IDENTIFYING DESIGN OPPORTUNITIES THROUGH A CULTURAL UNDERSTANDING OF MEDICAL NEEDLE USE, FEAR AND PAIN WITHIN THE UNITED STATES AND DEVELOPING NATIONS

by

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10% of the global population exhibits some level of medical related needle fear, but meaning and cause for phobia presumably varies greatly by culture (Abramowitz and Deacon, 2006). In the United States, 90% of pediatric populations are believed to exhibit some level of fear around procedures that involve a needle (Taddio et al, 2012). As a result, individuals can exhibit various consequential behaviors including healthcare avoidance, negative memory creation and conditioned anxiety responses. In order to understand the meaning of fear within the United States, psychological, physiological and emotional factors must be examined in pediatric populations.

In developing countries, however, needles are not viewed as frightening objects and instead have positive connotations. Injections are welcomed by populations and are the preferred method of treatment and therapy. In order to understand the preference for injections, one must understand the cultural beliefs around efficacy, the economic interests of providers and the poor communication that exists between patients and providers (Van Staa et al, 1996). As a result, injections are administered in unnecessary quantities. Because of the poor policy and regulations that exist within healthcare systems, the consequence of blood-borne disease transmission becomes a source of fear for global populations.

For both user groups, it is important to understand the cultural and behavioral implications for various types of fear. Through primary and secondary research, my final outcome will produce design opportunities that aim to decrease morbidity, mortality and cost in cross-cultural contexts.

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Chapter 1: Introduction

1.1 Intent

The purpose of this work is to determine if the concept of 'needle fear' is a universal condition across populations in the United States and developing countries and if meaning for fear is consistent. Further, this research will determine if it is possible to leverage a single universal design that can help reduce a component of needle fear for various cultural populations. If needle fear is found to exist within many cultural groups, then the sources and factors that contribute to different types of fear will need to be identified and analyzed.

As a designer, one must identify user behaviors, consumer insights and market opportunities when beginning the design process. Without full awareness for a project's user needs and problems, a successful design cannot be conceived. Compounded issues of culture, socioeconomics, history, physiology and psychology are important factors to evaluate when understanding complex issues such as global needle use, fear and pain. Interdisciplinary lenses will need to be used in research. As a final outcome, design opportunities, trends and constraints will be presented based on primary and secondary research findings.

1.2 Needle Fear: United States

Within the United States, needles used for medical purposes can be viewed as painful and frightening. The concept of needle fear is frequently observed in medical settings and refers to a fear of procedures that require the insertion of a needle into the body (Andrews et al, 2010). Needle fear can be low where only minimal levels of fear, anxiety and aversion can be observed. Or fear can be severely disabling and sometimes

life threatening, as in cases of pathologic needle phobia and instances where vasovagal (fainting) responses occur (Kettwich et al, 2007 and Abramowitz and Deacon, 2006).

Needle - related medical procedures can greatly improve the health and survival of individuals and are considered significant medical advances for patient health. However, literature suggests 10% of individuals within the United States report an "excessive" fear of needles in medical settings (Abramowitz and Deacon, 2006). This fear can consequently trigger avoidance behavior, distress and/or impairment, which can adversely impact and restrict important aspects of an individual's life (Abramowitz and Deacon, 2006). These are significant consequences and therefore, the condition of needle fear should not be taken lightly and opportunities to reduce fear should be explored.

1.3 Definitions

Fear

"An unpleasant emotion caused by the belief that someone or something is dangerous, likely to cause pain, or a threat; can cause change in brain and organ function and ultimately a change in behavior" (Oxford Dictionaries).

Anxiety

"Anxiety is distinctive from fear because fear occurs in the presence of an external threat. Anxiety is a psychological and physiological state characterized by cognitive, somatic, emotional, and behavioral components**.** Anxiety is the result of threats that are perceived to be uncontrollable or unavoidable" (Aspira, 2009).

Pain

"Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage". (Merskey and Boduk, 1994.)

1.4 Needle Fear: Developing Countries

Between the United States and developing countries there is a huge contrast in connotations of medical needles. Research suggests that developing countries show huge popularity for needles, specifically injections (Van Staa et al, 1996). It has been observed that many populations will frequently request injections for their perceived efficacy. Further, cultural, socioeconomic and historical factors have lead to frightening levels of injection administration. Given poor policy, funding and regulation within medical contexts, issues of needle reuse and repackaging can have significant effects on morbidity and mortality. Therefore, any fear that is derived from needles in global contexts is less associated with pain and more so with larger consequences including sterilization, disease transmission and contamination that result from needle reuse.

Needle use is a complicated issue that combines cultural ideas around illness, socioeconomic factors, historical accounts of efficacy and poor patient-doctor relationships. While it may not be possible to fix the entirety of the problem which includes needle overuse, reuse and misuse, designing for one part of the problem can still have significant effects on human health and safety.

Chapter 2: Methods

This project uses primary and secondary methods to determine cause for needle fear in United States and global populations. By using design principles to build cultural empathy, rationale for needle fear, context for the problem and a definition of consequences, design opportunities can be identified which will aim to decrease morbidity, mortality and cost in cross-cultural contexts.

2.1 Defining User Populations

In defining the user populations, this work looks at pediatrics in the United States, and adult populations within developing countries. Research in the United States suggests youth populations exhibit significantly higher levels of distress and needle fear when compared to adult populations (Taddio et al, 2012). At the global level, a majority of published literature is focused on studies of adult populations and most injection misuse is reported amongst adults.

2.2 Defining Needle Use Cases

For the purpose of this work there will be a focus on a single needle use case for each country or cluster of countries. This singularity will help focus the research and insights for each user population. For the population of pediatrics within the United States, this work will focus on needles used mostly in intravenous situations also known as venipuncture needle use. A venipuncture procedure is the most feared medical experience for children, so it is appropriate to research the physical, psychological and emotional responses that lead to pain, distress and needle aversion (Crowley et al, 2010). For developing countries there will be a focus on needle use cases that involve

injections. Needle abuse in developing countries is mostly attributed to therapeutic injection overuse and a majority of the adverse consequences that lead to fear are due to injections.

