Valuing the voices of children

A case study of involving children in the process of medical equipment design in the hospital environment

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This thesis is submitted to the Auckland University of Technology for the Degree of Masters of Philosophy.

Attestation of Authorship

'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 of other institution of higher learning, except where due acknowledgment is made in the acknowledgments.'

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Abstract

Paediatric 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 paediatric hospital environments. This should extend to furniture and equipment in the environment. However little evidence suggests children are involved in the design of either 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 trialled in hospital. While trialled, 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/consulting 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 organisations to seek the involvement of children through the process if improving their healthcare environment, service and products.

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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; Landro, 2013). These four negative emotions are commonly felt by children because of their experience in hospital and can adversely affect their physical and psychological well being (Lambert, Coad, Hicks et al., 2013). Many factors contribute to children feeling this way because of admission to hospital, such as the treatment, the disconnection from their usual routines, unfamiliarity with the environment, limited communication and the loss of self-determination as is illustrated below.

One major cause of anxiety and pain for children is associated with the admission process and the experience of waiting for treatment (Biddiss, McPherson, Shea et al., 2013; Uehira and Kay, 2009; Pelander & Leino-Kilpi, 2010), as well as the treatment itself (Lambert, Coad, Hicks et al., 2013; Eisen, Ulrich, Shepley et al., 2008). Another contributing factor relates to children's experience of disconnection from their usual routines; going to school, going home, playing with their toys and socialising with their friends (Hutton, 2005; Pelander, and Leino-Kilpi, 2010; Lambert, Coad and Hicks et al., 2013; Soderback, Coyne & Harder, 2011). Once admitted to hospital, their usual routines are exchanged for hospital environments, medical staff and medical procedures. Children seek normality and a connection to their lives before hospitalisation (Lewis, Kerridge & Jorden, 2009; Hunt, Brown, Coad et al., 2013). They placed considerable value on contact with their friends, as well as physical activity (Hunt, Brown, Coad et al., 2013; Robin and Wilson, 2009). 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).

Other influential factors contributing to children's negative emotions related to the unfamiliar nature of the hospital; the physical environment, the people, the noises and the smells (Landro, 2013; Lambert, Coad, Hicks et al., 2013). Admission to hospital entails that children cooperate 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 experience for children in hospital (Pelander & Leino-Kilpi, 2010).

The anxiety of children is heightened because of the limited communication they were 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 unnecessary worry, fear and anxiety" (Lambert, Glacken, McCarron, 2013a, p.339). 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).

One of the most influential factors in relation to this study is around the potential loss of self-determination that children experience while in hospital (Lambert, Coad, Hicks et al., 2013; Eisen, Ulrich, Shepley et al., 2008; Soderback, Coyne & Harder, 2011). Because of disconnection from their usual routines, the unfamiliarity of the hospital environment, and the lack of communication with children about their health, children lose their right to self-determine, 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 (Cavet & Sloper, 2004). 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 & Coad, 2008; Coad & Shaw, 2008; Lambert, Coad, Hicks et al., 2013; Pelander & Leino-Kilpi, 2010).

Evidence suggests the traditional approach of designing healthcare services and environments is medical-centered (Uehira & Kay, 2009). 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 needs (Lambert, Coad, Hicks et al., 2013) children's levels of fear, anxiety, stress and pain are increased. The medical-centered approach prioritises the clinical needs of health 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, Pryde & Evans, 2013; Soderback, Coyne & Harder, 2011; Taylor, Haase-Casanovas, Weaver et al., 2010).

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 stimuli (Altimier, 2004), alongside the careful aesthetics of the product such as rounded and soft forms, gentle movement and quiet sound (Marzano, 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 (Coad & Coad, 2008). Children's preferences lay with pale to mid-range colours, specifically blues and greens. It is also worth noting that colour preferences differed and depended on the ages of the children (Coad & Coad, 2008).

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 (Altimier, 2004), but to disregard these elements can have the opposite effect (Hutchison, 2007). 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 space (Caixeta & Fabricio, 2012).

Considerable international efforts are taking place 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; Lindeke, Nakai & Johnson, 2006; 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 others 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 (Lindeke, Nakai & Johnson, 2006). While health professionals are experts in the developmental needs of children (Lindeke, Nakai & Johnson, 2006), 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 terms 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 behaviours towards the child's participation in conversation and decisions (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 experiences 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 portion 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, Connors 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 (Hutton, 2005). Many would suggest the poor reliability of proxies' ability to communicate on behalf of their children (Stalker, Carpenter, Connors et al., 2004; Coad & Coad, 2008; Pelander & Leino-Kilpi, 2010; Soderback, Coyne & Harder, 2011). This is due to a range of factors, one being the parents 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; Soderback, Coyne & Harder, 2011; Pelander & Leino-Kilpi, 2010). First hand interaction is the best way of understanding the perspectives of children experiencing hospitalisation (Taylor, Haase-Casanovas, Weaver et al., 2010; Pelander & Leino-Kilpi, 2010).

"Traditional interpretation of children and young people's perspectives about health care has been gained from their adult carers, which the literature suggests is not an accurate representation"

(Coad and Coad, 2008, p.35).

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 healthcare 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 (James, 2001). This view of research with children acknowledges them as key stakeholders rather than "beneficiaries or passive recipients of services" (Robertson, Pryde & Evans, 2013, p.27). 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 researchers/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.862).

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, 2013a; Stalker, Carpenter, Connors 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 elicit information that reflects children's lives through enjoyment 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 Right of the Child created a political driver to involve children in decisions associated with their healthcare (Lambert, Glacken & 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.

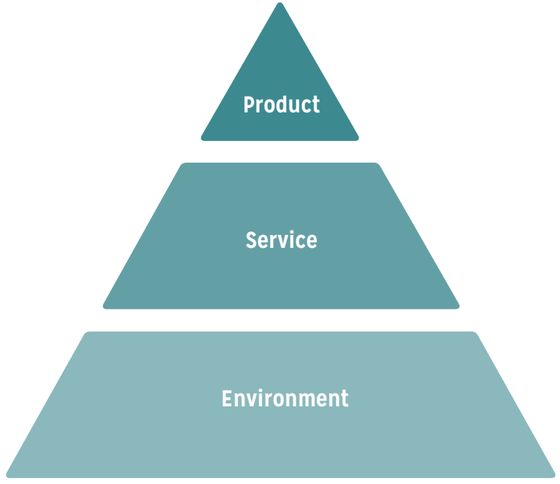


Figure 1. Paediatric Hospital Intervention Levels

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. This 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

"Medical device means any device, instrument, apparatus, or contrivance, including component parts and accessories thereof that is manufacturer, imported, sold, or supplied for use wholly or principally on or by 1 or more human beings for a therapeutic purpose; and included bandages and other surgical dressings, except medicated dressings where the medication has a curative function that is not limited to sterilising the dressing; but does not include"

(Medicine Act 1981).

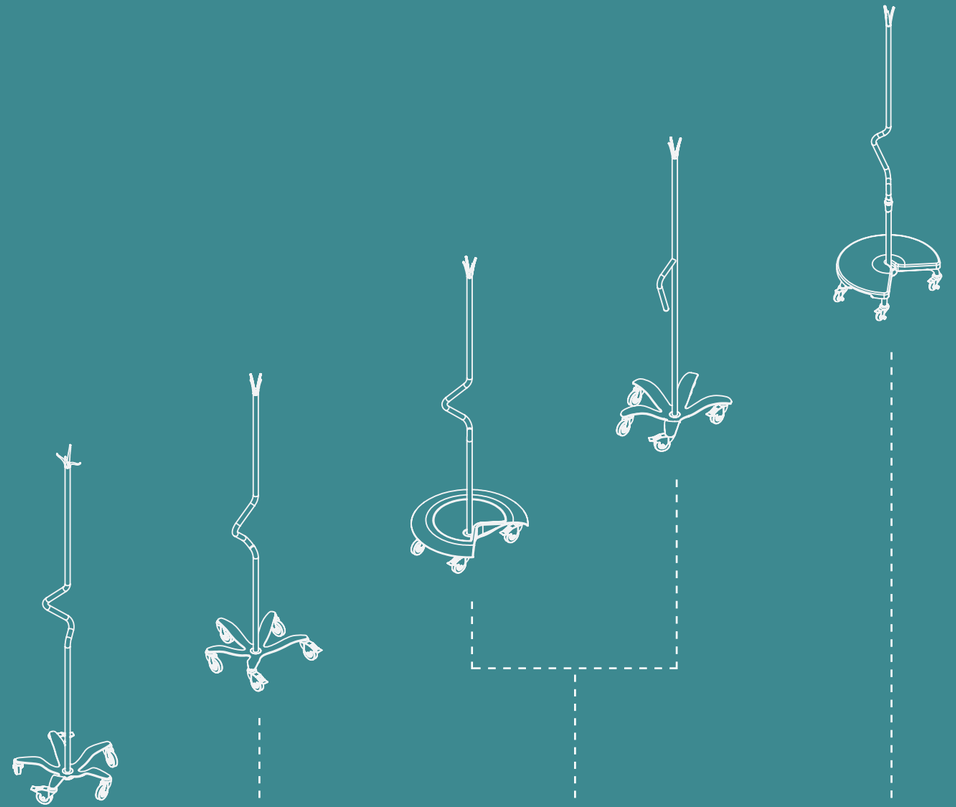


Figure 2. Sprout IV Pole generation four (2014)

Figure 3. Sprout IV Pole generation three (2013)

Figure 4. Sprout IV Pole generation two (2013)

Figure 5 Sprout IV Pole generation one (2012)

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 (Caixeta & Fabricio, 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 partner" involves considering them as an equal stakeholder (Druin, 2002). This level of involvement offers them the opportunity to partake 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 utilised 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-

perience 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 Bachelors 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 5). 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 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.

Figure 6. Starship Children's Hospital

METHODOLOGY

Designer's View - Social Constructivist
Design Process and Human Centered Design

Designer's View - Social Constructivist

As a product designer, I hold a social constructivist perspective. This dispenses with the belief that there is truth waiting to be discovered, instead holding the perspective that truth and meaning is constructed through the individual interactions of people, acknowledging how different people perceive the same things differently (Feast & Melles, 2010). The truth and meanings that people construct through interactions with objects recognises the dependency this experience has on varying influential factors that our sensory system responds to as well as the social context (Freeman & Mathison, 2009). These factors include the colour, shape, behaviour and texture of the object; the personality, skills, background, culture, values and motives of the person; the cognitive process required such as perceiving, exploring, using, remembering, comparing, and understanding; as well as the social, economic and physical contexts of interaction (Desmet & Hekkert, 2007).

In the context of this project, the children interacted with a range of different kinds of medical equipment throughout their time in hospital, one being their IV Pole. One of the intentions of the design of Sprout IV Pole was to be child-friendly, but this didn't necessarily equate with the perception that children held of the design. Children instead attached their own meaning to the product that was unique to their experiences (past and present) and the encounters they had with the product (Park, 2012). This recognises that each child will have a different experience informing their perspective, that children do not experience life in a universal manner (Freeman & Mathison, 2009).

With the design of products, the experience that the product creates I believe is not a property of the product, but is created through the individual interactions that people have with the product (Desmet & Hekkert, 2007). This said, each individual's experience with the product cannot not 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.

Part of this perspective also acknowledges the impact my background as a designer/researcher has had upon the research (Mackenzie & Knipe, 2006). As a researcher, my perspective and assumptions about children shape the research, and how they are represented in the study (Freeman and Mathison, 2009). This perspective is shaped by my personal experiences of childhood, which cannot be expected to be the same as my recollections of those times today (Druin, 2002).

Self-reflexivity in terms of the act of exploring ones assumptions about children is an important step for researchers when understanding how this influences our perceptions and interactions with children, and what we expect of them (Freeman & Mathison, 2009). Understanding and considering these influences is important to be aware of to ensure these do not bias information we gain from children (Druin, 2002). My belief is that childhood holds its own culture, different to adulthood. This has informed my desire to value children's voices and consult them directly throughout the study instead of through adult proxies.

This approach acknowledges that as the designer/researcher I am not the expert in designing to cater to the need 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.

This study aimed to explore how a designer might understand the experiences of health professionals (Nurses), children and their parents contextually bound to the hospital environment. This perspective recognises that each of these groups, as well as the individuals within these groups hold different perspectives of the product based upon their own personal experiences and influential factors.

But most importantly, to value the voices of children, through the social constructivist perspective, appreciates the unique knowledge and position children hold to provide insight in to their experience of hospitalization to evaluate the design of Sprout IV Pole (Freeman & Mathison, 2009). The true value came from consulting and involving the children directly "through the eyes of children" not through the assumptions of their parents and health professionals (Freeman & Mathison, 2009, p. 57).

To embody all these values and understand the contributing factors, the social constructivist approach aligns more so with the qualitative or mixed method approach (Mackenzie & Knipe, 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 include 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 innovation, come along and put a beautiful wrapper around the idea" (Brown, 2008, p.86). Over time this has evolved with designers 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 (Bremner & 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; Desmet & 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; Refer to figure 7). 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 inform the refinements of the design.

The ideation phase consists of designing to address opportunities identified

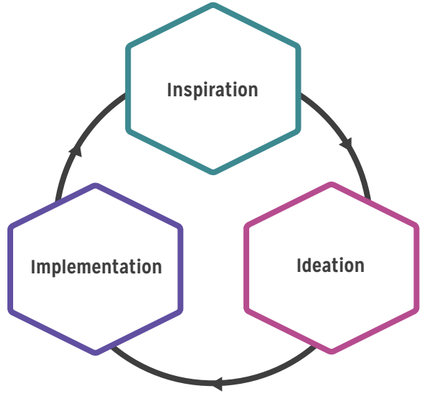


Figure 7. Design Process by Brown (2009).

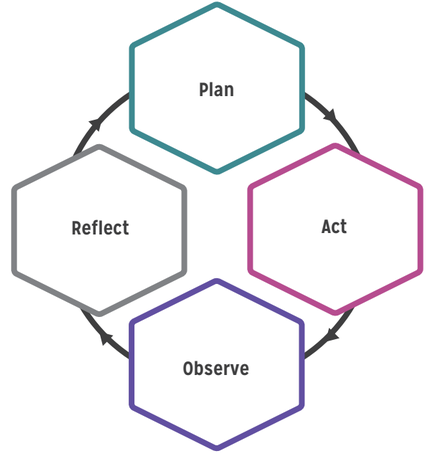


Figure 8. Action Research Cycle by Gray (2009).

in the inspiration phase (Brown, 2008). These ideas range from incremental (changing the colour of a product) to radical (changing the whole function, look and feel of the product) (Brown & Wyatt, 2010). This research focused on the redesign of the Sprout top, moving between this phase and the inspiration phase to seek feedback on the design.

