# Designing a Novel Support System for Feeding Pumps - A Case Study in User Involvement in Medical Design

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Thesis submitted to the University of Houston
In partial fulfillment of the requirements for the degree of
Master of Science in Industrial Design
2019

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## ABSTRACT

Usability is an important aspect of medical product design, yet in spite of this fact, many medical device developers do not incorporate user-centered design methods when they design their products. One study found that only one in eleven medical device manufacturers involved users in their design process (Money et al., 2011). One reason that the companies did not involve users was that they considered the opinions of "low-ranking" users like nurses, patients, or family caregivers to not be valuable. The present study hypothesizes that involving "low-ranking" users in the design process will ultimately lead to better design outcomes. Equipment used to hang enteral feeding pumps, such as IV poles and specialized backpacks, was selected as an area of exploration for a case study in user involvement in the medical product design process. Four families whose children use enteral feeding pumps participated in the study. Phase one of the research involved visiting the families' homes to better understand their difficulties with the equipment and gather their ideas for how it could be improved. "Works-like" prototypes of two different feeding pump holder designs were developed based on their ideas. These two prototypes were tested by the participants in phase two of the study, and they provided feedback on the design. When asked to rank each prototype and their previous feeding pump hanging method on a variety of usability criteria, participants preferred Concept 2: the quick-release system. A final design was developed based on Concept 2 and the participants' suggestions to further improve it. The final design outcome was "Tag Along," which is a modular system consisting of a short pole that holds the feeding bag and the feeding pump together as one unit, and can quickly be snapped into a tabletop stand, snapped into a clamp that can be attached to various equipment like wheelchairs, or can hang independently. The participants made valuable contributions to the design in both phases of the research. The results of the case study supported the hypothesis, because the involvement of users in the design process led to a design that was preferred by the users.

# ACKNOWLEDGEMENTS

Many thanks to the families that participated in this study. Without their generous donation of their time and input, this project would not have been possible.

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# CHAPTER 1: INTRODUCTION

## 1.1 BACKGROUND

Parents and caregivers caring for children with medical needs at home face many difficulties, from the emotional difficulties related to having a child with special needs, to the physical toll of the increased workload of caring for the child. Caregivers often use various types of medical equipment to care for disabled children at home. They can encounter a multitude of problems with this equipment, and some of these problems are related to the design of the equipment itself. Problems may stem from the fact that many caregivers don't have formal medical training, yet are using equipment designed for someone who does. Or the problem may be one of context; the caregivers are using equipment that was initially designed for a hospital setting and trying to fit it into a totally different context and lifestyle. In some cases, the design of the medical equipment itself is has not been optimized for lay users nor for a home context, and thus some problems could be remediated through an improvement in the design of the equipment.

To find out more about where these difficulties with the equipment may setm from, the process that medical device companies go through to solicit feedback from users in their design process was investigated. User involvement in the design process has been shown to improve functionality, usability, and quality (Shah & Robinson, 2007). However, one study found that in practice, only one in eleven medical device companies was involving users in their design processes (Money et al., 2011). One reason given for this was that the opinions of "low-ranking" users like nurses and caregivers were not seen as useful or valuable, and the companies instead relied on opinions of more senior medical personnel such as surgeons and hospital administrators to inform their designs. This was particularly surprising since nurses, caregivers, and patients are the primary users of many medical devices. The present study hypothesizes that involving "low-ranking" users in the medical device design process would lead to outcomes that functioned better for these users.

The design of hanging equipment used with home-use feeding pumps, such as an IV poles or backpacks, was investigated as a case study. In-home interviews with caregivers of children who use feeding pumps were conducted, and their ideas for how the equipment can be improved were gathered. Based on their insights and feedback, two prototypes of novel feeding pump supporting systems were designed and tested in the home context with the caregivers. The caregivers then rated each system, and their ratings were compared with ratings of their previously-used systems. These ratings and test feedback informed the final design of the feeding pump holder.

## 1.2 CONCEPTUAL FRAMEWORK

The philosophical approach in this study was heavily influenced by the transformative worldview, which "places central importance on the study of lives and experiences of diverse groups that have traditionally been marginalized" (Creswell, 2014). It seemed unjust that the primary uses of medical equipment, such as caregivers, nurses, and patients themselves, were not being included in the design process for medical equipment. Adding to the issue, the majority of engineers (89%) ("Women in STEM | National Society of Professional Engineers," 2011), industrial designers (est. 85-90%) ("Women in Industrial Design," 2010), surgeons (81%) (Wolfe, 2018), and hospital executives (60%)("Women make up 80% of health care workers—but just 40% of executives," 2014) are men, while the majority of nurses (92%) ("Women's Bureau (WB) - Statistics on Registered Nurses," 2003) and at-home caregivers (75%) ("Caregiver Statistics: Demographics | Family Caregiver Alliance," 2016) are women . Therefore, this phenomenon of medical devices designers not including the opinions of "low-ranking" users like nurses and family caregivers in their design process most likely also a phenomenon of male designers designing for a majority-women group without seeking input from women.

The overarching research framework in this study is a case study. A case study was selected because it can be used to test a method. The primary goal of this study is to test a design method in which users and involved in the design process of a medical device.

Within the method of user engagement, this study employs qualitative descriptive research (Kim, Sefcik, & Bradway, 2017). Qualitative descriptive research seeks to observe a phenomena in its natural state, and invovles conducting individual interviews with minimal structure as a primary data collection strategy, both of which occur in this study.

## 1.3 SIGNIFICANCE OF STUDY

This study seeks to shed light on the fact that “low-ranking” users like caregivers or patients with no formal medical training have good ideas of how to improve medical equipment, and their insight should be sought out when designing equipment that may one day end up in a home setting. The hypothesis is that doing so will ultimately yield better design outcomes. This study employs a case study which seeks to provide an example of how lay users can be included in the design process of a medical device. It is hoped that others who are designing medical equipment can learn from this example and implement similar methods in their own research and development process so that more devices can be developed with input from “low-ranking” users like family caregivers.

# CHAPTER 2: LITERATURE REVIEW

## 2.1 THE ROLE OF USABILITY IN MEDICAL TECHNOLOGY

Usability is an important issue in medical technology as it can help prevent costly medical errors and to ensure patient adherence to treatment plan. Because usability is so important, user-centered design and different methods of testing and evaluation should being early and continue through device development (J. L. Martin, Clark, Morgan, Crowe, & Murphy, 2012). While companies that design medical equipment often believe user-centered design to be cost-prohibitive and too time-consuming, employing user-centered design principles can actually mean reduced time to market, an improved product, and saved time and cost of producing an inappropriate prototype (J. L. Martin et al., 2012). User involvement in the design process has been shown to improve functionality, usability, and quality (Shah & Robinson, 2007). For medical devices that are subject to regulation, good usability isn't just a suggestion, but a requirement. The "Global Harmonisation Task Force" standard 60601-1-6 requires developers to adopt a usability engineering process to ensure medical electrical equipment safety and provides brief guidance as to how the iterative design and development process should be implemented. Ideally, "usability engineering should begin early and continue through the equipment design and development life cycle" (J. L. Martin, Norris, Murphy, & Crowe, 2008).

Usability can also play an important role in patient adoption of the device and adherence to the plan of care. In studying a device used by adolescent cystic fibrosis patients, it was found that the design of the device played a significant role in adherence for use. The device was difficult and time-consuming to use; this sometimes resulted in low adherence or abandonment of the device (Sharples et al., 2012). Appropriate design could act as a catalyst to the speed of the device use or increase its impact. "Development of medical devices from users' perspectives requires not only the involvement of healthcare professionals but also that of the ultimate end users, that is, patients, people with disabilities and/or special needs, and their caregivers. The evidence shows that such end users quickly discard devices that do not fulfill their personal expectations, even though both manufacturers and healthcare professionals may consider those end users' requirements met" (Shah, Robinson, & AlShawi, 2009).

## 2.2 BARRIERS TO USER-CENTERED DESIGN AND USER-INVOLVEMENT IN MEDICAL DESIGN

Despite the fact that usability is so important, user-involvement throughout the cycle of the design process is not currently employed by most medical device manufacturers. In order to determine the reason for this, seven barriers to user-centered design in medical technology were identified. These include the diversity of the user, complexity of the system, failure to consider low-ranking users, disconnect between the purchasers and users, lack of resources, regulation, and technology.

**Diversity of the user group**

In medical technology the "user" is often a wide variety of different types of people, and devices are frequently used by multiple user groups in a variety of settings (J. L. Martin et al., 2012). This problem can also be defined as the diversity of users, and the combined impact of users, device, and context (Sharples et al., 2012). "Developers, including those with a clinical background, may struggle to appreciate that user requirements encompass more than just clinical effectiveness and that for any one device there will be a number of different users to consider, including doctors, nurses, technicians, maintenance staff, patients and carers." Users will include intended, trained operators as well as those who are not the intended operators. The fact that the needs of multiple users must be considered distinguishes medical devices from other ergonomic domains (J. L. Martin et al., 2008).

**Complexity of the system**

It is common for medical devices to migrate from more sophisticated settings, like the ICU, to less sophisticated, such as inpatient wards, outpatient clinics, and patients' homes. This migration can also occur in the patient spectrum, such as from pediatric patients to small adults. Those who design medical devices should try to predict these scenarios and design with them in mind to prevent dangerous errors (Weinger, Wiklund, & Gardner-Bonneau, 2010). There is a need to better understand the healthcare system including the users of that system as the context into which design solutions must be delivered, instead of into one specific context like a hospital room. Without the broader understanding that the system itself is the context, there will be no single design that can reduce costly medical errors (Clarkson et al., 2004).

**Failure to consider users who don't have seniority**

"Manufacturers are prone to rely on advice from 'thought leaders' who are accomplished and interested physicians. These people are biased with more sophisticated knowledge than a representative user. Design teams should seek users that are more representative of user needs and get reactions to designs in progress" (Weinger et al., 2010). In one study, in-depth interviews with 11 medical device manufacturers were carried out. Manufacturers were hesitant to involve users in the design process because they held a belief that there is no need to do so given the "all-knowing" nature of senior health care staff. Less-senior healthcare practitioners and patients were rarely seen as being able to provide valuable input into the process (Money et al., 2011).

This problem isn't only limited to device design, but spans into other areas of health care. For example, it was found that plans for improving patient safety in medical care often ignore the patient's perspective, despite the fact that patients have a key role to play in the process of reaching an accurate diagnosis, making decisions about appropriate treatment, choosing a safe provider, ensuring appropriate administration of treatment, identifying adverse events, and taking appropriate action (C. A. Vincent & Coulter, 2002).

When it comes to pediatric care, the input of family members is very important. Family is the primary unit for delivering health care to infants and children. Family environment is probably the greatest influence on children's health. Parents are the only ones who see the children in all settings and therefore they are the "experts." Their observations must be taken seriously if the health care is to be family-centered (Shelton, Jeppson, Johnson, & Association for the Care of Children's Health, 1987).

### Disconnect between purchasers and usability

Medical device design is often complicated by reimbursement procedures within healthcare. Procurement decisions are made by people who are not using the products themselves, i.e. centrally within hospitals, remotely within trusts, or nationally. This means that usability may not even be considered or acknowledged in purchasing decisions (J. L. Martin et al., 2008). Purchasing decision-makers have very little info about usability, therefore, methods need to be developed for them to incorporate that into their process (Liljegren, 2006). If medical device companies don't have to make user-friendly devices in order to sell their product, they may lack motivation to do so at all. And if those who decide which medical devices to purchase don't have information about which ones are most user-friendly, how can they be expected to incorporate that into their decision process?

### Lack of resources available to perform user-centered design

Smaller companies can lack the expertise and knowledge necessary to involve the user in the design process or do user-testing (J. L. Martin et al., 2012). The perceived amount of time and money required to involve user in the design process is also a barrier (Shah & Robinson, 2007), (Money et al., 2011). In some larger medical device development companies, different departments are responsible for different parts of the design (i.e. mechanical engineering, industrial design, and software engineering), and it can be unclear which department would be responsible for involving the user in their process, and where the overlap or gaps would be (C. J. Vincent, Li, & Blandford, 2014).

### Regulation

The fact that medical devices are subject to extensive regulation is a challenge when it comes to user involvement (J. L. Martin et al., 2008). Companies may believe that it will be too much trouble to get approval for user involvement, or that it will not be possible to do so.

**Technology-driven**

"Users are not usually brought in to the developmental process until after a design brief for a new product has been produced. This may be because medical devices are frequently technology-driven rather than arising from an identified unmet need" (J. L. Martin et al., 2008). For the medical device industry to shift to a more user-centered design approach, they would likely need to do more "needs-finding" with users to guide their decision-making process for what future products to bring to market to serve unmet needs in the medical care community. This "needs finding" would need to not only be limited to interviewing high-ranking leaders in the medical system, but discovering needs in the lives of the patients themselves.

## 2.3 SELECTION OF FEEDING PUMP HANGING EQUIPMENT FOR STUDY

Feeding pump hanging equipment was selected as a focus area for this study because the researcher had previous experience using the equipment in a home setting and had encountered many problems with it. The researcher had also observed that other friends and acquaintances had similar problems with the equipment. This led the researcher to believe that the problems were likely widespread and would be a good area of investigation for this project.

## 2.4 INTRODUCTION TO ENTERAL NUTRITION

Enteral feeding has been in existence in some form for 3,500 years (White & King, 2014). Modern enteral feeding involves the delivery of a liquid formula into either a patient's stomach or the jejunum, the upper part of the small intestine. Feeding tubes may be inserted through the patient's nose and down the esophagus, in the case of nasogastric or nasojejunal tubes, or surgically through a hole in the patient's skin and directly into the stomach, in the case of gastrostomy or gastrojejunostomy tubes (Delegge, 2002).

*Figure 1.* **Nasogastric Tube**

*Figure 2.* **Gastrostomy Tube**

People who have difficulty transferring food from the oral cavity into their stomach may use enteral nutrition. These patients may have neurological dysfunction, upper gastrointestinal cancers, anorexia, or failure to thrive (Delegge, 2002). Other diseases that may be associated with feeding tube use include Chron's disease, cystic fibrosis, dysphagia, gastroparesis, pancreatitis, gastrointestinal mobility disorders, premature birth, congenital heart defects, genetic syndromes, and renal disease. Most patients who use feeding tubes use a specialized liquid formula meant to provide complete nutrition. Use of a "blenderized diet" of regular foods rather than formula is also growing in popularity (K. Martin & Gardner, 2017).

## 2.5 PREVALENCE OF ENTERAL NUTRITION

A 2013 study estimated that there were 436,874 individuals in the United States utilizing home enteral nutrition. This represented a 187% increase since 1992. The 2013 study acknowledges that their number could actually be an underestimation because it only utilized data related to insurance claims, so people who purchased supplies out of pocket or used home-made blenderized foods may not have been counted in their study. They estimated that among the users of home enteral nutrition, 43.8% are pediatric patients and 56.2% are adult patients (Mundi, Pattinson, McMahon, Davidson, & Hurt, 2017). It is believed that the use of enteral feeding at home is becoming more and more widespread (Alsaeed, Furniss, Blandford, Smith, & Orlu, 2018).

## 2.6 METHODS OF TUBE FEEDING

Some patients with feeding tubes are fed through "bolus feeding," which involves pushing the formula into the tube using a syringe. Other patients are fed through "gravity feeding," in which the formula is poured into a "gravity bag" attached to the feeding tube (K. Martin & Gardner, 2017). The bag is hung at a higher level than the patient's stomach, and the formula is allowed to flow in by gravity. An adjustable wheel on the gravity bag's

*Figure 3.* **Gravity Feeding Through Syringe** (youtube.com)

*Figure 4.* **Bolus Feeding Through Syringe** (youtube .com)

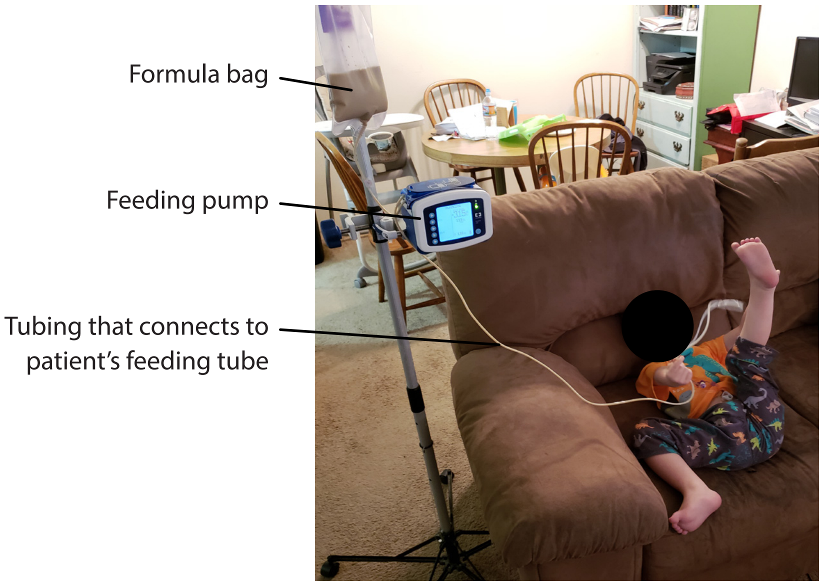



*Figure 5.* **Feeding Pump System**

tubing allows some control over the flow rate. Gravity feeding may also be achieved through a open-backed syringe. Patients who cannot tolerated bolus feeding or gravity feeding use feeding pumps. Most feeding pumps involve two main components, a plastic bag containing the formula with long tubing at the end to attach to the patient's feeding tube, and a peristaltic pump to push the liquid through the tubing at a programmable rate. Recently, an international standard was established for the way feeding pump tubing connects to the patient's feeding tube. These new connectors are called "ENFit" and are intended to reduce errors in connections (K. Martin & Gardner, 2017).

## 2.7. COMMONLY USED FEEDING PUMPS

A survey of 433 US-based feeding pump users found that 61% of users use the Enteralite Infinity Enteral Feeding Pump (Moog), 37% have the Kangaroo Joey Enteral Feeding Pump (Covidien), 1% have the Kangaroo ePump Enteral Feeding Pump (Covidien), and 1% have the Kangaroo Connect Enteral Feeding Pump (Covidien). 90% of survey respondents were caregivers describing a baby/child user, and 10% were adult users.

The Enteralite Infinity Pump and Kangaroo Joey Pump are both designed for home use. They are relatively lightweight, weighing 2.5 lbs and 3.5 respectively, including the weight of 500 mL of water in the feeding bags. Their small size and weight make it possible for ambulatory patients to carry them around in specialized backpacks. The Kangaroo ePump is more commonly used in hospital settings, and does not appear to have been designed for home use or backpack portability. The Kangaroo Connect Pump claims to be "the first enteral feeding pump with wireless connectivity" (cardinalhealth.com) and is for use both in hospitals and at home.