2.3 United States Research Methods

Peer reviewed literature will be reviewed to provide background, context, and relevant research around the issue of pediatric needle fear within the United States. In addition, a primary research study and a series of observations will be performed at Oregon Health & Science University (OHSU) at Doernbecher Children's Hospital. Methods for primary data collection include doing observation in the pediatric clinics for routine vaccinations amongst children aged 0 - 15 and observation of children undergoing anesthesia for surgical or MRI purposes amongst patients aged 3 – 12 at the sedation unit. This will provide a brief ethnography to help define key behaviors and reactions to needle use in medical contexts. Further, interviews with nurses, anesthesiologists, medical assistants, resident assistants and parents will be used to gain professional and personal insight. Lastly, surveys sent to pediatric anesthesia nurses will provide quantitative data to justify design work. This series of interviews, observations and surveys will help define pain points and problem areas related to vaccine and anesthesia delivery within a specific user population. Trend analysis will help inform design opportunities and will identify gaps in existing methods of vaccine or anesthesia delivery. Although the focus is on venipuncture needle use, observation of vaccination delivery will still help inform how children exhibit distress around any kind of needle. During observation, it will be important to recognize existing coping or distraction methods and their success at reducing distress.

2.4 Global Research Methods

Research performed at the global level will include a survey of peer-reviewed literature and interviews with first-generation healthcare providers born and raised in Iraq, Korea and Japan. This will help compare and contrast healthcare delivery within foreign developing and developed countries. The literature survey will include an understanding of different cultural reactions to needles and an exploration for why developing countries have higher rates of injection use. Further, the adverse consequences of injection misuse and overuse will be explored. These consequences include disease transmission, unnecessary economic burden and over and unnecessary medication of individuals.

2.5 Design Process

While this project will not be taken through the entire design process, heavy focus on user research, analysis and trending will help produce design opportunities and design constraints that look at the issue of reducing needle fear in various populations. My design objectives include understanding user behavior around needle use and understanding cultural perceptions of needles and pain. This will allow for analysis of various use case scenarios for both end users and healthcare providers. Finally, as a culmination of primary and secondary research, I will present design opportunities for reducing needle fear, constraints for universal design and key trends that exist within each user group. All research and findings will be presented in an accompanying trends book that will visually communicate through infographics.

Chapter 3: Literature Review: Needle Fear in the United States

3.1 Defining Needle Fear

Trypanophobia, the medical term associated with needle fear, is a globally prevalent condition and has been formally recognized by the DSM – IV (American Psychiatric Association Diagnostics and Statistical Manual of Mental Disorders) as "the presence of fear and the occurrence of avoidance behavior [in relation to medical needle use]" (Sokolowski et al, 2010). Specific symptoms of this condition vary greatly by the individual but physical and emotional reactions can include "fear, anxiety, erratic heart rate, hypertension, increased sensitivity to pain, shock, vertigo, fainting, excessive sweating and nausea" (Andrews et al, 2010). Further, physiological indicators can include changes in blood pressure, electrocardiogram, heart rate and stress hormone levels (Sokolowski et al, 2010).

In severe cases of needle fear, patients choose total avoidance of healthcare practices to eliminate any exposure to needles. However, because a majority of modern medicine is dependent on the hypodermic needle for medical testing, vaccine delivery and/or drug therapies, this poses serious risks to both the individual and to larger populations (Sokolowski et al, 2010). Ultimately, the fear and anxiety associated with medical needle use can inhibit a patient's ability to receive medically essential treatment, which puts them at risk for future problems (Abramowitz and Deacon, 2006).

Clinical approaches to reducing needle fear are often left to the digression of the nurse or medical assistant. There is little clinical obligation to provide pain management for needle use and needle fear. Within pediatrics, existing research and

literature highlights that children's pain is a low priority and is therefore negated and undertreated by healthcare professionals (Carlson et al, 2000). That being said, clinicians should be aware that needle fear is a common condition that may lead to avoidance of medical treatment, which can result in intensifying existing or non-existing medical problems (Sokolowski et al, 2010). Therefore, medical staff should seriously explore coping methods for needle fear, especially in high-risk populations, which includes pediatrics.

3.1 Needle Fear in Pediatric Populations

It is not surprising that children fear needles and the perceived pain they inflict (Humphrey et al, 1992). While there is research that proves needle fear is present in adults, trypanophobia is an issue that is more prevalent in youth populations. In contrast to 10% of the general population suffering needle fear, 90% of young American children exhibit severe distress around needles (Taddio et al, 2012). While all types of medical needle procedures induce fear for kids, children see venipuncture as the most fearful aspect of attending a hospital (Duff, 2003). Venipuncture procedures involve intravenous placement of a needle for delivery of liquids or for drawing of blood, where there is some puncture of a vein. Fortunately, a majority of children are at least able to tolerate venipuncture related experiences using a variety of coping strategies based on age and gender (Duff, 2003). Research indicates there is still a large proportion of children who are unable to tolerate these experiences and consequently display high levels of pain, fear and behavioral distress (Duff, 2003). Many times, this resistance leads to needle insertion being abandoned or the child having to be restrained or sedated.

Taking some of these more severe actions can lead to further distress for everyone involved (Duff, 2003). These highly traumatic experiences make follow-up visits exponentially harder and can create lasting and increased needle fear for the child.

Every year, about 30 million children make visits to the emergency department (ED) in the United States (Cavender et al, 2004). Needle placement or venipuncture is a common healthcare procedure that frequently takes place in the ED, which is already a foreign environment for children. Foreign environments reduce the amount of control a child has over the situation and inhibit their awareness for what is happening. Therefore, children often associate procedural pain with ED visits (Crowley et al, 2010). One study of pediatric patient and procedural pain determined the placement of an intravenous catheter as being the *most* common source of pain cited (Crowley et al, 2010).