The third phase of the design process saw the implementation of the design, as well as development and refinements made through testing (Brown, 2009). 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 required consideration 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 revisiting the inspiration phase on multiple occasions to work with new input and information from sources such as health professionals, which resulted in refinements to the design.

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; Swann, 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 inquiry 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.

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, as well as with children during the evaluation trial.

This collaboration is fundamental to the human centered approach, as a means of developing empathy for the users of the product to understand their perspectives and cater to their needs through the design process (Brown, 2008). Although it may be difficult to access certain users such as children, I believe it is my responsibility as the designer to advocate for the children when their voices may not be present during the process of refining with health professionals.

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).

METHODS

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

Expectation

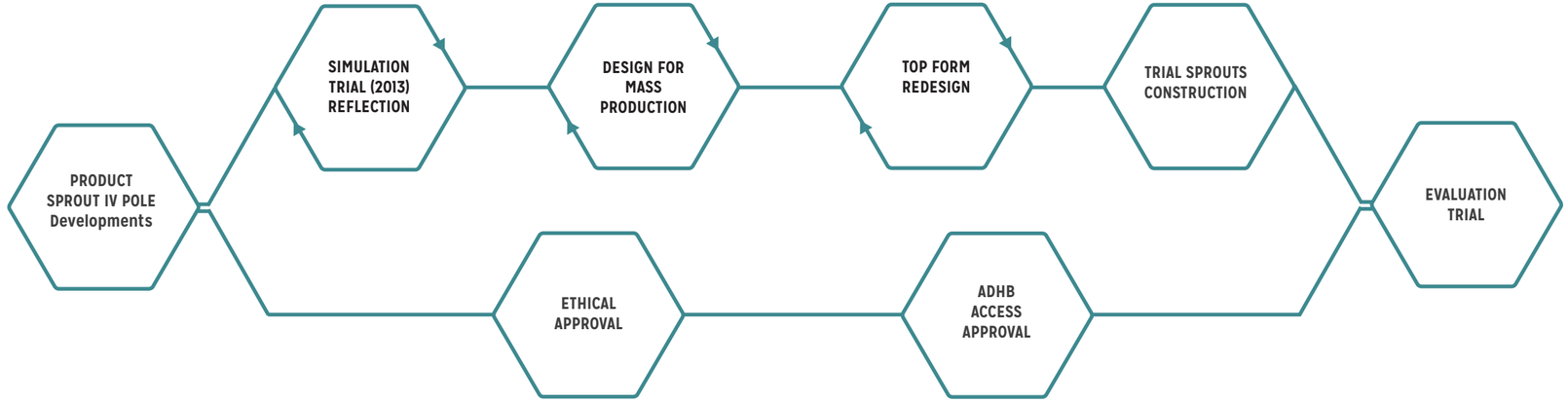


Figure 9. Process Expectations based on assumptions from other studies from the literature

Reality

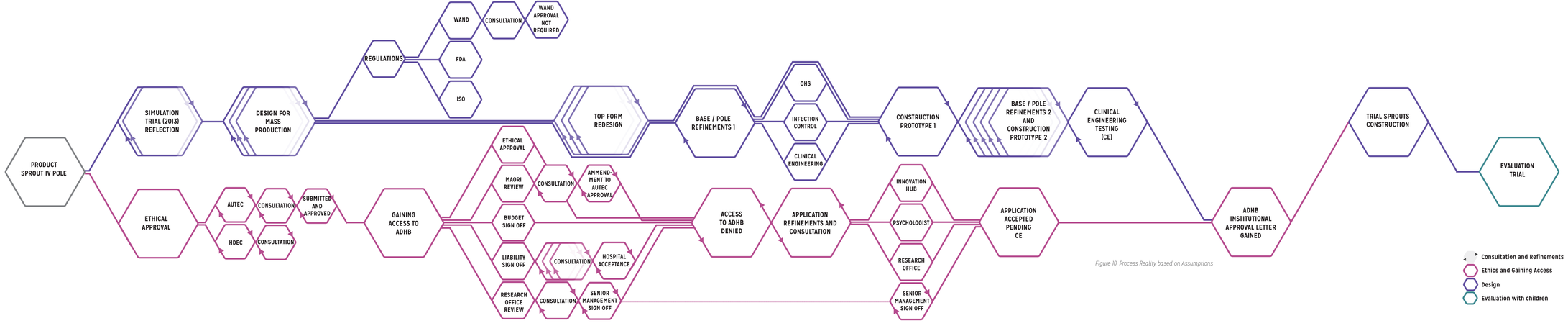


Figure 10. Process Reality based on Assumptions

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 (Hodge, 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 extensively 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.

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 comfortable (Cavet & Sloper, 2004). The literature acknowledges that there isn't one optimal approach to researching with children, but that there are particular practices that lend themselves better to research with children to produce richer data (Freeman & Mathison, 2009). These interviews are said to provide a richer and more in-depth responses from participants (Koshy, Koshy & Waterman, 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 (James, 2001). 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 Research 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 Innovation Hub, it was discovered that the issue was a consequence of the open qualitative nature of interview questions as distinct from structured questionnaires.

Literature suggests that the reason the Review Office required these changes was the scientific /quantitative nature of the healthcare domain (Jones, 2013), which contrasts with the social constructivist view of a designer. Considerable literature reporting on studies aiming to access children in hospital also encountered the need to adjust their research design as a condition of access. This seemed to be a common issue for research (Freeman & Mathison, 2009; Stalker, Carpenter, Connors et al., 2004). Thus, there is a strong conflict of preferences between healthcare organisations and designers seeking rich qualitative data around human experiences (Jones, 2013). Essentially, this leaves designers and researchers with very little control over their study (Jones, 2013). They are faced with competing interests and conflicting needs for the design, which allows them to only make short term decisions as things are required to change the practice, design and research, leaving a very limited "problem scope" (Jones, 2013, p.17). Overall, this process is described as lengthy, most commonly resulting in the need for the researcher to compromise their study as a condition of access (Freeman & Mathison, 2009). This case study utilised questionnaires with open ended responses.

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 involvement with the planning ensured that the hospital was comfortable with the study before it took place, as well as reducing the amount of problems encountered when complying with hospital regulations (Haboush, 2010; Stalker, Carpenter, Connors et al., 2004). One of her key recommendations was the need for a research assistant with nursing qualifications and, preferably, paediatric experience to conduct the study. Recruiting an appropriately qualified person proved difficult because of the nature of the work and availability requirements; 9:00am – 5:00pm, five days a week, for three to four weeks. Eventually, through quick networking and word of mouth a research assistant was identified two weeks before the evaluation trial commencing.

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).

Informed Voluntary Consent

Informed consent is one of the key principles in research. It involves the process of informing all potential participates of the risks and benefits associated with the study so that they can make an informed decision about whether they would like to participate (Alderson & Morrow, 2011). Participants were provided with information about the study in simple language and legible print to ensure that they understood what their involvement in the study entailed (Haboush, 2010). When researching with children, it is important to recognise their varying ages and provide them with information they can understand (Kirk, 2006). This was done by providing young children (5-11) with

information sheets appropriate to their cognitive ability, while older children (11-17) were given the option of receiving either the parent/guardian information sheet or child information sheet.

Alongside parental consent, children's assent was required, recognising their ability to self-determine whether they would like to participate in the evaluation (Kodish, 2012; Freeman & Mathison, 2009). To ensure that continual assent was maintained throughout their involvement, the research assistant revisited this verbally during their time with the evaluation trial of Sprout IV Pole.

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 provided through the study was only discussed with the researcher (myself) and my supervisors. Participants were assured that no identifiable information would be 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 risk perceived by adults may be different to risk felt by children (Alderson & Morrow, 2011). Common risks that need to be considered when researching with children include the potential for inconvenience (Sieber, 2009; Alderson & Morrow, 2011), the intrusive nature of questions, distress from previous experiences, being treated like objects, and a disregard for their privacy (Alderson & Morrow, 2011).

The risk associated with this study-included exposure to the research assistant and potential embarrassment when asked to share their views. To help mitigate these risks, children were assured that they could conclude the interview if they wished to discontinue. Additionally, the research assistant worked to build trust with the children so that they would feel comfortable. Children were interviewed in the presence of their parents, which also enabled parents to feel comfortable with their child taking part in research. As the evaluation of Sprout IV Pole included using a new product, engagement with the product presented risk. To help mitigate this, children were offered the opportunity to view Sprout IV Pole before assenting to participate in the study. The likelihood of harm occurring could be equated to the "everyday risk" that people experience when not involved in the study (Alderson & Morrow, 2011). To ensure that children felt comfortable participating in the study, the risks as well as the benefits were communicated through the information sheets.

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; Lambert, Coad Hicks et al., 2013). 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). Research should not put one child at risk for the benefit of others in the future.

Potential conflict of Interest

To reduce any potential conflict of interest I may have towards favouring Sprout IV Pole, a research assistant was required to conduct the evaluation trial. The study also utilised a cross-over strategy, swapping the first pole encountered each day to ensure that children had equal experience of the new Sprout IV Pole as well as the existing Pole during the evaluation trial (Dummer, Epton, Cowan et al., 2009. These were both conditions for gaining access to the hospital to conduct evaluations with children.

Gaining access to children in hospital

To conduct research with children in the Starship Children's Hospital access approval was required. It was expected that it would be reasonably straightforward to gain this approval by applying through the ADHB (Auckland District Health Board) Research Office, illustrated in figure 9. However, the process was considerably more complex than anticipated as illustrated in figure 10. This was because of the need for considerable consultation to explain the purposes of the study to people within the healthcare organization. Not only was the organisation unfamiliar with research aiming to involve children in the process of evaluating and testing a new piece of medical equipment, but also with research conducted by a university student and not a company.

This created a barrier to planning the evaluation of Sprout IV Pole in hospital, resulting in the need to alter the study method from conversations to questionnaires. Access gained because of changes made to the study design is a common constraint that researchers face when conducting research with children (Carter, 2009; Freeman & Mathison, 2009). Although a questionnaire was not the desired method of gathering children's input, the study was adapted to seek their voices in this way.

ADHB Research Review Process

Through consultation I learnt that the approval required to conduct research within the hospital was obtained from the ADHB Research Office. The process consisted of five strands - Ethical approval, Maori Research Review, Budgetary approval, Liability approval and a final Research Office Review application and sign off. Ethical approval was sought and approved from AUTEC.

The Maori Research Review was essential before research could take place in Starship Children's Hospital (Health Research Council of New Zealand, 2010). Consultation with the Maori Research Review representative informed the addition of an ethnicity identification question in the questionnaire for all participants. This was to help gather data exploring whether Maori held different views to other ethnic groups.

The budgetary sign off included determining the financial implications of evaluating Sprout IV Pole for the hospital; i.e. the cost to hospital resources. As a research assistant conducted the study and no changes were required to the current treatment a child would receive, there were limited implications for Starship Children's Hospital financial resources. This was important for ensuring that the evaluation didn't interfere with existing workloads and that their priority could remain with children's treatment (Langdon, 1948).

Liability involved gaining sign off from a representative willing to guarantee liability for Sprout IV Pole use in hospital in case anything adverse were to take place such as damaging property or injury to someone. Through consultation with the hospital general counsel, I learnt that companies conducting

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 a student evaluating a piece of medical equipment in hospital (because of funding constraints and my own limited financial position).

This complication was not reported in literature, because when environments do not under go product trials. As there were no previous examples, especially in my case as a design student, there was no clear path to follow. Through consultation with my supervisors, the general counsel, and the DHW Lab representatives it was agreed, the ADHB would take liability for any damage to hospital property that the Sprout IV Pole may cause. As I was a student studying within the DHW Lab, it was deemed appropriate to protect me (the student).

The final requirement to gain access to children in Starship Children's Hospital required ADHB Research Office Review and approval (a review of documentation supporting the study, and the study protocol). If a study is deemed low risk, the Research Review Committee Manager can approve the study through an expedited route. Higher risk proposals require full review by the Research Review committee (Refer to Appendix 4 for the ADHB Research Review Application).

This process was far from straightforward, requiring resubmission and considerable changes to the study. To resubmit, further consultation was sought to understand the issue. This consultation informed the reformatting of the application to fit the standard protocol format that the Research Office was accustomed to. This consisted of one cohesive document answering specific questions in a specific order with all additional paperwork embedded as appendices (Refer to appendix 5).

The Research Review Manager granted ADHB Research Office approval pending a review of the product by Clinical Engineering (a hospital department) deeming the product safe for use in the hospital (described in chapter 3). Once Clinical Engineering validated the product an official letter of approval was gained from the Research Office on October 23rd, 2014/ (Refer to Appendix 3).

Data Collection

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, Koshy & Waterman, 2011; Scott and Mazhindu, 2005b). Their use with children is typically uncommon as children typically view direct questions as a test, responding with 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 questionnaires 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 through Likert Scales (Scott and Mazhindu, 2005). 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 Mazhindu, 2005b; Refer to appendix 5).

The questionnaire began with the aim of understanding the value all participants placed on these factors (movement, safety, look and function) in the design of their IV Pole in general. They were then asked questions around five topics:

- Mobility of the IV Pole to understand how easy it was to move, how well it went through doorways and into the bathroom and how quiet it was.
- Safety of the product including the stability, strength, safety for children's use and ease of storage for nurses.
- Look and aesthetics of the product.
- Functionality of the IV Pole from the perspective of medical treatment completed by the nurses such as the ease of attaching pumps, hanging fluid bags/bottles, and keeping the pole stationary.
- Interaction of the product with children, so the importance of the pole to children, whether they liked using the pole, whether they were able to move it, and whether they used the pole in unintended ways.