## 2.8 SUPPORTING EQUIPMENT FOR FEEDING PUMPS

Patients typically receive their pumps through a durable medical equipment


Infinity Pump

**61%** of US users


Kangaroo Joey Pump

**37%** of US users


Kangaroo ePump

**1%** of US users


Kangaroo Connect Pump

**1%** of US users

*Figure 6.* **Commonly Used Feeding Pumps**

supplier. These companies are reimbursed a monthly rental fee for the pump through the patients' insurance plans. The patients also typically receive monthly shipments of the feeding bags, since the feeding bags are intended to be used for 24 hours and then disposed. The durable medical equipment suppliers typically provide the patients with an IV pole on which to mount the feeding pump. They may also supply the patient with a backpack to place the pump in, but this isn't always the case as insurance companies often don't consider the backpacks to be medically necessary.

*Figure 7.* **Feeding Pump Backpack and IV Pole**

**Alternative feeding pump holder designs**

A few feeding pumps that are available outside the USA have smaller frames that are neither IV poles nor backpacks. This equipment looks like it would potentially be more portable for travel and more convenient for patients, but does not appear to be available in the USA.

*Figure 8.* **Abbot Freego**

*Figure 9.* **Nutricia Flocare Infinity**

The Kangaroo Connect, which is available in the USA, has the option to clamp the pump straight to a table, but the bag must still be held above the pump. Instructional

*Figure 10.* **Kangaroo Connect Pump**
(cardinalhealth.com)

videos show an image of a small, table-top IV pole being used to do this. This pump appears to be fairly new, and very few survey respondents reported using this pump.

The "FreeArm Tube Feeding Assistant" is a very recent product (estimated to have been released Jan 2019) that seems primarily directed at users of an open syringe for gravity feeding. It is a flexible stick with clips on each side. One side can clip to a surface like a piece of furniture, and the other side can clip to the syringe. However, the website also shows users using this to hold the feeding bag above the Infinity pump and clipping the pump and bag to a surface. Interestingly, this product was developed by parents who had a tube-fed child.

*Figure 11.* **Freearm Tube Feeding Assistant**
(freearmcare.com)

## 2.9 EFFECT OF ENTERAL FEEDING ON PATIENTS AND FAMILIES

In general, "the growth in unmet home care needs, particularly for long-term care, is resulting in an increasing burden on family caregivers" (Landers et al., 2016). Many studies have looked specifically into the effects of home-based enteral feeding on families and caregivers. Enteral feeding has been found to have considerable physical, social, and psychological effects on the lives of patients and their caregivers (Day, 2017). One study found that caregivers of children with chronic diseases who utilize home enteral nutrition are at risk of feeling burdened and experiencing a high level of anxiety and psychological distress (Pedrón-Giner, Calderón, Martínez-Costa, Gracia, & Gómez-López, 2014). One meta-analysis on the psychological effects on mothers of tube-feeding their children concluded that there were more questions than answers regarding the long-term developmental outcomes for tube-fed children and their parents, but that it was important to learn more about the impact of tube feeding on their parents, since the children are dependent on their parents for everything (Wilken, 2012).

In a survey of parents who had been using a feeding pump to feed their children at home for one year, sleep disturbance, frequent tube dislodgement, tube blockage and entanglement, and faulty pumps were cited as the main problems (Evans, Holden, & MacDonald, 2006). However, the issues addressed in this survey included overnight feeding, tube problems, pump usage and servicing, home delivery of feed and equipment, and obtaining and managing feeds. It does not appear that this survey sought to investigate the issues surrounding pump hanging equipment like IV poles and backpacks. One more recent study did make mention of the extra equipment involved in tube feeding, and noted that feeding pump users are typically attached to the pump for a large portion of the day, which can make it difficult for them to go places. This study also pointed out that because home enteral feeding involves large amounts of formula and equipment, patients can feel that it's too difficult to go on trips (Day, 2017).

With the exception of the aforementioned study, the majority of studies into home-based enteral nutrition have focused on clinical outcomes of the patients, the safety and accuracy of the pump's delivery of formula to the patient, and the general psychological well-being of the caregiver. While all these issues are critically important, the area of the supporting equipment for the pump appears to be generally unexplored. One master's thesis has explored a design concept for a more discreet and portable enteral feeding pump system for adults that would be worn under the clothes (Cindy Sjoblom, Umea Institute of Design).

## 2.10 FEEDING PUMP SUPPORTING EQUIPMENT AS AREA OF FOCUS IN THIS STUDY

The researcher became interested in this particular area of study after having personal experiencing caring for a family member who used feeding pump equipment in a home setting. In this experience, multiple issues were encountered with the supporting equipment for the feeding pump. Potential for improvement on current designs was identified in three main areas: functionality, aesthetics, and comfort.

**Functionality**

The IV pole was large and heavy and could not be taken outside the home. Later, a foldable IV pole was acquired. This pole could still not fold small enough to fit into a suitcase so it could not be used when travelling. The IV pole could not be used in different situations in daily life when the feeding pump needed to be used, such as in the car, while the child was riding in a stroller, etc. The backpack could be used in some of these settings, but was at risk of tipping over unless it was hung from something to keep it upright. If the backpack tipped over, air would enter the feeding pump tubing and cause an error on the pump.

**Aesthetics/Emotional Reaction**

Both the IV pole and backpack were very institutional looking and did not match the aesthetic of any consumer children's products. This led to an increase in emotional distress by acting as a constant reminder of the family member's medical needs.

**Comfort**

The IV pole had many sharp edges near the bottom, leading to a risk of injury if the child was crawling around near it.

The backpack was too heavy for the child to wear, because it weighed more than 10% of the child's body weight. However, because the backpack was sized for a small child, it was also too small for the caregiver to comfortably wear while transporting the child.

**Possible reasons for poor design in feeding pump hanging equipment**

Feeding pump equipment is subject to many of the "barriers" to user-involvement in medical design identified in the section 2.2, making it an interesting topic to explore for a design project with user-involvement in the design process. Feeding pumps are used in the treatment of a variety of medical conditions and by patients of all ages (diversity of the user group). They may be used by lay users with no medical training and varying backgrounds (diversity of the user group, failure to consider users who don't have seniority). In a hospital setting, feeding pumps are operated by nursing staff, rather than "higher ranking" individuals like doctors and surgeons (failure to consider users who don't have seniority). Feeding pumps were originally designed for use in hospital settings, but the designs have now "migrated" to home settings (complexity of the system). Most patients in the USA don't pay for their feeding pumps out-of-pocket, but get them through their insurance. Their insurance usually pays a monthly rental fee to a medical supply company, who provides the feeding pump to the patient. The patient and/or caregiver may not be asked which brand or model of feeding pump they would prefer to receive, and though they could likely switch medical suppliers if necessary in order to get a different type of pump, this would require effort on their part. Feeding pump users don't typically have the same ability to "comparison shop" in the same way most consumers are accustomed to when deciding which product to use (disconnect between purchasers and usability).

While the description of these barriers may serve as an explanation for the current weaknesses in the design of feeding pump hanging equipment, it also indicates the potential to improve the design of feeding pump hanging equipment by involving users in the design process.

## 2.11 CAREGIVER-DRIVEN INNOVATION

In addition to the "formal" innovation of the parents who created the FreeArm tube feeding assistant, many innovative caregivers come up with their own "DIY" solutions for feeding pump equipment. An initial internet search revealed that some innovative caregivers are already working on solutions of their own to improve IV poles, since what was provided to them at the outset did not sufficiently meet their needs. Many people decorated their IV poles or modified consumer children's backpacks to use in place

Small frame constructed with PVC pipes

Towel bar and hooks mounted above bed

Kids' backpack retrofitted to hold feeding pump

Decorated IV pole

Hanger used to hang feeding bag in hotel room

*Figure 12.* **User Innovations and Modifications**
(via Google images)

of the generic black backpacks provided by medical suppliers. Some people made their own smaller IV poles by using PVC pipes. Others used innovative hanging solutions like hanging a feeding bag from a hotel lamp with a hanger, or mounting hooks and towel bars on the wall next to the bed to use in place of an IV pole. The fact that many caregivers are working out their own solutions because the standard equipment was not meeting their needs reinforces the prevalence of this problem.

# CHAPTER 3: RESEARCH METHODOLOGY

A case study was performed to test a design method of involving users in the design process of a medical device. The design method employed qualitative descriptive research to observe the use of feeding pump equipment in a natural setting and understand difficulties users have with feeding pump equipment in their homes. In phase one of the study, qualitative data was gathered through direct observation, minimally structured interviews conducted in a conversational style, and photographs. Following phase one, a prototype was developed based on the users' ideas. In phase two of the study, the users tested the prototypes on their own with minimal guidance, and their reactions and feedback were gathered in a follow-up interview. The final design outcome was based on the users' feedback after prototype testing.

## 3.1 PARTICIPANT SELECTION

Four families who use feeding pumps to deliver nutrition to their children participated in this study. Three of the families were found through word-of-mouth and social media, and the other was an acquaintance of the researcher. To be eligible for the study, participants had to be home-based caregivers of a child with a feeding pump, speak English, and be over the age of 18. Across the four families that were interviewed, formal responses were gathered from four mothers and one father. Across the four families that were interviewed, five children used feeding tubes, since one family had two children who used feeding tubes. Three of the families were located in the greater Houston area, so the researcher was able to visit them in their homes. The other family was located out-of-state, so interviews took place over the phone, instructions and forms were explained over the phone and delivered by email, pictures were collected via email, and the prototype was delivered via mail.

Much of this study was designed around a basic understanding of the lifestyle of the type of participants that were desired. It was assumed that since the participants had children with medical needs, they were likely to be busy, and likely to have difficulty finding childcare. For these reasons, the study was designed so that the participants would not have to leave their homes or find childcare to participate. All travel would be done by the researcher. While it would have been interesting to get the participants together as a group and have them share ideas with one another, it was decided that this would likely be too difficult to arrange given their lifestyle constraints, so a decision was made to have all the research take place in the individual homes of the participants.

## 3.2 PHASE ONE OF USER RESEARCH

In phase one, the researcher visited the participants in their homes to interview them about their experiences using the feeding equipment. During the home visits, the following questions were asked:

- Where do you typically feed your child? How do you set up the equipment for that?
- How many times a day do you feed your child?
- Do you ever feed your child away from home (such as in the car, at a doctor's appointment, at a park, etc.?) How does that setup work?
- Do you feed your child overnight? How does that work?
- Have you ever travelled out of town with the feeding pump? What equipment did you bring with you? How did that work?
- What are the hardest and easiest parts of using the feeding pump with your child?

The questions were asked in a conversational style, with additional follow-up questions asked depending on the responses given to the initial questions. The participants were also asked to show the researcher the different locations in their home and car where they fed their children, and the researcher took pictures of all these locations. The participants were asked to demonstrate any problems they had with the equipment, and the researcher took pictures of those things.

## 3.3 PHASE TWO OF USER RESEARCH

In between phases one and two of the user research, the "works-like" prototypes for the feeding pump holder system were developed based on the ideas shared by the participants in phase one. A works-like prototype is a prototype that works the same way that a final design will work, but doesn't look the same way that the final design will look. Two different prototype systems were developed, and both were tested by the participants. The testing and validation phase of the research was executed over a period of a few weeks. Because there was only one sample of each prototype, testing with the participants had to take place in sequence rather than concurrently. The participants were given written and verbal instructions as to how to use the prototypes, and were instructed to keep the prototypes for about four days and test them on their own. During the testing period, they could record their observations about the prototypes in a "Prototype Testing Diary" form that was left with them. The Prototype Testing Diary asked the subjects to record their observations while using the prototypes, including the places they used it, the problems or difficulties they had while using it, and the helpful or good things about it.

At the end of the testing period, the researcher returned to the subjects' homes to collect their feedback about the prototypes. The subjects filled out a final questionnaire, the "Prototype Evaluation Form," which served as a comparison tool for the prototypes. This questionnaire was intended to serve as a comparison tool to see which system worked best for the participants: their current method, prototype Concept 1, or prototype Concept 2. The questionnaire asked the participants to rate various aspects of each system on a 10-point scale. The following aspects were asked about:

- How easy is it to use overall?
- How easy is it to use at home?
- How easy is it to use away from home in daily life, i.e. while leaving the house to go to a doctor's appointment?
- How easy is it to use away from home when going on an overnight trip, i.e. going to a hotel, staying with a relative, or going camping?
- How easy is it to setup a feed?

- How easy is it to clean the feeding bag after a feed?
- How much do you like the system?

For the prototype systems, the users were asked to guess how easy it would be to take it away from home if they did not have a chance to do so during their testing period. Finally, the participants were asked to choose which was their preferred system.
This evaluation was used to determine which style of prototype, if any, should be moved along in the design process and refined to create the final design.

# CHAPTER 4: PHASE ONE RESULTS AND ANALYSIS

## 4.1 GENERAL SITUATIONS OF PARTICIPANTS

| Participant Number | Parents Interviewed | Age of tube-fed children | Feeding Schedule | Pump Used | Tube Type | Length of experience with tube-feeding |
|---|---|---|---|---|---|---|
| 1 | Mother and Father | 4 years | 8 hour overnight feed | Kangaroo Joey | Nasojejunal | 5 months |
| 2 | Mother | 3.5 years, 9 months | 4 times a day for 1 hour, 4 times a day for 1 hour + a 3 hour nighttime feed | Kangaroo Joey | Gastrostomy | 3.5 years |
| 3 | Mother | 4 years | 5 times a day for 1 hour + slow overnight feed | Infinity | Gastrostomy | 3 years |
| 4 | Mother | 12 years | 4 times a day for 2 hours | Kangaroo Joey | Gastrostomy | 9 months |

*Table 1.* **Participant Situations**

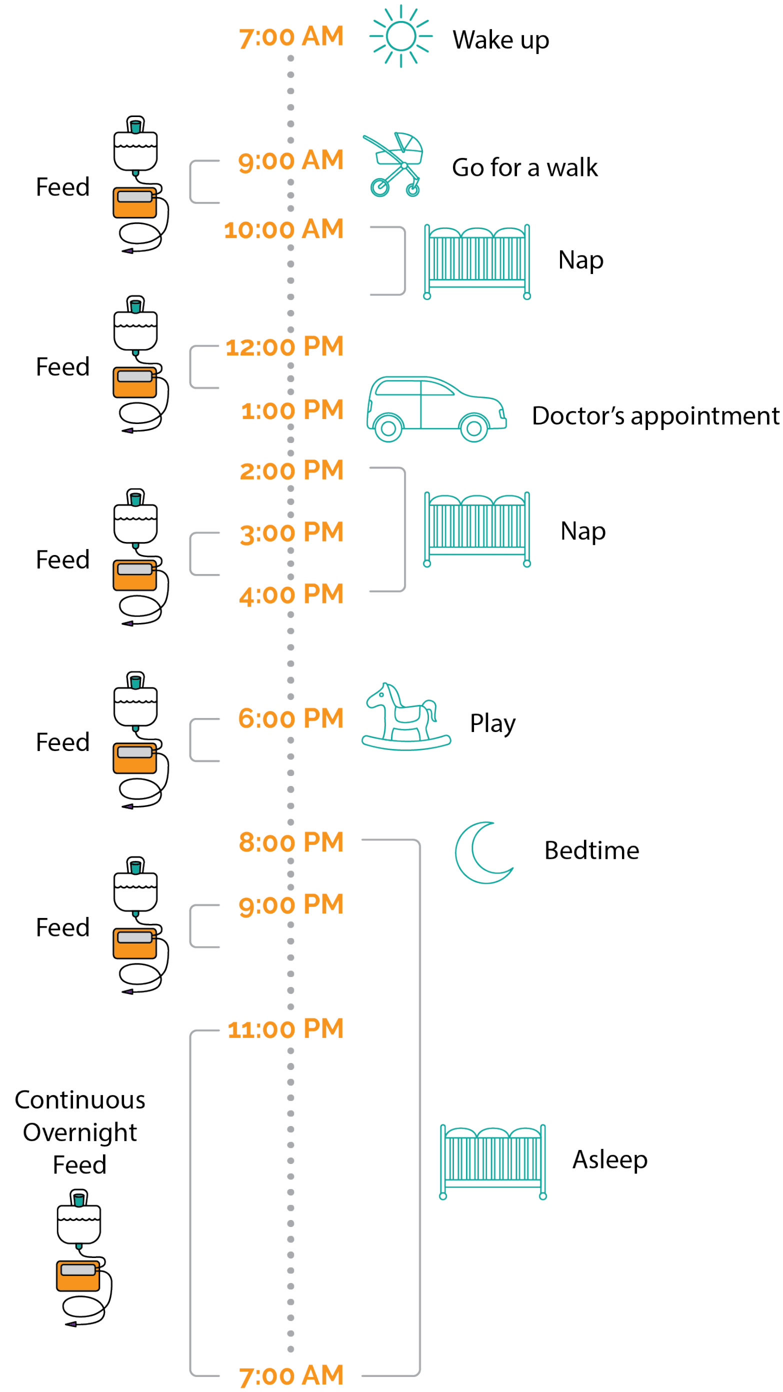



*Figure 13.* **Typical Daily Schedule of a Tube-fed Child**

**Feeding Situations**

The participants in the study ranged from 3 months to 5 years of experience using feeding pumps to feed their children. Four of the children used gastrostomy tubes, and one used a nasojejunal tube. One child was fed just during the night, one just during the day, and the other three were fed both day and night. Daytime feeds lasted from one to two hours each, occurring three to five times a day. Nighttime feeds lasted up to eight hours. Three of the participants used the Kangaroo Joey pump, and one used the Infinity pump.

**Locations that the participants reported feeding their children:**

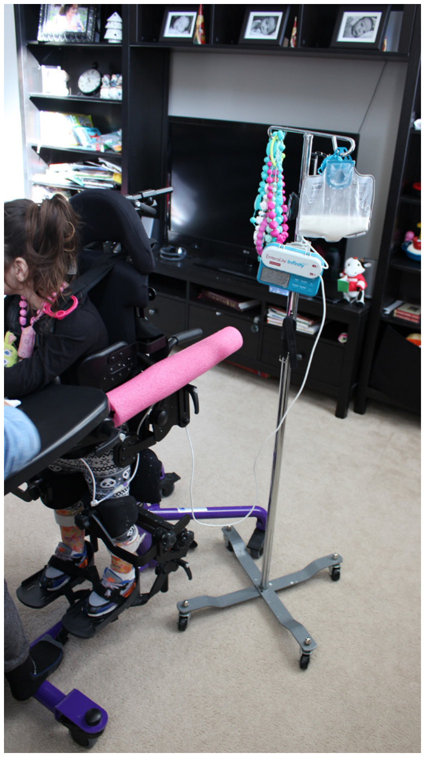
- Bedroom while child is asleep
- Other rooms of the house
- Car
- Other people's houses
- Restaurants
- Zoo/Renaissance Festival/Mall

IV Pole next to regular bed

Medical bed

*Figure 14.* **Feeding Locations Identified in Research**

In a car (medical car seat)



Child feeding while in standing frame

Walker

Feeding while lying on the floor

Medical Stroller

*Figure 15.* **Feeding Locations Identified in Research Continued**

- Doctor's appointment
- Camping (tent)
- Hotel

**Specific locations the children were in during feeds:**
- Couch
- Floor
- Bed
- Crib/portable crib
- Medical bed (special medical bed designed to keep the child safe at night. This bed had a built-in IV pole.)
- Wheelchair
- Gait trainer
- Stander
- Stroller

## 4.2 PARTICIPANTS' EXPERIENCE WITH THE IV POLE

All the participants in the study used an IV pole regularly to hang the pump at home. When asked what they thought worked well with using the pump on the IV pole, the participants reported that it was easy to load the formula when the bag was hanging from the IV pole, and it was easy to clean the feeding bag. One participant also pointed out that their child was able to wheel the IV pole around the house while attached to the pump when needed. (This was the only ambulatory child in the study, the other children would not have been able to do this.)