The level and intensity of anticipatory fear caused by these situations can contribute to the intensity of pain and emotional distress. This creates an increasing and cyclic pain-emotional distress cycle (Carlson et al, 2000). Therefore, as pain increases, emotional distress also increases which makes children more sensitive to physical pain. Now, the situation begins to negatively spiral and is dreaded by the child, the parents and the healthcare provider. An intervention to reduce anticipatory fear could be successful at reducing physical pain and emotional distress.

3.2 Pediatric Pain Management

Within the medical community, there is a growing recognition that children experience avoidable pain and distress during invasive procedures within pediatric emergency and non – emergency care. These invasive procedures can include venipuncture, injections and intravenous catheter placement (Crowley et al, 2010). The pain from these experiences will likely play a significant role in shaping a child's pain response to future events, likely in a negative manner.

There are many theories to why adequate pain management for invasive procedures is overlooked by medical staff. There is growing evidence that children exhibit high levels of psychological distress and physical pain during invasive needle procedures, therefore it is surprising greater efforts have not been taken to reduce needle fear. Some believe there is a misperception that managing procedural pain is overly time consuming and results in treatment delay (Crowley et al, 2010). Additionally, there is "the misrepresentation of pain as anxiety, a lack of pain assessment, inadequate knowledge of pharmacological and non-pharmacological pain management, and fear of adverse reactions to medications" (Crowley et al, 2010). However, efforts to reduce pain and distress in pediatrics can lead to increased patient satisfaction and enhanced job satisfaction among nurses. There is such a large cost to unmanaged pain for the psychological and physiological well being of children, that pain management is a worthy cause for research, exploration and design (Carlson et al, 2000).

3.3 Distress as a Result of Needle Fear

During a venipuncture procedure, the child will directly experience distress. However, when a child experiences distress, parents and participating healthcare professions can feel similar emotions. (Taddio et al, 2009). The term ‘distress’ refers to a combination of fear, anxiety and pain (Duff, 2003). There are many theories in understanding how children acquire fear but “contemporary explanations have attributed causation to interactions between genetically linked behavior patterns, temperamental predispositions, normal developmental fears, parental psychopathology, and discrete learning experiences, either direct or vicarious, which over time are maintained by irrational thoughts and attention biases” (Duff, 2003).

Chapter 4: Field Study: Oregon Health & Science University

4.1 Pediatric Clinics

Methods:

- Observation of eight patients aged 0 – 13 undergoing routine vaccination
- Interviews with nurses, medical assistants and registered nurses who perform routine vaccinations on children

User population: Random population of patients who were available during the observation period on December 12, 2013.

- 10 - month old baby boys (2)
- 12 - month boy
- 12 - month girl
- 11-year old boy
- 10 - year old boys (2)
- 13 - year old boy.

Insights: When comparing the user groups of babies (age 0 – 12 months) and older children (age 10 – 12), there are significant differences in reactions and cause for fear or pain. In young infants, physical pain is the main source of distress, fear and pain however in older children, psychological factors lead to anticipatory fear, procedural fear and emotional distress.

Infants (age 0 -12 months):

Babies react purely to physical pain and therefore only begin crying once the needle has been inserted into their body. Given a lower cognitive awareness for what is

happening, babies seem to only respond on physical instinct, as opposed to factoring in anticipatory, procedural pain or psychological pain. It takes a couple seconds for infants to respond to the pain, but in my observations, their reaction to emotional distress is always to scream or cry.

Given babies react strongly to physical stimuli, it is important for parents or nurses hold the infant's arms and legs in place as it is instinctual for them to try and grab what is causing pain. During injection procedures, the biggest concern is safety. Providers must make sure that a patient does not grab or bump the needle, as this is dangerous for the child and the provider.

Babies typically are given shots in their thighs and at certain times during their immunization schedule, can receive four shots simultaneously. Usually two nurses will administer all the shots at one time so the procedure can be as fast as possible. Once the procedure is done, the parent is usually instructed to pick up the baby and comfort him/her. Each parent appears to have his or her own coping mechanism and may either try to be calm around the baby or be loud and more distracting to the child.

At the provider level, there are different beliefs around what is most effective in comforting or distracting a baby. Some nurses believe that if a baby is given a mixture of sugar and water before their injection, their level of pain can be lowered. However, even when the four babies were given the sugar mixture, they still cried and screamed intensely. Further, some pain nurses will suggest nursing the baby during the immunization, while registered nurses will advise against this practice. The nurses and medical assistants reported there is little training in nursing school for distraction or coping techniques and anything they implement is learned on the job. Sometimes

devices like flashing toys or lights can help distract an infant and reduce their crying time. But regardless of how much distraction or comforting is implemented, babies appear to always cry during a needle stick, given it is a direct pain stimulus.

Children (10 – 13 years):

Children age 10 – 13 experience very different behavior during their immunizations. Psychological factors play a big role in cause for fear. In observing the four children aged 10 – 13, it seems older children like to know exactly what is happening and how much the injection is going to hurt. Some of the children will ask "how much is this going to hurt", "where are you going to put the needle", "where is it going to hurt" and "when is this going to happen". These questions suggest anticipatory fear and procedural fear as the main cause for distress. Although children are afraid of the physical pain, they realize the injections did not hurt as much as they thought after the fact. Children typically request the site of the least pain and tend to look away from the needle when the injection takes place. Children want the procedure to be as quick as possible and demonstrate extreme relief after the procedure. It appeared that the children prefer a countdown to the needle injection, as this seems to give them more control and knowledge of the situation.

Physical reactions include tightening of the muscles and clenching the arms closer to the body. Unfortunately, when a child tightens their muscles, this makes the injection more painful and more difficult for the nurse. Further, this can result in bruising. If a child can stay relaxed and calm, the experience will be more successful and less painful.