This was supplemented with open-ended questions allowing participants to explain their reasoning behind their Likert Scale responses for each section. These questions allowed children, their parents and nurses to elaborate on their Likert scale responses. The process of supplementing one data set with another (the quantitative with the qualitative) is referred to as "complementarity" to enhance the data as well as provide clarification (Padgett, 2012). Eliciting the thoughts and opinions of users is an essential element that allows the designer to gain a thorough understanding of their users (Brown, 2008). Without this addition of qualitative findings, the evaluation trial would have been purely quantitative, meeting only the adult agenda of the study to distinguish whether the Sprout IV Pole provided benefit over the existing IV Poles used in hospital (Freeman & Mathison, 2009). The implications of using a questionnaire as part of this study had the potential to produce a limited understanding of children's choices and is sometimes seen as a sub optimal method of data collection (Koshy, Koshy & Waterman, 2011).

Utilising questionnaires also pushed back the date of the evaluation trial by two months. Time delays gaining access is a consistent issue faced by researchers aiming to involve children with research in hospitals (Jones, 2013; Stalker, Carpenter, Connors 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 nurse advisor.

Duration

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 participant 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

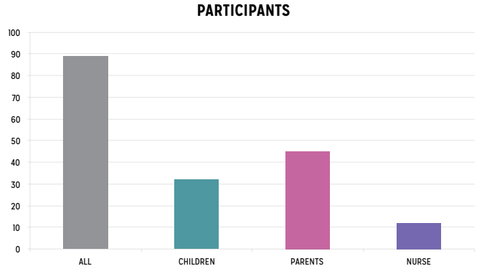


Figure 11. Number of each user group participants

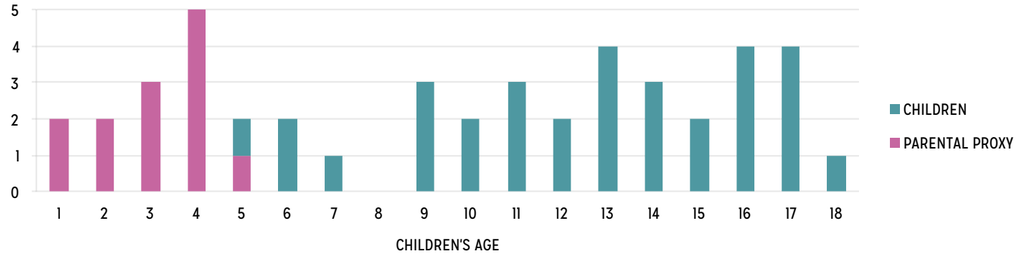


Figure 12. Ages of children participants (Representing themselves or by their parent)

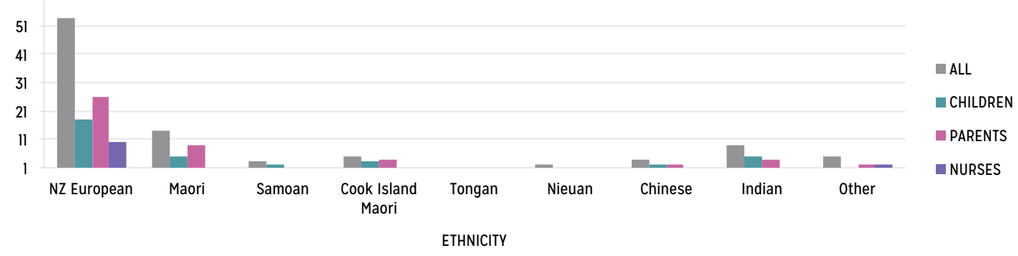


Figure 13. Ethnicity of each user group participants

remained to answer any specific questions about the research. If children and their parents wished to participate in the study, the signed consent and assent forms were then returned to the research assistant.

Registered nurses at the time of the trial who were tending to patients taking part in the evaluation were invited to evaluate Sprout IV Pole using the questionnaire. If they wished to participate, the information sheet and consent form were then signed and returned to the research assistant. The nurses could complete the questionnaire in their own time.

Procedures

The children participating in the trial were given the use of an existing IV Pole as well as a Sprout IV Pole during their time in the hospital (the infusion time was split equally between the two poles). At the end of the children's IV infusion, they were interviewed using the questionnaire to provide feedback upon their experience with both IV Poles. Parents provided feedback using a questionnaire filled out at the same time. For the full evaluation trial protocol and procedures Refer to Appendix 5.

Data Collection

Children completed the questionnaire through an interview with the research assistant, while parents and nurses were provided with questionnaires to complete on their own. This was done with different children to help them relax and to minimise a test-like feel (Darlington & Scott, 2002; Lambert, Glacken & McCarron, 2013b).

Children and their parents' perspectives were sought separately to allow both to share their unique views. Literature recommends interviewing parents and children together to allow parents to feel more comfortable with their child's involvement, but this can also negatively affect the child's responses as there may be a tendency to default to their parent's perspective even if they think differently (Darlington & Scott, 2002; Greene and Hogan, 2005). To balance these two factors, children were interviewed in the presence of their parents while the parents also completed the questionnaire.

Data Analysis

Quantitative

The quantitative data collected through the questionnaires was summarised using descriptive statistical analysis. This method of analysis aimed to illustrate the common features of the data in a summarized comprehensible manner (Scott and Mazhindu, 2005a). This method was used to describe the data, providing a complete picture quickly (Scott and Mazhindu, 2005a). However, the method does not factor in the reliability of the internal consistency of the questions (Scott and Mazhindu, 2005b). Therefore, a Cronbach alpha reliability analysis was conducted to determine internal consistency and whether questions were working in the same direction as data collection (Scott and Mazhindu, 2005b). This analysis produces a co-efficiency value between 0.00 and 1.00, and above 0.7 indicated reliability (Scott and Mazhindu, 2005b). If a question had nothing in common with other questions, then the co-efficiency decreased.

The statistical analysis of variance (ANOVA) through t-test was conducted by an AUT lecturer using SPSS to understand whether there was a significant difference between the means of two independent variables, Sprout IV Pole and the Existing IV Pole (Lund Research, 2013). Traditionally, One-way ANOVA 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 value 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 of 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 questionnaire.

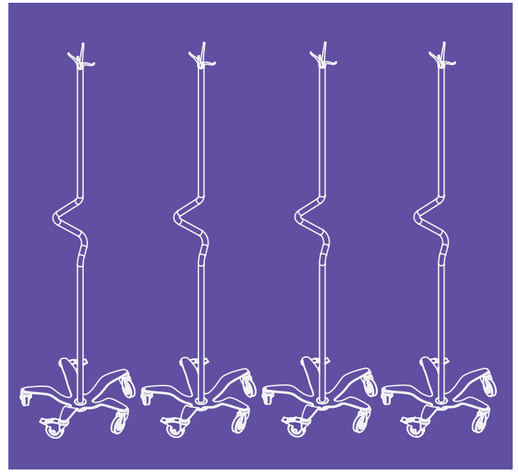


Figure 14. Sprout IV Pole trialled with children during the evaluation trial

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 to 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.

Figure 15. Sprout IV Pole generation two, selected handle and base

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 (Altimier, 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).

Iterations of this design reduced the visual weight of the base to deter children from standing on it. The colours of the base and handle were also informed by feedback from children during the simulation trial that recommended including more colour in the product. This design was 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.

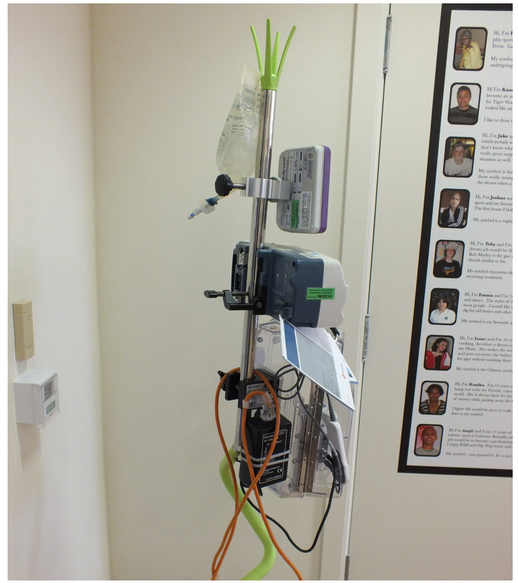


Figure 16. Sprout IV Pole generation three role playing on a lean

Design for Manufacture

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).

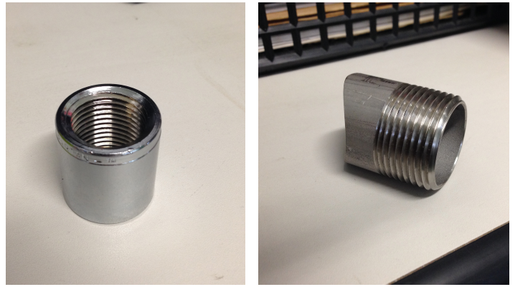


Figure 17. Socket and Nipple joint

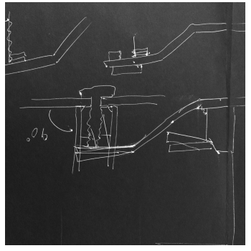


Figure 18. Bolting the pole to the base

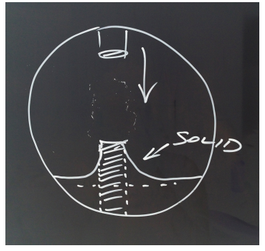


Figure 19. Screwing the pole into weight

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 1,000 units), as the set up costs are large ($50,000 estimation). Through the recommendations of designers, a manufacturing process of silicon moulding was identified in China at a fraction of the cost ($100 -$200).

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 this, changes were required to the top form as well as finalizing height details.

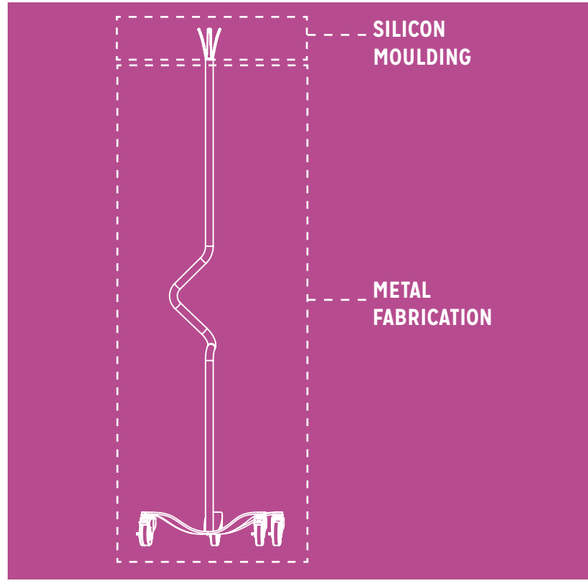


Figure 20. Two manufacturers sought for Sprout IV Pole productions

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

"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).

intended to strike a balance between assuring the complete safety and effectiveness of products, and 'rushing a product to market' (Medina, Kremer & Wysk, 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 1 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 Standardisation (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 increase 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 $20- $200 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 orientated 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.

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 utilising 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.

Figure 21. Incremental Solution

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,

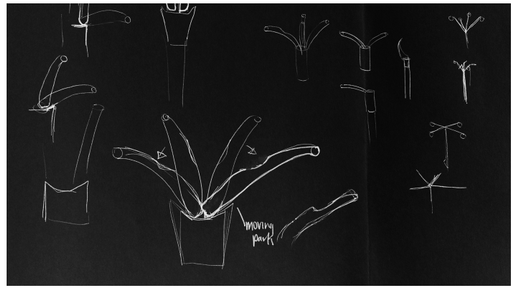


Figure 22. Radical Solution

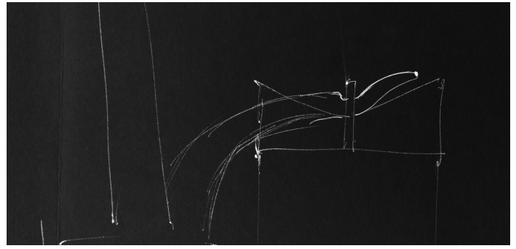


Figure 23. Median Solution

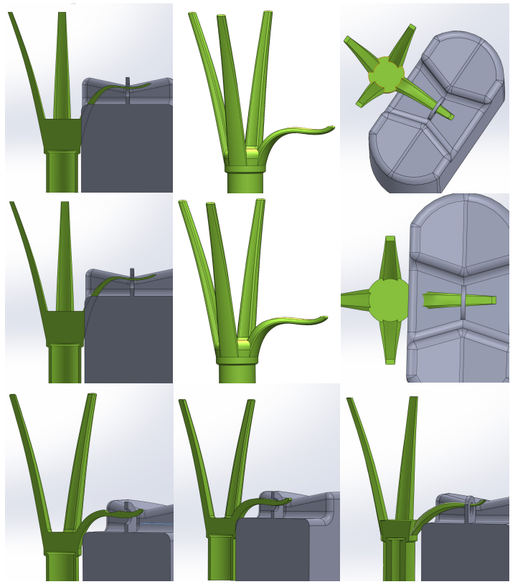


Figure 24. Median Solution Development - reforming one prong

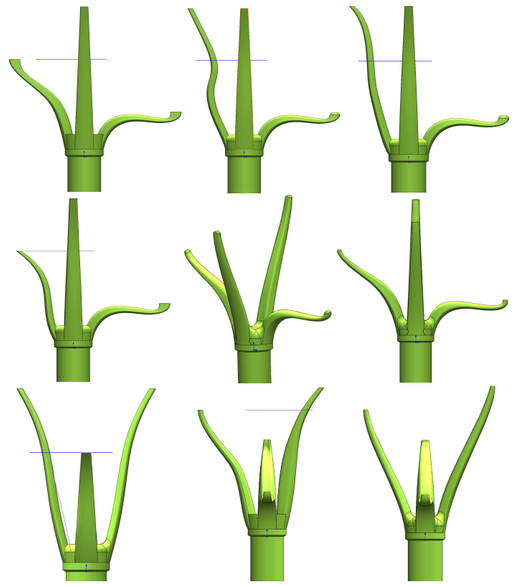


Figure 25. Developing the form of all the prongs

Figure 26. Glass bottle required in the Day Stay Unit and O-ring Solution

a new glass bottle was presented. These bottles were extremely fragile and required protection from hitting the pole. Because of the low frequency of use, a short-term solution was provided through O-rings, which were cheap and easy to attach (Refer to figure 26).

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).

