although senior management see that it was their responsibility to protect children and look after them this should not be mistaken as a license to take away children’s ability to participate (Cavet & Slopers, 2004). The “politics of access” to these organisations require the researcher to adapt to the schedules of healthcare organizations and potentially alter the research design (Freeman & Mathison, 2009). This was the case with the design of the evaluation trial, which required a change from semi-structured informal interviews to a questionnaire. Although senior management see that it was their responsibility to protect children and look after them this should not be mistaken as a license to take away children’s ability to participate (Cavet & Slopers, 2004).

Navigating Hierarchy
Navigating the hierarchy of the hospital organisation for the first time also posed complexities with the process of seeking the involvement of children. Even though the process of gaining access to children in hospital to evaluate Sprout IV Pole proved difficult; the information sought from children during the evaluation trial illustrated the importance of consulting them. Valuing the involvement of children in the evaluation of the product allowed them to participate, build confidence and develop their opinions (Stalker et al., 2004). This also aligns with a study presented by Hunt, Brown and Coad (2013) in the UK, where children valued the environment and services whereas their parents valued information. In order to best understand the perspectives of children experiencing hospitalisation direct consultation with them is required (Tayla, Hauser-Casanovas, Weaver et al., 2015; Hesler & Leon-Krapi, 2010). They are unique individuals and very different to adults (National Association of Children’s Hospitals and Related Institutions, 2007). For a design student wishing to involve children in the process of evaluating Sprout IV Pole understanding and navigating the hierarchy of the organisation was essential for gaining this access but this also produced complexities regarding the level of entry to the organisation and the time delays imposed upon the process.

Working with the Starship Children’s Hospital required a clear a partnership to create a level of understanding around the project (Stalker, Carpenter, Connors et al., 2004). At the beginning it was unclear who within the hierarchy I was required to forge a partnership with. Consulting health professionals lower down the hierarchy provided a wealth of knowledge around the usability of Sprout IV Pole but no one was able to speak on behalf of the organisation. Whereas people higher up in the hierarchy were able to provide information on behalf of the organisation but held little understanding about the needs of the users. This was consistent with Jones (2013).

The implications of navigating this hierarchy often resulted in time delays for the research process which is also commonly reported through the literature (Jones 2013; Stalker, Carpenter, Connors et al., 2004). This condition is acknowledged to have detrimental effects on short-term studies. The need to engage with ethics committees and health organisation reviewers requires a generous timeline and a committed design/research team (Jones, 2013). The implications of navigating this hierarchy often resulted in time delays for the research process which is also commonly reported through the literature (Jones 2013; Stalker, Carpenter, Connors et al., 2004). This condition is acknowledged to have detrimental effects on short-term studies. The need to engage with ethics committees and health organisation reviewers requires a generous timeline and a committed design/research team (Jones, 2013).

Importance of consulting Children
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Differences between adults and children
Even through a compromised study design, the evaluation trial still indicated there were enough differences with adults to value the involvement of children. The value that children place upon the aesthetic of Sprout IV Pole as well as their ability to be independent and move on their own indicated strong differences between adults and children. The value that children place upon the aesthetic of Sprout IV Pole as well as their ability to be independent and move on their own indicated strong differences between adults and children.

Instructions from gatekeepers (Freeman & Mathison, 2009). This is a common issue for researchers aiming to involve children (Stalker, Carpenter, Connors et al., 2004). For a design student wishing to involve children in the process of evaluating Sprout IV Pole understanding and navigating the hierarchy of the organisation was essential for gaining this access but this also produced complexities regarding the level of entry to the organisation and the time delays imposed upon the process.

“You’ve heard the saying countless times: Children are not small adults” (National Association of Children’s Hospitals and Related Institutions, 2007, p.1). “You’ve heard the saying countless times: Children are not small adults” (National Association of Children’s Hospitals and Related Institutions, 2007, p.1).
Limitations

Alongside insights into the process of involving children in medical equipment design, a range of limitations were placed upon the study, which potentially affected the involvement of children as well as the design of Sprout IV Pole. These revolved around the evaluation trial location, the quantitative nature of the study, the need for a research assistant, and the overall misalignment of the study with a social constructivist/designers approach, which will be explained below.

Trial location

The location set by the nurse advisor of the hospital indicated the two wards within which the trial would take place. These were selected to participate in the study, as they were assumed too young to comprehend the value of the study and provide informed opinions. Instead their parents were asked to provide feedback on the design. This produced a double jeopardy situation where these young children were deemed ‘incompetent,’ to their parents communicated personal information about them that may not have reflected their views (Carter, 2009, p.186). Researchers should aim to ignore this age of children and favour tools that enable all children of all ages to participate, acknowledging their ‘situational context’ and ability to comprehend and communicate their thoughts (Kirk, 2006, p.156).

The results of the predominantly quantitative questionnaire used with children provided limited depth of access to the perspectives of children and the reasoning behind their views. Questionnaires have been criticized for providing superficial information, as they don’t allow probing to extract meaning from an approach based on semi-structured interviews with children to provide feedback on the design. This produced a “double jeopardy” situation where these young children were deemed “incompetent,” so their parents communicated personal information about them that may not have reflected their views (Carter, 2009, p.186). Researchers should aim to ignore this age of children and favour tools that enable all children of all ages to participate, acknowledging their “situational context” and ability to comprehend and communicate their thoughts (Kirk, 2006, p.156).

The research assistant contracted to conduct the evaluation of Sprout IV Pole with children, their parents and nurses presented a few limitations to the study given her background and issues of reflexivity. As stipulated by the nurse advisor, the research assistant contracted was required to have a nursing background preferably in paediatrics and experience working in Starship Children’s Hospital. Although this was priority, this did have limitations when researching with children. This was associated with the research assistant’s status as an authoritative figure equal to the nurses treating the children, instead of being equal to the children (Freeman & Mathison, 2009). The research assistant’s position needed to be clearly distinguished from the nurses. However, because her background reflected the nurses’ role she was naturally drawn to assisting the nurses if required (Lambert, Glacken, & McCarron, 2010), as well as associating the hospital with her role as a nurse (Freeman & Mathison, 2009).

Misalignment with the Social Constructivism/designer approach

The social constructivist/designer approach places value on the individual participants in research, as well as the role of the researcher to influence and shape the role of children in the research. Through the decision of the healthcare organisation, a research assistant was required to conduct the study as I could potentially bias the data if I were to conduct the study myself. This was a consequence of the objective perspective commonly held in quantitative studies (Elliott, 2010). The social constructivist/designer approach places considerable value on the researcher’s ability to understand the participants, build empathy and value input and perspective on the research (Brown, 2008; Freeman & Mathison, 2009).