**Difficulties with the IV pole**

When asked what difficulties they had with the IV pole, the participants came up with a lot of answers. One pointed out that when the pump was mounted onto the IV pole, it was at a location that was difficult to see, and he had to kneel down in order to program the pump (Figure 16).

*Figure 16.* **Tall Adult Kneeling Down to Program Pump**

A general trend was that the participants felt the pump didn't really "belong" in their home. One said, "it has no good place to go in the house." Another reported that it gets in the way for other kids and family members. When the IV pole was next to the child's wheelchair, the pump tubing would be suspended between the IV pole and the child. This tubing became an additional trip hazard for the other children in the family. Participants had difficulty wheeling the IV pole around the house. One difficulty would arise if the floor was cluttered, because the parents would then have to clear a path in the room before rolling the IV pole to another room. Another difficulty was faced when the tube-fed child was sitting in a piece of equipment like a wheelchair, stander, or gait trainer. If one adult wanted to transport the child to another room during a feed without assistance from a second adult, it was extremely difficult to wheel the child and the IV pole simultaneously.

One participant pointed to the excessive number of hooks at the top of the IV pole as a indicator that it was meant to be in a hospital, not a home. Another participant agreed that the IV pole wasn't intended for the home, and said, "the home use stuff all feels like an afterthought. It all feels like it's designed for institutional use." Another complaint was that despite being so large, the IV pole had no spot to hold other essential items for tube feeding, such as the syringes used the flush the tube. Finally, one participant pointed out that because the IV pole was always located in the child's room and the pump was always on the IV pole, anytime they went into the child's room at night to set up a feed, the pump would make loud beeps in the room and risk waking up the children.

## 4.3 PARTICIPANTS' EXPERIENCE WITH THE BACKPACK

Only three out of the four participant families had a feeding pump backpack that they used regularly. For two of the participants, the backpack was their "go-to" solution for using the pump outside of the house. These participants felt that the backpack was

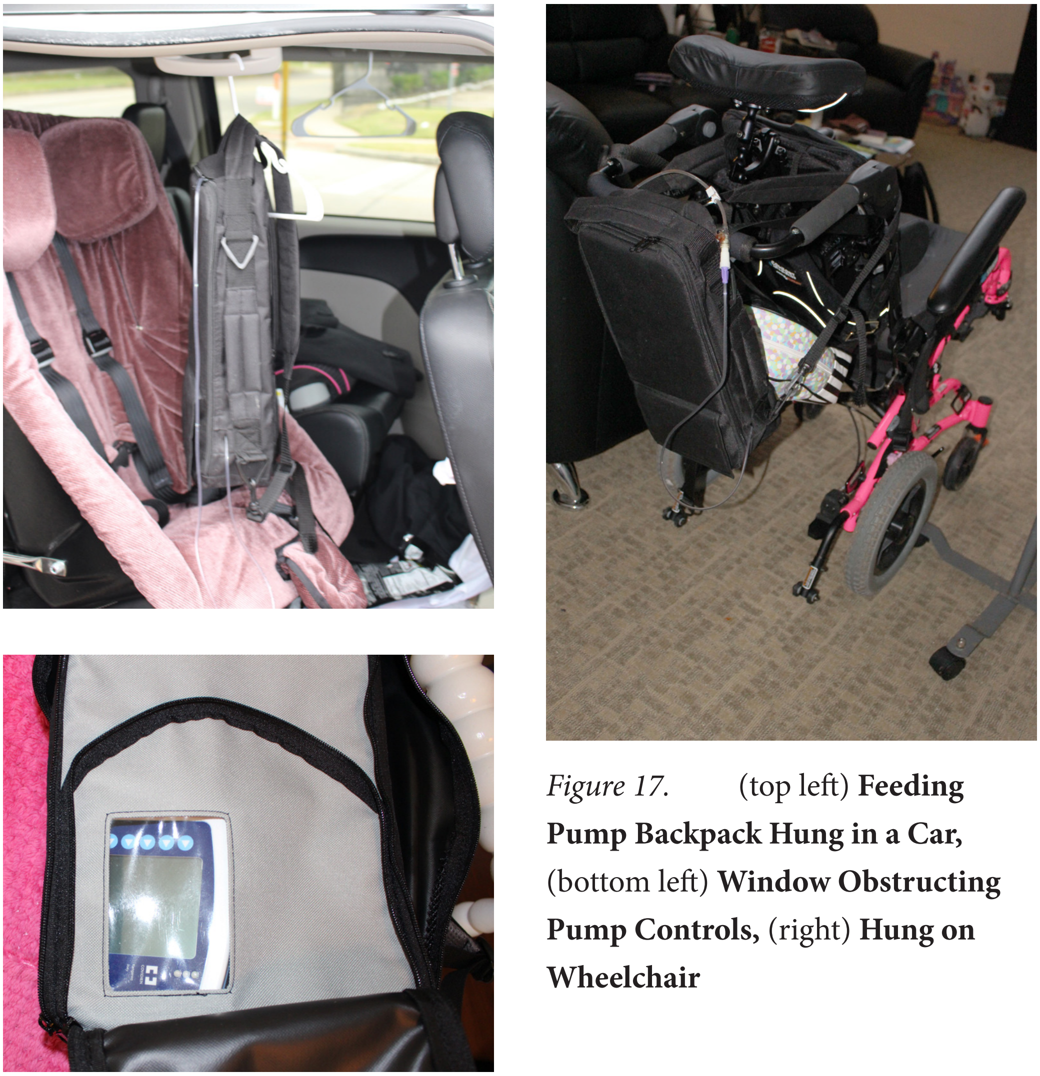


*Figure 17.* (top left) **Feeding Pump Backpack Hung in a Car,** (bottom left) **Window Obstructing Pump Controls,** (right) **Hung on Wheelchair**

a good flexible solution and that they could take it anywhere. However, they never used the backpack as it was intended (meaning worn on the back with the straps over the shoulders) and instead used it as a bag to attach to other things. Only one child in the study was completely ambulatory, and this child would have theoretically been able to wear the backpack as intended, but this child only used the feeding pump during the night when asleep, so the IV pole was used instead. The rest of the children in the study were either non-ambulatory or not strong enough to walk while wearing the backpack with the feeding pump in it. One participant reported sometimes wearing the backpack herself on one shoulder while carrying her child. One participant mentioned liking the fact that the backpack hid the equipment, allowing them to be discreet when going out. However, when asked further about this point, none of the participants said that it was very important to them to hide the feeding equipment, and none of them said they would be very concerned if the feeding equipment was visible when they were out. The reason some liked having it hidden was to avoid unwanted questions from strangers.

**Difficulties with the backpack**

One subject reported finding the backpack very confusing, and it was hard to figure out where the feeding pump and feeding bag were supposed to go inside the backpack. Interestingly, another subject had another style of backpack which had an attached instruction card inside the flap to show how to use it. One participant's backpack had a window that was meant to allow for control of the pump, but partially obscured the pump controls.

One participant, who frequently used the backpack outside of the house but the IV pole in the house, reported that other family members often wanted to help with the child's care, but they had difficulty transferring the pump from the backpack to the IV pole, so they would have to come get her to help them with that task, and this interfered with her ability to take a break from her child's care.

*Figure 18.* **Carabiner**

## 4.4 USING THE PUMP OUT OF THE HOUSE IN DAILY LIFE

When going out of the house in daily life, participants frequently came up with creative ways to attach the pump to different things. This usually involved either using a carabiner to hang the feeding bag and placing the pump in or on something else, or placing the pump and feeding bag into the pump backpack and hanging the backpack.

**Creative methods participants used to hang the pump in daily life:**

- Hung from back of their stroller with carabiner
- Hung feeding bag from back of the car seat with carabiner, and placed pump into pouch in car seat back


*Figure 19.* **Feeding bag hung from stroller with pump balanced on stroller** (via Google images)

- Hung backpack from ceiling handle of car with a coat hanger
- Hung backpack from ceiling hook in car
- Hung the feeding bag from gait trainer with a carabiner and balanced the pump

somewhere else on the gait trainer (though the pump would frequently fall off of this balanced spot)

- Hung bag from stroller with carabiner and placed pump into the stroller basket
- Hung the formula bag in cooler bag with ice when outdoors on a hot day

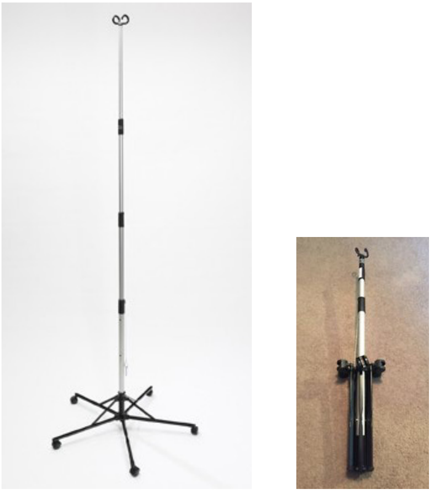


*Figure 20.* **Sharps Pitch-it IV Pole expanded and collapsed**

## 4.5 USING THE PUMP WHEN TRAVELLING

As a general trend, the participants seemed to have more difficulty using the feeding pump equipment in locations outside of their daily routine, such as while travelling. While at least one model of "portable" IV pole does exist and is distributed to some enteral nutrition patients, not all medical supply companies are giving this type of IV pole to their patients. Coram CVS Specialty Infusion Services, a large US durable medical equipment supplier, distributes the Sharps Pitch-it IV Pole, which can collapse and fold-up for travel (Figure 20).

Only one participant had been provided with this style of IV pole. The others all had been given heavy-duty, non-collapsible IV poles. One participant reported using a screw driver to take apart the non-collapsible IV pole to transport it to a relative's house. They said they certainly wouldn't do that again, as it was very hard to put back together and was more trouble than it was worth. Another participant had a spare IV pole which was kept at the grandmother's house for use when they travel there. When staying at a hotel, this participant used a bed rail guard on the hotel bed, and hung the feeding bag from this bed rail with a carabiner clip rather than bringing the IV pole.

When camping, another participant used a carabiner to hang the formula bag from something in the tent, and set the pump on something else so that it was about the right distance away. Another participant reported using the backpack when travelling, and would either set it somewhere or hang it from the child's wheelchair.

## 4.6 PARTICIPANTS' IDEAS FOR AN IMPROVED PRODUCT

The participants were asked for their ideas of how to improve the equipment. Every participant was able to come up with at least two suggestions of improvements, and many came up with even more.

**Ideas that the participants came up with to improve the hanging equipment:**

- Clip backpack to things with a clasp/buckle
- Attach the pump to things with a "grabber" like a flexible camera tripod
- Hang the pump from things like a bed, lamp, doorknob
- Mount the pump and feeding bag to bed frame
- Highlight key areas of backpack with a different color
- Give the backpack a more kid-friendly aesthetic
- Envisioned a vice/clamp to attach pump to various equipment, similar to the clamp that holds the pump onto the IV pole, and holds bag and pump together at the right distance so that the tubing between the pump and bag won't kink
- Wanted a way to hold or control the tubing, so it's not hanging down and getting tangled/tripped on.
- Wanted a place to store the little end cap so it doesn't get dirty.
- Wanted to take their child on an airplane trip, and wanted something that would work to use the pump on the plane.
- Wishes there was a remote for the pump so it could be easily silenced if it started to

beep while driving*
- Wishes they could know when the last feed was, how long it lasted, etc.*

*These ideas weren't directly related to the hanging equipment but were more related to improving the interaction with the pump itself

## 4.7 CONSTRAINTS FROM THE USER MANUALS

The user manuals of the two pumps were also reviewed to make sure the design continued to use the pumps within the manufacturers' recommendations. Some users mentioned that they thought the pump was supposed to be located above the level of the patient's head or body in order to work properly. However, this fact was not found in the user manuals. The Kangaroo Joey Pump manual said, "for optimal accuracy, the top of the starting volume of formula should be 6 inches above the pump" but made no mention of the height of the pump in relation to the patient. It also said there are two recommended placement methods for the KANGAROO JOEY Enteral Feeding Pump. 1) Attached to a vertical IV pole via the pole clamp peripheral device, included with the pump. 2) Placed on any stable surface."

The Infinity Pump manual said in regards to pump placement, "hang feeding bag or container so that the bottom of bag is at or above the level of the pump door...or, if an EnteraLite Infinity pack is to be used, load the pump and feeding bag into the proper compartments, securing pump, bag and tubing with the pack's straps."

# CHAPTER 5: PROTOTYPE DESIGN APPROACH

In spite of the fact that each family interviewed had a unique situation and unique needs surrounding their feeding equipment, the goal of this project was to design a single solution that could work for anyone. Therefore, the approach to designing the prototype was to try to incorporate everyone's needs into one design. It was thought that this may lead to the design having some features that were irrelevant to some users, but hopefully a wide enough net could be cast to cover the essential features for each user. The following considerations were identified and acted as guidelines for the duration of the ideation and prototyping process.

## 5.1 DESIGN CONSIDERATIONS

**Hangs from things**

Multiple participants mentioned a desire to hang the pump from various objects, such as a bed frame or doorknob. Participants already were hanging their pump from the stroller, car seat back, and ceiling handle in the car. In almost every instance of this, the participants were adding their own product to the feeding equipment to facilitate hanging, such as a carabiner clip or a clothes hanger. Though the feeding backpacks typically have handle at the top, this handle was in the form of a closed fabric loop and could not be used to hang the backpack from anything that didn't have a protruding hook. It was also considered that whatever material is used to interface with the objects to facilitate hanging should be non-damaging, so as not to cause scratches or tears on people's furniture or other objects.

**Clamping to things in the house**

Multiple participants also expressed a desire to clip or clamp the feeding equipment to various furniture or other adaptive equipment. One participant mentioned he thought it would work well to clip the feeding equipment to the bed frame. He suggested that something like a flexible camera tripod might work to grab onto different surfaces (Figure 21). Another participant pointed out that most of her daughter's adaptive equipment, like the wheelchair, stander, and gait trainer, had vertical poles on them (Figure 22). She saw a connection between these vertical poles and the IV pole, and figured that if the pump could clip to the IV pole, the pump could also clip to the vertical poles on the adaptive equipment in a similar way. The clip would need grab onto the vertical poles from the side, rather than sliding onto the end, since the ends of the poles were obstructed. Just as in the hanging equipment, the design of this clamp would need to be non-damaging to the surfaces that it attached to.

*Figure 21.* **Flexible camera tripod** (www.cgtrader.com)

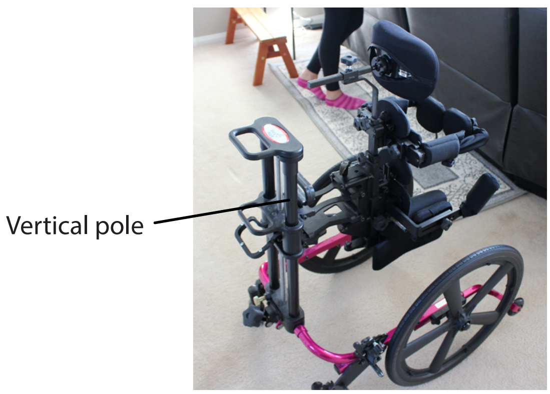



*Figure 22.* **Vertical poles on gait trainer**

**Freestanding option for unpredictable environments**

Multiple participants expressed that it was important for their family to be able to travel, and that they would sometimes stay in hotels, with relatives, or camp in tents. When visiting these environments, there is some level of unpredictability as to what furniture would be available to clip or hang the pump to. Because of this, it was determined that the most flexible solution would also include a self-contained option for the pump be able to stand up/prop up on its own without hanging from any other objects. This freestanding solution could be placed atop a table or even on the floor, depending on the situation.

**Interface between hanging equipment and pump**

Since it was determined that 98% of feeding pump users in the USA were using either the Kangaroo Joey pump or Infinity pump, and 100% of the participants in this study had one of those two pumps, it was concluded that the design should accommodate both of these pumps. Because the participants did not own the pumps, but had them provided through their insurance renting them from a durable medical equipment supplier, it was very important that the interface to attach the pumps to the new design did not damage the pumps in any way. It was also important that the design did not obstruct the pump controls, but that they remained easily accessible while the design was in use. The design should be able to hold up to 3.5 lbs, which is the weight of the heavier pump (Kangaroo Joey) will a full 500 mL feeding bag.

**Other potential features**

One other feature that was proposed by the participants was to have a place to keep the end cap of the tubing clean (Figure 23). Some current clamps used to connect the feeding pump to the IV pole do have a round cutout area that can be used for this purpose. One participant also proposed including a way to control excess tubing.

**Convenience**

The participants expressed that it would important for the solution to be quick to set up, and quick to move around. They thought it should be light-weight as well.

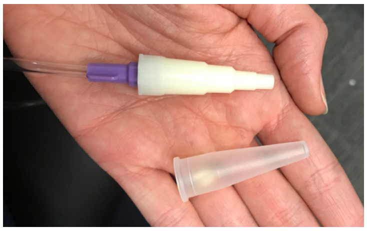


*Figure 23.* **Tubing end cap**

**Intangible emotional qualities**

Some participants expressed distaste for the clinical aesthetic of the hanging equipment they had been provided with. For example, one family had a feeding backpack that was completely black, and felt that its appearance was inappropriate for their child. They had been told that there used to be a colorful, tie-die patterned backpack which was no longer available. They said they would have preferred a design like this for a kid. Multiple participants also expressed that the IV pole did not have an appearance that they liked having in their home, and that it seemed very clinical. Since IV poles are a very commonly known and easily recognizable hospital item, there is a good possibility that seeing the IV poles in their home every day served as a constant reminder of their child's health problems. It was apparent that for at least one family, the symbolism of the IV pole felt out of proportion with their child's condition, because they didn't feel their child was sick enough to need such a hospital-like product in her bedroom.