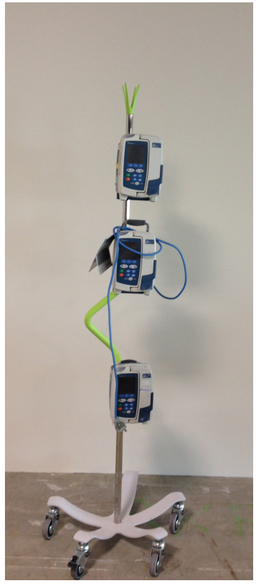
Base/ Pole Refinements 1

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.



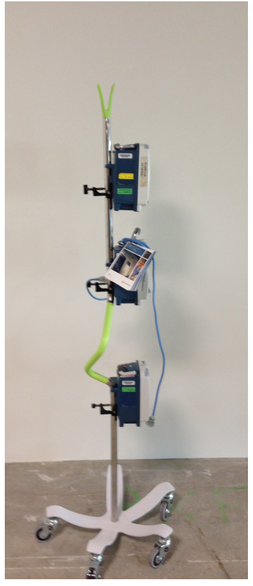


Figure 27. Sprout IV Pole role playing with the Nurse Advisor

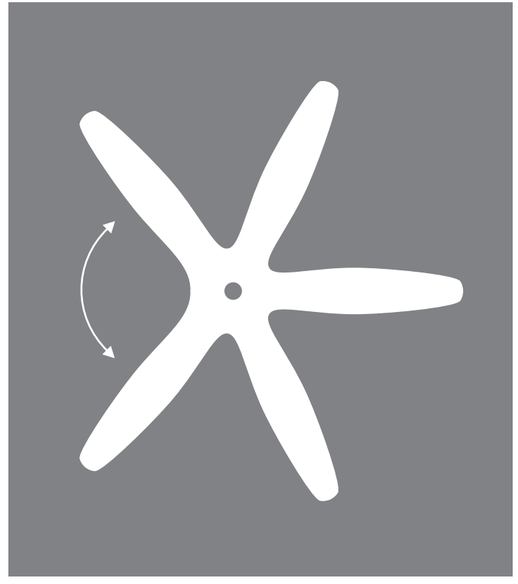


Figure 28. Uneven splay of legs Clinical Engineering wanted removed

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.

Figure 29. Colour exploration and matching with powder coating

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.

Figure 30. Inconsistent forming of the base with drawings

Figure 31. Nut spacers required for wheel rotation

Base/ Pole Refinements 2 and Construction Prototype 2

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. The spacer also created a lever that could move, especially when directional force was applied, for instance, by someone standing on one leg. 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).

Figure 32. Option 1, wheel exploration and understanding

Figure 33. Option 1, wheel exploration and understanding

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 manufacturers 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 37). 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.

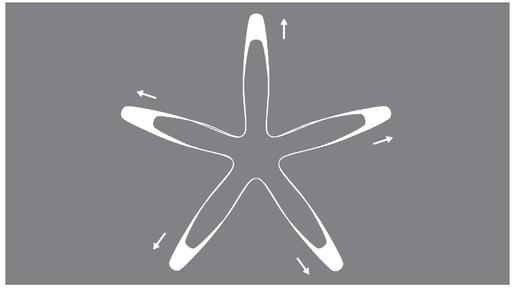


Figure 34. Option 2, extending the legs further horizontally

Figure 35. Option 3, pressing machine tool

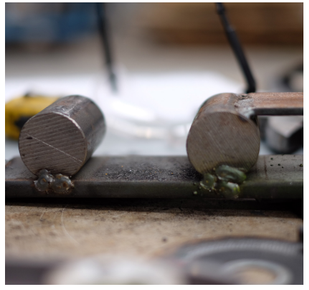


Figure 36. Option 3, reforming the base and the tooling required

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).

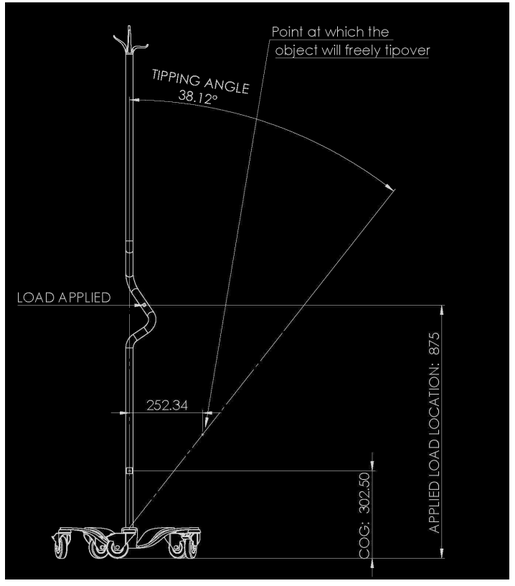


Figure 39. Engineer simulation of Sprout IV Pole (without weight)

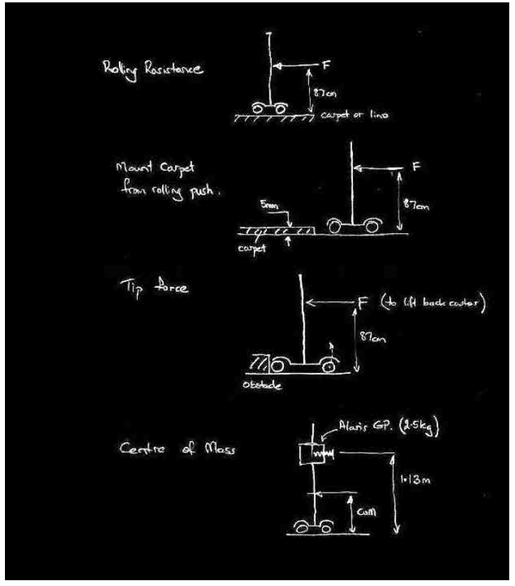


Figure 40. Tests completed by Clinical Engineering

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.

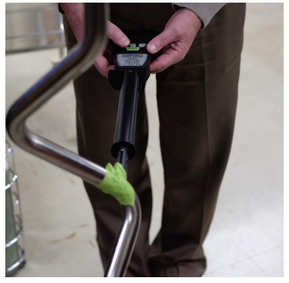


Figure 41. Clinical Engineering tests

	1. Sprout	2. DCCM	3. Amtech	4. Plastic
1. Wheelbase radius (cm)	25	29	27	29
2. Weight (kg)	6.3	6.9	10.3	4.2
3. Centre of Mass (cm above floor)	55	63	50	83
4. Rolling force on lino (N)	1.5-2	1.5-2	5.5-7	6.4
5. Rolling force on carpet (N)	3.4-4.4	3.4-4.9	7-9.6	10.8
6. Force to mount 5mm thick carpet (N)	6-7.8	-	22	13.7
7. Force required to tip stand (N)	9.8	13.7	19	8

Figure 42. Clinical Engineering IV Pole safety evaluation results

Figure 43. IV Poles evaluated along Sprout IV Pole by Clinical Engineering

Fourth Generation Sprout IV Pole

Figure 44. Fourth generation Sprout IV Pole evaluated with children in Starship Children's Hospital

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

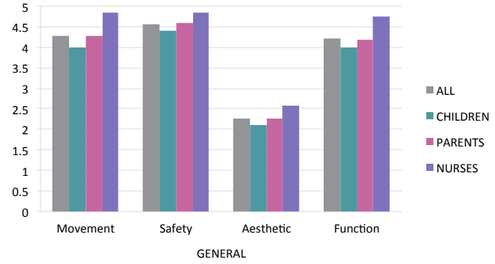


Figure 45. General value of factors associated with IV Poles

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 Tukry test showed that children's (x = 4.00) responses were different from nurses (x = 4.83), 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 Tukry test showed that children's (x = 4.00) responses were different from nurses (x = 4.75), but not parents (x = 4.18), 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.

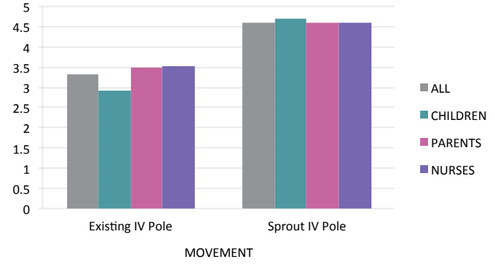


Figure 46. Movement comparison

Overall, Sprout IV Pole (x = 4.6) moved significantly better then 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 then the existing IV Pole (x = 2.9) (t (29) = 9.76, P<0.001). Parents reported that Sprout IV Pole (x=4.6) moved significantly better then the existing IV Pole (x = 3.5) (t (42) = -8.98, P<0.001). Nurses reported that Sprout IV Pole (x = 4.58) moved significantly better than the existing IV Pole (x = 3.52) (t (10) = 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.

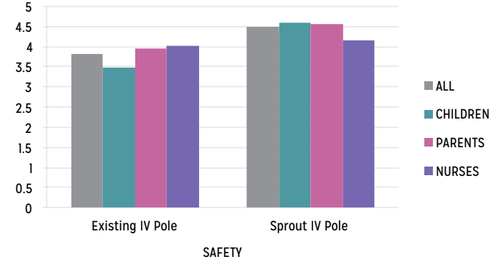


Figure 47. Safety comparison

Safety

A reliability analysis of all the participants' responses to safety questions revealed a co-efficiency value of 0.693 for the existing IV Pole and 0.693 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 = 4.5) was significantly safer then the existing IV Pole (x = 3.81) (t (81) = 5.73, P<0.001). Children reported that Sprout IV Pole (x = 4.6) was significantly safer then the existing IV Pole (x = 3.49) (t (27) = 5.19

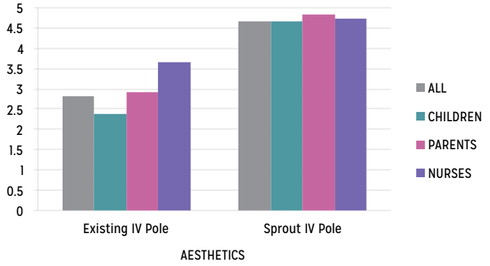


Figure 48. Aesthetic comparison

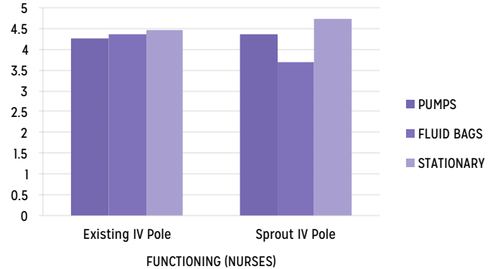


Figure 49. Medical functional comparison answered by nurses

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).

Storage

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).

Aesthetic

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 = 2.39) (t (30) = 7.182, P<0.001). Parents reported that Sprout IV Pole's aesthetic (x = 4.84) was significantly better than the existing IV Pole (x = 2.93) (t (43) = 9.99, P<0.001). Nurses reported that Sprout IV Pole's aesthetic (x = 4.73) 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).

Function (nurses)

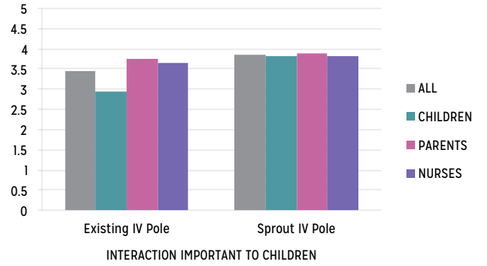


Figure 50. Interaction section - importance to children

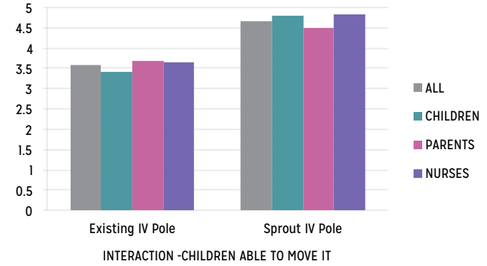


Figure 51. Interaction section - children's ability to move it

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

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).

Interaction

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

All uses indicated Sprout IV Pole (x = 3.85) was significantly more important to children than the existing IV Poles (x = 3.45) (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 = 3.57) (t (76) = 7.37, P<0.001). No significant difference was reported between Sprout IV Pole (x = 1.86) and the existing IV Pole (x = 1.71)

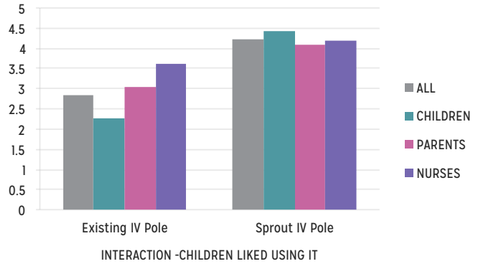


Figure 52. Interaction section - enjoyment of children

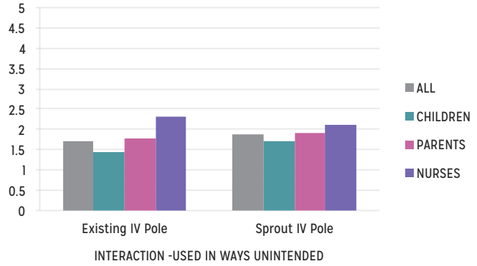


Figure 53. Interaction section - used in ways unintended

in terms of their unintended use (t (76) = 1.20, P>0.05), i.e. riding on the Pole.

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 48).

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 = 4.08) significantly 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 snap shot of the perspective of children, their parents and nurses which was explored further through the qualitative data.

Qualitative Findings

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.

“Its Child Friendly”

This theme of being child friendly encompasses the feeling of positive emotions by children and the feeling of comfort.

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, 2013). Children stated that Sprout IV Pole had "Good colour, looks modern – not scary and metal. More inviting for little kids."

One child stated that Sprout IV Pole was more important to them because of the design and colour. Children observed that Sprout IV Pole's aesthetic suggested that it was designed for children to use.

The aesthetic also provided clear 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 green 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, stating: "contemporary design was quite inspiring, if the hospital were revamped too, overall the environment would be fantastic." These were made alongside comments from the nurses saying that they liked "the colour of the handle, it is kid friendly, better wheels, four hooks at the top."

Elicit positive emotions

The value of the aesthetic of Sprout IV Pole was also evident from its ability to elicit specific positive emotions from the children. The power of colour to trigger emotions (Coad & Coad, 2008) and promote healing (Landro, 2013) is well known, as well as its ability to determine the kind of interaction that a product can have with its user (Desmet & Hekkert, 2007). Emotions triggered by the colour of Sprout IV Pole were generally positive – there was general approval and excitement towards the design.