Research Assistant

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Figure 54. The Road Map recommendations to Designers

- Establishing Connections
- Ethical Approval
- Hospital Partnership and Design Champion
- HDC
- Research Office / Review Board
- Clinical Engineering
- Hospital Departments
- Infection Control
- External Organisations / Regulations
- Testing / Evaluation
- Liability
- Consultation Method

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Figure 54: The Road Map recommendations to Designers.
in hospital to increase the value of the research to children as well as the value of the findings. To offer children greater control over the research where they can exercise their autonomy, their involvement should be sought throughout the process of establishing the research focus, data collection and data analytic (Road & Coyle, 2008). This not only provides children with the opportunity to shape and reshape, but also improves the understanding of children’s voices, as they are interpreted and analysed by children instead of relying on adult interpretations (Kirk, 2006).

This approach to research with children entails a greater level of time planning in order to gain access to children (Stalker, 2012). Researchers need to account for this with generous timelines to allow flexibility if issues are encountered (Stalker, Carpenter, Connors et al., 2004). This is supported by literature that suggests including a hospital representative in the design/research team also highlights the value of partnerships (Haboush, 2010). Their role would also involve overseeing preparations for the study, such as the study design, organisation expectations, funding applications and establishing connections.

**Establishing Connections**

Once hospital partnerships have been created, an array of consultations can be offered to (student) researchers and the design of their hospital experience. In light of these limitations on the study, a range of recommendations can be offered to (student) researchers and designers about approaches to valuing the voices of children, eliciting their voices through research and the design of their hospital experience.

**Designers**

For a designer/design student undertaking a project that involves children in the design of medical equipment, a range of recommendations can be offered. These provide indications to others embarking on this journey of what they need to consider whilst acknowledging that each study undertaken differs considerably. These recommendations are targeted at involving children through the design of medical equipment, but aspects can be applied to other studies that involve children in the design of their hospital experience. These are illustrated in the Road Map figure 32.

**Hospital Partnership and Design Champion**

When embarking on a study that involves children in a health service organisation, the buy-in and partnership of the institution is a fundamental basis of gaining access to children. Literature supports the need to build relationship with organisations in order to gain their participation and co-operation with the study (Haboush, 2010). The lack of partnership and understanding around a project/research could result in gatekeepers denying access. Within this partnership, a “design champion” from the health service organisation is required as a hospital liaison and project manager, willing to assist with understanding the organisation in order to inform the study and ease the process of gaining access (Stalker, Carpenter, Connors et al., 2004). This is supported by literature that suggests including a hospital representative in the design/research team also highlights the value of partnerships (Haboush, 2010). Their role would also involve overseeing preparations for the study, such as the study design, organisation expectations, funding applications and establishing connections.

**Recommendations**

Alongside recommendations to health service organisations, recommendations can be offered to researchers embarking on consultation with children in hospital to increase the value of the research to children as well as the value of the findings. To offer children greater control over the research where they can exercise their autonomy, their involvement should be sought throughout the process of establishing the research focus, data collection and data analytic (Road & Coyle, 2008). This not only provides children with the opportunity to shape and reshape, but also improves the understanding of children’s voices, as they are interpreted and analysed by children instead of relying on adult interpretations (Kirk, 2006).

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**Liability**

Acknowledging the output of this process as a product requires acknowledging its ability to fail. As designers of medical equipment, considerations such as the liability of the product, and insurance if the product were to break, hurt someone, or damage property are key considerations.

**Consultation Method Selection**

Aside from the preparation required to seek the involvement of children, consideration is required to the unique methods of eliciting the voices of children. Many methods commonly used with adults are not favourable when researching with children (Finneman & Mathison, 2010). Acknowledging this, during the selection of methods is important, as well as prioritising novel methods that enable children to communicate their perspectives more freely through pictures and storytelling (Kirk, 2006). Overall, these recommendations can offer designers some insights into areas of consideration before embarking on the journey to better prepare them for what they may encounter. In many ways, this will depend on the product design or their area of hospital experience interest.
Conclusion

During this process of implementing the Sprout IV Pole in a hospital setting, children were involved during the evaluation to provide their feedback on the design. The findings of the evaluation trial illustrated to senior management the preference that children had for the Sprout IV Pole over the existing IV pole. This has resulted in the manufacturing of 20 Sprout IV Poles for Starship Children’s Hospital with funding provided by the Starship Foundation, their five star sponsor Mercury Energy and their star supporters club, who are involved with the ongoing evaluation and use of the Pole.

Overall the feasibility of involving children throughout the entire process of designing as well as evaluating a piece of medical equipment requires a considerable amount of time preparing and planning. This level of involvement would need to consider children as ‘design partners’ providing them with more control over the process (Kuhn, 2002). The constraints of this project as a one-year Masters involving the manufactured output of Sprout IV Poles in conjunction with Starship Children’s Hospital meant that it was not possible to include this dimension.

This approach of involving children I believe is the best way of understanding how children can shape their experiences in hospital to improve healing and recovery. However, as Jones (2013) explains, ‘The problem is that everyone can have a different view of the meaning of getting and staying healthy. A lack of consensus among players in a complex system is one of the biggest barriers to innovation. One subgroup’s innovation is another subgroup’s loss of control’ (p.8).

In order to reach this consensus, compromise is required by designers, researchers and health service organisations to understand other perspectives. Without this compromise from all stakeholders, children cannot be acknowledged throughout the research and design of medical equipment in the hospital environment. Although these compromises may take time to reach consensus, I believe that engaging children through research will result in gaining much richer perspectives, enabling designers to truly empathise with their users, and thus improving health outcomes and services (Robertson, Pryke & Evans, 2013).
References


Langdon, O. (1949). A study of the uses of toys in a hospital CHILD DEVELOP-


Appendix 1 - Content Analysis

<table>
<thead>
<tr>
<th></th>
<th>Child</th>
<th>Parent</th>
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</tbody>
</table>

### Aesthetic - Colour
- Child: 26
- Parent: 35
- Nurse: 12

### Aesthetic - Form
- Child: 47
- Parent: 63
- Nurse: 13

### Child Friendly
- Child: 22
- Parent: 35
- Nurse: 5

### Emotions/ Feelings
- Child: 15
- Parent: 24
- Nurse: 3

### Functionality
- Child: 21
- Parent: 82
- Nurse: 41

### Ideas
- Child: 9
- Parent: 10
- Nurse: 7

### Mobility
- Child: 51
- Parent: 68
- Nurse: 22

### Safety
- Child: 31
- Parent: 43
- Nurse: 26
Contributors

**Users**

- Sick children who were one of the key users of the IV Pole in hospital. These children had first-hand experience of hospitalisation that provided feedback through the evaluation trial. Due to the ethical risk associated with consulting children during the evaluation of Sprout IV Pole in hospital, this consultation took two years to some extent.