## 5.2 DESIGN PROCESS

**Ideation**

The ultimate goal of the initial design phase of this project was to create a "works-like" prototype that could be produced quickly and inexpensively in order to be tested by users. The ideation process consisted of a combination of building simple models with cardboard, foam core, tape, and other inexpensive materials, drawing rough sketches of design ideas, and then moving into more sturdy materials like steel and aluminum to build mock-ups to test the ideas. Some existing off-the-shelf products were also used to test ideas, such as hooks, clamps, wheels, and music stands.

**Attaching to the pumps**

One of the design challenges this project faced was working with the existing feeding pumps and finding a way to attach the new system to the pumps. Various ideas were explored through sketching or through cardboard mock-ups. Some ideas that were investigated were to set the feeding pump inside of a cavity or rest it on something like a shelf. Eventually it was determined that these ideas wouldn't be able to hold the pumps very securely, or would require arms that came around the front of the pump and might obstruct the pump controls. Ultimately, it was decided that the best way to attach the pumps was to make use of their existing attachment mechanisms, since these would lead to a very secure connection that didn't obstruct the pump controls.

The Kangaroo Joey pump attaches to IV poles via a custom clamp, and there is also an intermediate piece that interfaces between the pump and the clamp. This intermediate piece screws onto the clamp and attaches to a round metal area on the back corner of the pump with a tightening lever. It is not difficult to remove the

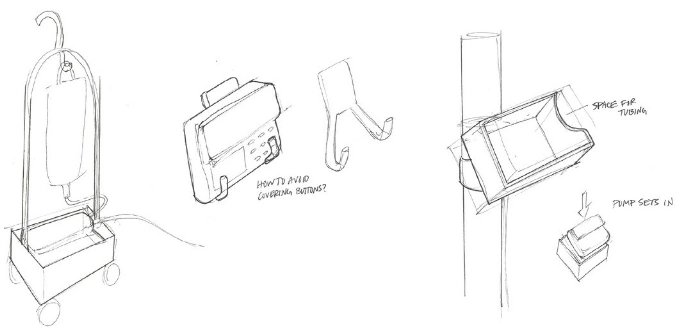



*Figure 24.* **Sketches of early pump attachment ideas**

intermediate piece from the clamp with a flathead screwdriver. It made sense to remove this intermediate piece and re-use it in the new design in order to avoid having to make any complex mechanisms that would attach to the pump, or in a sense, re-create the tightening lever. By creating a square hole on the bottom bar of the prototype, a spot was made to attach the intermediate piece with an additional washer and the existing screw.

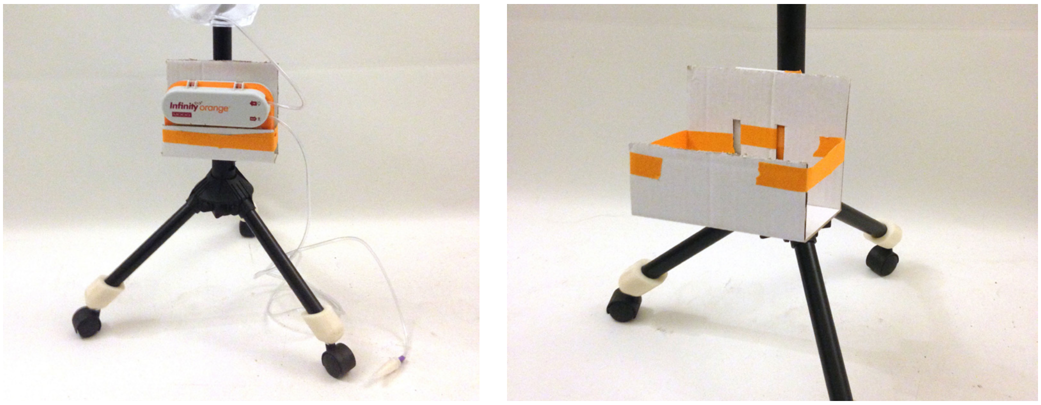


*Figure 25.* **Early mock-up of pump attachment**

The Infinity pump also attaches to IV poles with a custom clamp, and has a threaded hole in the back that allows the clamp to screw in to the pump. This threaded hole was a standard ¼ inch size and could take a standard machine screw of the matching size. This seemed to be the easiest way to attach to the Infinity pump to create a secure fit and not obstruct any controls.

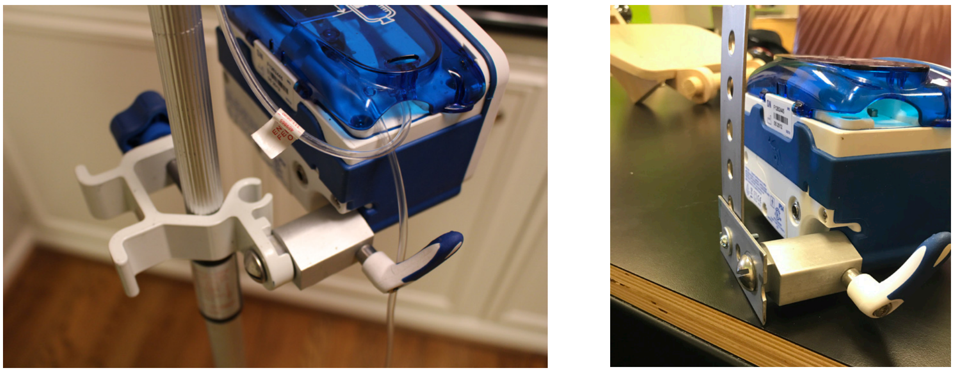


*Figure 26.* **Custom clamp on Kangaroo Joey pump, and intermediate piece attached to early prototype idea**

Creating one product that would be able to attach to both pumps posed a challenge, since the pumps had differences in not only their attachment mechanisms, but also the locations of attachment, size and shape of the pump, and size and shape of the feeding bag. The Kangaroo Joey pump has a much longer feeding bag (13 inches long) in contrast to the Infinity pump feeding bag which is 7 inches long. The Infinity pump screw

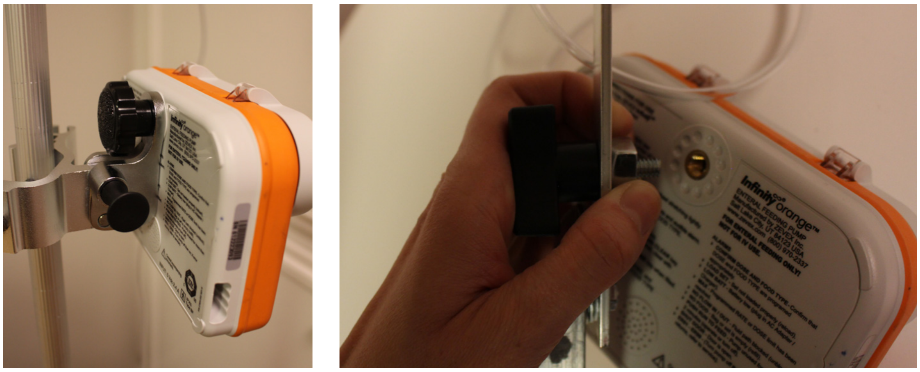


*Figure 27.* **Custom clamp on Infinity pump and attachment method on prototype**

connection area is along the center of the device, while the Kangaroo Joey connector is in the lower corner and about 2 inches off-center. Multiple ways of handling this size and shape discrepancy were considered, including making an extendable device with an adjustable, telescoping pole. However, this was decided against once taking into account the user scenario. Users were unlikely to be switching one device between pumps. The most likely scenario was that a user would purchase the device, then adjust it and attach it to the style of feeding pump that they are using. This adjustment would likely only take place one time, or at least very rarely, so it was decided that it wouldn't be necessary to have a telescoping device. Instead, a simpler solution was devised in which an L-shaped extension piece could be added on when the Kangaroo Joey pump was to be used. The L-shaped extension piece would simply not be needed if the Infinity pump was being used. This extension piece would attach with a screw and most likely only need to be attached once, upon initial setup of the device for use with the Joey pump.

**Top hanging method**

One major issue that was explored was how to address the function of hanging the device from different things. Multiple types of top mount mechanisms were considered, including a carabiner clip that could buckle around handles/bars, a Velcro strap that could attach around handles/bars, a flexible wire hook, and a fixed hook (Table 2). A hook was selected as the best solution since it would be able to attach to more types of surfaces. For example, a strap could go around a pole or beam, but would not be able to hook over a solid surface like the back of a chair. A hook, however, would be able to attach to both solid surfaces and open poles or beams. Adjustable size range hooks were considered, but before selecting this more complex option, testing was done to evaluate whether a fixed-size hook would be able to attach to a wide enough range of objects. A variety of sizes of hooks were collected and tested on different target objects, like stroller handles, back of chairs and beds, etc. (Figure 28). From this testing, a 2 inch width opening was selected as the most appropriate, and was found to be able to fit onto nearly every object tested. This was chosen for the final prototype design.

**Clamping mechanism development**

Another design aspect that required considerable exploration was the style of clamping/attachment that would be used. Multiple considerations were taken into account in selecting the best type of clamp for this application. One consideration was the desire to be able to clamp around both round profiles and square/rectangular profiles.

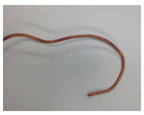
| Top Mount Style | Pros | Cons |
|---|---|---|
|  **Carabiner** | - Won't slide off<br>- Long-lasting | - Limited in size and type of object it can hook to<br>- Fixed size |
|  **Flexible wire** | - Flexible, changes sizes/shape<br>- Thin, can fit on many types of surfaces | - Could wear out over time |
|  **Fixed hook** | - Thin, can fit on many types of surfaces<br>- Long-lasting | - Fixed size |
|  **Velcro strap** | - Adjusts to different lengths<br>- Fits to different shapes<br>- Won't slide off | - Must have a hole/opening in object to connect<br>- Could wear out over time |

*Table 2.* **Top Mount Evaluation**

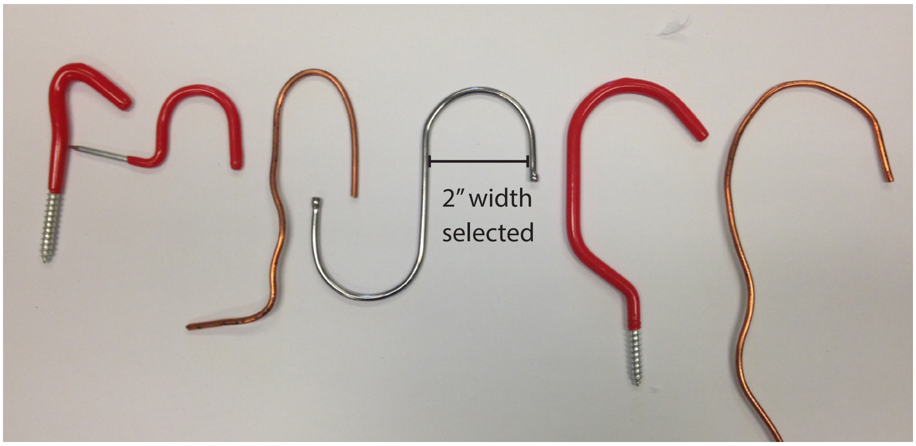



*Figure 28.* **Hooks for testing**

Another consideration was the fact that the clamp would need to be able to grab onto the pole/beam from the side, rather than sliding in on the end. Therefore the clamp would need to have a side opening to facilitate this. It was also important that the clamp type not rely on the hand strength of the user to be able to tighten securely. (The majority of the users were expected to be female, and females tend to have less hand strength than males.) Intuitive use was also important, since the target users of this product may not have much experience using clamps. Many clamps are commonly used in applications like carpentry or weight lifting, but it wasn't expected that the target users of this product would necessarily be familiar with those areas. The clamp should be fairly quick to adjust, and easy to remove if needed. The clamp should have an overall small size so as not to get in the way or interfere with other equipment. Various household objects that a person might want to clamp the equipment to were measured, and the determined width range was 0.5” to 2” that the clamp should be able to adjust to. A number of different clamp styles were tested and the pros and cons of each were considered before selecting a final mechanism style for the clamp (Table 3). From the styles of clamps considered, clamp type 3 was selected because of its open side, its small, unobstrusive design, its ability to adjust to the desired range of lengths, and intuitive use. Though the pictured design would not be able to attach to both round and rectangular profile shapes, the design was modified to enable this (Figure 29).

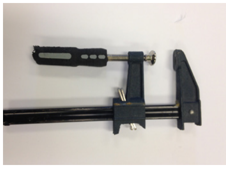
| Clamp style | Pros | Cons |
|---|---|---|
| 1)  | - Continuous adjustability<br>- Fast release<br>- Slides in from side<br>- Range of widths | -Only rectangular shapes<br>- Not obvious how to use the release mechanism |
| 2)  | - Fast release<br>- Slides in from side<br>- Range of widths<br>- Padded contacts | - Only rectangular shapes<br>- Requires bulky handles in order to get leverage<br>- Relies on user's grip strength |
| 3)  | - Fast release<br>- Slides in from side<br>- Range of widths | - Only rectangular shapes<br>- Relies on user's grip strength<br>- "Notches" of adjustability<br>- Requires bulky handles in order to get leverage |
| 4)  | - Continuous adjustability<br>- Slides in from side<br>- Range of widths<br>- Small<br>- Obvious how to use it | - Only rectangular shapes<br>- Slower release |
| 5)  | - Fast close<br>- Fast release<br>- Small | - Limited range of widths<br>- Only circular shapes<br>- Must slide in from top |
| 6)  | - Fast close<br>- Fast release<br>- Small | - Limited range of widths<br>- Only circular shapes<br>- Must slide in from top |

*Table 3.* **Clamp Evaluation**

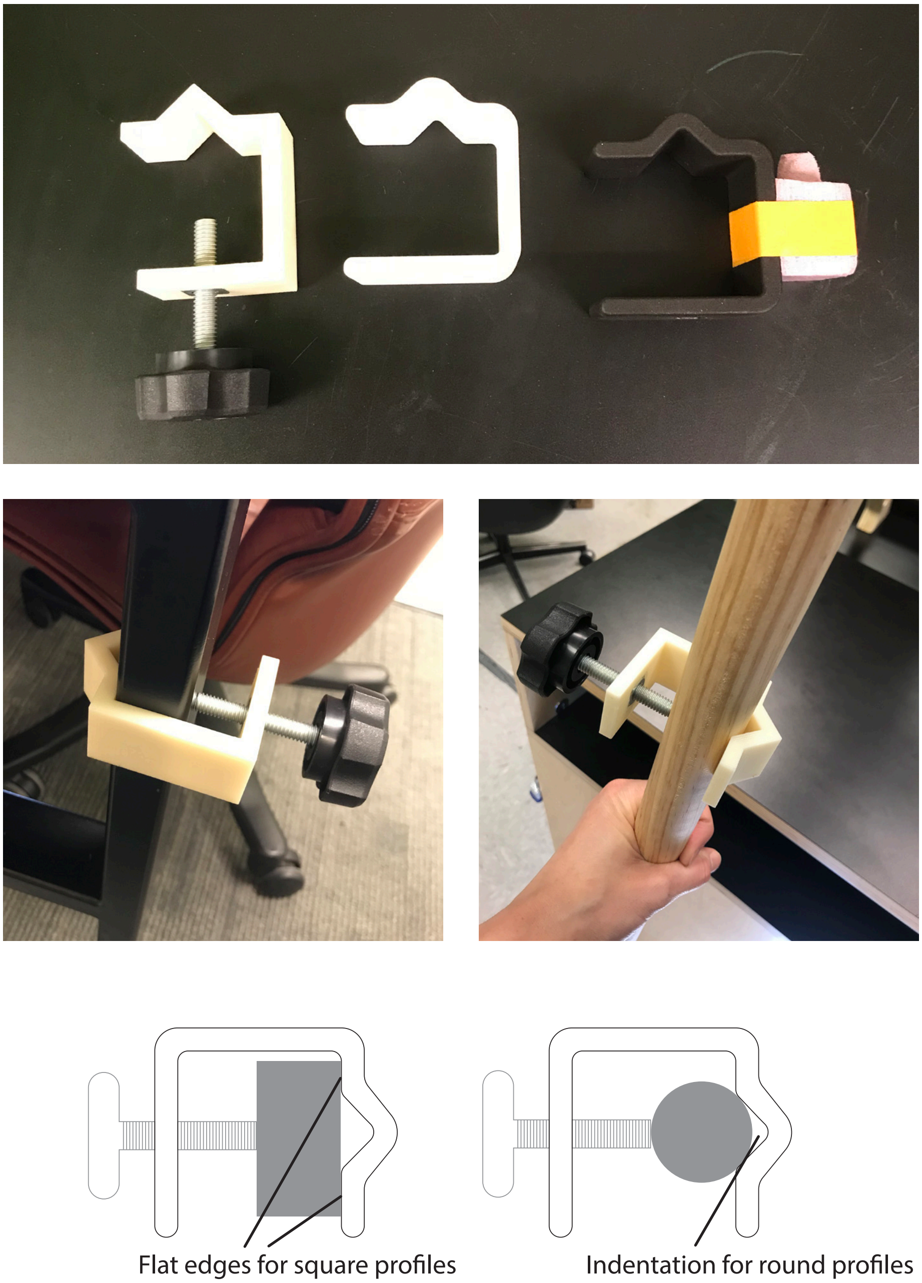



*Figure 29.* **Clamp profile development including 3D-printed clamps for testing**

**Quick-release mechanism**

In exploring how to best implement the clamp, a "quick-release" mechanism was desired, but none of the more "quick-release" style clamps seemed appropriate for this application. Another idea was devised which was to create a second mechanism to quickly attach and detach the main frame from the clamp. In this idea, the clamp would remain as-is, but the second mechanism would serve as the "quick-release" feature. A dovetail joint was explored, but this style of attachment, though quick to attach and detach, didn't seem like it would be secure enough and could get jostled out a place. So other types of mechanisms were investigated. Eventually, a "plate-mount retractable spring plunger" component was selected, since it would provide for a quick-release, a secure connection, and could be easily implemented into the prototype design.