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, healing and calm to people (Resene, n.d.). This 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, "appealing" "It gives hope, the features of it are cool, the way it's a sprout." "For some children colour looks like hope" "starship [Hospital] has a lot of colour so it fits more into the theme" "It looks different, exciting and appealing. Take one look and say wow that's cool to look at." Providing children with a product that they approved of, appreciated and made them excited brought them closer to the product, building a connection, and value for it (Desmet & Hekkert, 2007).

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 inviting for little kids. A few children stated; "Good colour, looks modern – not scary and metal. More inviting for little kids." "For young children having an IV drip can 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 hospitals less scary" and the parents want "Safety and anything that will make the 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 like 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, seen to my less intimidating.

“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, “All I needed to do was walk and push. It never stopped on its own” (child), “The Sprout Pole was more stable/strong, didn’t think I was going to trip over so I liked using it more” (child), “It felt like it would stay together easier, it felt safer” (child), “New pole easy to manoeuvre and quiet and no twisting,” “The new pole was easier to hold making it easier to move around.” Children and parents trusted Sprout IV pole, giving them confidence in the product to fulfill its function. This is important as unruly products that are difficult to use have the ability to increase stress and anxiety not only for the children, but for their parents and nurses too (Hutchison, 2007).

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, “legs are shorter so good for storage, designated hand held is good, easier to push,” “Glided 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 be more independent.

One parents stated, “My child was frustrated that she couldn’t push around the hospital one,” in comparison to “My son could move the green pole himself which made it easier.” Parents stated that their children enjoyed having their independence with Sprout IV Pole. “He was able to go to the toilet without my assistance, normally I would have to follow with the pole,” “Because 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 child the 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, Coad, Hicks et al., 2013; Eisen, Ulrich, Shepley et al., 2008; Soderback, Coyne & Harder, 2011).

Play

Another theme present in the findings was children’s desire to play. Children’s 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 Pole/IV pole, easier to run with Sprout,” “Like moving the pole around like it was a racing car,” “stood at the base of the pole and was wheeled around by dad,” and “Enjoyed spinning the Sprout Pole round and round (not while attached).”

From previous research, children had illustrated the value of improving their hospital experience by including play (Salmela, Salantera & Aronen, 2010; Landro, 2013; Lindeke, Nakai & Johnson, 2006). This was related back to factors that allowed children to feel comfortable as it provided them with something familiar to do. That said, the benefits of play extend beyond the abilities of allowing children to feel comfortable. Play also encourages growth, relaxation, and fun, key factors that are important for children in hospital (Paediatric Society of New Zealand & Starship Foundation, 2013). These opportunities for play allow children to express how they feel, as well as giving them a sense of control over what they do in their down time (Paediatric Society of New Zealand & Starship Foundation, 2013).

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 riding the IV Pole while their parent pushed 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 stating, “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 stress, anxiety 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 bendy 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

Discussion

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 of 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 and their needs differ from those of their parents and nurses.

Complexity of Involving Children

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). 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.

Children not were 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 ulti-

mate 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 designers/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 questionnaires. 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 (Coad & Shaw, 2008). The balance of protection versus offering children the ability to participate in research has not yet been reached, and remains contested (Stalker, Carpenter, Connors, et al., 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 (Cavet & Slopers, 2004). The "politics of access" to these organisations require researchers to navigate lengthy and complex processes, often requiring them to compromise (Freeman & Mathison, 2009, p.42). These procedures and protocols have been criticised for becoming "excessively complex" (Greene and Hogan, 2005), substituting the researcher's autonomy to direct their study for 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.

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 reviews requires a generous timeline and a committed design/research team (Jones, 2013).

"You've heard the saying countless times: Children are not small adults"

(National Association of Children's Hospitals and Related Institutions, 2007, p.1).

Importance of consulting 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 (Cavet & Sloper, 2004). This also aligns with the social constructivist view held throughout this project, valuing the children as the key users of the product who have a unique position providing insight in the usability of the Sprout IV Pole (Freeman & Mathison, 2009). This can be equated to the significant differences between children's responses and those of the nurses in the quantitative data, as well as their differing views communicated through the qualitative data.

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 values, which few parents and staff shared. This finding 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 (Taylor, Haase-Casanovas, Weaver et al., 2010; Pelander & Leino-Kilpi, 2010). They are unique individuals and very different to adults (National Association of Children's Hospitals and Related Institutions, 2007), implying that adults are unable to credibly speak of their behalf in research and design contexts (Coad and Coad, 2008; Lambert, Glacken & McCarron, 2013b). As a designer, this indicates the value of consulting the users of products directly through a human centred design approach.

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 elements 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 produce the most participants for the study each day over the four-week trial. Prioritising these criteria resulted in participants experiencing short admission times, with 64% of children only admitted for 1-2 hours. Some parents and children commented that they remained seated for the duration of their participation in the evaluation trial and were unable to accurately assess the mobility of the Sprout IV Pole. One parent criticised the study stating, "Hard to really give proper feedback. It was used ten minutes," "If you want real research – give it to the clinic with patients using for real length of times in proper use – this is just a loaded survey to tick the box – not buying this at all – try using the thing in real time – 5-10 minutes is fabricated nonsense! Respectfully." Recruitment strategies for the evaluation of Sprout IV Pole should have required that children be admitted over a few days, using the Sprout IV Pole over an entire day (eight hours), or for a few days (Bishop, 2013). This would have maximised the time within which children could experience Sprout IV Pole, develop their opinions, and explore the differences between Sprout IV Pole and the existing IV Pole.

Quantitative nature of the study

One of the biggest limitations of the study involved changing the study design from an approach based on semi-structured interviews with children to quantitative questionnaires, with a few qualitative questions. This provided children with limited opportunities to communicate their views and perspectives, as the questionnaire became targeted toward providing a quantifiable comparison of the designs to understand whether Sprout IV Pole offered value over the existing IV Poles, which was the adult agenda (Freeman & Mathison, 2009).

The questionnaire also excluded children below the age of five from participating 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," so their parents communicated personal information about them that may not have reflected their views. (Carter, 2009, p.860). Researchers should aim to ignore the ages 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.1256).

The results of the predominately 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 (Scott and Mazhindu, 2015b). The reasoning behind using this method over the original plan of semi-structured interviews with children came down to the organisation's biases towards statistical evidence (Jones, 2013). Designers are expected to adapt to the language of the health domain, rather than introducing their own language of design and user experience (Jones, 2013). Even though the perception of children is slowly changing to explore new methods of consulting children through research and design, it is argued that ethics committees and hospital review boards may not necessarily broadened their scope to accept this change (Freeman & Mathison, 2009). Instead they may apply the long-standing regulations of what constitutes ethical research to these new methodologies, requiring considerable compromise in the design of studies (Freeman & Mathison, 2009).

Research Assistant

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 nurse's role, she was naturally drawn to assisting the nurses if required (Lambert, Glacken, McCarron, 2013b), as well as associating the hospital with her role as a nurse (Freeman & Mathison, 2009).

Misalignment with the Social Constructivism/Designer approach

The social constructivism/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 view was a consequence of the objective perspective commonly held in quantitative studies (Collins, 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 and Mathison, 2009).

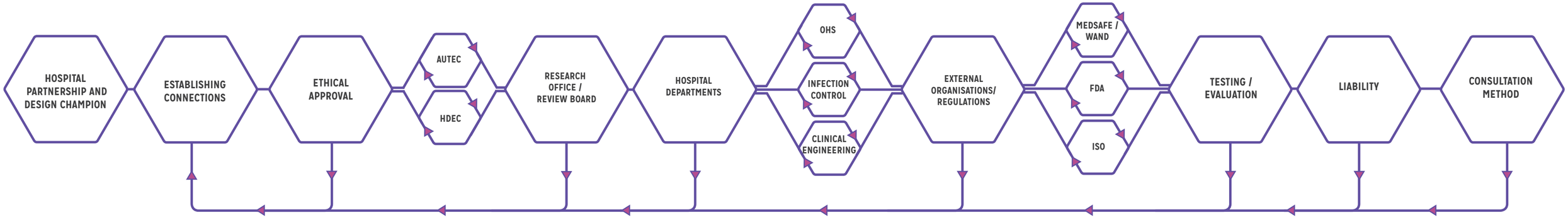


Figure 54. The Road Map recommendations to Designers

Recommendations

The experience of planning and conducting an evaluation trial that involved children in a hospital environment, revealed the complexities of working with children, the importance of consulting them as well as negotiating the array of limitations placed on the study. 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.

Researchers

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 analysis (Coad & Coad, 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 (Jones, 2013). Researchers need to account for this with generous timelines to allow flexibility if issues are encountered (Stalker, Carpenter, Connors et al., 2004).

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 others studies that involve children in the design of their hospital experience. These are illustrated in the Road Map figure 52.

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 organization 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.

Establishing Connections

Once hospital partnerships have been created, an array of consultations are important to establish connections. It is important to notify them that their involvement would be desired throughout the process of involving children in the design of medical equipment. All of these connections need to happen at the early stages of embarking on the project. Although they may not seem relevant in the early stages, when different stages of the process are reached, their assistance and input can be sought as they have already been alerted to the project. They can provide a wealth of understanding and knowledge that benefits the progression of the design outcome and gaining access to children. This creates a relationship of respect, valuing the time and expertise of these different departments and organisations.

Testing/evaluation (pre-user)

Testing and evaluating the product is required before implementing it in hospitals for use with sick children (Cross, 2006). Depending on the requirements of the product and the risk involved with life or death situations, different levels of evaluation/simulation would be required (Sherwin, 2012). The designer needs to consider and plan for this, seeking experts that are able to conduct this level of evaluation/simulation of the product before implementing its use with children.

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 (Freeman & Mathison, 2009). 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 insight 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 (Druin, 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, Pryde & Evans, 2013).

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Appendix

References
Appendix

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Appendix 1 - Content Analysis

	Child	Parent	Nurse
Like	109	124	33
Dislike	25	51	33
Neutral	8	21	1
Aesthetic - Colour	26	35	12
Aesthetic - Form	47	63	13
Child Friendly	22	35	5
Emotions/ Feelings	15	24	3
Functionality	21	82	41
Ideas	9	10	7
Mobility	51	68	22
Safety	31	43	26

Appendix 2 - Contributors

All the people listed on the following two pages are those who have been involved in the project over the past three years to some extent.

Users

Sick children 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 evaluating of Sprout IV Pole in hospital, this consultation took two years planning to undertake.

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 while in hospital and their feedback was sought during the evaluation of Sprout IV Pole.

Stakeholders

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 Design for Health and Wellbeing Lab is the collaboration between the ADHB and AUT Product Design department encouraging the integration of designers with the hospital. The co-directors provided guidance throughout my project as well as seeking contacts in the hospital such as Health Alliance, Clinical Engineering, OHS and Infection Control.

The Nurse Advisor is among the senior management team of Starship Children's Hospital. Her involvement as a key contact within Starship provided feedback in relation to the design, functional requirements, trial planning as well as approvals.

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

The General Manager is among the senior management team of Starship Children's Hospital. She was consulted during the project when seeking sign off and approvals to conduct the evaluation trial in Starship Children's Hospital.

Charge nurses are responsible for clinical and staff management within a ward or other clinical area. Starship charge nurses were collectively consulted for feedback by the Nurse Advisor on my behalf. Some charge nurses were consulted outside of these meetings, providing feedback upon the functional requirements of the design.

The Clinical Engineering department within ADHB are involved with repairing medical equipment among many other tasks for the hospital. They were involved by providing feedback upon the safety of the design, as well as conducting an analysis of the safety of the product in comparison to existing for the ADHB Research Office approval.

The ADHB Research Office Manager coordinates the review and approval of research to be conducted in the ADHB. She was consulted on many occasions around understanding the process of submitting an application, reviewing this projects application as well as granting the final expedited approval.

The ADHB Maori Research Review Manager reviews all research to be conducted in the ADHB from the perspective of protecting and advocating for the Maori population. She was consulted to inform how best to value Maori participants in the study as well as approving this research as one part of the five to the ADHB research review process.

The Research Review Committee reviews applications for research to be conducted in the ADHB that isn't low risk. The application for my research in Starship was submitted to the committee as it was perceived to be more that low risk. This misinterpretation of the study eventually resulted in the study being expedited by the Research Office Manager.

The General Counsel is the senior legal counsel for the ADHB providing legal advice. He was consulted in the project to discuss who held liability for Sprout IV Poles while being trailed in hospital. This made up one part of five to the ADHB research review process.

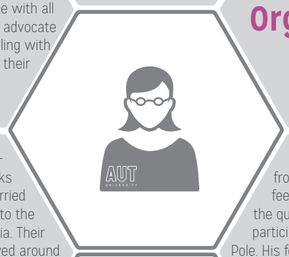
The Infection Control department within the ADHB ensure infections are kept under control and environments are clean and safe. They were consulted in the project to provide feedback upon the design to inform its cleanability and maintenance.

The Occupational Health and Safety department within the ADHB ensure products purchased for the hospital over $1,000 are robust, strong and safe through reviewing prior to purchase. Even though Sprout IV Pole falls below this threshold they were consulted to inform the design of any safety issues to design out.

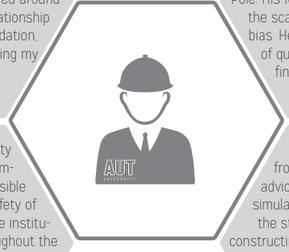
My Supervisors are both lecturers at AUT, my primary with a design background, and my secondary with a health background. Their role within my project was to provide guidance with all aspects of my work, as well as advocate for me as a student when dealing with external organisations and their bureaucracy.

AUT

The AUT Communications Team actively seeks stories about the work carried out in AUT to communicate to the wider public through the media. Their involvement in my project revolved around organising publicity for the relationship between AUT, Starship Foundation, and Mercury Energy supporting my project.



The Auckland University of Technology Ethics Committee (AUTEC) are responsible for assessing the ethical safety of conducting research within the institution. They were consulted throughout the project to inform my ethics application submitted for the Sprout IV Pole trial as well as granting ethical approval.