Nurses believe needle fear in kids is entirely psychological. Children get extremely worked up and nervous prior to the injection and then realize it was not as painful as they had thought. If the issue was only related to physical pain, there would be a stronger reaction after or during the injection, where the physical pain happens. But a majority of distress and pain comes before the actual injection. In worse case scenarios, older children will scream, cry, run and hide. In these instances, sometimes a parent or provider will postpone the immunization if it is not critical. Safety is still a main concern for all age levels as there have been instances where a child will try and grab a syringe or the nurse's arm and inadvertently scratch or hurt his/herself.

Nurses have different distraction or coping methods but find it harder to distract older children. Sometimes nurses try and talk to the child and ask questions, but kids do not seem to like talking during the procedure. Nurses think pinching a child at the same time can relieve some of the physical pain but usually total transparency about the pain and procedure is important. Saying things like "I warmed up the liquid just for you" can sometimes make a child less nervous. These types of instances, while small, can provide children with a feeling of being cared for and catered to.

Chapter 5: Literature Review: Addressing Needle Fear Through Coping, Intervention and Distraction

5.1 Prevention and Alleviation of Pain and Distress

There are several studies in primary literature that demonstrate how various interventions can help reduce pain and anxiety in association with medical needle use (French et al, 1994). These have included “empathetic delivery of information before giving the shot or [needle stick], extensive cognitive preparation and practice at home, skin coolant spray, and passive distraction using music”, amongst other techniques (French et al, 1994). Many of these experimental methods have provided some relief for pediatrics. However, evidence highlights many children receive immunization or needle sticks without any “formal attempt at reducing the fear and pain associated with this procedure” (French et al, 1994). This could suggest healthcare professionals either believe immunizations are not painful, or not painful enough to warrant intervention. Further, some believe any type of intervention would be too time consuming for a clinical setting and therefore not worthwhile. Regardless, extensive studies presented in primary literature suggest needle interactions are painful enough to create significant distress for children and some adults (French et al, 1994). Therefore, it is important to understand the role of pain management in relation to medical needle use, especially in pediatrics.

5.2 Cognitive Behavioral Treatment / Intervention

Psychological interventions for managing pain and distress in pediatrics are primarily “cognitive-behavioral treatment” (CBT) (Ulman et al, 2008). Existing

research suggests that interventions be developed that target emotional and sensory processes to reduce the child's discomfort during common medical procedures such as venipuncture (Cavender et al, 2004). "CBT interventions for pain management assist the child to develop and apply coping skills to manage the pain and distress, and when developmentally appropriate, help the child comprehend how thoughts and behaviors can alter their experience of pain" (Ulman et al, 2008). One research study defines cognitive interventions as "interventions that involve identifying and altering negative thinking styles related to anxiety about the medical procedure and replacing them with more positive beliefs and attitudes, leading to more adaptive behavior and coping styles" (Ulman et al, 2008). Further, behavioral interventions were defined as "interventions based on principles of behavioral science and learning, by targeting specific behaviors" (Ulman et al, 2008). A combination of cognitive and behavioral treatment requires some element of both.

5.3 Cognitive Strategy: Attitude

Coping strategies around attitude, empathy, instruction, and practice have all been shown to have successful effects upon pain and anxiety with medical procedures in general and those that deal with needle usage (Jacobson et al, 2001). For example, in a study titled *Making vaccines more acceptable –methods to prevent and minimize pain and other common adverse effects associated with vaccines*, data shows children suffer less distress with vaccinations when their parents value vaccinations (Jacobsen et al, 2001). This creates a positive association with vaccines, which reduces fear. Pediatric anesthesiology nurses believe that when parents make a procedure seem normal and 'just what needs to be done', children are calmer and more accepting. Other successful

methods to adjust attitude around needle use includes: empathic instruction at the time of needle use and instruction and practice at home prior to needle –related visits (Jacobsen et al, 2001). Further, when parents tell their child in advance of appointments, there is a reduction in distress observed at the time of the needle interaction. The American Academy of Pediatrics recommends that pediatricians advise parents to never threaten their child with injections or use them as punishment for inappropriate behavior. Vaccines and needle use in medical settings should never be viewed as a danger or punishment to children. Lastly, parents are instructed to act as comforting agents as opposed to restraining agents and should never negatively talk about procedures in front of their child.

5.4 Coping Strategy: Distraction

Research has demonstrated that children who use active methods of coping report less pain (Cavender et al, 2004). These coping strategies, which involve distraction methods, provide children with a larger sense of control and mastery of the experience (Cavender et al, 2004). Literature suggests distraction is an effective method for distress and pain prevention in children (Jacobsen et al, 2001). “Distraction, a cognitive, nonpharmacologic intervention, tends to refocus thinking by directing attention away from the pain associated with the procedure to a non-noxious stimulus in the immediate environment” (Cavender et al, 2004). Distraction effectiveness is very dependent on the patient’s individual interpretation of the pain and the diversional capacity of the distractor. An effective distractor must stimulate the senses and be developmentally sensitive. Further, the distraction tactic must be easily implemented, actutely engaging, and able to captivate and sustain a child’s interest. Some examples of

successful distractions include blowing bubbles, movies, cartoons, books, party blowers, nurse coaching, parental coaching, guided imagery, music, novel toys, illusion Kaleidoscopes, counting, breathing, video games, hypnosis, and virtual reality glasses (Cavender et al, 2004).

In the pediatric sedation unit at OHSU, distraction in the form of TV screens is highly successful at reducing fear. Moveable TV screens are placed directly in front of a child's face so they cannot watch what is going on. Positive reinforcement is provided in the form of stuffed animals that are handed to a child after the procedure. This acts as a positive reward system and gives comfort to the child and further distraction.

5.5 Coping Strategy: Body Position

The benefits of physical parental closeness in enhancing a child and parent's coping have been extensively explored. Providers at Rainbow Babies and Children's Hospital in Cleveland, Ohio witnessed that forcing a child to lie flat on a treatment table during venipuncture often result in "loss of control, panic, crying, and struggling to get up" (Cavender et al, 2004). This supine position contributed greatly to increasing the child's stress during venipuncture. Instead, the Cleveland practitioners created a program of positioning for comfort during invasive procedures that includes "a secure, parental- hugging hold and close physical contact during the procedure." (Cavender et al, 2004). This positioning required fewer people which promotes the child's sense of control and allows parents to fulfill an active role in supporting and comforting their child (Cavender et al, 2004). These are both important factors in reducing distress for child and parent.