- Parents of sick children in hospital were also one of the key users of the IV Pole. These parents had first-hand experience using the IV Pole with their children during the evaluating of Sprout IV Pole in hospital. These experiences with IV Poles as well as their expert opinions and advice were also sought for feedback by the Nurse Advisor during the evaluation trial as a user of Sprout IV Poles when administering medication to children. This allowed nurses to share their experiences with IV Poles as well as their expert opinions and advice.

- Charge nurses were also consulted in the evaluation trial as a user of Sprout IV Poles when administering medication to children. This allowed nurses to share their experiences with IV Poles as well as their expert opinions and advice.

- The Nurse Advisor is among the senior management team of Starship Children’s Hospital. She was consulted during the project when seeking sign off for approvals to conduct the evaluation trial in Starship Children’s Hospital.

- The Nurse Director is among the senior management team of Starship Children’s Hospital. She was consulted during the project when seeking sign off for approvals to conduct the evaluation trial in Starship Children’s Hospital.

- The Design for Health and Wellbeing Lab is the collaboration between the ADHB and AUT Product Design department, encouraging the integration of design work with the hospital. The design team provided guidance throughout all aspects as well as seeking feedback in the hospital such as Health Alliance, Clinical Engineering OHS and Infection Control.

- The Clinical Engineering within ADHB are responsible for clinical and staff management within a ward or other clinical area. Starship was submitted to the Maori population. She was consulted during the project when seeking sign off for approvals to discuss who held liability for Sprout IV Poles while being trailed in hospital. This made up part of the focus to the ADHB research review process.

- The Infection Control provides feedback upon the safety of the IV Poles while being trailed in hospital. This included the cleaning and safe use. They were consulted during the project when seeking sign off for approvals to discuss who held liability for Sprout IV Poles while being trailed in hospital. This included the cleaning and safe use. They were consulted.

- The ADHB Clinical Engineering reviews all research to be conducted in the ADHB. She was consulted on many occasions around understanding the process of the project and was involved in the project’s application as well as granting the final expedited approval.

- The ADHB Metaclinical Engineering reviews all research to be conducted in the ADHB. She was consulted on many occasions around understanding the process of the project and was involved in the project’s application as well as granting the final expedited approval.

- The ADHB Maori Research Review Manager reviews research to be conducted in the ADHB that isn’t low risk. The application for my research study was submitted to the ADHB Maori Research Review Manager. He was consulted in the project when seeking sign off for approvals to discuss who held liability for Sprout IV Poles while being trailed in hospital. This made up part of the focus to the ADHB research review process.

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- The Nurse Advisor is among the senior management team of Starship Children’s Hospital. She was consulted during the project when seeking sign off for approvals to conduct the evaluation trial in Starship Children’s Hospital.

- The Nurse Director is among the senior management team of Starship Children’s Hospital. She was consulted during the project when seeking sign off for approvals to conduct the evaluation trial in Starship Children’s Hospital.

- The Clinical Engineering within ADHB are responsible for clinical and staff management within a ward or other clinical area. Starship was submitted to the Maori population. She was consulted during the project when seeking sign off for approvals to discuss who held liability for Sprout IV Poles while being trailed in hospital. This made up part of the focus to the ADHB research review process.

- The Infection Control provides feedback upon the safety of the IV Poles while being trailed in hospital. This included the cleaning and safe use. They were consulted during the project when seeking sign off for approvals to discuss who held liability for Sprout IV Poles while being trailed in hospital. This included the cleaning and safe use. They were consulted.

- The ADHB Metaclinical Engineering reviews all research to be conducted in the ADHB. She was consulted on many occasions around understanding the process of the project and was involved in the project’s application as well as granting the final expedited approval.

- The ADHB Maori Research Review Manager reviews research to be conducted in the ADHB that isn’t low risk. The application for my research study was submitted to the ADHB Maori Research Review Manager. He was consulted in the project when seeking sign off for approvals to discuss who held liability for Sprout IV Poles while being trailed in hospital. This made up part of the focus to the ADHB research review process.

- The ADHB Product Design department within the ADHB ensure infections are kept to a minimum by ensuring products purchased for the hospital such as the IV Pole are clean and safe. They were consulted during the project when seeking sign off for approvals to discuss who held liability for Sprout IV Poles while being trailed in hospital. This included the cleaning and safe use. They were consulted.

- The Research Review Committee reviews applications for research to be conducted in the ADHB. She was consulted during the project when seeking sign off for approvals to discuss who held liability for Sprout IV Poles while being trailed in hospital. This included the cleaning and safe use. They were consulted during the project when seeking sign off for approvals to discuss who held liability for Sprout IV Poles while being trailed in hospital. This included the cleaning and safe use. They were consulted.
My Supervisors are both lecturers at AUT, primary with a science background and my secondary with a health background. Their role within my project was formidable guidance with all aspects of my work, as well as advising me as a student when dealing with external organisations and their bureaucracy.

The Health and Disability Ethics Committee (HDEC) was consulted throughout the project to inform my ethics application so they understood what it entailed.

The Health Alliance are an organisation that supports the procurement of products for the hospital and to gain key contacts to seek further information from people.

Medsafe are a national organisation that hold a record of all medical equipment in use in New Zealand. They were consulted to understand whether Sprout IV Pole required registration in their directory of medical products.

An Engineer was consulted prior to the validation of Sprout IV Pole by the Clinical Engineering department of the HDEC to run a digital simulation of the Sprout IV Pole to test the tipping forces, stress and pressure, as well as identifying equivalent strengths and areas for improvement in Sprout IV Pole.

The Health Innovation Hub’s Clinical Validation expert assists with the planning and conduct of clinical trials of medical products. She provided considerable guidance around the application process for the AUTEC, as well as planning the study to ensure the trial had commercial value. Through the validation of quantitative data, the Health Innovation Hub’s Clinical Validation expert assessed the commercial value of Sprout IV Pole. This informed many manufacturing choices.

A Psychologist lecturer from AUT was consulted for feedback upon the design of the questionnaires to be used with participants in the trial of Sprout IV Pole. He informed the questionnaires’ scales used as well as removing any jargon. He also conducted the analysis of quantitative responses of the findings produced from the Sprout trial.

A range of Manufacturers were approached and consulted with throughout the process of constructing Sprout IV Pole. They were approached for manufacturing quotes and their expertise and construction to inform the design and manufacturing techniques to reduce cost and improve the strength of Sprout.

The Health Innovators Hub’s Clinical Validation expert assists with the planning and conduct of clinical trials of medical products. She provided considerable guidance around the application process for the HDEC, as well as planning the study to ensure the trial had commercial value. Through the validation of quantitative data, the Health Innovation Hub’s Clinical Validation expert assessed the commercial value of Sprout IV Pole. This informed many manufacturing choices.