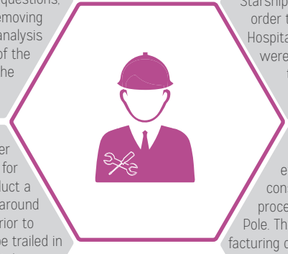
External Organisations

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

An Engineering lecturer from AUT was consulted for advice around how to conduct a simulation of Sprout IV Pole around the strength and stability prior to constructing the prototypes to be trailed in Starship Children's Hospital.

Starship Foundation are the charity attached to Starship Children's Hospital. They were the donors of the project, providing the financial support, as well as liaising with the hospital. They were consulted with throughout the process to ensure expectations were being met and to inform them of difficulties holding up the process.

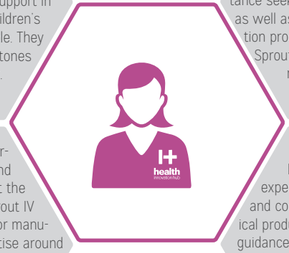
Mercury Energy is an electricity company that are five star sponsors of the Starship Foundation. They provide the financial support to projects the Starship Foundation want to support in order to improve Starship Children's Hospital such as Sprout IV Pole. They were informed of key milestones throughout the project.



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 around construction to inform the design and manufacturing techniques to reduce cost and improve the strength of Sprout.

The Research Assistant conducted the trial of Sprout IV Pole. As requested by the hospital, she was a qualified paediatric nurse with previous experience working in Starship. Having someone with no investment in the project provided a neutral conductor of the study, removing the potential of bias if I was conducting it.

The Health Innovation Hub's Innovation Manager assists with the validation of medical products for their future commercial value. He provided assistance seeking contacts within the hospital, as well as weaving in the commercialisation process to the design process for Sprout IV Pole. This informed many manufacturing choices.

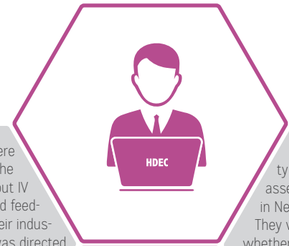


The Health Innovation Hub's Clinical Validation expert assists with the planning and conduct of clinical trials of medical products. She provided considerable guidance around the application process for the ADHB Research Office, as well as planning the study to ensure the trial had commercial value, through the addition of quantitative data.

Product Designers were consulted throughout the process of designing Sprout IV Pole to provide guidance and feedback upon the design with their industry experience. Their feedback was directed towards the aesthetic of the product as well as catering to the user needs.

A Patent Attorney was consulted throughout the process of designing Sprout in order to protect the commercial value of Sprout IV Pole by registering the design. He informed me of how I should protect my design while approaching people for feedback prior to registration.

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



The Health and Disability Ethics Committee (HDEC) assess studies to be conducted in New Zealand that are high risk. They were consulted to understand whether their approval was required as a vulnerable population (children) were involved. This involved explaining my study so they understood what it entailed.

Health Alliance are an organisation that supports the procurement of products for the hospital to purchase. They were consulted to understand they process of procuring IV Poles for the 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 to their directory of medical products.

Appendix 3 - ADHB Institutional Approval Letter

AUCKLAND DISTRICT HEALTH BOARD
Te Toka Tumai

Research Office
Level 14, Support Bldg
Auckland City Hospital
PB 92024, Grafton, Auckland
Phone: 64 9 307 4949 Extn. 23854
Fax: 64 9 307 8913
Email: mwoodnorth@adhb.govt.nz
Website: www.adhb.govt.nz/ResearchOffice

Date 23 October 2014

Institutional Approval

Neerali Parbhu
6 Harwood Street
Sandringham
Auckland 1041

Dear Neerali

RE: Research project A+ 6396 Paediatric Hospital Experiences: Sprout IV pole evaluation. (AUT/14/180).

The Auckland DHB Research Review Committee (ADHB-RRC) would like to thank you for the opportunity to review your study and has given approval for your research project.

Your Institutional approval is dependant 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 may be withdrawn for your study if you do not keep the Research Office informed of the following:

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

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-Anne Woodnorth
Manager, Research
ADHB

c.c. Catherine Byrne (ADHB contact), Emma Maddren, Sarah Little

..../continued next page

MAINTAINING YOUR RESEARCH APPROVAL

Your Ethical and Institutional approval is dependant 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. While the RO endeavours to send reminders for annual approvals and missing documents, it is **your responsibility** to ensure you have kept Ethics and the Research office up to date and have the appropriate approvals.

Please note, when missing or updated document reminders are sent, if the RO receives no response from you after **3 reminders** it will be assumed that your research has been completed and we will notify the relevant Department CD, the RRC and Ethics Committee that your **Locality Assessment Approval has been withdrawn**. This will not be reinstated until all issues have been resolved.

All documents / communications must be referenced with the **ADHB project number**. For simplicity when sending information to the Ethics Committees, please cc the RO. When receiving letters from Ethics, please copy and send to RO for our records.

TOPIC	REQUIREMENT	ACTION
ETHICS		
All Ethics Correspondence	All formal Ethics Committee communications to you	○ send a copy to RO immediately
Annual Ethics Renewal	Use Ethics form, complete and submit **BEFORE** anniversary date of original research approval	○ copy to Ethics ○ copy to RO (e-copy) ○ send copy of Ethics approval letter to RO when received
Changes to Research (design, PI, protocol etc)	Write letter detailing changes, Mark up changes in relevant documents. Ethics approval must be received **BEFORE** implementing	○ copy of changes to Ethics ○ copy changes to RO ○ send copy of Ethics approval letter to RO when received
Stopping Study or Study Complete	If the study is stopped for any reason or study is complete	○ notify Ethics and attach relevant documents (final report etc) ○ notify RO and attach relevant documents
Final Report	Complete Ethics template for final report	○ Send to Ethics and RO ○ Inform RO if all finance elements also complete
LEGAL		
Contracts, Indemnities, Agreements, insurance certificates	All legal must be reviewed and approved before signing	○ Send all legal documents to RO
Amendments – Non-financial	As above	○ Send all legal documents to RO
Amendments - financial	As above and revise Budget	○ Send all legal documents to RO ○ Send revised budget using template to RO
FINANCIAL		
Budget Changes i.e. change in visits or tests or proposed income Budget maintenance	Liaise with accountant and adjust budget accordingly it is recommended that you review and update budgets at least quarterly	○ Send revised budget using template to RO ○ Liaise with accountant and forward update to RO

All documents must be referenced with the ADHB project number and can be sent via email to: RDOAdmin@adhb.govt.nz. All paper copies can be faxed to: 09 307 8913 or by post to: Research Office, Level 14, Support Building, Auckland City Hospital, Private Bag 92024, Auckland, New Zealand.

For further information go to www.adhb.govt.nz/researchoffice/

Appendix 4 - ADHB Research Review Office Form

APPLICATION FORM FOR APPROVAL OF A RESEARCH PROJECT at ADHB

ADHB (A+) Number: A+6396 Ethics Number:

Section A. General Summary

Full project title: Paediatric Hospital Experiences: Sprout IV Pole Evaluation

Short project title: Sprout IV Pole Evaluation

Principal (Co-ordinating) Investigator's name and position: Neerali Parbhu
Masters Student
Auckland University of Technology

Physical address: [redacted]

Work phone No. [redacted]
Emergency No. [redacted]
E-mail [redacted]

ADHB Co-investigator names and addresses: 1. Day-Stay Unit Charge Nurse 2.
3. 4.
5. 6.
7. 8.

Is the research project an interventional study/ clinical trial? NO

If YES **all** investigators must be trained in ICH E6 GCP (Good Clinical Practice for investigators) within the last two years. Send evidence of training (e.g. training certificate) for all investigators to researchoffice@adhb.govt.nz **OR** ensure all investigators are on the Research Office ICH GCP training register.

Coordinator name Contact details: Research Assistant

Contact details for communication if not via Principal Investigator or coordinator

Contact name
Contact details
Work phone No.
Emergency No.
E-mail

ADHB Contact name (*Required for non-ADHB researchers*): Cath Byrne Signature: Cath Byrne

Contact details: NB Innovation Hub involvement
Work phone No. 021676596
E-mail CByrne@adhb.govt.nz

Scientific Review		Describe	
Scientific Review Documents Attached			
Conflict of Interest		Describe	

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 (researchoffice@adhb.govt.nz). Submit this **fully signed** application form in scanned or pdf version, via email (as above), or as a paper copy to:
Research Office
Level 14, Support Building
Auckland City Hospital
Private Bag 92024
Auckland 1142

Section C: Proposed Research

Brief Abstract	The design of medical products is often based on the needs of service providers. Whereas the design of Sprout IV Pole is based on the needs of service providers, as well as the service users informing its design. Sprout IV Pole has gone through a rigorous design process of cyclical stages continuously revisited and refined. This process is based on considerable consultation with all 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 wants of its users. Throughout this process, Sprout 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 over existing IV Poles. The information gathered will be used to better understand whether the newly designed Sprout IV Pole provides benefit over existing IV poles for nurses, children, and parents using it in Starship Children's Hospital.
Research Proposal (use	Aims/Hypotheses The aim of this trial is to understand whether Sprout IV Pole provides added benefit over

up to 4 pages)

existing IV Pole designs in the Day Stay Unit of Starship Children's Hospital.
It is believed that it will provide benefit over existing IV Pole Designs. It is also believed that children will hold different perspectives to their parents and the nurses.

Background/Justification

The process used to design current IV Poles is based on consultation solely with the service providers of the product using it. Service users are often overlooked in the design of medical products, due to range of reasons – limited access to patients, lack of understanding around the value consulting users holds, as well as limited time. This process is lengthy, as products need to abide by strict guidelines and regulations, prior to testing with humans in hospital (Medina, Okudan Kremer and Wysk, 2012). Whereas the process employed to design Sprout IV Pole has been very different.

Sprout IV Pole 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 associated with the design of their healthcare services and treatment (Soderback, Coyne, Harder, 2011). This has informed this process to value the voices of children in the already lengthy process of designing medical products.

This process started out by identifying issues with current IV Poles for the users and service providers. Children often find these IV poles awkward to use; they are difficult to move around in smaller spaces (such as bathrooms), and are often difficult to use for smaller people. In addition, the aesthetic conforms to current functional medical equipment, which may not meet the needs of child users. This revealed a gap in the market that IV poles are not made specifically for paediatric use, and use by children, as well as lacking functionality and usability.

After many alterations to the original prototype, two variations of Sprout IV Pole were trailed alongside an existing IV pole in a simulated hospital environment with healthy children. The simulation findings revealed the value children place on the look and simplicity of the product to be deemed "child-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 created the need to evaluate Sprout IV Pole in hospital with sick children and nurses, to understand how it compared to current standard IV Poles.

Research Design

Participants

Nurses

- Registered nurses working in the Day-Stay Unit (Monday- Friday).
- Any nurses working in the Day-Stay Unit attending to children taking part in the trial are welcome to participate.
- Nurses can provide feedback through the questionnaire once.

Children

- Children being treated in the Day-Stay Unit that require an IV pole for IV infusion.
- Children must be able to comprehend and provide assent (alongside their parents consent) to participate in the trial, between the ages of five-seventeen.
- A range of one-four children each day, for three weeks, Monday to Friday. Cath Bryne (Starship Nurse Advisor) indicated this sample size based on her understanding of daily admissions to the Day Stay Unit. If more than four children require IV poles in the Day-Stay Unit then the four to participate will be on a first in first served basis.

- 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.
- One-two parents per child are welcome to participate in the trial.
- 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

For nurses in the Day-Stay Unit, they will be informed about the study through their charge nurse. If they wish to take part in the study or 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 time 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 children/young people. If children are between five to seventeen years old and require an IV Pole for IV infusion, 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 affect on their ongoing treatment or care. Children/young person and parents will be given different information sheets, which will explain the trial in an understandable language specific to them.

The researcher assistant will then visit the child/young person and parent in the waiting room to answer any questions. Once reading the information sheets, if the child/young person and parents wish to participate in the study they will be provided consent/assent 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 in to the trial.

Trial

On odd days, all children/young people recruited into the trial will be given a Sprout IV Pole to trial initially. Midway through the day this will be changed to a standard IV Pole, to allow participants to be able to make a comparison. The initial allocated pole will alternate each day, Sprout IV Pole on odd days, and a standard IV Pole 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/ legal guardian. The parent/s will be provided questionnaires to complete evaluating the products. During this time, the research assistant will interview the child/young person from a set questionnaire. The responses will be documented on the questionnaire.
Questions are grouped under five categories, general questions, questions about movement, safety, look 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 likert scale (quantitative). Questions vaguely differ between children, parents and nurses.

Instruments

Nurse questionnaire
Parental/legal guardian questionnaire
Child/paitent questionnaire
Child visual Likert 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/young person they will pause the interview to reassess assent into the study. The interview may potentially resume at a later time if that participant does not withdraw after consulting with their nurse.
Participants may feel exposed to the research assistant, as the research assistant will be unknown to participants. It is important for the research assistant to gain the participants trust so they feel comfortable with their presence.

Risk/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 all the different stakeholders.

Endpoints/Analyses

Qualitative data will be analysed using thematic analysis.
Quantitative data will be analysed using statistical analysis, informed through discussions with a bio statistician depending on the successful recruitment of over 50 children.
The data will be searched for common ideas that have similar meanings and then grouped into themes.
The responses will indicate a preference towards an IV Pole. It will also signal areas of the design that may benefit from alterations/refinement.

Timeline description (Gantt chart recommended)	Monday – Friday for three weeks. Each Day • Admission to the Day Stay Unit • Informed about the trial from their nurse and provided information sheets • Research coordinator answers questions and provides consent/assent forms • Consent forms/ assent forms signed and returned • Connected to their IV Pole – (On odd days of the trial, this will be Sprout 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

Section D: Financial

Budget attached	☐
Describe reasons if no 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 nurses would take place depending on the health of each individual child
	Non-standard care **extra** for this research project: • Each child and their parents 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 parents to gain consent/assent and answer any questions • The research assistant will prompt each child's nurse to switch their IV Pole once during the day • Each child will be visited one more time during their time in the ward by the research assistant to fill out a questionnaire (parents) and interview (child).
Describe/justify ADHB resource impact	• Undertaking the interview with the child/parent in their room (or where ever they are located in the ward). • Discussing the study with the children in the waiting room of the Day-Stay Unit. • ADHB nurse time for the interview (They can dictate when they have time) and switching the pole • ADHB Day Stay Unit charge nurse liaising 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
	Radiology N/A
Investigator time (if applicable)	
Co-ordinator/Research Nurse time:	Study preparation and approval: indicating eligible participants to the research assistant
	Study visits and CRF completion N/A
	Monitoring N/A
	Other costs N/A
Miscellaneous Costs:	Travel / taxi vouchers N/A
	Refreshments N/A
	Stationery: Pens, questionnaire copies, clip boards, thank you certificates, thank you letters (provided by the Principal Co-ordinator Investigator)
	Archiving N/A
	Other miscellaneous costs N/A

Income source for study	Funding from the Starship Foundation

Funding letter attached?	Yes	Date funding result expected			
Trust funding support Requested	N/A	Trust funding support application attached		N/A	
Savings identified in budget?	N/A	Describe			
Capex Required					
Capex approval attached		If not why not?			