For patients at the sedation unit at OHSU, children lay in little beds that allow them to be propped up at a comfortable level. Most children cope well with this position, but some of the more anxious children need to sit in their parent's lap. If a child sits in a parent's lap, a nurse can perform the needle stick without the child watching and the extra support from the parent can make sure the child does not move and injure him/herself.

5.6 Coping Strategy: Parental Involvement

Direct coaching by parents on the use of distraction techniques increase a child's level of coping. The type of parental behavior is very influential on a child's emotional response. High parental coping and low parental distress is a very strong correlation for better coping and less distress in children (Cavender et al, 2004). Parental distress and anxiety will negatively influence a child's state.

5.7 Pharmaceutical Intervention: Refrigerant Topical Anesthetics

It is not recommended to use ice as a topical anesthetic but instead to use refrigerant topic anesthetics as a means of anesthesia. Studies have found that a eutectic mixture of 2.5% lidocaine and 2.5% prilocaine (EMLA) is an effective topical anesthesia for children (Jacobsen et al, 2001). One study by Halperin et al, demonstrated less pain with EMLA than placebo for the administration of measles-mumps-rubella.

The logistics with EMLA have several drawbacks in relation to vaccinations. First, the application of the mixture must happen 30 - 60 minutes prior to injection which means this must happen in the child's home as opposed to a clinical setting. This

becomes a parental responsibility and could lead to increased anticipatory fear. Second, this topical anesthesia requires physician's prescription. And lastly, the cream is relatively expensive and its routine use with vaccinations may dramatically increase the cost of the childhood vaccination program (Jacobsen et al, 2001). Therefore, accessibility may be a limiting factor. Further, EMLA may prevent physical pain but it will not prevent or treat distress, anxiety and anticipatory fear (Jacobsen et al, 2001).

At OHSU, children arrive to the sedation unit with significant time to spare before their sedation time. This allows nurses to place EMLA cream on the site of the needle stick and cover it will tape to prevent children from removing it. The cream takes 30 minutes to activate and is largely successful at reducing the amount of physical pain children can feel. The combination of numbing cream and distractions can greatly reduce negative experiences and can often prevent a child from seeing or feeling the needle placement.

Chapter 6: Factors that Contribute to Needle Fear

6.1 Fear in Pediatrics

Children generally report various types of fear including social fear, medical fear, fear related to animals, fear of danger and dying and fear of the unknown (Bloch et al, 2008). In medical and hospital contexts, the most intense fears reported by elementary aged children include "fear of separation from the family, having injections and blood tests, staying in the hospital for long periods of time and being told 'bad news' in regards to their health status" (Bloch et al, 2008). By understanding different types of fear amongst pediatrics, literature has inferred different factors that contribute to an individual's experience. These include individual factors, parental factors and situational factors. Further, there are demographic and psychological characteristics that are also associated with fear. Every individual has his or her unique set of factors that create needle phobia.

6.2 Individual Factors

At the individual level, age has been consistently shown to co-vary with needle pain and fear where ratings decrease with an increase in age (Duff, 2003). Individual temperament is another key indication where children that are more active, intense or negative in mood can generally be seen to display higher levels of distress. (Duff, 2003). Temperament can determine whether or not a parent is willing to psychologically prepare their child for venipuncture experiences (Duff, 2003). Further, individual cognitive abilities influence how children perceive, understand, remember and report pain and distress.

An individual's quantity of venipuncture experiences does not show a correlation to higher pain or distress levels, however, children are able to remember medical experiences quite vividly (Duff, 2003). In highly negative experiences, there is an increase in subsequent anxiety, distress and non-cooperation. So perhaps the quantity of *adverse* experiences is influential. In a study performed with a sample of 7-18 year olds, 63% recalled having a very unpleasant and painful needle-stick, and of these, 46% rated their fear as being "very" or "extremely" high (Duff, 2003). The individual level of distress that a child experiences during an needle related procedure is very important for how the child will remember the event. "Greater distress is associated with more negative memories, which lead to more reports and displays of pain and distress at future encounters of the same stressful event" (Taddio et al, 2009). Negative memory creation amongst venipuncture experiences is pivotal in leading to increased worry and anticipation. Further, sensory stimuli in the clinical context are more invasive. Therefore, most medical experiences can be triggered by memories of smell, taste, sight and touch.

6.3 Parental/ Family Factors

Parents find visits to hospitals with their child an anxiety provoking experience. While a child is directly experiencing pain and distress, seeing one's child in pain causes significant distress for parents. Parents experience distress and anxiety knowing their child is sick, but also from knowing that their kid will have to endure painful procedures that involve needles. "There is strong correlation between parental anxiety and child distress during venipuncture" (Duff, 2003). Parents typically prefer to be present during venipuncture and almost a majority of children find this to be the most

helpful technique for reducing distress. Those parents taught to use explicit distraction and comforting techniques found them helpful and useful in aiding their child. Therefore, parental presence is very important as is a parent's temperament.

One of the children at the OHSU sedation unit had a twin sister (4 years old) who had recently gone through the same procedure. The parent explained how she had prepared her sister for the experience by saying, "the procedure does not hurt as much as you think". This seemed to help tremendously in the coping of her sister. While the patient had a little bit of pain during the needle stick, she was still relatively calm during the whole procedure. Therefore, positive reinforcement by the family and communicating positive experience will help lower anticipatory fear.

6.4 Situational Factors

There is strong correlation with the level of distress and the setting and conditions under which needle insertion is performed. Children who enter very foreign environments i.e. accident and emergency units have little familiarly and few pre-existing coping strategies. These user groups are reported to find needle insertion more distressing than those who have the procedure undertaken by known clinicians in familiar settings (Duff, 2003). Further, those patients with recently diagnosed chronic illness report higher levels of pain and fear than those individuals with a longer history of illness (Duff, 2003). However, patients who are more familiar with clinical settings still become very anxious when exposed to visual procedural cues including seeing medical equipment, blood samples from other patients or hearing other children in distress (Duff, 2003).