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Medsafe are a national organisation that holds a record of all medical equipment in use in New Zealand. They were consulted to understand whether Sprout IV Pole required registration in their directory of medical products.
Appendix 3 - ADHB
Institutional Approval Letter

Dear Noel,

ADHB Research project: An 8566 Paediatric Hospital Experiences: Sprout IV pole evaluation.

The ADHB DHB Research Review Committee (ADHB-IRC) would be happy to consider your application for the approval of your research project.

Your Institutional approval is dependent on the Research Office having up-to-date information and documentation relating to your research and being kept informed of any changes to your study. It is your responsibility to ensure you have kept Ethics and the Research Office up to date and have the appropriate approvals. ADHB approval will be withdrawn if you do not keep the Research Office informed of the following:

- Any communication from Ethics Committees, including continuation of annual ethics renewal
- Any amendment to study documentation
- Study completion, suspension or continuation

More detailed information is included on the following page. If you have any questions please do not hesitate to contact the Research Office.

Yours sincerely,

On behalf of the ADHB Research Review Committee
Dr Mary-Ann Woodworth
Manager, Research
ADHB

C.C. Catherine Byrne [ADHB contact], Emma Maddren, Sarah Little

Institutional Approval

- The Auckland DHB Research Review Committee (ADHB-IRC) would be happy to consider your application for the approval of your research project.
- Your Institutional approval is dependent on the Research Office having up-to-date information and documentation relating to your research and being kept informed of any changes to your study. It is your responsibility to ensure you have kept Ethics and the Research Office up to date and have the appropriate approvals. ADHB approval will be withdrawn if you do not keep the Research Office informed of the following:

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Yours sincerely,

On behalf of the ADHB Research Review Committee
Dr Mary-Ann Woodworth
Manager, Research
ADHB

C.C. Catherine Byrne [ADHB contact], Emma Maddren, Sarah Little
Appendix 4 - ADHB Research Review Office Form

APPLICATION FORM FOR APPROVAL OF A RESEARCH PROJECT at ADHB

ADHB (in) Number A1296

Section A. General Summary

Full project title
Nephrolith Hospital Experiences: Sproust IV Pole Evaluation

Short project title
Sproust IV Pole Evaluation

Principal Investigator
Nesrali Partinie

Institution's name and position
Auckland University of Technology

Physical address

Work phone no
Emergency No

Email

ADHB Co-Investigator
1. Day Stay Unit Charge Nurse
2. 4.
3. 5.
4. 6.
5. 7.

Is the research project an intervention study (clinical trial)? NO

Coordinator name
Research Assistant

Contact details for communication if not via Principal Investigator or co-investigator

Address

Signature

Fax

Contact details

Brief Abstract
The design of medical products is often based on the needs of service providers. Whereas the design of Sproust IV Pole is based on the needs of service providers, as well as the medical needs informing its design. Sproust IV Pole has gone through a rigorous design process of cyclical stages continuously reviewed and refined. This process is based on considerable consultation with users and stakeholders. It is believed to design products through collaboration with the users and stakeholders will lead to better product design, suited to address the needs and worries of its users. Throughout this process, Sproust IV Pole has seen many alterations as a result of feedback from users. But now it has reached a stage that trialing in hospital is essential to understand whether the design offers value even existing IV Poles. The information gathered will be useful to better understand whether the newly designed Sproust IV Pole provides benefits beyond existing IV Poles for nurses, children, and parents using it in Starship Children’s Hospital

Research Proposal Use

The aim of this trial is to understand whether Sproust IV Pole provides added benefit over

Section B: Document checklist

REQUIRED FOR ALL APPLICATIONS

- Study protocol
- OTHER SUPPORTING DOCUMENTS - remember to submit the following with this application form if relevant
  - Signed budget
  - Ethics application form
  - Ethics approval letter
  - Participant Information Sheets and Informed Consent Forms
  - Central lab letter
  - Questionnaires / Surveys
  - Evidence of Māori consultation
  - Funding application (e.g. to Health Research Council)
  - Any other supporting documentation relevant to the application

IMPORTANT - submit supporting documents in electronic version by email to the Research Office study coordinator (if known) or to the generic Research Office email address: research.office@adhb.govt.nz. Submit this fully signed application form to the Ethics Committee, via email (as above), or as a paper copy to:
Research Office
Level 14, Support Building
Auckland City Hospital
Private Bag 10204
Auckland 1141

Scientific Review

Documents Attached

Conflict of Interest

Section C: Proposed Research

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<td>Describe</td>
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<td>Describe</td>
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RMC/24/13/014

RMC Application Form January 2014
If a child/young person cannot communicate in English verbally (or in writing) then they will be excluded from the study.

They will also be excluded from the study if they have already participated.

Legal Guardian/Parents

Parents/guardians with a child in the Day Stay Unit that is taking part in the study

Over two parents per child are welcome to participate in the study.

If a legal guardian/parent cannot communicate in English verbally (or in writing), then they will be excluded from the study.

They will also be excluded from the study if they have already participated.

Recruitment

Nurses in the Day Stay Unit, will be informed about the study through their changes nurse. If their wish to take part in the study and find out more information they can approach the research assistant within the three weeks to provide consent and participate. They will also need to indicate a date during the three weeks when they are available to provide feedback through the questionnaire individually, or through an interview with the research assistant.

Children and Parents

Upon arrival at the Day Stay Unit, a nurse will greet the child/young person. If children are between five to seventeen years old and requires fit for the Day Stay Unit, they will be provided information sheets informing them about the trial.

The information sheets will clearly indicate that not choosing to participate in the study will have no effect on their ongoing treatment or care. Child/young person and parent will be given different information sheets, which will explain the trial in an understandable language specific to them.

The research assistant will then visit the child/young person and parent in the waiting room to answer any questions. Once reading the information sheet, if the child/young person and parent wish to participate in the study they will be provided consent forms to complete. The research assistant will provide these forms and collect them. These forms will be shown to their nurse to indicate their recruitment to the trial.

Trial

On cold days, all children/young people recruited into the trial will be given a Spurs fit for trial instability. Milkfeud through the day this will be changed to a standard fit for the trial. Allowing participants to be able to make a comparison. The initial allocated pulse will be allowed the same, fit for cold days, and a standard fit for pulse on even days. This method is called repeated measure cross over design.

Data Collection

At the end of each day, the research assistant will approach the child/young person and their parent's legal guardian. The parent will be provided questionnaires to complete and evaluate the products. During this time, the research assistant will introduce the child/young person to each set of questionnaires. The responses will be documented on the questionnaires.

Questionnaires are grouped under five categories, general questions, questions about movement, safety, look and interaction (Nurses will give an additional category around function). Each category contains four to five questions. These questionnaires are either scored through open-ended responses (qualitative) or on a likert scale (quantitative). Questions may differ between children, parents and nurses.