Section E: Contracts and Legal

Contract required		Legally reviewed and approved		Consult with Bruce Northey
Final contracts attached		Date Contract anticipated to be finalised by		
ACC study		Non-ACC study		
Indemnity & Compensation signed		Date		
Current Insurance Certificate		Expiry date		

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

Clinical Director / Clinical Leader / Medical Director / Nursing Leader (etc) :

- *I agree that the study aligns with department/service area interests and access to patients/staff/health information is justified YES / NO/ N/A*
- *I agree that access to care for non-study patients will not be adversely affected YES / NO / N/A*
- *I agree that the study is feasible and clinically appropriate YES / NO / N/A*
- *I agree that staff workload is acceptable and PI and team are suitably qualified and experienced YES / NO / N/A*
- *I agree that the potential group of patients/clients is not over researched already YES / NO / N/A*
- *I agree that the recruitment target is achievable YES / NO / N/A*
- *I agree that the department/service area can manage the research in the time frame suggested YES / NO / N/A*
- *I agree that there are no conflict of interest issues that need declaring/addressing YES / NO / N/A*

Name Sarah Little

Do not sign if any of above are *NO*, if you are an investigator or supervisor, or you are not authorised to do so

Signature

Date 01-08-2014

Dept / Service Area

Job title

Comments or qualification about the study?

Name

Do not sign if any of above are *NO*, if you are an investigator or supervisor, or you are not authorised to do so

Dept/ Service Area

Signature

Job title		Date
Comments or qualification about the study?		

Principal (Co-ordinating) Investigator or ADHB site lead investigator:

- *I assert that all the known uses of ADHB resources related to operationalising of the research have been considered and any potential costs identified have been discussed with a research accountant.*
- *I confirm I will inform the ADHB Research Office when the study is complete.*
- *(where applicable)I confirm I will submit a progress report to the Health and Disability Ethics Committee annually, and a final report when the study has been completed.*

Name & Service Area		Signature	
		Date	
Comments or qualification about the study?			

Service Manager:

- *I agree the research project is ADHB policy compatible YES / NO / N/A;*
- *I agree that any usage of existing and future resource has been fully identified and is acceptable YES / NO / N/A*
- *I agree the research project has HR requirements identified for non-ADHB personnel i.e. screening, ID & confidentiality YES / NO / N/A*
- *I agree the research project is financially viable and payment schedules (where applicable) have been noted and are appropriate YES / NO / N/A*
- *I agree the research project has all resources/costs identified and accounted for YES / NO / N/A*
- *I agree if savings are identified for use or transfer YES / NO / N/A*

Name & Service Area		Signature	
		Date	
Comments or qualification about the study?			
Name & Service Area		Signature	
		Date	
Comments or qualification about the study?			

Section G: Clinical trial registration

Clinical Trial Number	
Trial Website	
Comment	

Appendix 5 - Sprout IV Pole Evaluation Protocol

Protocol Title: Paediatric Hospital Experience: Sprout IV Pole Evaluation

Principal Investigator: Neerali Parbhu
Supervisiors: Dr. Stephen Reay and Dr. Tineke Waters
Research Coordinator: Research Student

Medical Device: Sprout IV Pole

Table of Contents

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 eliminate an immediate hazard to a research participant. In such case, 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 metal pole with five 'legs' with wheels attached to allow the pole to move around with ease. Children often find these IV Poles awkward to use; they are difficult to move around in smaller spaces (such as bathrooms), and are often difficult to use for smaller people. In addition, the aesthetic conforms to current functional medical equipment, which may not meet the needs of child users. This revealed a gap in the market that IV Poles are not made specifically for paediatric use, 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 weak plastic bases break when children stand on them
- Plastic two part wheels clog with hair and don't spin, and are difficult to clean
- The height adjustment mechanism breaks easily
- Old IV Poles rust

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 be aesthetically pleasing for children/young people, and to meet the physical needs around mobility/functionality. Making it easier to move around, convenient to hold and manoeuvre.
The new design has been created through the design process. The purpose of this process is not just to design pleasing objects, but is also designed to consider how users will experience a new product (Felton, Zelenko & Vaughan, 2012). The process of converting this understanding of users' needs and experiences into useful insights, that may later become a commercial design, has been termed "Design Thinking" (Brown, 2008). Designers need to be able to empathise and understand the specific needs of those who will ultimately use the product.
To redesign this IV Pole to meet users needs, including the children/young people, their voices need to be heard (Bishop, 2013). This trial provides sick children/young people in hospital an opportunity to influence and shape an aspect of their hospital experience.
As end users of the redesigned IV pole it is important that children/young people have a voice and opportunity to be involved in the design project, both in the development and trialing of the product. Children/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 in helping to ensure it will meet their needs. Consideration of the needs of all stakeholders, including the children, is invaluable to the process of redesigning hospitals to provide the patients with peace of mind (Marzano, 1998).

1.3 Medical Device

1.3.1 Name of Investigational Device

Sprout IV Pole

1.3.2 Intended Use of the Investigational Device

An IV pole supports an IV bag/bottle or syringe, which contains blood, medicine, or saline solution, connect-

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 top – Where the IV bag/bottle hang. One specifically protrudes out more than others to cater to wide 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 clog free wheels (Two with brakes)

1.4 Preclinical 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 response.
During this trial children evaluated two variations of Sprout IV Pole and a standard IV Pole.

Sprout to be trialed

Sprout variations trial in November 2013

The Sprout variations included two different handle designs, and two different bases revealing the preference towards the twisting 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 children place on the look and simplicity of the product to be deemed "child-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.

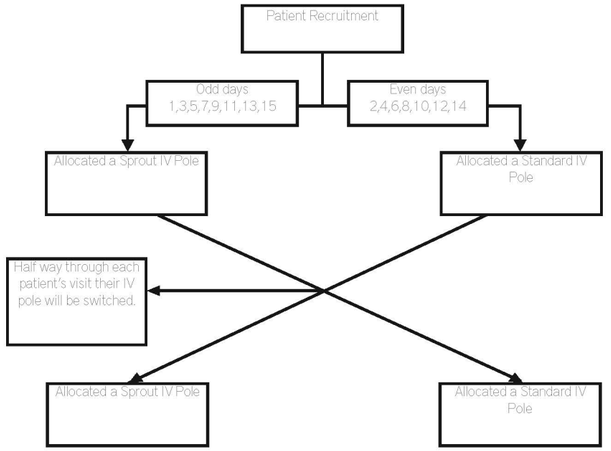
2.0 Trial Objectives
The information gathered will be used to better understand whether the newly designed Sprout IV Pole provides benefit over existing IV poles for nurses, children, and parents using it in Starship Children's Hospital.

3.0 Trial Design

3.1 General Design
This trial is designed to collect data from children that will use an IV Pole during their admission in to the Day Stay Unit, their accompanying parents/legal guardians, and the nurses tending to them. Children's responses will be sought through structured qualitative/quantitative interviews, recorded through a questionnaire. Nurse's responses and parents responses will be sought through a structured quantitative /qualitative questionnaire they will fill out.
Each child will participate in the trial for one day. A range of 1-4 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 Poles 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/assent forms.
On odd days, all children/young people recruited into the trial will be given a Sprout IV Pole to trial initially. Midway through the day this will be changed to a standard, to allow participants to be able to make a comparison. The initial allocated pole will alternate each day, Sprout IV Pole on odd days, and a Standard IV Pole on event days. This method is called repeated measure cross-over design.
At the end of the day they will provide feedback upon their experience 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



Questionnaires
The questionnaires are designed to collect information about both IV Poles trialed during the day. Questions are grouped under five categories, general questions, questions about movement, safety, look 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 likert scale (quantitative). Questions will vaguely differ between children, parents and nurses.
For the purpose of this trial the questionnaire is available in English only.

3.2 Primary Trial Endpoints
To establish which IV Pole is the preferable design for all three users from the responses to the questionnaires.

3.3 Primary Safety Endpoints
To establish the safety of Sprout 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 of Starship Children's Hospital
- Children/young people being treated in the Day-Stay Unit that require an IV pole for IV infusions between the ages or 5-17.
- Parents/legal guardians of a child in the Day-Stay Unit that require an IV pole for IV infusion 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 Participant
- Children: One to four children each day, (fifteen 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
1. Admitted to the Day Stay Unit during the three weeks of the trial
2. Require an IV Pole during their time in the Day Stay Unit
3. Provide assent to participate, as well as parental/legal guardian consent
4. English speaking
5. Between the ages of 5-17

Parent/legal guardian
1. Their child requires an IV Pole during their time in the Day Stay Unit
2. Able to provide consent
3. English speaking

Nurses
1. Working in the Day Stay Unit during the trial
2. Tending to children in the trial
3. Able to provide consent
4. English speaking

4.4 Exclusion Criteria
Child
1. Cannot provide assent to participate in the trial
2. Do not speak English
3. Do not have parental/legal guardian consent
4. Have already participated in the trial on a previous visit to the Day Stay Unit

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

Nurse
1. Does not work in the Day Stay Unit during the time of the trial
2. Is not tending to children in the trial
3. Does not speak English
4. 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 in to the trial upon arrival to the Day Stay Unit. Their nurse will provide information about the trial verbally and supply information sheets (individual information sheets for children, younger children, and parents).

4.6 Early Withdrawal of Participants

4.6.1 Criteria for Removal from Trial
Participants 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 trial.
-If a parent withdraws from the trial, as long as 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 Product Procedures

5.1 Description
Participants will be considered for this trial as long as they fit the inclusion criteria, and no exclusions apply. If so, informed consent/assent 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, (odd day or even) this will indicate which IV Pole they will be allocated initially during their time in the Day Stay Unit.

5.3 Participant Compliance Monitoring
Children will be asked to use one IV Pole for half their time in the Day Stay Unit, and their nurse will switch their IV Pole to allow them to trial the other IV Pole midway through the day. Compliance to this 50/50 split of their time between IV Poles will be the responsibility of the research coordinator to indicate to the nurses

when switching is required.

5.4 Receiving, Storage, Dispensing and Return

5.4.1 Receipt of Investigational Device Supplies
The principal investigator for the trial will provide the four Sprout IV Poles, and the four standard IV Poles will be sourced from the Day Stay Unit's current supply of IV Poles.

5.4.2 Storage
The Day Stay Unit will be required to store the IV Poles during the three weeks of the trial in a secured room.

5.4.3 Dispensing
Within the allocation of either a standard IV Pole or a Sprout IV Pole, the specific IV Pole will be selected at random.

5.4.4 After Trial
The standard IV Poles will be returned to the Day Stay Unit for regular use. The principal investigator will collect the four Sprout IV Poles after the final day of the trial, or these will be gifted to the Day Stay Unit.

5.4.5 Maintenance
It is envisaged that all IV Poles will withstand the duration of the trial. In the case of a standard IV Pole becoming faulty, it will be replaced with another in the Day Stay Unit (or sourced from another Unit if need be). If a Sprout IV Pole becomes faulty, the product will no longer be trialed, and fewer participants will be recruited.

6.0 Trial Procedures

6.1 Odd Days
On all odd days of the trial (1st, 3rd, 5th, 7th, 9th, 11th, 13th, and 15th).
- Admission to the Day Stay Unit
- Informed about the trial from their nurse and provided information sheets
- Research coordinator answers questions and provides consent/assent forms
- Consent forms/ assent forms signed and returned
- Connected to their IV Pole - a Sprout IV Pole by their nurse
- Switching to a Standard IV Pole indicated by the research coordinator to their nurse
- Data collection, completion of questionnaire
- Discharged from the Day Stay Unit

6.2 Even Days
On all even days of the trial (2nd, 4th, 6th, 8th, 10th, 12th, and 14th).
- Admission to the Day Stay Unit
- Informed about the trial from their nurse and provided information sheets
- Research coordinator answers questions and provides consent/assent forms
- Consent forms/ assent forms signed and returned
- Connected to their IV Pole - a Standard IV Pole by their nurse
- Switching to a Sprout IV Pole indicated by the research coordinator to their nurse
- Data collection, completion of questionnaire
- Discharged from the Day Stay Unit

6.3 Follow-up Procedures

Participants will be provided information about the findings of the trial if indicated to the research coordinator through their consent form.

7.0 Safety and Effectiveness Assessments

Observations of incidences will be recorded on the "further comments" section under Adverse Events on the questionnaires.
If a child has an accident with their Sprout IV Pole the trial will be paused and the situation will be assessed with the principal investigator and charge nurses before recommencing.

8.0 Statistical Plan

8.1 Sample Size Determination
Should I recruit more than 50 children into the trial then a bio statistician will be consulted to discuss the best methods of analyzing this data.
This sample size was recommended by Cath Byrne as enough to determine whether Sprout IV Pole can compare to standard IV Poles. The sample size it not based on any formal statistical criteria.

8.2 Statistical Methods
Comparisons between different user groups will be undertaken using paired t-tests. This will be to test whether there are statistically significant differences between the different user groups, ages of children, ethnic groups, but most importantly between IV Poles across all users to determine the endpoint, a preference towards one IV Pole design.
Quantitative data will also be analysed using means, medians, standard deviation and percentages for different categorical data.

Any deviations from the previously described statistical plan will be described and justified in a protocol amendment.

8.3 Participant Population(s) for Analysis
Includes all participants who provided feedback through questionnaires.

8.4 Interim Analysis
No interim analysis is planned. Confirmation will take place by the principal coordinator and supervisors.