When looking at the pediatric population at OHSU within the sedation unit, children are very familiar with hospital visits. Of the 5 patients observed, all had been to the hospital at least one time that year, with some patients having up to 4 visits in a year. As a user group, the children seemed very calm around the procedure of an IV catheter placement. Only one child cried and screamed prior to the procedure, but all the other children were calm and watched attentively to the procedure. When talking to the parents, they often responded, “she is so used to it that it doesn’t bother her at all. She has no fear around the procedure”. In comparing these patients with the immunization patients, the immunization patients had significantly more fear and distress. This suggests patients who make more trips to the hospital are therefore more familiar with the process, procedure and nursing staff. As a result, they have less distress than children who view hospitals as foreign environments. Further, an anesthesia nurse commented that children who are in chronic pain and have chronic illness express no level of pain or fear around needle procedures as the level of pain they feel from their condition is so much greater than a needle stick. Additionally, the hope the needle stick or injection will make them feel better outweighs the slight pain inflicted from a needle. Therefore, if pain warrants feeling better, it is worthwhile and less distressing.

6.5 Demographic and Psychological Characteristics

Younger age, lower body weight and first time experiences can have a large impact on emotional and physical response (Abramowitz and Deacon, 2005). Psychological factors including blood and injury fear and pain sensitivity can greatly influence adverse reactions, including vasovagal responses (Abramowitz and Deacon, 2005). Additionally, disgust plays a large role in understanding fear. Disgust reactions

to phobic stimuli can provoke an individual's fear of needles because they believe there is a potentially contaminated stimuli from the blood or injections that they must protect themselves from, thus there is a creation of fear. (Abramowitz and Deacon, 2005). Disgust reactions are often associated with parasympathetic activity and therefore put individuals at risk for adverse emotional reactions and fainting.

6.6 Fear versus Phobia

Fear can be considered a normal response to threatening stimuli that involves three response systems: "physiological arousal, covert feelings and thoughts, and overt behavioral reactions" (Duff, 2003). Phobia "is an unreasonable response to a benign stimulus, resulting in at least one of the three elements being excessively and persistently activated" (Duff, 2003). There are many debates around what is benign versus threatening. But "some believe that needles and venipuncture are not benign stimuli for children, but unpleasant sensory and emotional experiences which invade physical and psychological space and threaten a loss of control" (Duff, 2003). Therefore, what is seen in clinical contexts is neither fear or phobia but an anticipatory fear and distress. Typically, children and adults do not become fearful of viewing needles outside of a medical context, which would suggest the fear is not exclusively related to needles as objects. Context, including situational factors, is how the fear is derived. Lastly, "ratings of fear are much higher prior to needle insertion, after which they sharply decrease and are no different when children are offered a needle-less injection system" (Duff, 2003). Therefore, perhaps there is fear around the procedure, rather than the needle stick itself. Fear associated with needles in medical contexts

should not be considered as purely ‘phobic’ but rather as ‘anticipatory’ or ‘procedural’ distress (Duff, 2003).

6.7 Physical Pain That Derives Fear

The International Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (Taddio et al, 2009). Pain is highly subjective—at an individual level and a cultural level. This official definition of pain demonstrates the individuality of pain and the importance of life experiences, especially those in early years of life. A healthy child’s main interactions with needles in their early life are through immunizations. Therefore these iatrogenic pain experiences have the potential to play a significant role in shaping the child’s pain during similar events in the future (Taddio et al, 2009). In research studies, it has been reported that children perceive immunization pain differently than adults, where children report more pain (Taddio et al, 2009). Therefore, children are the population where pain management should be taken the *most* seriously. Negative experiences can adversely impact an individual for life and if needle fear can be avoided and managed at a young age, this can reduce fear in adulthood.

The physical pain that comes from injections or venipuncture needle use is through “activation of peripheral nociceptors during two separate events” (Taddio et al, 2009). First, is when the needle punctures the skin and tissues and second, when the vaccine constituents are deposited into the tissue (for vaccination delivery) (Taddio et al, 2009). The level of distress that is typically experienced by children undergoing needle interactions in medical environments is much higher than expected given the

extent of the actual physical injury that is sustained from the procedure- which is very low. There are many experiences that can cause significantly more physical pain that are not as feared by children. So it must be the anticipatory fear that is derived from an irrational perception of how painful the experience will be that leads children to fear needles so greatly.

The planned nature of vaccination or venipuncture events tends to create induced anticipatory fear response. It is normal for children, or adults, to fear potentially threatening or harmful situations, which could include vaccine injections or venipuncture procedures. But this type of anticipatory fear can dramatically increase pain and distress during the actual procedure (Taddio et al, 2009).

Chapter 7: Addressing Differing Cultural Perceptions of Pain

7.1 Cultural Conceptions of Pain

It is believed there is universality to pain, given pain is part of the human condition. However, pain complaints vary by culture (Free, 2002). All humans experience the stimulation of pain fibers, which tell the human brain that something is wrong, however, the perceptions and control of pain varies from culture to culture (Free, 2002). Pain is completely subjective as it resists medical testing and has no meters or chemical measures (Free, 2002).

Pain is a pervasive condition in large and diverse societies such as the United States (Free, 2002). “In the USA, pain is among the biggest cause of disablement and, hence, is responsible for a substantial apportionment of disability payments” (Free, 2002). Healthcare professionals are always trying to provide the best management for an individual’s pain and suffering so a cross-cultural exploration of pain perception is necessary to understand how to treat individuals on a cultural-case by case basis.