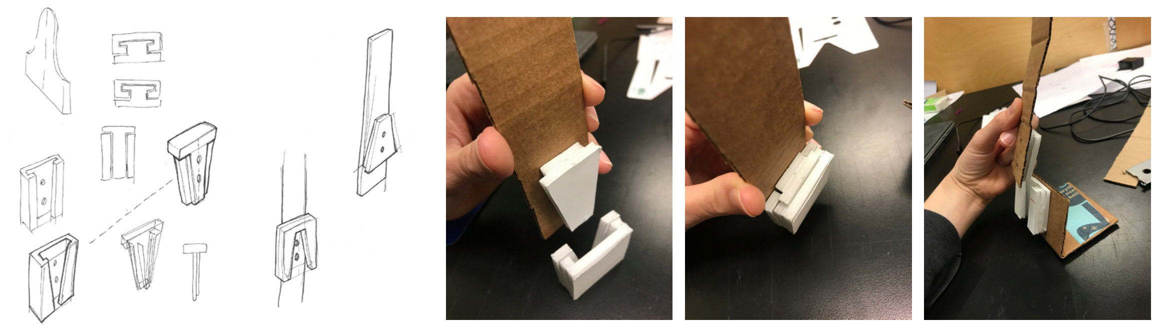


*Figure 30.* **Quick-release feature exploration**

*Figure 31.* **Plate-mount retractable spring plunger**


*Figure 32.* **Exploration of ideas**

## 5.3 PROTOTYPE DESIGN

**Two versions of the prototype**

Though it wasn't initially planned to create two different versions of the prototype to be tested, after the development of the quick-release feature, it was determined that it would be best to test two versions of the prototype: one with the quick-release feature, and one without it. The first version, called "Concept 1: All-in-one System" did not have the quick-release mechanism, and contained all components in a single unit. This version of the prototype included a hook at the top, a clamp at the back, and was able to stand up on it's own. The Kangaroo Joey pump has a rectangular shape and is fairly heavy, so it was able to serve as its own base in Concept 1. For the Infinity pump, the clamp served as a stand when tilted back, so this pump was able to stand on its own as well.

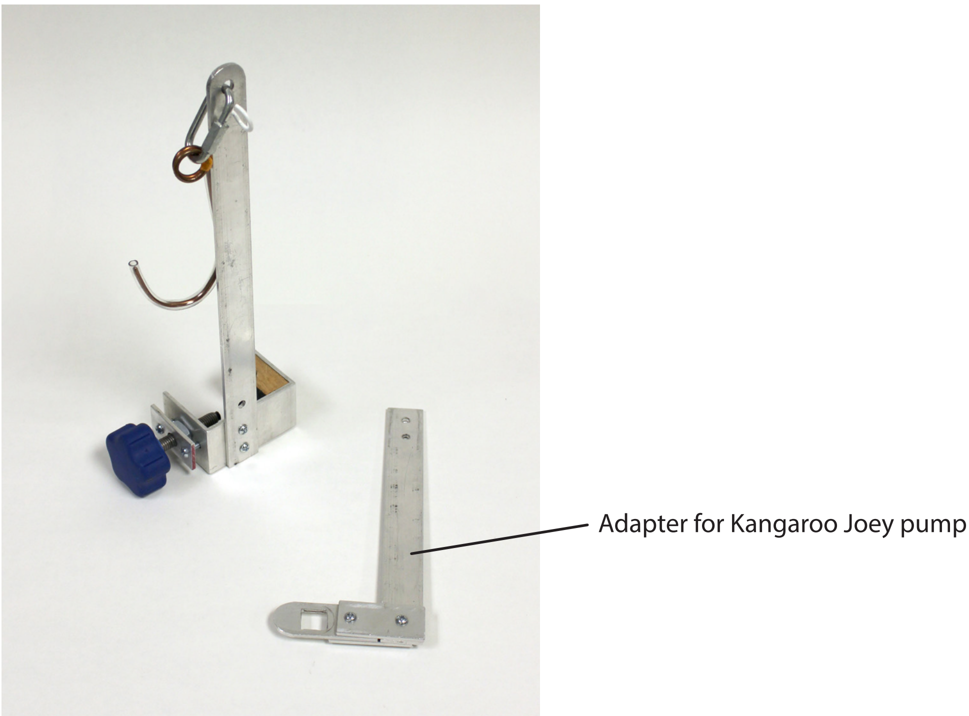



*Figure 33.* **Concept 1: All-in-one System**

*Figure 35.* **Concept 1 using Kangaroo Joey pump**


*Figure 34.* **Concept 1 using Infinity pump**

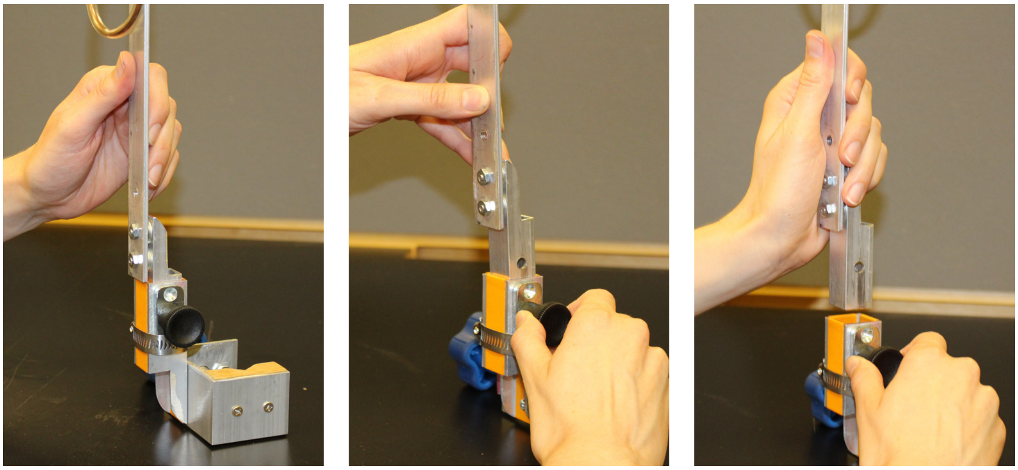


*Figure 36.* **Quick-release mechanism**

*Figure 37.* **Concept 2: Quick-release system**

The second version, called "Concept 2: Quick-release System," utilized the quick-release mechanism. It had separate pieces, consisting of the main body of the design which attached to the pump and had a hook at the top, two identical clamps, and a stand. In the case of this prototype, the stand was constructed from a repurposed guitar stand

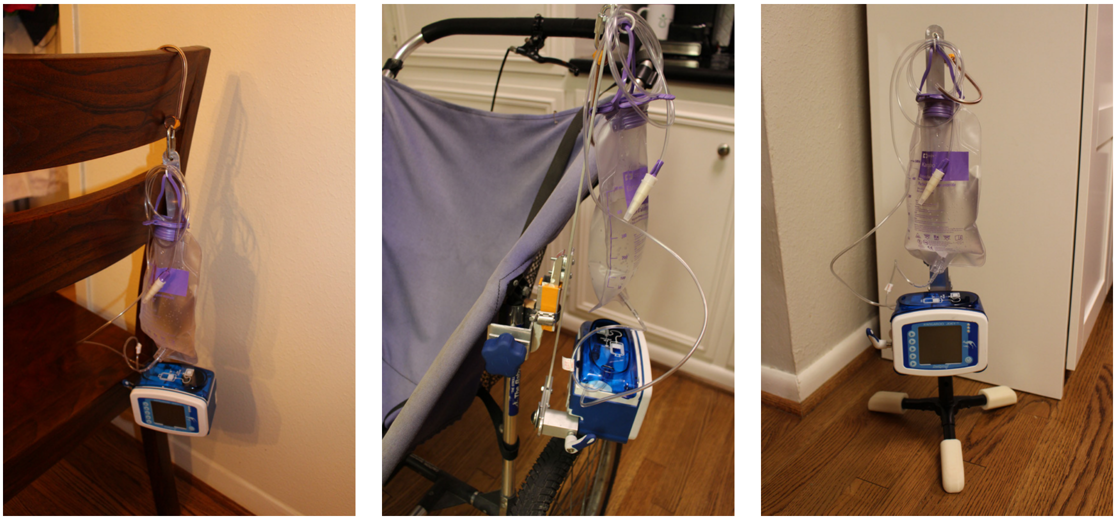


*Figure 38.* **Concept 2 using the Kangaroo Joey pump**

*Figure 39.* **Concept 2 using the Infinity pump**

which had the legs cut off and 3D-printed feet attached. In this concept, it was intended that the users would attach the clamps to different items, such as a wheelchair or bed frame, and leave them there the majority of time. They could quickly transport the main body of the device with the pump attached between the different locations.

**Constructing the works-like prototypes**

1/8” x 1” flat aluminum rod was used to create the main body of the prototypes. 3/4” square profile aluminum tubing and 1” square profile aluminum tubing were used to create the nesting parts for the quick-release mechanism. Cardboard spacers were taped into the 1” aluminum tubing to create a slightly tighter fit between the parts. 3” by 2” C channel aluminum rod with a thickness of 1/8” was used to construct the clamp, and wood was used to create the notched area on the clamp. Off-the-shelf threaded screw knobs were used on the clamp, and rubber tape was used to create a non-damaging, non-slip surface on the inner contact points of the clamp. A door-stopper tip was added to the ends of the screw knobs to create a non-damaging, non-slip contact point.

**Further development to be implemented later**

In this phase of prototyping, more “detailed” aspects of the design, such as creating a spot to store the tubing cap or a way to control excess tubing, were not considered. The main focus of this initial prototyping phase was to test the high-level aspects of the design to make sure that they worked. Details would be revisited in the refinement phase of the design after initial testing. The aesthetics and emotional impact of the design would also be revisited during the refinement phase, once the general design direction was validated.

# CHAPTER 6: VALIDATION AND TESTING

After each participant had tested the prototypes for at least 4 days, their feedback was collected. This took place through a combination of in-person, verbal feedback, written feedback on the "Prototype Testing Diary" and "Prototype Evaluation Form," and photographs taken by the subjects. From both the written and verbal responses given by the participants, positive and negative feedback was collected about each prototype design. The participants were informed that the aesthetic appearance of the designs would change in the future, so they should focus their feedback on the functional aspects of the designs.

## 6.1 QUALITATIVE RESULTS

**Locations the subjects used Concept 1:**

- Living room, hanging on the back of the wheelchair
- Living room, on coffee table
- Bedroom, hooked onto the bunk bed rail
- Bedroom, on the night stand next to the head of the bed
- Bedroom, hooked over the side of crib
- Dining room, hooked on back of chair
- Hooked on assistive devices (stander, gait trainer)

**Critiques of Concept 1:**

*"Depending on the device, it was difficult to attach the clamp to the varied shaped and sized poles, or area to clamp to."*

*"The hook for the bag (white one) was curved or tight making getting the bag on or off it*

*more difficult."*

*"When hanging on the back of the wheelchair it hangs too low to comfortably reach."*

*"Needs something to help contain the feeding tube to avoid getting pulled out."*

*"Hard to plug in power cord when pump is mounted to unit."*

*"Bag hangs a little too low, making it hard to run tubing to the pump. Would be nice if the bag hook was slightly higher, or the height was adjustable."*

*"Pole clamp may work better rotated 90°, so that the unit could hang flush when hung from the hook."*

*"Some feature to make it foldable/collapsible/telescoping would be great for travel!"*

*"It would be nice if there were a place to store the cap."*

*"It made it easier for my daughter to mess with the buttons."*

*Figure 40.* **Concept 1 being tested**

*Figure 41.* **Concept 1 being tested by another participant**

**Positive feedback for Concept 1:**

*"It is very versatile, easy to move from one location to the other."*

*"Much less obtrusive than traditional IV stand."*

*"My girls share a room, and I did not have to worry about sister tripping over it if she had to get out of bed."*

*"Small, would be easy to transport or travel with. I wish we had something like this when we went on vacation or spent the night at grandma's!"*

*"I liked that it didn't have wheels, so I didn't have to clear a path on the floor to move it around the house."*

*"I loved how small it was in general. Doesn't get in the way."*

*"I love how portable it is and can hang pretty much anywhere."*

*"It would be so much easier to take places and to have overnight."*

**Places the subjects used Concept 2:**

- Bedroom, on the night stand next to the head of the bed
- Living room, on stand on couch or coffee table
- Bedroom, hooked onto the bunk bed rail
- Bedroom, hooked over the side of crib
- Dining room, hooked onto back of chair
- Hooked from assistive devices (stander, gait trainer)
- Clamped to assistive devices

**Critiques of Concept 2:**

*"I couldn't get it to clamp onto a spot where wanted it to go."* (This was a 0.6" diameter hexagonal pipe on the gait trainer. The subject was able to hang it from this device with the hook instead.)

*"Cannot plug in power cord when pump is attached."*

*"Would be nice to have a place to store the cap for the e-pump set."*

*"Folding feature would be nice."*

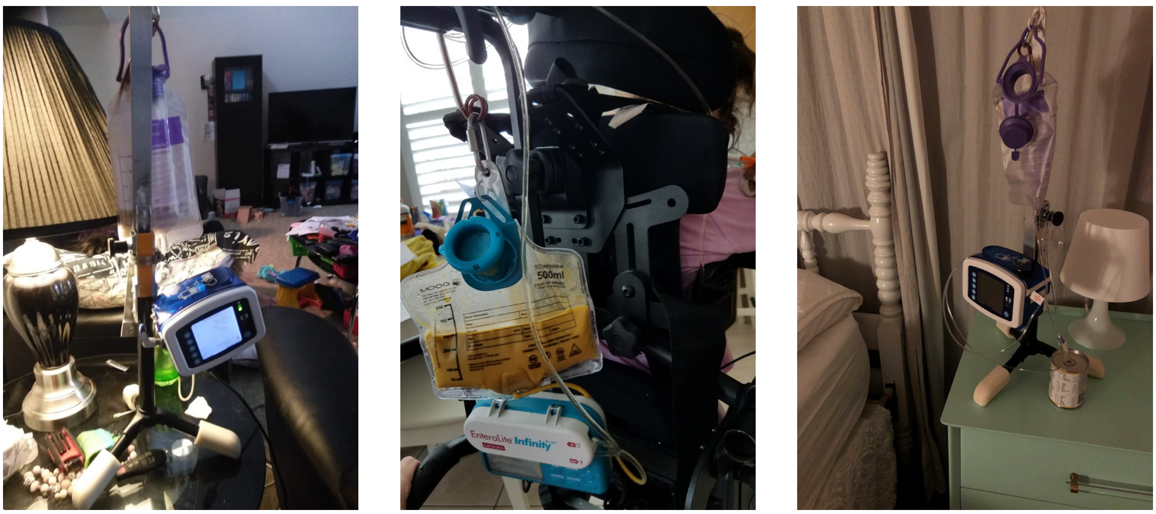



*Figure 42.* **Concept 2 being tested**

*"Due to the specific nature of one of her devices, the height of the quick-release system prevented us from using the clamp, the hook, however, made it very easy to use with any device."*

**Positive feedback for Concept 2:**
*"Quick release easy to use."*

*"Convenient size. Does not take up floor space in room."*

*"Did not need to use, but the extra clip options make this concept very versatile, especially if you were travelling with the pump or using during the day. Thanks for letting us try it out!"*

*"Very versatile."*

*"I love the stand and how small it is. It's so much easier to move around the house, go through doorways, and the walls don't get banged up."*

*"This one was still more versatile overall as it had the hook to hang, but also could be snapped in to the tripod."*

*"Kept bag and pump at perfect distance, kept bag upright, no air in tube!"*

*"I liked that it didn't have wheels, so I didn't have to clear a path on the floor to move it around the house."*

*"I love how the legs on the stand were short. That made it so much easier to carry from room to room."*

## 6.2 USABILITY COMPARISON

The "Prototype Evaluation Form" asked the subjects to rate different aspects of their current pump hanging method and the prototypes on a scale of 1 to 10, 1 being the hardest and 10 being the easiest for questions 1-6, and 1 being the least and 10 being the most for question 7. Answers from each participant were compiled and the averages are presented in Table 4. Concept 2 received the highest ratings in all categories.

| | **Current Method** | **Concept 1 (All-in-one)** | **Concept 2 (Quick-release)** |
|---|---|---|---|
| 1) Overall, how easy is it to use? | 6.25 | 9.25 | 9.5 |
| 2) How easy is it to use at home? | 7 | 9.5 | 9.5 |
| 3) How easy is it to use away from home in daily life? | 3 | 8.25 | 9.75 |
| 4) How easy is it to use away from home on an overnight trip? | 2.25 | 7.75 | 9.75 |
| 5) How easy is it to set up a feed? | 8.25 | 8.75 | 9.5 |
| 6) How easy is it to clean the feeding bag? | 7.67 | 9.67 | 9.67 |
| 7) How much do you like it? | 5.75 | 9.5 | 9.5 |
| Overall average | 5.64 | 8.91 | 9.58 |

*Table 4.* **Quantitative Survey Results (n=4)**

## 6.3 OVERALL DESIGN PREFERENCES

The final question in the "Prototype Evaluation Form" asked the participants to choose their preferred hanging method for the feeding pump, either their current method, Concept 1, or Concept 2. Three participants voted for Concept 2, the quick-release system. One participant voted for Concept 1, the all-in-one system. However, this participant's child only used the feeding pump at night, and the participant stated that if their situation had been such that they used the pump during the day or for travelling, they would instead prefer the quick-release system. None of the participants chose their current method as the preferred method.

## 6.4 DISCUSSION

**Limitations of the study**

A few factors affected the consistency of the testing. Participants who used the Kangaroo Joey pump had to move a piece from one prototype to the other. The custom clamp part (which is normally provided with the Kangaroo Joey pump) was provided to the participants and came already attached to Concept 1, along with instructions of how to transfer this part to Concept 2. The participants already owned this part and had it attached to their own IV poles, but rather than asking them to disassemble their clamps, one was provided for them to use. However, the researcher only had one copy of this part, and relied on the participants to perform this transfer halfway through the testing. Participants were provided with a flathead screwdriver and an instruction sheet with written directions and pictures to show the participants how to perform the transfer. One participant lost the instruction sheet that was provided with the prototypes, and as a result when transferring that custom clamp, she attached it backwards onto Concept 2. Surprisingly, Concept 2 still worked relatively well for her, and was still her preferred design. However, she wasn't able to use it one of her desired scenarios, which was to clamp it to the child's bed frame. This was discovered during the final home visit when the researcher went to pick up the prototype. The researcher moved the custom clamp to show the participant the correct orientation, and the participant confirmed that in that orientation it would indeed work to clamp Concept 2 to the bed frame. This confirmed her choice to select Concept 2 as her preferred design. However, it is unclear how else this affected her testing, and it is also unclear whether having lost the instruction sheet affected other aspects of her testing.

Looking back, a few changes would have improved the study design. First of all, the researcher could have purchased an additional custom clamp part so that both prototypes could have had the custom clamp pre-attached. Also, it would have been better to email a copy of the instruction sheet along with the hardcopy so that the subjects could refer back to it in the event that they lost the hardcopy. Though the participants were told that they could contact the researcher during the testing if they had any questions, none of them did so. It might have been better to reach out to them halfway through the testing to ask if they had any questions in order to open the lines of communication and make it easier for them to vocalize any concerns or confusion they were experiencing.

Another factor that may have affected the consistency of the testing was the fact that one subject was out of town, so none of the interviews or testing direction was able to take place in person. The prototype was delivered to this subject by mail, but this turned out to create considerable difficulty due to some issues with the package delivery system at her place of living. This caused a large delay in the testing timeline, and also involved considerable risk as the only copies of the prototypes were lost in the mail for some time. Thankfully, the package was recovered and the subject was able to test the prototypes. However, it was much easier from the researcher's standpoint to deliver the prototypes to the subjects in person, because there was no risk of them getting lost, there was complete control over the time schedule, and the researcher was able to demonstrate how to use the prototypes in person to ensure the best chance that the subject understood how to use them and would use them correctly.