Observations

The process used to design current fit for pulse is based on consultation solely with the service providers of the protocol used. Service users are often overlooked in the design of such protocols. In the study, specific actions (involving the service users, lack of understanding around the roles consulting users hold, as well as limited input. This process is lengthy, as protocols need to be strict guidelines and regulations, prior to being tested with human in models (Molino, Gokul Kisser and Wijaya, 2012). Whereas the protocol used to design Sprout fit for pulse has been very different.

Sprout fit for pulse has been designed through a rigorous design process, based on continuous consultation with the service providers as well as the users. When designing for paediatrics, new guidelines inform the need to consult children in decision-making areas associated with the design of their healthcare services and treatment (Dotenbach, Cyrude, 2013). This has informed this process to value the role of children in the already lengthy process of designing medical products.

This process started out by identifying teams with current fit for pulse for the users and service providers. Children often find these fit for pulse awkward to use, they are difficult to wear around in smaller spaces (such as bathrooms), and are often difficult to use for smaller people. In addition, the aesthetics of current functional medical equipment, which may not meet the needs of child users. This revealed a gap in the market that fit for pulse are made specifically for pediatrics use, and use by children, as well as lactating functionality and usability.

After more alterations to the original prototype, two variations of Sprout fit for pulse were trailed alongside an existing fit for pulse in a simulated hospital environment with healthy children. The simulation findings revealed the value children placed on the simplicity of the product to be deemed "child-friendly." The findings also acknowledge that the majority of children were able to use a fit for pulse without any problems, with the majority still considering the understanding of the control to provide feedback in line with children who have used it.

This created the need to evaluate Sprout fit for pulse in hospital with sick children and nurses, to understand how to compare current standard fit for pulse.

Design Participants

Nurses

Registered nurses working in the Day Stay Unit (Monday - Friday).

Any nurse working in the Day Stay Unit accepting children taking part in the trial are welcome to participate.

Nurses can provide feedback through the questionnaire area.

Children

Children being treated in the Day Stay Unit that require an fit for pulse for infusion.

Children must be able to communicate and provide consent (alongside their parents consent) to participate in the trial, between the ages of five and seventeen.

A group of six to four children each day, for three weeks, Monday to Friday. (Sprout Nurse Advice) indicated this sample size based on her understanding of daily activities in the Day Stay Unit. If more than four children require fit for pulse in the Day Stay Unit then the four to participate will be on a first in first served basis.
Nurse questionnaire
Parents/legal guardian questionnaire
Child/patient questionnaire
Child visual linear scale

Risk Mitigation Plan
Participants should experience no discomfort or embarrassment during the trial: if any participant does feel embarrassed during the interview, they can request the research assistant to leave and come back, or withdraw from the trial. If the research assistant detects discomfort or stress of the child/youth person they will pause the interview to reassess consent/assent. The interview may potentially resume at a later time if that participant does not withdraw after consulting with the research assistant. Participants may feel exposed to the research assistant, as the research assistant will be seeking sensitive information. The research assistant will gain the participants trust so they feel comfortable with their presence.

Risks/Benefits
The benefits of the study to the hospital include a new IV Pole design that potentially provides benefits over current standard IV poles, which has been informed by the different stakeholders.

End of Page

Timeline description
(Smallest box recommended)
Saturday – Friday for three weeks.

Monday
• Administer to the Day Stay Unit
• Informed about the trial from their nurse and provided information sheets
• Research coordinator answers questions and provides consent/assent form
• Consent forms/assent forms signed and returned
• Connect to their IV Pole – (0-3 days after the trial, this will be Sprague IV Pole, and on even days of the trial, this will be the standard IV Pole)
• Switching to the other IV Pole indicated by the research coordinator to their nurse
• Data collection through questionnaire
• Discharged from the Day Stay Unit with participation certificate

Tuesday – Thursday

Friday

Saturday

Sunday

Monday

Tuesday

Wednesday

Thursday

Friday

Saturday

Sunday

Monday

Tuesday

Wednesday

Thursday

Friday

Section D: Financial
Budget attached
Describe reason for budget attached
Clearly describe what patient care is standard and what is extra for Research

Study Assessments / Visits

Standard care
• Children visit this ward and require an IV Pole for their treatment.
• Consulting each child and their parents by the nurse would take place depending on the health of each individual child

Study Vitals

Non-standard care extra for this research project.
• Each child and their parent will be informed by their nurse upon arrival to the ward about the study and provided with information sheets.
• The research assistant will then speak with the child and their parent to gain consent/assent and answer any questions.
• The research assistant will prompt each child to switch their IV Pole once during the day.
• Each child will be asked one more time during their time in the ward by the research assistant to fill out a questionnaire (parents) and interview (child).

Describe/Identify ADHD
 • Undergoing the interview with the child/parent in their room (or where ever they are located in the ward).
 • Discussing the study with the child/parent in the waiting room of the Day Stay Unit.
 • ADHD nurse time for interview (They can dictate when they have time) and switching the pole.
 • ADHD Day Stay Unit change nurse pairing with the research assistant to indicate participants as well as informing nurses about the study to participant, and to inform their patients if a potential participant.

Breakdown / Explanation of Budget

Working Expenses
Laboratories, N/A
Pharmacy, N/A
Pathology, N/A

Investigator time (£ payable)

Coordinator/Research Nurse time

Study preparation and approval: indicating eligible participants to the research assistant
Study visits and OHR completion N/A
Monitoring N/A
Other costs N/A

Miscellaneous Costs
Travel/surcharge N/A

Incomesource for study
Funding from the Starship foundation

RBC Aesthetics Form January 2016
5 of 8

RBC Aesthetics Form January 2016
6 of 8
Section E: Contracts and Legal

Contract required: [Legally reviewed and approved]

Final contracts attached: [Date Contract approved for finalisation]

ACC study: [Non-ACC study]

Indemnity & Compensation signed: [Date]

Current Insurance Certificate: [Expire date]

Section F: ADHB Departmental sign-off (this is to be undertaken by more than one ADHB department, obtain extra signatures on appropriate)

Clinical Director / Clinical Leader (Medical Director / Nursing Leader (NIC)):
- I agree that the study aligns with departmental service area interests and access to patients/health workforce is justified.
- I agree that access to data for study purposes will not be granted selectively.
- I agree that the study is innovative and ethically appropriate.
- I agree that the study is feasible and the study population has been carefully assessed.
- I agree that the study will be conducted with the necessary ethical and scientific standards.
- I agree that there are no conflicts of interest that would undermine the study.

Name: [Signature]

Date: [DD-MM-YYYY]

Section G: Clinical trial registration

Clinical Trial Number: [Signature]

Trial Website: [Signature]
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1.0 Introduction

1.1 Trial Conduct

This trial will be conducted in compliance with the protocol approved by the Auckland University of Technology Ethics Committee (AUTEC), and according to Good Clinical Practice standards. No deviation from the protocol will be implemented without the prior review and approval from AUTEC except where it may be necessary to alleviate an immediate hazard to a research participant. In such cases, the deviation will be reported to AUTEC according to its policies and procedures.