7.2 Case Study: Pain Perception in the United States versus Africa (Ghana and Ethiopia)

In a research study that looked at pain perception of HIV patients in the United States, Ethiopia and Ghana, United States patients rated their pain severity much higher than the Ethiopian or Ghanaian populations. In the United States, the average pain intensity was 6.6 on a numeric scale of 0 – 10: 0 being no pain and 10 being pain as bad as one can imagine (Jelly, 2011). In the Ethiopian population average pain intensity was measure as 4.54 and in Ghana, the average pain intensity was measured as 4.73 (Jelly,

2011). African patients reported much lower levels of pain affecting daily activities such as bathing and dressing in comparison to American patients (Jelly, 2011). Further, American and African patients had different outlooks on the impact of pain on overall mood. American patients have a mean level of interference of pain on mood of 6.07 and Ethiopian patients report a mean level of 2.3 and Ghanaian patients have a mean level of 2.8. Even though American HIV patients receive stronger analgesic medication than African HIV patients, they were still more likely to report lower levels of pain relief achieved through pain medications (Jelly, 2011).

There are various explanations to explain the results. Cultural differences in self reported pain levels can be a result demographic, socioeconomic and clinical variables. Further, coping mechanisms and social support are important variables that can influence pain perception. Lastly, genetic or biological differences exist across cultures and can influence medical co - morbid medical conditions and history of pain issues.

7.3 Case Study: Pain Perception in the United States versus India

In 2000, a study was performed across the United States and India and took a cross-comparative study of pain reporting across college students in the US and India. The outcomes of the study concluded that Indian students presented a higher threshold for pain tolerance, and a lower rate of overall reporting of pain, than students from the United States (Houser and Zamponi, 2011). The participants appeared to have no physiological correlation that suggests Indian students innately possess a higher pain tolerance than US students. Instead, the study demonstrated that social conditioning and

values can greatly influence pain expression and pain reporting (Houser and Zamponi, 2011).

7.4 Pain and Cultural Rituals

Many cultures throughout the world have rituals that entail some component of physical pain. For example, ritual crucifixion in the Philippines includes physical pain as an integral component of their cultural expression of faith (Houser and Zamponi, 2011). Further, in Malaysia, three day *Thaipusam* festivals require individuals to fast, enter into trances and pierce the skin and flesh with hooks and needles. This self-induced pain is believed to be a pathway into the divine (Houser and Zamponi, 2011). Practioner firewalkers carry kavadis, which is a self-constructed symbolic burden that severely pierces the flesh. Researchers believe that the hyper arousal experienced by participants in such situations results in the increase release of adrenaline, which is known to elevate the tolerance of pain. At the physiological level, this increase of adrenaline interferes with pain signaling at the spinal level, which allows practioners to endure the pain and have lower self - reporting levels (Houser and Zamponi, 2011).

7.5 Cultural Differences around Pain Expression and Communication

Within the ethnic group of the Bariba, located in Benin and Nigeria, pain is seen as a shameful sign of weakness. Young boys are expected not to cry during painful situations and women are expected to deliver their own babies with no outward signs of pain (Jarrett, 2011). In surveys of other ethnic groups and pain expression, India populations rate expression of pain as less acceptable. Further, Japanese populations report high levels of stoicism and rate it as less appropriate for people of either gender

to express pain. has different terms for pain depending on the status of the sufferers (Jarrett, 2011).

Perhaps in the United States it is more acceptable to discuss and admit pain. Americans often report higher levels of pain during various situations, whether or not it is medically related. It also seems there is higher expectation within the United States for pain management. Americans willingly seek medication to reduce small signs of pain, whereas other cultures are very resistant to medicating things like headaches. But since there is no universal test or chemical measure for how much physical pain someone is in, research must rely on individual communication and perception of pain. These perceptions of pain greatly impact levels of fear. Since there is such a high level of fear around pain from needles within the United States, it is questionable whether or not other cultures see fear of pain as a concern.

Chapter 8: Literature Review: Differentiating Needle Use in Developing Countries

Within the United States, there is great amount of fear around medical needle use, but most of this fear is attributed to anticipating pain that can be inflicted, both physically and psychologically. While the development of the hypodermic needle and other injection devices are Western creations, it seems the condition of needle fear is also a Western created condition. According to peer-reviewed literature, this fear and distress is not greatly reported in other populations and instead injections are sought after.

8.1 Popularity of Injections In Developing Countries

In many developing countries there is a large preference for injections over oral medication, which leads to widespread misuse and overuse. Unlike the United States where fear can create healthcare avoidance, needles and injections are welcomed in developing countries. This is a great cause for alarm for many healthcare professionals and for the World Healthcare Organization. Research believes there is an enormous popularity of injections because of “local and cultural beliefs about illness and concepts of efficacy, economic interests of private providers and lack of patient-provider communication” (Van Staa et al, 1996). Further, historic, cultural and socioeconomic factors are important considerations that help answer the question of ‘why injections are so popular in many developing countries’.

Historically, individuals saw the amazing cures that were achieved by injections such as “quinine to treat malaria, and penicillin to treat jaws” (Van Staa et al,

1996). Throughout generations, injections are connected with efficacy and this idea continues to be passed down. Further, socioeconomic factors are determinants in the widespread misuse of injections. Research demonstrates that healers are able to demand a higher fee for administering injections as opposed to prescribing tablets. So if healthcare workers or healers can convince individuals that injections are more effective, they can consequently increase their profits. Given high respect for healthcare workers, patients often blindly follow the advice of doctors because there is so much trust and respect. Further, there are many cultural factors that lead populations to believe injections are more effective due to their ability to fight 'deeper diseases'.

The overuse and misuse of injections can lead to several adverse consequences including disease transmission, unnecessary economic burden and over and unnecessary medication of individuals. This issue is overwhelming because intervention is not a one step process. In order for policy or change to be implemented, there must be a truly holistic understanding of "the cultural meaning of injection, their place in medical practices, and their influence on human relations" (Van Staa et al, 1996). Further, cultural empathy is intrinsic to any type of change and solution.