Asking the subjects to take photographs of the testing provided a little bit of difficulty as well. Not as many photographs were submitted as the researcher had originally hoped, due to the fact that one subject forgot to take photos until the last minute, a miscommunication about the date of completion of testing caused another subject to not have as much time to take pictures as she had thought. However, the photographs were not the most important part of the feedback being gathered from the subjects, and their observations and written/verbal feedback after the testing was extremely valuable and not at all limited by the number of photographs they provided.

One limitation of this study was the limited number of participants. Only four families participated in this study. While they did have a fair amount of diversity in terms of their needs and feeding situations, there are some ways that the sample group could have been improved. It would have been ideal to have greater representation of each feeding pump within the sample group. Only one of the users used the Infinity pump, so the testing with the Infinity pump was more limited than with the Kangaroo Joey pump, which had three testers. Though this study intentionally focused on families with tube fed children, looking back it may have been advantageous to include adult users as well, since they could also be potential customers should this product be commercialized. It would be valuable to understand their feeding situations and include their perspectives.

**Successes of the study**

During the prototype testing, the participants did a very good job focusing their feedback on the functionality of the designs and did not get hung-up on the appearance of the prototypes or their unfinished nature. It was surprising how positive their feedback was, given that they had previously been using professionally manufactured IV poles and backpacks, and then transitioned to testing very utilitarian prototypes which were not perfect by any means. This ability to critique the intention and functionality of the design rather than the aesthetics or production quality really spoke to the participant group's ability to make valuable contributions to design development early in the process.

Though the sample group was small, there was good consistency in the participants' opinions about the prototype designs. This suggests that a high number of participants may not be necessary to get a representative sample of users in order to develop a strong product design that users will like. It was also nice to see that users appreciated features other than what they had suggested themselves. For example, one participant who had not proposed any sort of hanging feature used this feature successfully and like it. This suggests that users didn't just like the designs because they saw their own ideas reflected, but genuinely liked the features that others had suggested and found them helpful.

# CHAPTER 7: DESIGN REFINEMENT

## 7.1 FINAL DESIGN DIRECTION

Based on the feedback received from the prototype testing, Concept 2, the quick-release system, came out as the clear favorite and was selected for the final design direction. The participants made many good suggestions as to how this design could be improved and refined, and these were all taken into consideration in the design refinement stage.

**Top hook**

In the initial prototype, the top hook was attached to the unit with a chain link. This allowed some flexibility of movement, but not enough that the unit would always hang in the desired orientation. One situation that was considered was hanging the unit from the back of the passenger or driver's seat in the car. In this case, it would be ideal for the hook to be able to both tilt and rotate. To get this desired behavior, a rotating feature was added to the original chain link style connection.

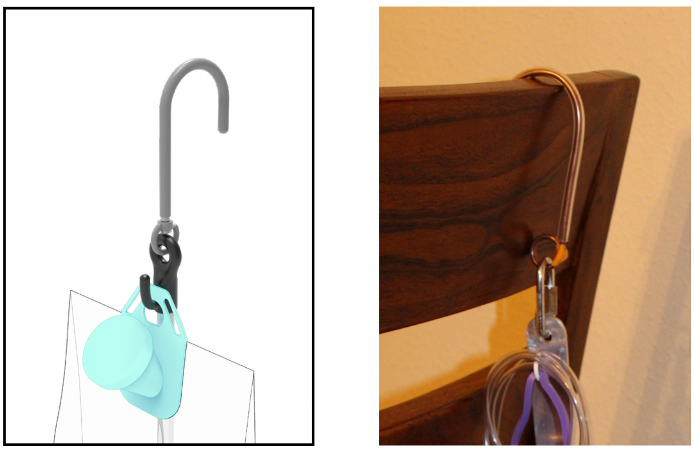


*Figure 43.* **Top hook with rotating feature and hook design in prototype**

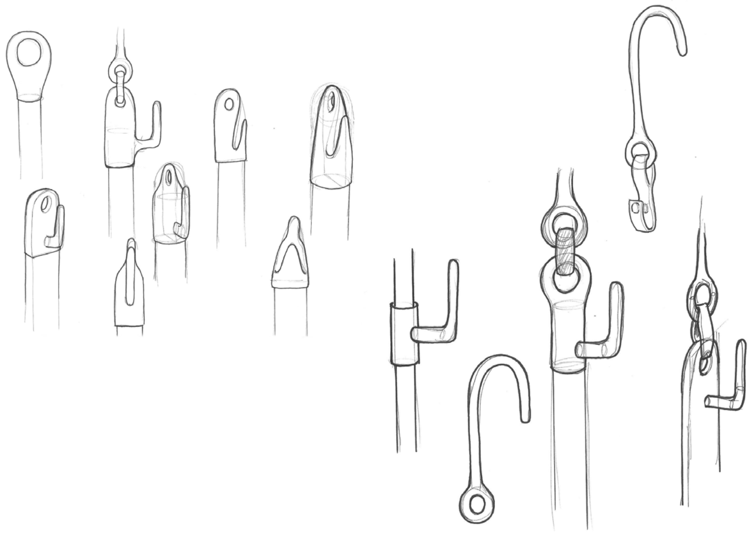


*Figure 44.* **Top hook and feeding pump hook refinement sketches**

**Feeding bag attachment**

While the participants who used the Kangaroo Joey pump didn't have difficulty with the feeding bag attachment, the participant who used the Infinity pump did report that it was challenging to get the feeding bag on and off of the feeding bag hook. This is likely because the Infinity pump feeding bag is more bulky at the top in comparison to that of the Joey pump. The design of the hook was changed to a more open design to make it easier to slide the bag on and off. This more open hook design could also be used to hold loops of excess tubing if needed.

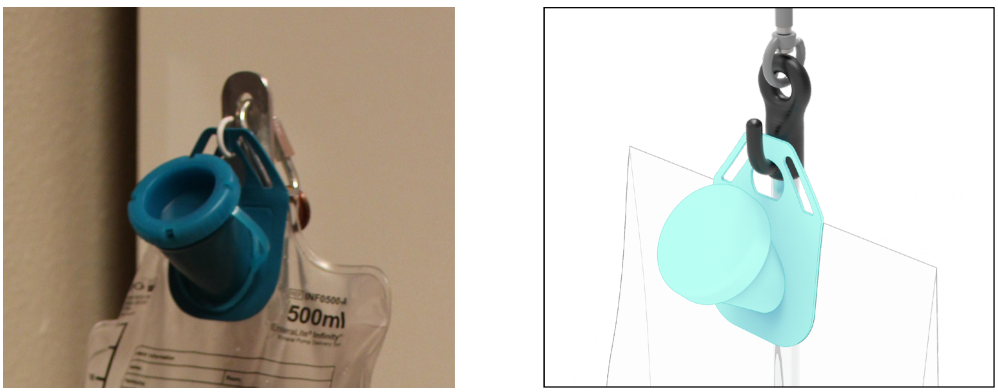



*Figure 45.* **Feeding bag hook design in prototype and new design**

**Feeding pump attachments**

One participant who used the Kangaroo Joey pump found that the connection area obstructed the charging port on the pump. Based on this feedback, the shape of the Kangaroo Joey attachment piece was changed, so rather than a 90° angle, it is at a 135° angle and does not obstruct the charging port. The angled design was selected so that the Kangaroo Joey pump could hang midline. The piece was also lengthened vertically since one of the participants felt that the feeding bag hung too low.

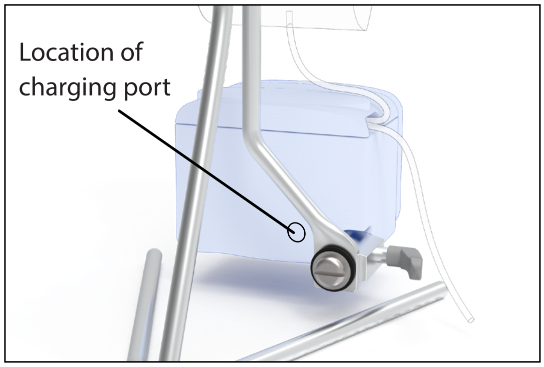



*Figure 46.* **Kangaroo Joey pump attachment in prototype and new design**

**Base**

A variety of shapes were explored for the base design. A fixed rather than folding design was selected because it was simpler and could be designed with more minimal use of materials.

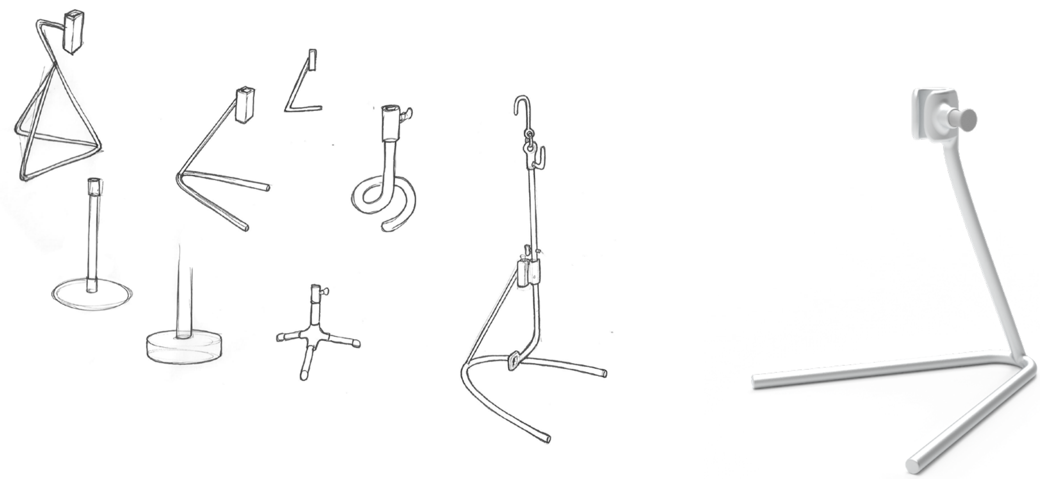


*Figure 47.* **Base refinement sketches and final base design**

**Clamp**

The functional design of the clamp remained largely unchanged, and was primarily minimized in size. One participant wasn't able to attach the clamp to a small 0.6" diameter pole on a piece of equipment. The original intent of the clamp design was to adjust down to 0.5", but this was not actually achieved in the prototype due to the availability of materials. In the final design, the clamp adjustment range is 0.5" to 2".

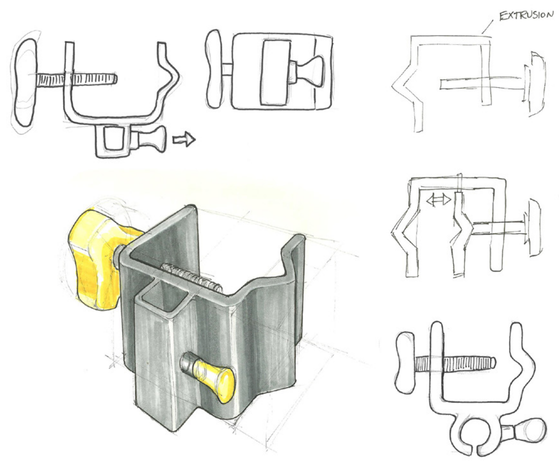



*Figure 48.* **Clamp refinement sketches**

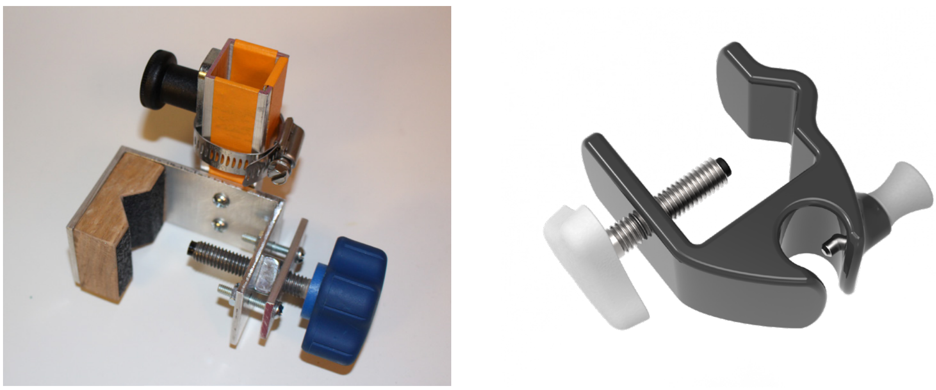


*Figure 49.* **Clamp design in prototype and in final design**

**Quick-release mechanism**

The general design of the quick-release mechanism remained largely unchanged, as the participants found it easy to use. The profile of the connective elements was changed from square to round, to allow for an easy accommodation for storage of the tubing cap.

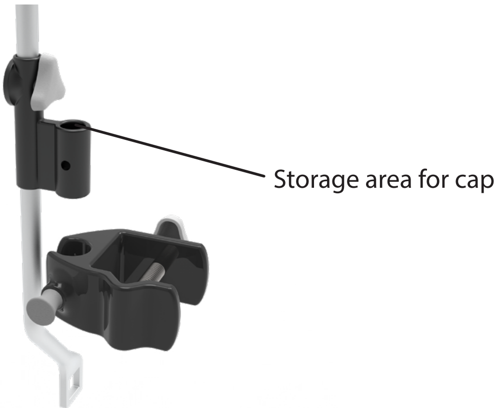



*Figure 50.* **Quick-release mechanism in final design**

**Cap storage**

Since the participants desired a place to store the tubing cap, an appropriately-sized hole was placed in the quick-release area in which to store the cap.

**Addition of syringe attachment**

Based on the need demonstrated by the FreeArm device, which was designed to hold syringes for gravity feeding, a consideration was made to add this same functionality to the final design. A solution was found to add a single part that could accommodate the syringe, so that the syringe could be held by either the base or the clamp.

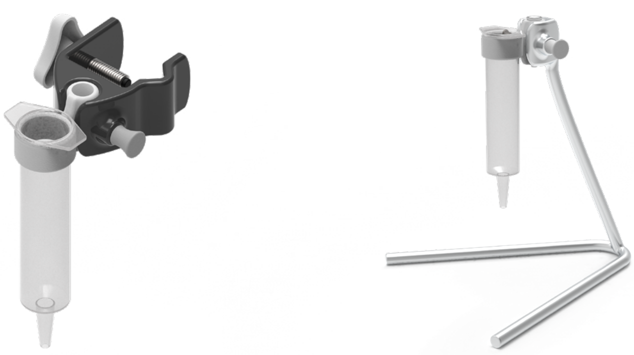


*Figure 51.* **Syringe attachment in use with clamp and base**

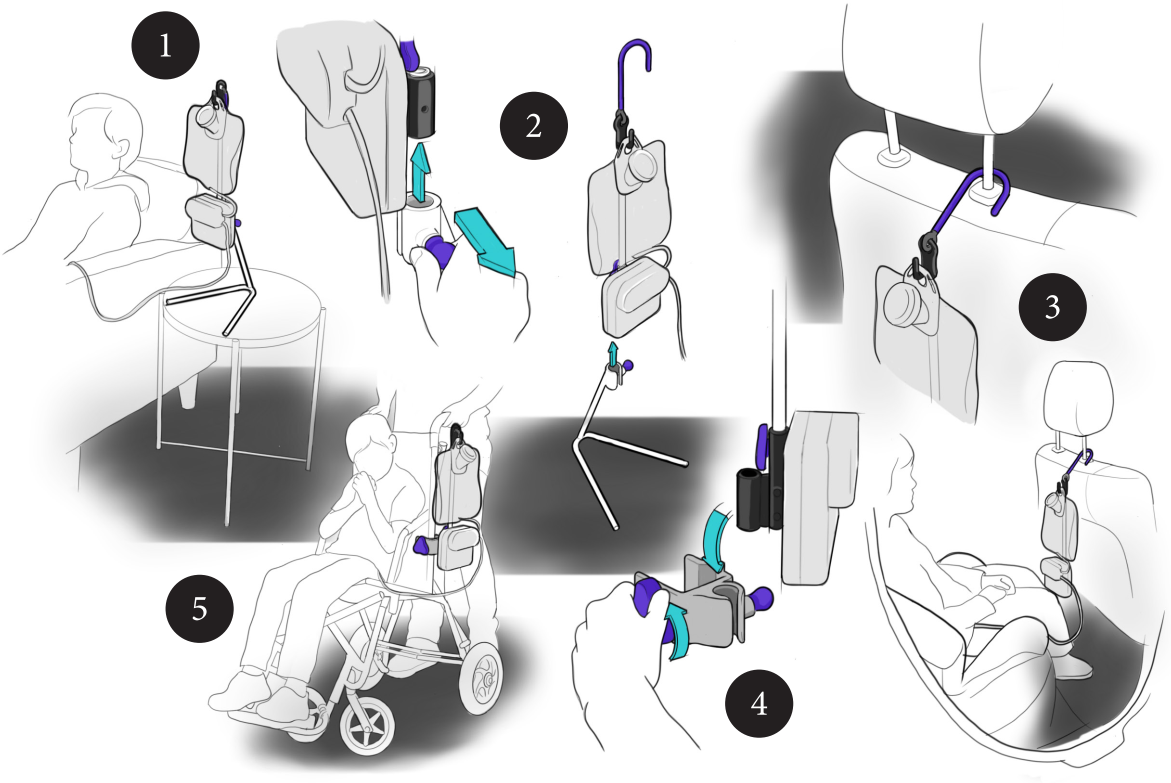



*Figure 52.* **Illustration demonstrating functionality of the design**
1) Attached to base, which is sitting on side table 2) Detaches from base with quick-release 3) Hangs from back of car seat 4) Attaches into clamp with quick-release 5) Clamp can be attached to wheelchair

**Final full design**

The final design is called "Tag Along," because the main benefit of this new device is that it allows users the freedom to easily bring their feeding pump equipment anywhere. For the final design, curved shapes shapes and edges were used when possible in order to create a "soft" and "friendly" form. Because approximately 44% of the users of feeding pumps are pediatric users and 55% adult users, multiple color options were selected in an attempt to appeal to both demographics. The "neutral" color option features neutral colors that may be of more appeal to adults or anyone with a preference for more muted tones. After close consultation with a 4-year-old girl and a 7-year-old boy, a pink, silver, and teal option was created, as well as a blue, black, and teal option.