1.2 Background

There are many brands of IV Poles. Most designs consist of a bedside pole with two "legs" with wheels attached to allow the pole to move around with ease. Children often find these IV Poles awkward to use as they have to move around in small spaces (such as bathrooms) and are often difficult to use for smaller people. In addition, the aesthetic costs to current functional/medical equipment, which may not meet the needs of children. This raises a gap in the market that IV Poles are not made specifically for paediatric uses and use by children, as well as lacking functionality and usability.

Consultation with Starship Children's Hospital charge nurses revealed many issues surrounding the functionality of the current IV Poles in use. These include:

- The plastic poles break when children stand on them.
- Plastic poles are difficult to clean.
- The height adjustment mechanism breaks easily.

Therefore, the current IV Poles do not always meet the physical or aesthetic needs of children, or the functional requirements of staff.

The Sprout IV Pole has been designed to aesthetically pleasing for children and young people, and to meet the physical needs around mobility and usability by making it easier to move around and convenient to use and handle.

The new design has been created through the design process. The purpose of this process is not just to design pleasing objects, but also to design something that we will use experience to produce a new product. Other factors to consider are aesthetic design and usability. The process of creating this understanding of users needs and experiences is vital to the development of a design. In this way, we can ensure that the product is designed for the intended users.

As end-users of the redesign for IV pole it is important that children and young people have a voice and opportunity to be involved in the design process, both in the development and testing of the product.

Children and young people move and interact with their environment in different ways both physically and emotionally in comparison to adults. Therefore, their perspectives on the use of products are essential to help us ensure it will meet their needs. Consideration of the needs of all stakeholders, including the children, is in line with the requirements of the researcher to design hospitals that provide a positive experience for the patient.
ed to a pump fixed to the pole and attached to the patient by a tube and needle, usually into their arm.

1.3.3 Description of the Investigational Device

Sprout IV Pole - Where the IV bag/bottle hang. One specifically promotes out more than others to cater to side bottles.

Straight pole – Room to attach pumps

Green pole – Handle for children and adults to use

Green base – Weighted base to stabilize the pole, and lower the center of gravity

Wheels – Heavy duty stop tree-wheels (Two with brakes)

1.4 Preliminary Data

Simulation Trial November 2013

A trial of earlier Sprout IV Pole prototypes in a simulated hospital environment with sixteen healthy children was conducted to understand how children would respond. During this trial children evaluated two variations of Sprout IV Pole and a standard IV Pole.

The Sprout variations included two different handle designs, and two different bases revealing the preference towards the fixing handle, and green base. But children could acknowledge this base (to ride on) was unnecessary and unsafe for children in hospital.

The simulation findings revealed the value of children place on the look and simplicity of the product to be deemed ‘tactile friendly.’ The findings also acknowledge that the majority of children were unfamiliar to the hospital scene, potentially lacking the understanding of the context to provide feedback in line with children who have experienced hospitalization.

This creates the need to evaluate Sprout IV Pole in hospital with sick children and nurses to understand how it compares to current standard IV Poles.

2.0 Trial Design

2.1 General Design

This trial is designed to collect data from children that will use an IV Pole during their admission to the Day Stay Unit, that accompanying parents, legal guardians, and the nurses handing to these children’s responses will be sought through structured qualitative/quantitative interviews, recorded through a questionnaire. Nurses’ responses and parents responses will be sought through a structured qualitative/quantitative questionnaire (they will all fill).

Each child will participate in the trial for one day. A range of 3-4 children/young people will be recruited into the trial each day. There will be a maximum of four Sprout IV Poles for the trial. The number of participants each day will be dependent on the expected admissions of children/young people requiring IV’s for IV infusions in the Day Stay Unit. It is expected that recruitment will take place over three weeks (Monday to Friday).

Children and their parent(s) will be recruited upon arrival to the Day Stay Unit in Starship Children’s Hospital, where they will be provided information about the trial, as well as consent forms. On 3-4 days, all children/young people recruited into the trial will be given a Sprout IV Pole to trial initially.

Throughout the trial, each child will thus change to a standard IV pole in order to make a comparison. The initial allocated pole will be withdrawn each day, Sprout IV Pole on odd days, and a Standard IV Pole on even days. This method is called ‘repeated measures cross-over design.’

At the end of the trial, they will be provided feedback upon their experiences with each IV Pole through an interview with the research assistant. Parents will be provided a questionnaire to fill out during the same time.

Repeated Measures Cross-over Design

![Diagram of repeated measures cross-over design]
The questionnaires are designed to collect information about both IV Poles trialed during the trial. Questions are grouped under five categories: general questions, questions about movement, safety, tool and interaction. Nurses will be given an additional category around function. Each category contains four to five questions. These questions are either recorded through open-ended responses (qualitative) or on a 1 to 5 scale (quantitative). Questions will equally offer between children, parents and nurses. For the purpose of the trial the questionnaire is available in English only.

3.2 Primary Feasibility
To establish which IV Poles is the preferable design for all three users from the responses to the questionnaires.

3.3 Primary Safety Endpoints
To establish the safety of Spot IV Pole by monitoring for adverse events. Adverse events will be noted in further comments of the questionnaires.

4.0 Participant Selection and Withdrawal

4.1 General Characteristics of the Proposed Participant Population
- Registered nurses working in the Day Stay Unit (DSU) of Children’s Hospital
- Children/younng people being treated in the Day Stay Unit that require an IV pole for IV infusions between the ages of 5-17.
- Parent/legal guardian of a child in the Day Stay Unit that require an IV pole for IV infusions and is taking part in the trial.

That is during the three-weeks of the evaluation (Monday – Friday 7:00am-7:00pm) when day stay is open. Prior to the trial commencing, the principal investigator, the research coordinator, Cath Byrne (Nurse Advisor) and the Day Stay Unit Charge Nurse will identify potential participants through admissions to the Day Stay Unit that require an IV pole for IV infusion during the three-weeks of the trial.

4.2 Anticipated Number of Research Participates
- Children: One to four children each day, each three days, up to 60 potential participants in the trial
- Parent/legal guardian: One to two per child, up to 120 participants in the trial
- Nurses: 5 + participants in the trial

4.3 Inclusion Criteria

Children
- Admitted to the Day Stay Unit during the three-weeks of the trial.
- Require an IV Pole during their time in the Day Stay Unit.
- Provide consent to participate, as well as parent/legal guardian consent.

4.4 English-speaking
- Between the ages of 5-17

Parent/legal guardian
- Their child requires an IV Pole during their time in the Day Stay Unit.
- Able to provide consent.

3. English-speaking

Nurses
- Working in the Day Stay Unit during the trial.
- Tend to children in the trial.
- Able to provide consent.