9.0 Risk Analysis

9.1 Anticipated Risks
The total anticipated risk from participating in the trial does not exceed any normal risk associated with using an IV Pole.

9.2 Adverse Event Definitions
Adverse effect. Any untoward medical occurrence in a clinical trial of an investigational device; regardless of the causal relationship of the problem with the device.

Associated with the investigational device or, if applicable, other trial treatment or diagnostic product(s). There is a reasonable possibility that the adverse effect may have been caused by the investigational device.

Disability. A substantial disruption of a person's ability to conduct normal life functions.

Life-threatening adverse effect. Any adverse effect that places the participant, in the view of the research coordinator, at immediate risk of death from the effect as it occurred (i.e., does not include an adverse effect that, had it actually occurred in a more severe form, might have caused death).

Unexpected adverse effect. Any adverse effect, the frequency, specificity or severity of which is not consistent with the risk information described in the trial protocol(s) or elsewhere in the current AUTEC application, as amended.

9.3 Recording of Adverse Events

All observed or volunteered adverse effects (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 pursued and/or obtained so 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 casual relationship between the adverse effect and the investigational device.

Adverse effects or abnormal test findings felt 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 is accompanied by clinical symptoms
- The test finding necessitates additional diagnostic evaluation(s) or medical/surgical intervention; including significant additional concomitant drug treatment or other therapy
  - Note: simply 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 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; 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 final determination of causality is "unknown and have questionable relationship to the investigational device" 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 final determination of causality is "unknown but not related to the investigational device or", this determination and the rationale 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

w9.5.1 Reporting of adverse reactions to Medsafe.

For the purpose of this trial, Sprout IV Pole does not require registration in WAND, as indicated by Medsafe. Pending ADHB Research Review Committee approval, Medsafe will be notified about the trial. In the event of an adverse effect, the principal investigator will submit a completed form to Medsafe for medical device adverse event reporting for any observed or volunteered adverse effect that is determined to be an unanticipated adverse device effect. A copy of this completed form will be provided to all participating sub-investigators. The completed form will be submitted to Medsafe as soon as possible and, in no event, later than 10 working days after the investigator-sponsor first receives notice 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 addressed a similar adverse effect experience and will provide an analysis of the significance of newly reported adverse effect in light of the previous, similar report(s).

9.6 Stopping Rules

In the case of safety concerns for the use of Sprout IV Pole in the Day Stay Unit of Starship Children's Hospital, then Medsafe will be notified immediately.

10.0 Data Handling and Record Keeping

10.1 Confidentiality

Information about trial participants will be kept confidential and managed according to the requirements as approved by AUTEC.

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 clinical findings, 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 and for a period of ten years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol..

Research records and original signed consent forms are to be retained by principal investigator for at least ten 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 per other applicable regulatory requirements. The 6 year minimum retention of authorizations complies with the privacy regulation requirements.

10.4 Ethics Committee

Through consultation, AUTEC approval was appropriate for this trial. The principal investigator alongside supervisors will be responsible for maintaining Ethics Committee Correspondence.

11.0 Trial Monitoring, Auditing and Inspecting

11.1 Trial Monitoring Plan

11.1.1 Trial Staff Responsibilities and Training

Protocol Procedure Training

Day Stay Unit nurses will be delegated the task of switching IV Poles part way through the day, which will be indicated by the research coordinator, training 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 Medsafe, of all Unanticipated Problems.

12.0 Ethics

This trial will be conducted in compliance with the protocol approved by the ADHB Research Review Committee, the relevant regulations, and policies and procedures according to Good Clinical Practice standards. No deviation from the protocol will be implemented without the prior review and approval of the Research Review Committee except where it may be necessary to eliminate an immediate hazard to a research participant. In such case, the deviation will be reported to the Research Review Committee according to its policies and procedures.

All participants for this trial will be provided a consent form describing this trial and providing sufficient information for participants to make an informed decision about their participation in this trial. This consent form will be submitted with the protocol for review and approval by AUTEC for the trial. The formal consent of all participants will be sought using the AUTEC-approved consent form. Before a participant undergoes any trial procedure, an informed consent discussion will be conducted and written informed consent obtained with a consent form signed by the participant or legally acceptable surrogate if applicable. An investigator-designated research professional will obtain written informed consent from participants.

13.0 Trial Finances

13.1 Funding Source

This trial is financed through a grant from Starship Foundations Five Star Sponsor Mercury Energy and their Star Supporters Club.

13.2 Conflict of Interest

Any investigator who has a conflict of interest with this trial as defined by the DHB policies will have the conflict reviewed by a properly constituted Conflict of Interest Review Committee with a committee-sanctioned conflict management plan that has been reviewed and approved by AUTEC prior to participation in this trial. All DHB investigators will follow the DHB conflict of interest policy.

14.0 Publication Plan

The results of this trial carried out under this protocol will potentially be published in a journal article, as well as in the principal investigator's Master's thesis. No identifiable information is collected from participants, so anonymity is unquestionable. The principal investigator will also have no contact with participants directly.

15.0 References

Bishop, K. (2013). Through Children's Eyes: Understanding how to create supportive healthcare environments for children. Design & Health. Retrieved from http://www.worldhealthdesign.com/Through-Childrens-Eyes.aspx

Brown, T. (2008). Design Thinking. (P. Sachse & A. Specker, Eds.) Harvard Business Review, 86(6), 84–92. doi:10.5437/08956308X550300

Felton, E., Zelenko, O., & Vaughan, S. (2012). Design and ethics. Oxon: Routledge.

Marzano, S. (1998). Creating value by design: thoughts and facts. Blaricum: V+K Publishing.

Söderbäck, M., Coyne, I., & Harder, M. (2011). The importance of including both a child perspective and the child's perspective within health care settings to provide truly child-centred care. Journal of Child Health Care, 15(2), 99–106. doi:10.1177/1367493510397624

16.0 Attachments

NURSE #

1. What is your Ethnicity? Circle one

NZ European Māori Samoan Cook Island Maori Tongan Niuean Chinese Indian

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

GENERAL 2. How important is	NOT IMPORTANT	SOMEWHAT IMPORTANT	IMPORTANT	VERY IMPORTANT	EXTREMELY IMPORTANT
-Being able to move it easily	○	○	○	○	○
-The safety of the pole	○	○	○	○	○
-The look of the pole	○	○	○	○	○
-How the pole functions	○	○	○	○	○

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

Please answer questions in relation to each pole

MOVEMENT	NEVER		SOMETIMES		ALWAYS	NEVER		SOMETIMES		ALWAYS
4. The pole was easy to move around	○	○	○	○	○	○	○	○	○	○
5. The pole went through doorways and bathrooms	○	○	○	○	○	○	○	○	○	○
6. The pole was quiet when moving	○	○	○	○	○	○	○	○	○	○
7. Where did you hold the pole when using it										

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

Please answer questions in relation to each pole		

SAFETY	NEVER	SOMETIMES	ALWAYS	NEVER	SOMETIMES	ALWAYS
9. This pole was stable	○ ○	○ ○	○ ○	○ ○	○ ○	○ ○
10. The pole was strong	○ ○	○ ○	○ ○	○ ○	○ ○	○ ○
11. This pole was safe for children to use	○ ○	○ ○	○ ○	○ ○	○ ○	○ ○
12. This pole was easy to store when not in use	○ ○	○ ○	○ ○	○ ○	○ ○	○ ○

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

LOOK	DISAGREE	NEUTRAL	AGREE	DISAGREE	NUETRAL	AGREE
14. I liked the look of the pole	○ ○	○ ○	○ ○	○ ○	○ ○	○ ○
15. What did you like?						
16. What would you change about each pole?						

17. Can you explain how it could be better?

Please answer questions in relation to each pole		

FUNCTION	NEVER	SOMETIMES	ALWAYS	NEVER	SOMETIMES	ALWAYS
18. Pumps were easy to attach	○ ○	○ ○	○ ○	○ ○	○ ○	○ ○
19. Fluid bags/bottles were easy to hang	○ ○	○ ○	○ ○	○ ○	○ ○	○ ○
20. The pole was easy to keep stationary when required	○ ○	○ ○	○ ○	○ ○	○ ○	○ ○

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

INTERACTION	DISAGREE	NUETRAL	AGREE	DISAGREE	NEUTRAL	AGREE
22. The pole is important to children	○ ○	○ ○	○ ○	○ ○	○ ○	○ ○
23. Children liked using the pole	○ ○	○ ○	○ ○	○ ○	○ ○	○ ○
24. Children were able to move it	○ ○	○ ○	○ ○	○ ○	○ ○	○ ○
25. Children used it in ways not intended	○ ○	○ ○	○ ○	○ ○	○ ○	○ ○

26. Can you explain why you have answered in this way?

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

PARENT #

1. What is your Ethnicity? Circle one

NZ European Māori Samoan Cook Island Maori Tongan Niuean Chinese Indian

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	NOT IMPORTANT	SOMEWHAT IMPORTANT	IMPORTANT	VERY IMPORTANT	EXTREMELY IMPORTANT
-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

MOVEMENT	NEVER		SOMETIMES		ALWAYS	NEVER		SOMETIMES		ALWAYS
5. The pole was easy to move around	○	○	○	○	○	○	○	○	○	○
6. The pole went through doorways and bathrooms	○	○	○	○	○	○	○	○	○	○
7. The pole was quiet when moving	○	○	○	○	○	○	○	○	○	○
8. Where did you hold the pole when using it										

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

Please answer questions in relation to each pole

SAFETY	NEVER		SOMETIMES		ALWAYS	NEVER		SOMETIMES		ALWAYS
9. This pole was stable	○	○	○	○	○	○	○	○	○	○
10. The pole was strong	○	○	○	○	○	○	○	○	○	○
11. This pole was safe for your child to use	○	○	○	○	○	○	○	○	○	○

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

LOOK	DISAGREE		NEUTRAL		AGREE	DISAGREE		NUETRAL		AGREE
13. I liked the look of the pole	○	○	○	○	○	○	○	○	○	○
14. What did you like?										
15. What would you change about each pole?										

16. Can you explain how it could be better?

Please answer questions in relation to each pole										
INTERACTION	DISAGREE		NUETRAL		AGREE	DISAGREE		NEUTRAL		AGREE
17. The pole is important to your child	○	○	○	○	○	○	○	○	○	○
18. Your child liked using the pole	○	○	○	○	○	○	○	○	○	○
19. Your child was able to move it	○	○	○	○	○	○	○	○	○	○
20. Your child used it in ways not intended	○	○	○	○	○	○	○	○	○	○

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

22. 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 Maori Tongan Niuean Chinese Indian
2. How old is are you? 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	NOT IMPORTANT	SOMEWHAT IMPORTANT	IMPORTANT	VERY IMPORTANT	EXTREMELY IMPORTANT
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										
MOVEMENT	NEVER		SOMETIMES		ALWAYS	NEVER		SOMETIMES		ALWAYS
5. The pole was easy to move around	○	○	○	○	○	○	○	○	○	○
6. The pole went through doorways and bathrooms	○	○	○	○	○	○	○	○	○	○
7. The pole was quiet when moving	○	○	○	○	○	○	○	○	○	○
8. Where did you hold the pole when using it										

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

Please answer questions in relation to each pole		
SAFETY	NEVER SOMETIMES ALWAYS	NEVER SOMETIMES ALWAYS
9. This pole was stable	○ ○ ○ ○ ○	○ ○ ○ ○ ○
10. The pole was strong	○ ○ ○ ○ ○	○ ○ ○ ○ ○
11. This pole was safe for you to use	○ ○ ○ ○ ○	○ ○ ○ ○ ○
12. Can you explain why you have answered this way?		
LOOK	DISAGREE NEUTRAL AGREE	DISAGREE NUETRAL AGREE
13. I liked the look of the pole	○ ○ ○ ○ ○	○ ○ ○ ○ ○
14. What did you like?		
15. What would you change about each pole?		
16. Can you explain how it could be better?		

Please answer questions in relation to each pole		
INTERACTION	DISAGREE NUETRAL AGREE	DISAGREE NEUTRAL AGREE
17. The pole is important to you	○ ○ ○ ○ ○	○ ○ ○ ○ ○
18. You liked using the pole	○ ○ ○ ○ ○	○ ○ ○ ○ ○
19. You were able to move the pole on your own	○ ○ ○ ○ ○	○ ○ ○ ○ ○
20. You used the pole in ways not intended	○ ○ ○ ○ ○	○ ○ ○ ○ ○
21. Can you explain why you have answered in this way?		
22. Any further comments to add? Did any adverse events take place?		

CHILD LIKERT SCALES
When children are interviewed they will indicate their responses by pointing to these charts. The research coordinator will document their responses on the questionnaire.

NOT IMPORTANT	SOMEWHAT IMPORTANT	IMPORTANT	VERY IMPORTANT	EXTREMELY IMPORTANT
○	○	○	○	○

NEVER		SOMETIMES		ALWAYS
○	○	○	○	○

DISAGREE		NEUTRAL		AGREE
○	○	○	○	○

NOT IMPORTANT	SOMEWHAT IMPORTANT	IMPORTANT	VERY IMPORTANT	EXTREMELY IMPORTANT
○	○	○	○	○

NEVER		SOMETIMES		ALWAYS
○	○	○	○	○

DISAGREE		NEUTRAL		AGREE
○	○	○	○	○

AUT UNIVERSITY
TE WĀNANGA ARONUI O TĀMAKI MAKAU RAU

AUTEC SECRETARIAT

26 June 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 submitting your application for ethical review. I am pleased to confirm that the Auckland University of Technology Ethics Committee (AUTEC) has approved your ethics application for three years until 23 June 2017.

AUTEC would like to commend the research team on the thorough and thoughtful application

AUTEC suggests the Information Sheet for the older children would benefit from further simplification of the language used.

As part of the ethics approval process, you are required to submit the following to 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 within their.

To enable us to provide you with efficient service, we ask that you 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 Parbhu neerali.parbh@gmail.com

Auckland University of Technology Ethics Committee
WA505D Level 5 WA Building City Campus
Private Bag 92006 Auckland 1142 Ph: +64-9-921-9999 ext 8316 email ethics@aut.ac.nz

AUT UNIVERSITY
TE WĀNANGA ARONUI O TĀMAKI MAKAU RAU

AUTEC
SECRETARIAT

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 Parbhu neerali.parbhu@gmail.com

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