*Figure 53.* **In-context rendering**

*Figure 54.* **Final design in use with Infinity pump and Kangaroo Joey pump**

*Figure 55.* **Final design in neutral, pink, and blue color options**

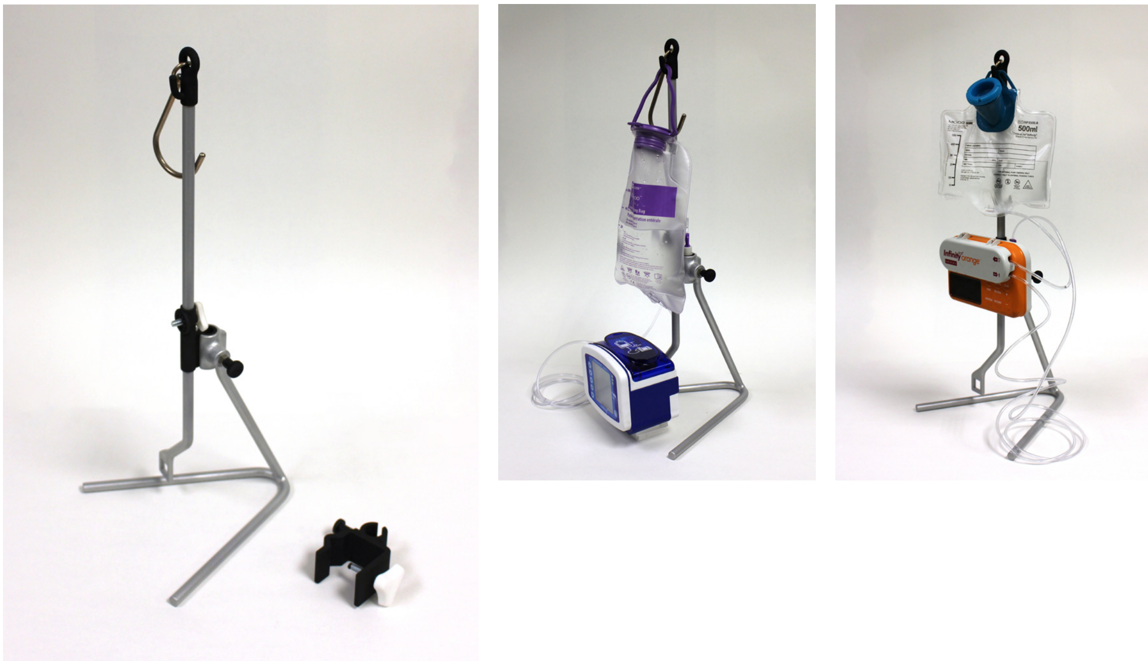


*Figure 56.* **Final proof-of-concept model**

**Final Model**

A final proof-of-concept model was constructed for demonstration and testing purposes. This model was made from 7/16” aluminum rod for the base and center pole, 3D-printed nylon, 3D-printed metal, and off-the-shelf retractable spring plungers (Figure 56).

**Materials Selection**

Aluminum was selected as the primary material for the device because it is lightweight rust-resistant. An anodized finish was chosen since it would be resistant to damage from scratching, leading to a long-lasting good appearance. The base and main frame would be constructed from 7/16” diameter aluminum rod. Other weight-bearing components would be made from injected aluminum. Non-structural handles and knobs would be made from injection-molded plastic. The clamp and top hook would be dip-coated in silicone material to protect any surfaces they come in contact with, such as furniture or medical equipment.

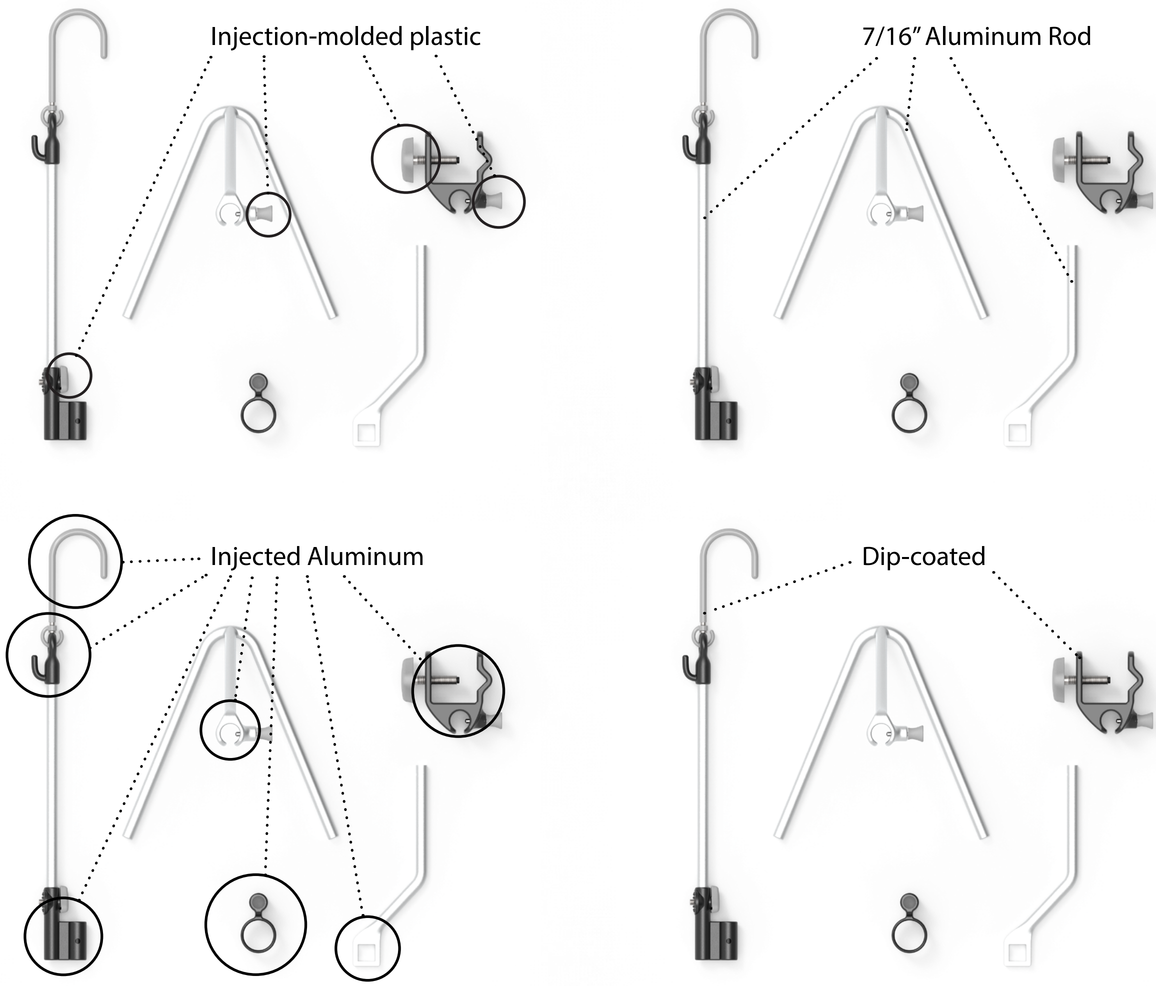



*Figure 57.* **Materials Specifications**

**Cost Estimate**

Components: spring plunger = $2.50 (x2), screws = $0.10

Injection-molded plastic parts = $0.73

Injected aluminum parts = $20.78

Aluminum rod parts = $7.85

Welding and finishing labor = $25

Total: $59.46 (tooling costs not included)

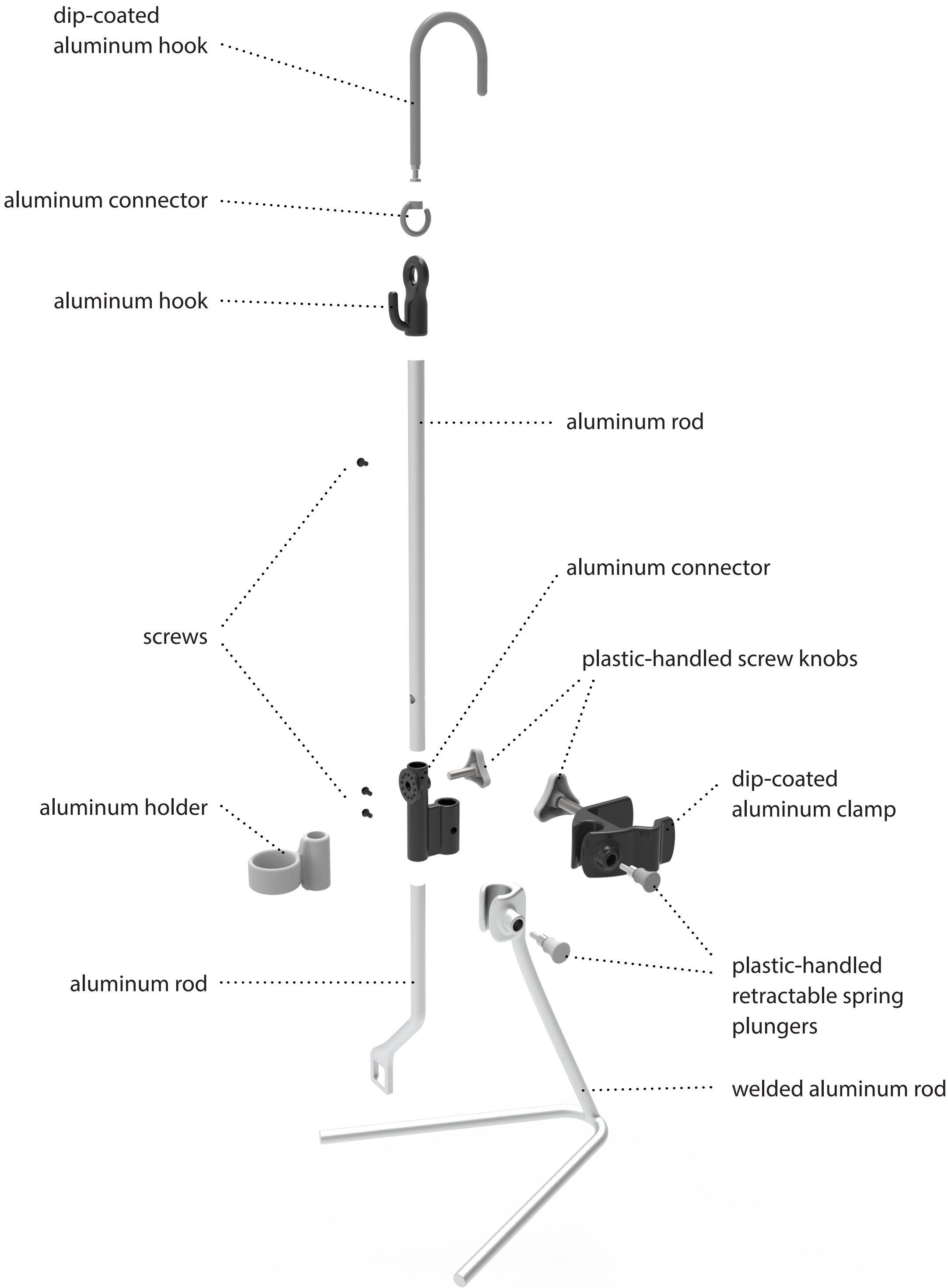



*Figure 58.* **Exploded view rendering**

# CHAPTER 8: CONCLUSION

## 8.1 CRITICAL TAKEAWAYS

Enteral feeding has been in existence for a long time but is growing in prevalence in recent years. As more and more people utilize this method of nutrition, it is increasingly important to ensure that the design of the equipment does not act as a hindrance to their lifestyle and desired activities or an additional burden to caregivers. Unfortunately, many manufacturers of medical equipment do not involve users in their design process, leading to poorer usability in their design outcomes. The present study hypothesized that involving "low-ranking" users in the medical device design process would lead to outcomes that functioned better for these users. Hanging equipment for feeding pumps was used as a case study to test this hypothesis. Four families who use feeding pumps to feed their children participated in the study by providing initial ideas for how the equipment could be improved, and testing and giving feedback to prototype designs. After testing the prototypes, all participants found the prototypes of the new design to be easier to use than their previous methods. They all chose the one of the new designs as their preferred method to use to hang the feeding pump. This outcomes supports the hypothesis, since involving these users in the design process led to an outcome that functioned better for the users.

The users shared a lot of very valuable ideas in both phases of the research, and were able to identify a lot of potential design features that the researcher would not have thought of independently, even though the researcher had prior experience with the subject area. This suggests that parents or family caregivers are a valuable resource for anyone designing medical products.

The case study presented in this study can serve as an example for medical device designers who wish to include more user input in their design process. The results of this case study suggest that some of the perceived barriers to user involvement in medical device design may actually be relatively easy to overcome if the desire is there. The methods presented in this case study have a relatively low barrier to entry. It was not too difficult to use social media and word-of-mouth to find a small pool of users who were willing to share their experiences and participate in testing. Other ways to recruit users that were not tried in this study but may also be effective include partnering with a doctor or clinic to seek participants among their patients, and/or to offer compensation to the participants. Regulation need not be a barrier to having user participation in the design process. Though user-testing of some types of products should take place carefully and may need to be approved by an IRB, doing initial needs finding interviews and gathering user ideas does not need to be a regulated activity.

However, the possibility does exist that optimizing usability for patients and their families isn't always the primary goal of medical device manufacturers, and they may be valuing other aspects, like profit, over good design. In addition to this disconnect, one of the barriers to user-centered design in medical devices was the disconnect between the purchasers and users. This issue is particularly relevant to the issue of feeding pump hanging equipment, because in most cases the users aren't given a choice in which products to use. A doctor writes a prescription for the equipment, but this prescription does not specify which model of feeding pump the patient will receive. A durable medical equipment company will supply the patient with a feeding pump and an IV pole at minimum, but will most likely not ask the patient which model or style they prefer. Some patients may seek out the "best" equipment by doing their own researcher and then asking the medical supply company if they can switch to another model. Or a particularly proactive patient may even switch medical supply companies in pursuit of their preferred equipment. But the fact remains that the "purchaser" of the equipment is the medical supply company, who is most likely motivated to purchase the most low-cost equipment regardless of the usability concerns for the patient. This issue applies not only to the feeding pumps and hanging equipment, but to the feeding tubes as well, since feeding tubes are often placed by surgeons in the hospital, and selected by the surgeons rather than the patients. (This selection would be dictated by the hospital's supplier contracts and/or the surgeon's personal preference.)

One limitation of this study is the scope. Only a single design area, hanging equipment for feeding pumps, was explored. Though this design area led to a successful outcome, it is a fairly simple concept that did not involve and electronic or software components. The possibility exists that outcomes could be different if this design method were applied to different products or more complex categories of medical products. Limitations also existed in the design development and testing. This study there were only four participant families. Testing with more users could uncover more differences of opinion about the design. Only one user tested the design with the Infinity pump, and no one tested the design to hold a syringe for gravity feeding. This study also did not include any participants who were adult users of feeding pumps, or caregivers of adult users. These groups may have had different ideas or different needs.

The introduction of the FreeArm device to the market was an interesting development that occurred after the start of this project (the first promotional videos for the product are dated in January 2019, while the project started in August 2018). The introduction of this device supports the hypothesis in this study that good medical device design can be achieved with user involvement, since the device was developed by parents of a tube-fed child. It also reinforces the stated need for better equipment in this area.

## 8.2 FUTURE WORK

Future work on this project could include research and testing with adult users of enteral feeding equipment, and users of syringes for gravity feeding. More testing with users of the Infinity pump could be completed as well.

As a way to further the design, a bag/cover feature could be added. This could be a fabric cover that would cover both the formula bag and the feeding pump. This would have multiple benefits for the user. First of all, it would allow for a more privacy/discretion when out in public with the pump. Also, if a sleeve was added in which to insert an ice-pack, this could provide an easy way for to keep the formula cool. Many families already use some sort of sleeve hold ice against the formula bag for cooling. Finally, it could have the added benefit of preventing children from tampering with the pump during a feed.

In section 2.9, other burdens associated with home enteral feeding were explored, including difficulties with the feeding tubes and feeding pumps themselves. Future design projects in the area of home enteral feeding could seek to address these burdens. In fact, the design of the feeding pumps was a very limiting factor in this project. Much of the design of Tag Along was dictated by the design of the existing feeding pumps. Even the feeding pumps that are designed for home settings appear to be a direct carryover from those designed for hospital use, particularly the feature of hanging a disposable feeding bag above the pump. This single-use disposable makes sense for a hospital setting, but may be unnecessary for the home setting, where reusable containers are commonly used for feeding and washed between feedings. However, the enduring popularity of the "razor-razorblade model" in business suggests that it's unlikely feeding pump manufacturers will deviate from this design. The design of the feeding pumps also seems particularly tailored to use with an IV pole, which is appropriate for a hospital but based on the findings of this study was not desirable by users at home. The feeding pump system itself could theoretically be completely redesigned to be more compact and more easily mounted onto various objects. Or, the feeding pump and feeding bag could be integrated as more of a single unit that could be placed in any orientation without concern for air entering the tubing. Manufacturers of future feeding pumps would do well to consider the lifestyles of home users in future version of their designs, and "think outside the IV pole."

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# APPENDIX A: PROTOTYPE TESTING DIARY

**Prototype Testing Diary**
**Concept 1: All-in-one System**

**Subject Number___**
**Please record your observations while using the prototype this week.**

**Places I used it**

**Problems/difficulties I had while using it**

**Helpful/good things about it:**

**Prototype Testing Diary**
**Concept 2: Quick-release System**

**Subject Number___**
**Please record your observations while using the prototype this week.**

**Places I used it:**

**Problems/difficulties I had while using it:**

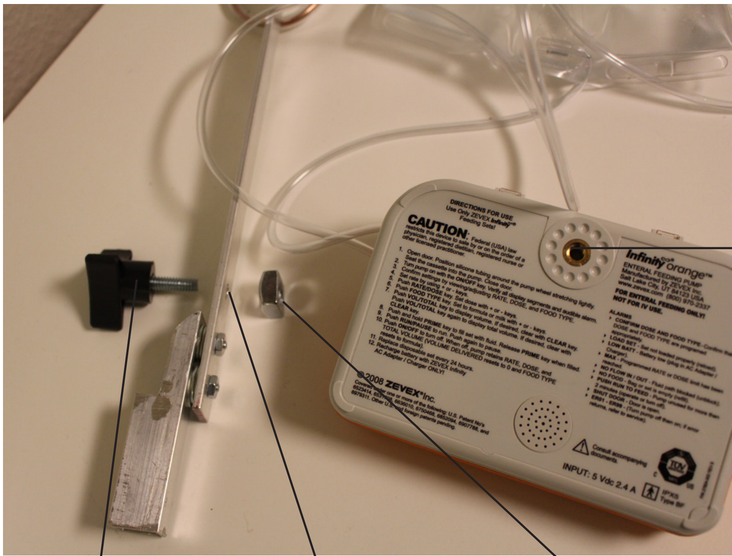
**Helpful/good things about it:**

# Feeding Pump Holder Prototype Instructions for Use - Infinity Pump

**How does the Infinity pump connect to the prototype?**
Typically, the Infinity pump attaches to an IV pole like this:

The infinity pump attaches to the prototypes in the same way, a screw going into the threaded hole in the back of the pump.