4. English-speaking

4.4 Exclusion Criteria

Child
- Cannot provide consent to participate in the trial.
- Do not speak English.
- Do not have parent/legal guardian consent.
- Have already participated in the trial or are on a previous visit to the Day Stay Unit.

Parent/legal guardian
- Their child does not require an IV Pole.
- Do not speak English.
- Cannot provide consent to participate in the trial.
- Have already participated in the trial or are on a previous visit to the Day Stay Unit.

Nurse
- Does not work in the Day Stay Unit during the time of the trial.
- Is not tending to children in the trial.
- Does not speak English.
- Cannot provide consent to participate in the trial.

4.5 Participant Recruitment and Screening

Potential participants identified by the principal investigator, the research coordinator, Cath Byrne (Nurse Advisor) and the Day Stay Unit Charge Nurse will be recruited to the trial upon arrival to the Day Stay Unit. Their nurses will provide information about the trial verbally and supply information sheets (individual information sheets for children, younger children, parents).

4.6 Early Withdrawal of Participants

4.6.1 Criteria for Removal from Trial
- Participant may withdraw from the trial at any time.

4.6.2 Follow-up for Withdrawn Participants
- If a child withdraws from the trial, parents can still provide feedback upon the IV Poles being trialed.
- If a parent withdraws from the trial, as long as the consent for their child still stands, then the child can still participate in the trial.
- If a nurse withdraws from the trial, other nurses can provide feedback through the questionnaire, at least five are desired in the trial.

5.0 Trial Procedures

5.1 Description
Participants will be considered for the trial as long as they fit the inclusion criteria and no exclusions apply. An informed consent/consent will be sought upon arrival to the Day Stay Unit prior to participating in the trial.

5.2 Method for Assigning Participants to Treatment Groups
Depending upon the day of admission, the odd day or even this will indicate which IV Pole they will be allocated individually during their time in the Day Stay Unit.

5.3 Participant Compliance Monitoring
Children will be asked to use one IV Pole for full their time in the Day Stay Unit, and their nurses will check their IV Pole to allow them to use the other IV pole midway through the day. Compliance to the 50/50 split of their time between IV Poles will be the responsibility of the research coordinator to indicate to the nurses.
Participants will be provided information about the findings of the trial if indicated to the research coordinator through their contact form.

7.0 Safety and Efficacy Assessments

8.0 Statistical Plan

8.1 Sample Size Determination

8.2 Statistical Methods

8.3 Participant Population(s) for Analysis

8.4 Data Analysis

9.0 Risk Analysis

9.1 Anticipated Risks

9.2 Adverse Event Definitions

9.3 Follow-up Procedures
Uncollected adverse effect. Any adverse effect, the frequency, specificity or severity of which is not fully described in the risk information described in the trial protocol(s) or elsewhere in the current AUSC application, as amended.

9.9 Recording of Adverse Events
All observed or unobserved adverse events (serious or non-serious) and abnormal test findings will be recorded in the “Further Comments” section of each participant’s questionnaire. For all adverse effects, sufficient information will be provided and/or obtained as to permit 1) an adequate determination of the outcome of the effect (i.e., whether the effect should be classified as a serious adverse effect) and 2) an assessment of the causal relationship between the adverse effect and the investigational device.

Adverse effects or abnormal test findings not to be associated with the investigational device will be followed until the effect (or its sequelae) or the abnormal test finding resolves or stabilizes at a level acceptable to the research coordinator. An abnormal test finding will be classified as an adverse effect if one or more of the following criteria are met:

- The test finding(s) is accompanied by clinical symptoms
- The test finding necessitates additional diagnostic evaluation(s) or medical/surgical intervention(s) including significant additional concomitant drug treatment or other therapy
- Noting simple repeating a test finding, in the absence of any of the other listed criteria, does not constitute an adverse effect.
- The test finding leads to a change in participant’s participation in the research trial
- The test finding is considered an adverse effect by the research coordinator of principal investigator.

9.4 Causality and Severity Assessment
The research coordinator or principal investigator will promptly review documented adverse effects and abnormal test findings to determine 1) if the abnormal test finding should be classified as an adverse effect and 2) if there is a reasonable possibility that the adverse effect was caused by the investigational device, and 3) if the adverse effect meets the criteria for a serious adverse effect. If the research coordinator or principal investigator rule that determination of causality is unknown and have question to the invesgational device then the adverse effect will be classified as associated with the use of the investigational device for reporting purposes. If the research coordinator or principal investigator rule that determination of causality is unknown but related to the investigational device or this determination and the recioinor for the determination will be documented in the respective “Further comments” section of the participant’s questionnaire.

9.5 Reporting of Adverse Effects and Unanticipated Problems
Who: Reporting of adverse reactions to Medscii.
For the purpose of this trial, Spons X V Pols does not have an Investigator in WRAN, an Investigator. Performing AUSC Research Review Committee approved, Medscii will be notified about the trial. In the event of an adverse effect, the principal investigator will submit a completed form to Medscii for medical review- event reporting for any observed or unobserved adverse effect that is determined to be an unanticipated serious adverse device effect. A copy of the completed form will be provided to the physician each investigator. The completed form will be submitted to Medscii as soon as possible and in no event later than 10 working days after the investigator becomes aware of the adverse effect.

If the results of the principal investigator follow-up evaluation show that an adverse effect that was initially determined to not constitute an unanticipated adverse device effect does, in fact, meet the requirements for reporting, the principal investigator will submit a completed form as soon as possible, but in no event later than 10 working days, after the determination was made.

For each submitted document, the principal investigator will identify all previously submitted reports that address a similar adverse effect experience and will provide an analysis of the significance of these reported adverse effect in light of the previous, similar report(s).

9.6 Stopping Rules
In the event of any adverse events for the use of Spons X V Pols in the Day Stay Unit of Stanspa Children’s Hospital, the event will be notified immediately.

10.0 Data Handling and Record Keeping
10.1 Confidentiality
Information about the participant will be kept confidential and managed according to the requirements as approved by AUSC.

10.2 Source Documents
The research coordinator will approach participants with questionnaires to collect data towards the end of their admission to the Day Stay Unit. The questionnaires will be collected by the research coordinator and passed on to the principal investigator.

Source data are all information, original records of data collection, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents.

10.3 Record Retention
It is the investigator’s responsibility to retain trial essential documents during the investigation for a period of five years from the end of the trial. All the data that are the result of the investigation is determined or involved in the data that will be no longer required for purposes of supporting a subsequent approval or a notice of completion of a product development protocol.

Research records and original signed consent forms to be retained by principal investigator for at least 10 years if the form includes authorization for use of private health information. Investigators may need to retain these documents for a longer period if required by an agreement with a sponsor or other applicable regulatory requirements. The 10-year minimum retention of authorizations complements the privacy regulation requirements.

10.4 Ethics Committee
Through consultation, AUSC’s approval was appropriate for this trial. The principal investigator alongside su- pervisors will be responsible for maintaining Ethics Committee Correspondences.

11.0 Trial Monitoring, Auditing and Inspecting
11.1 Trial Monitoring Plan
11.1.1 Trial Site Responsibilities and Training
Principal Investigators Training
Day Stay Unit nurse will be delegated the task of switching X Pols pass way through the day, which will be identified by the research coordinator, training to is not required.

11.1.2 Safety Monitoring
The principal investigator will complete the appropriate report form and logs; assist the PI to prepare reports and notify Medscii, of all Unplanned Problems.

12.0 Ethics
This trial will be conducted in compliance with the protocol approved by the ACHB Research Review Committee. The relevant regulations, anti-procedures, and procedures according to Good Clinical Practice (GCP) and the International Conference on Harmonization (ICH) will be followed. Any deviation from the protocol will be reported to the Research Review Committee. In the case of any deviation, the trial will be suspended and no further patients will be recruited. The trial will be conducted at the University Department of Medicine, University of XYZ.

All participants for this trial will be provided with a consent form describing the trial and providing sufficient information for participants to make an informed decision about their participation in the trial. This consent form will be submitted to the protocol review and approved by the Institutional Ethics Committee. All participants will be informed of the trial procedure and the potential risks and benefits associated with it.

13.0 Trial Finances
13.1 Funding Source
This trial is funded through a grant from the Fast-Track Foundation and the Star Sponsor Company. Any participant requests for funding will be approved by the Institutional Ethics Committee.

13.2 Conflict of Interest
Any investigator who has a conflict of interest with this trial as defined by the ICH will discontinue the trial. Any conflict will be reviewed by a properly constituted Clinical Trial Committee with a committee-sanctioned protocol management plan that has been reviewed and approved by both the Institutional Ethics Committee and the Research Review Committee.

14.0 Publication Plan
The results of this trial will be published in a peer-reviewed journal, as well as in the principal investigator's Master's thesis. All data in the thesis will be collected from participants, and the confidentiality of data will be protected by the Institutional Ethics Committee.

15.0 References


16.0 Appendices

Please answer question 2 in relation to IV Poses in general:

**IV Poses**

2. How important is

- Being able to (check only one)
  - The safety of the pose
  - The accuracy of the pose
  - The comfort of the pose
  - The ease of using the tool

**Very Important**

Please answer questions in relation to each pose:

3. Can you explain why you have answered this way?

4. The pose was easy to perform and comfortable

5. The pose went through the doorways and entrances

6. The pose was quick when moving

7. Where did you hold the needle when using it

8. Can you explain why you have answered this way?
Please answer questions in relation to each pole.

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<td>15. What did you like?</td>
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<td>16. What would you change about each pole?</td>
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<td>17. Can you explain how it could be better?</td>
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<td>18. Pumps were easy to attach</td>
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<td>19. Hard tag/hoopstes were easy to hang</td>
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<td>20. The pole was easy to keep in position when not in use</td>
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<td>22. The pole is important to children</td>
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<td>23. Children liked using the pole</td>
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<td>24. Children were able to move it</td>
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<td>25. Children used it in ways not intended</td>
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<td>26. Can you explain why you have answered this way?</td>
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| 27. Any further comments to add? Did any adverse events take place? |       |         |       |          |         |       |
**CHILD**

1. What is your Ethnicity? Circle one.
   - NZ European
   - Māori
   - Samoan
   - Cook Island Māori
   - Tongan
   - Chinese
   - Indian
   - Other

2. How old is your child? Circle one.
   - 1
   - 2
   - 3
   - 4
   - 5
   - 6
   - 7
   - 8
   - 9
   - 10
   - 11
   - 12
   - 13
   - 14
   - 15
   - 16
   - 17
   - 18+

Please answer question 2 in relation to IV Poles in general.

**GENERAL**

3. How important is...
   - Being able to move it easily
   - The safety of the pole
   - The look of the pole
   - How the pole functions

4. Can you explain why you have answered this way?

Please answer questions in relation to each pole.

**INTERACTION**

17. The pole is important to your child

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18. Your child liked using the pole

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19. Your child was able to move it

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20. Your child used it in ways not intended

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21. Can you explain why you have answered this way?

Any further comments to add? Did any adverse events take place?

**MOTION**

5. The pole was easy to move around

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6. The pole went through doorways and hallways

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7. The pole was quiet when sliding

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8. Where did you hold the pole when using it?

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9. Can you explain why you have answered this way?
Please answer questions in relation to each pole

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<td>9. This pole was stable</td>
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<td>13. I liked the look of the pole</td>
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15. What would you change about each pole?

16. Can you explain how it could be better?

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<td>17. The pole is important to you</td>
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<td>18. You liked using the pole</td>
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<td>19. You were able to move the pole on your own</td>
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<td>20. You used the pole in ways not intended</td>
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21. Can you explain why you have answered in this way?

22. Any further comments to add? Did any adverse events take place?

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2 July 2014

Stephen Reay  
Faculty of Design and Creative Technologies

Dear Stephen,

Re: Ethics Application: 14/180 Paediatric hospital experiences: Sprout IV pole evaluation.

Thank you for your request for approval of an amendment to your ethics application.

I have approved the minor amendment to your ethics application allowing a question on ethnicity to be added to your questionnaire.

I remind you that as part of the ethics approval process, you are required to submit the following to the Auckland University of Technology Ethics Committee (AUTEC):

- A brief annual progress report using form EA2, which is available online through http://www.aut.ac.nz/researchethics. When necessary this form may also be used to request an extension of the approval at least one month prior to its expiry on 23 June 2017;

- A brief report on the status of the project using form EA3, which is available online through http://www.aut.ac.nz/researchethics. This report is to be submitted either when the approval expires on 23 June 2017 or on completion of the project.

It is a condition of approval that AUTEC is notified of any adverse events or if the research does not commence. AUTEC approval needs to be sought for any alteration to the research, including any alteration of or addition to any documents that are provided to participants. You are responsible for ensuring that research undertaken under this approval occurs within the parameters outlined in the approved application.

AUTEC grants ethical approval only. If you require management approval from an institution or organisation for your research, then you will need to obtain this. If your research is undertaken within a jurisdiction outside New Zealand, you will need to make the arrangements necessary to meet the legal and ethical requirements that apply there.

To enable us to provide you with efficient service, please use the application number and study title in all correspondence with us. If you have any enquiries about this application, or anything else, please do contact us at ethics@aut.ac.nz.

All the very best with your research,

Kate O’Connor  
Executive Secretary  
Auckland University of Technology Ethics Committee

CC: Neerali Parbhoo, neerali.parbhoo@gmail.com