The black-handled screw will go through the hole in the prototype, through the spacer nut, and screw into the threaded hole in the back of the pump.

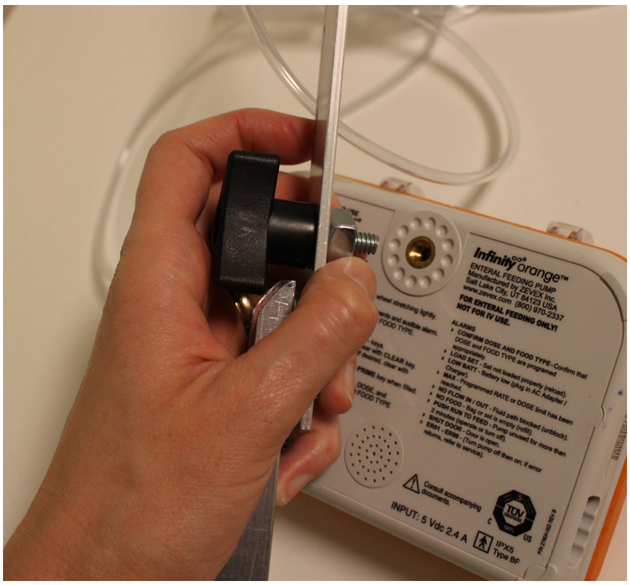



Threaded hole in prototype

Black-handled screw

Hole in prototype

Spacer nut



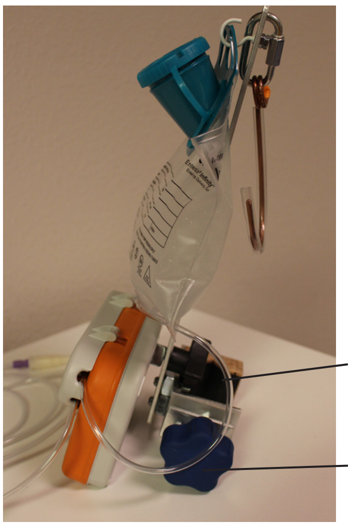

The feeding back hangs from the white hook at the top of the prototype.

# Concept 1 - “All-in-one system”

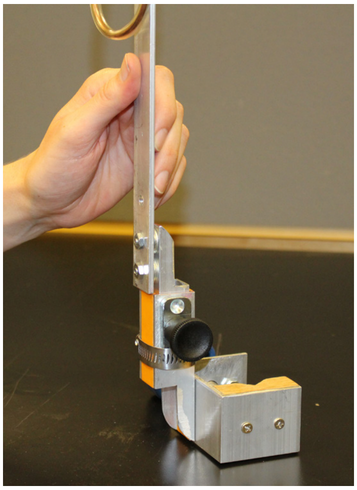
Once the pump is attached to the prototype, it can be set on a counter or floor and will support itself.

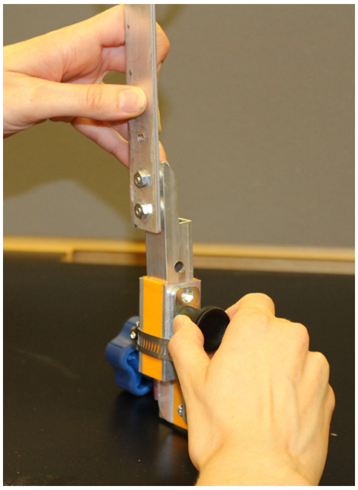

It can also hang from things with the hook.

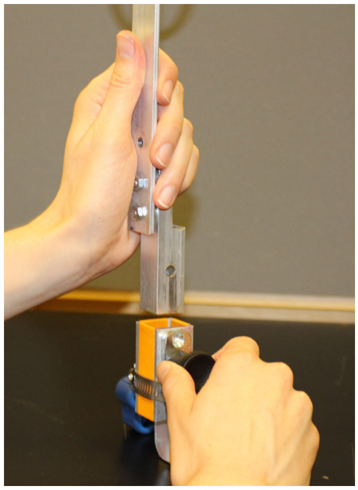

The clamp can be used to hook it to vertical poles. For example, here is it hooked to a stroller. Screw the knob on the clamp to hook it to poles the same way you typically connect the pump to the IV pole.



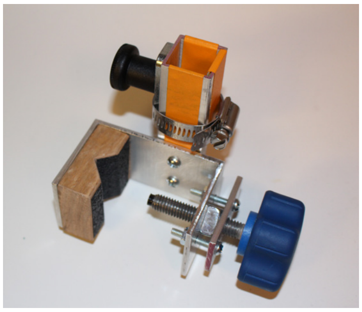

## Concept 2 - "Quick-release System"





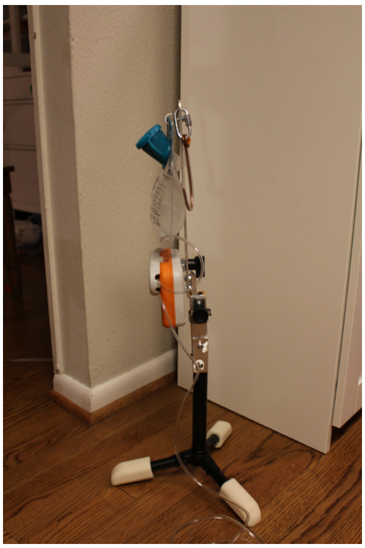


In the "quick-release system," the clamp portion separates from the vertical piece that holds the pump and feeding bag. The clamp can stay mounted to object while the rest of the system is taken off. The black handle is the "quick-release handle." Pulling this handle out will allow the rest of the system to be released. The handle snaps into place when the rest of the system is securely attached.



This system can also clip to vertical poles. If desired, the clamp can stay attached to the vertical pole while the rest of the system is released.

This system contains a stand, which has the same quick-release mechanism as the clamp.



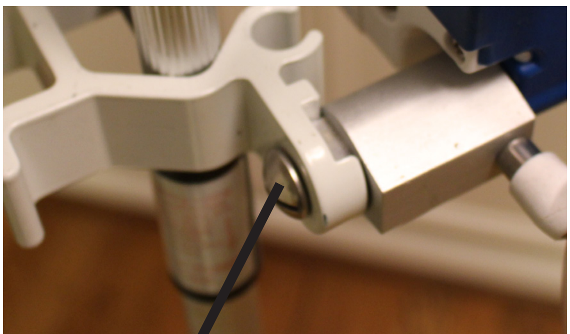
The hanging function works the same way as in concept 1.

# Feeding Pump Holder Prototype Instructions for Use - Kangaroo Joey Pump

## How does the Kangaroo Joey pump connect to the prototype?

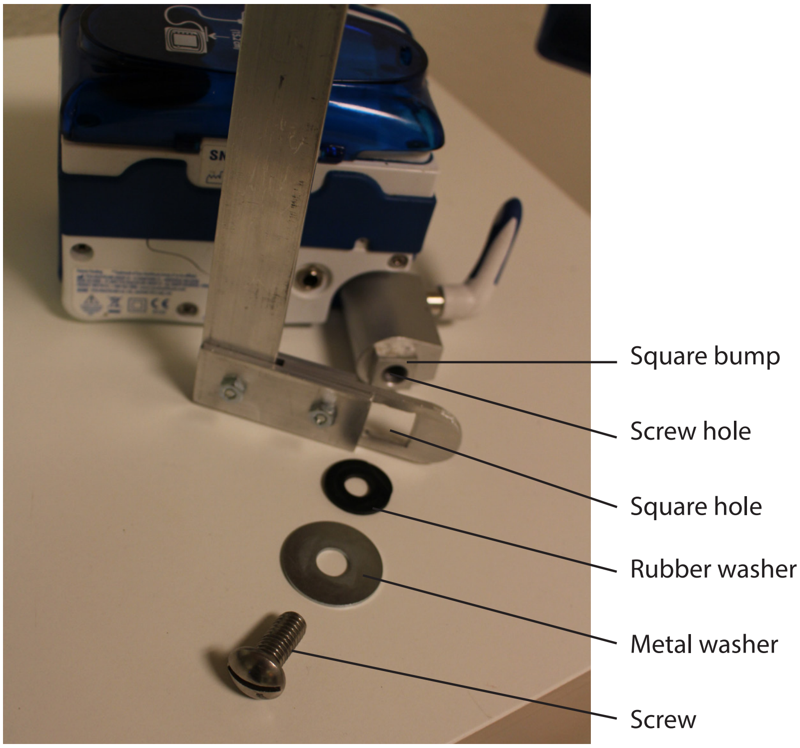
Typically, the Kangaroo Joey pump attaches to an IV pole like this:

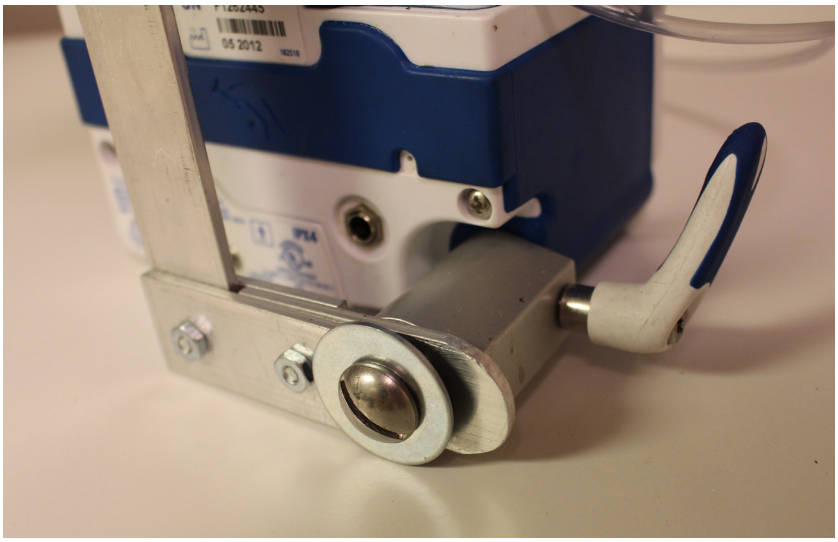
The Kangaroo Joey pump attaches to the prototypes the same way.



Unscrew this screw with a flathead screw driver. You will use this screw again to attach the feeding pump to the prototype.

Align the square hole on the prototype with the square bump on the feeding pump. Thread the screw through the metal washer, then the rubber washer, then insert the screw into the screw hole on the feeding pump. Tighten the screw with the flathead screw driver. Everything should feel secure.



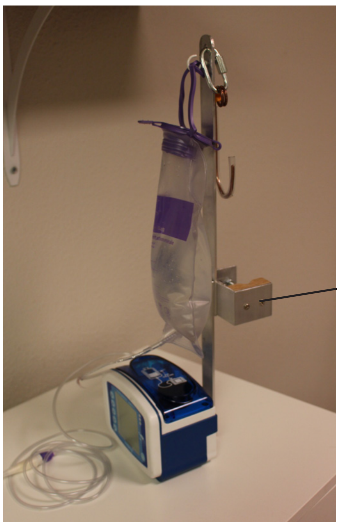
The purple loop on the feeding bag can be hung over the white hook on the prototype. If desired, the purple loop can be wrapped around the hook a few times to raise the height of the bag.

# Concept 1 - "All-in-one system"

Once the pump is attached to the prototype, it can be set on a counter or floor and will support itself.

It can also hang from things with the hook.

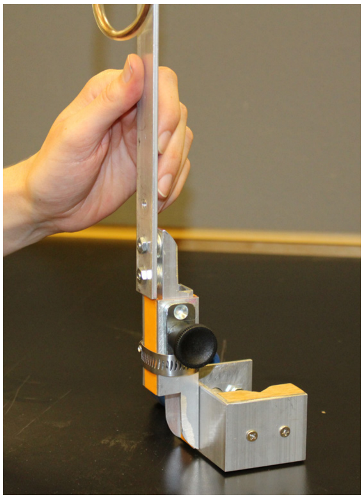
The clamp can be used to hook it to vertical poles. For example, here is it hooked to a stroller. Screw the knob on the clamp to hook it to poles the same way you typically connect the pump to the IV pole.

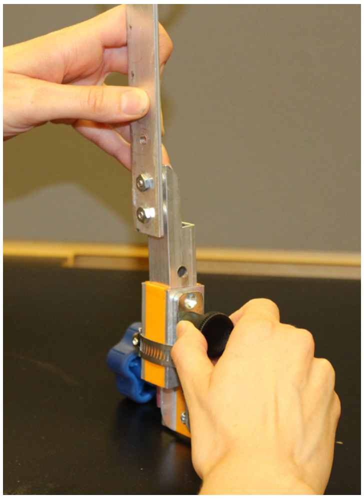

Clamp

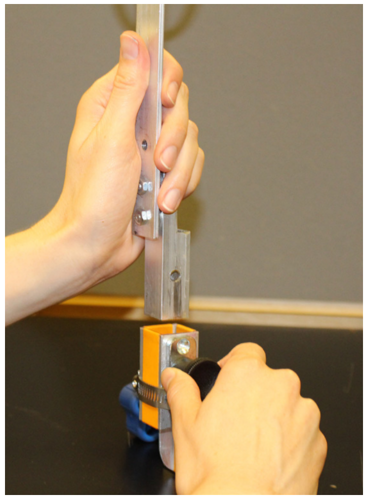
Knob

Pole on stroller

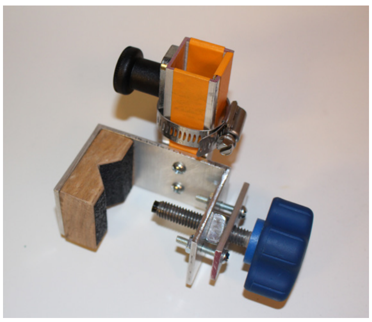
## Concept 2 - "Quick-release System"

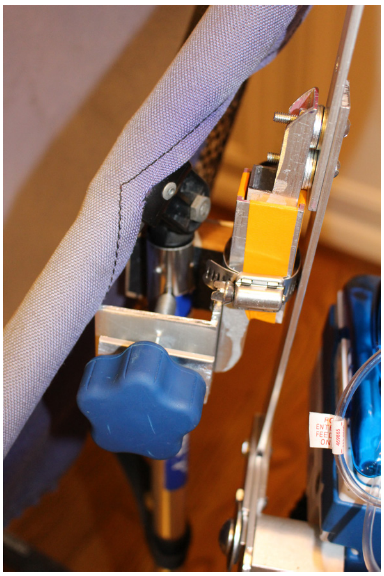






In the "quick-release system," the clamp portion separates from the vertical piece that holds the pump and feeding bag. The clamp can stay mounted to object while the rest of the system is taken off. The black handle is the "quick-release handle." Pulling this handle out will allow the rest of the system to be released. The handle snaps into place when the rest of the system is securely attached.





This system can also clip to vertical poles. If desired, the clamp can stay attached to the vertical pole while the rest of the system is released.


This system contains a stand, which has the same quick-release mechanism as the clamp.



The hanging function works the same way as in concept 1.

## APPENDIX C: PROTOTYPE EVALUATION FORM

**Prototype Evaluation Form**

**Subject Number___**
**Feeding Pump Used: ________________**
**Briefly describe your current method of hanging your feeding pump (i.e. IV pole, backpack, combination of IV and backpack, etc.):**

**The method described above is your "CURRENT METHOD."**
**Please evaluate your current method below by circling a number for each answer.**

**Overall, how easy to use is the CURRENT METHOD?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How easy is it to use the CURRENT METHOD at home?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How easy is it to use the CURRENT METHOD away from home in daily life, i.e. while leaving the house to go to a doctor's appointment?**

**Very Difficult** **Medium** **Very Easy**
**1 2 3 4 5 6 7 8 9 10**

**How easy is it to use the CURRENT METHOD away from home when going on an overnight trip, i.e. going to a hotel, staying with a relative, or going camping?**

**Very Difficult** **Medium** **Very Easy**
**1 2 3 4 5 6 7 8 9 10**

**How easy is it set up a feed with the CURRENT METHOD?**

**Very Difficult** **Medium** **Very Easy**
**1 2 3 4 5 6 7 8 9 10**

**How easy is it to clean the feeding bag after a feed with the CURRENT METHOD?**

**Very Difficult** **Medium** **Very Easy**
**1 2 3 4 5 6 7 8 9 10**

**How much do you like the CURRENT METHOD?**

**Very Little** **Medium** **Very Much**
**1 2 3 4 5 6 7 8 9 10**

**Concept 1: ALL-IN-ONE SYSTEM**

**Overall, how easy to use is the ALL-IN-ONE SYSTEM?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How easy is it to use the ALL-IN-ONE SYSTEM at home?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How easy would it be to use the ALL-IN-ONE SYSTEM away from home in daily life, i.e. while leaving the house to go to a doctor's appointment?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How easy would it be to use the ALL-IN-ONE SYSTEM away from home when going on an overnight trip, i.e. going to a hotel, staying with a relative, or going camping?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How easy is it set up a feed with the ALL-IN-ONE SYSTEM?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How easy is it to clean the feeding bag after a feed with the ALL-IN-ONE SYSTEM?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How much do you like the ALL-IN-ONE SYSTEM?**

| Very Little | | | | Medium | | | | | Very Much |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**What areas of feeding were more difficult with the ALL-IN-ONE SYSTEM than with your CURRENT METHOD?**

**What areas of feeding were easier with the ALL-IN-ONE SYSTEM than with your CURRENT METHOD?**

**If you could change anything about the way the ALL-IN-ONE SYSTEM works, what would you change?**

**Concept 2: QUICK-RELEASE SYSTEM**

**Overall, how easy to use is the QUICK-RELEASE SYSTEM?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How easy is it to use the QUICK-RELEASE SYSTEM at home?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How easy would it be to use the QUICK-RELEASE SYSTEM away from home in daily life, i.e. while leaving the house to go to a doctor's appointment?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How easy would it be to use the QUICK-RELEASE SYSTEM away from home when going on an overnight trip, i.e. going to a hotel, staying with a relative, or going camping?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How easy is it set up a feed with the QUICK-RELEASE SYSTEM?**

| Very Difficult | | | | Medium | | | | | Very Easy |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**How easy is it to clean the feeding bag after a feed with the QUICK-RELEASE SYSTEM?**

**Very Difficult Medium Very Easy**

**1 2 3 4 5 6 7 8 9 10**

**How much do you like the QUICK-RELEASE SYSTEM?**

**Very Little Medium Very Much**

**1 2 3 4 5 6 7 8 9 10**

**What areas of feeding were more difficult with the QUICK-RELEASE SYSTEM than with your CURRENT METHOD?**

**What areas of feeding were easier with the QUICK-RELEASE SYSTEM than with your CURRENT METHOD?**

**If you could change anything about the way the QUICK-RELEASE SYSTEM works, what would you change?**

**Overall, which is your preferred system:**

**__ Current Method**

**__ All-in-one system**

**__ Quick-release system**