8.2 Injection Types

Injections in developing countries are not exclusive to just vaccinations, which is typically how injections are thought of in US contexts. Rather, the types of injections that are typically identified include therapeutic injections, infusions (large volumes), contraceptives and immunizations (Van Staa et al, 1996). A majority of the injections used in developing countries are for therapeutic purposes and in Southeast Asia, intravenous infusions are popular (Van Staa et al, 1996). In Pakistan, doctors offer

special mixtures of injectable medication, for example “an antibiotic, mixed with an antimalarial, a steroid and/or vitamin B12” (Raglow et al, 2001).

In Uganda, there was no reported use of infusions, contraceptive injections or immunizations being received in the household. Access to immunizations, contraceptives and infusions are restricted to established medical facilities. Therapeutic injections are much more readily available than contraceptives or immunizations. Further, therapeutic injections can be delivered anytime someone is sick, whereas contraceptive and immunization injections must follow a more strict time guideline. In Uganda, infusion injections or intravenous infusions are only used when a patient is in a very critical state and these are viewed as signifying death and pain (Van Staa et al, 1996). Further, contraceptive injections are stigmatized and associated with infertility and irregular menstruation (Van Staa et al, 1996). For these and other reasons, these types of injections are not as popular.

8.3 Therapeutic Injection Overuse

Every year, over 12 billion injections are administered annually (Hutin and Chen, 1999). And for every single vaccination injection, nine therapeutic injections are administered. It is believed by the World Healthcare Organization that injections administered in formal and non-formal healthcare settings are the most frequent percutaneous (effected through the skin) procedure worldwide. Many of the medications used in primary healthcare today, can be prescribed as oral medication. This along with population-based injection frequency surveys suggests that there is a huge overuse of therapeutic injections in developing countries (Hutin and Chen, 1999).

The high level of injection and needle use is present at both the household level and the health facilities level (Van Staa et al, 1996). The prevalence of injection use is defined "as the percentage of households in the surveys receiving one or more injections in the past two weeks" (Van Staa et al, 1996). 40% of households in Indonesia had received one or more injection in the last two weeks and 30% of households in Uganda had received one or more injections in the last two weeks (Van Staa et al, 1996). In Indonesia, doctors in the public sector administer a majority of the injections. However, in Uganda, the bulk of injections are administered by non-formal providers - in the home or by family members. This demonstrates the informalization of medicine in Uganda where there is great risk for the spread of viral epidemics including HIV/AIDS and Hepatitis.

8.4 Case Study: Middle East (Pakistan)

A study performed by Raglow et al 2001 in Karachi, Pakistan highlights the major overuse of injections across the Middle East. The city has no regulation for health practitioners or pharmacies and there is no enforcement for pharmaceutical regulations (Raglow et al, 2001). Of a population of 198 patients, 49% had received at least one injection and 51% of patients had the visit within one - week prior. 35% of patients had received 10 or more injections in the previous year and 64% mentioned that injections were believed to be more powerful and therefore, patients said they were willing to pay more for them than pills (Raglow et al, 2001). 91% of patients explained doctors always recommend injections while only 9% of patients had actually asked for an injection (Raglow et al, 2001). Most patients said they would opt for oral medication if it had the same effects as injections.

Evidently, doctors or general practitioners play a huge role in convincing patients to receive injections. In Pakistan, doctors frequently and indiscriminately administer injections without proper cause or safety precaution. There appears to be a lack of communication between doctors and patients, and often patients follow doctor's advice blind to adverse consequences. The lack of policy and regulation around health practioners and pharmaceuticals is additionally worrisome as the people patients are looking to for health advice may be improperly trained and educated. This leaves the population at huge risk for faulty and ill – advice healthcare recommendations.

8.5 Case Study: Africa (Uganda)

In many rural regions of Uganda, healthcare providers are very motivated by a desire to make money. For many, an injection must be provided in order to attract clientele. This is on the basis that most patients believe that they are only getting their money's worth if an injection is provided. In a research study by World Healthcare Organization (WHO), provider survey findings highlight that the provider's profit motivation favors injections because they yield more money than oral therapy (Van Staa et al, 1996). For example, in comparing malaria treatment, "the study findings indicate that 84% of the anti - malarial prescriptions at the profit-oriented health facilities are injections compared to 66% at the non-profit oriented facilities" (Van Staa et al, 1996). Similarly, at one of the private clinics, a full treatment of chloroquine tablets earns a profit of 240 Ugandan shillings compared to 2000 shillings for injection treatment. Due to pricing, there is a huge monetary incentive for healthcare providers to promote injections over oral remedy. Over 20% of the profits from injection treatment are gained from the sales of syringes and needles (Van Staa et al, 1996). Healthcare providers can

often justify their preference for administering injection therapy as they can claim non-compliance with oral therapy.

Typically, when Ugandans are ill, they begin self-medicating through oral therapy, but when this fails or they seek faster relief, they solicit injections from healthcare providers. Ugandans find injections so favorable that a majority of citizens keep a syringe and needle for injection in their home and bring the equipment to healthcare appointments. This is also an attempt to protect one's self from cross-contamination of needles and the spread of HIV/AIDS and hepatitis.

A cultural understanding of illness is an important consideration for understanding the Ugandan preference for injections. There are strong cultural beliefs that present injections as a method of therapy that has higher efficacy. This belief comes from local ideas of illness and the efficacy around various treatment options. Many users believe that injected medicine goes directly to the blood stream and does not leave the body as quickly as oral medication. Oral medication is compared to food, which is processed by the digestive system and eventually leaves the body. Many believe that diseases are centered in the blood, which makes injections a convenient therapy option.

As a final reason for the large injection preference in Uganda, side effects are perceived to be lower with oral treatment. In cases of malaria treatment, injections are greatly preferred because there are more perceived side effects with oral treatment (chloroquine tablets). Further, the tablets have unpalatable tastes and can be difficult to administer to children. Injections are seen as the less painful method of treatment – which is contrary to what is seen in the United States.

8.6 Case Study: Southeast Asia (Indonesia)

Indonesian populations similarly prefer injections and for many of the same reasons as seen in Uganda. However in Indonesian culture, there is a social element to the high numbers of injections. Many Indonesian healthcare providers are the key influence in keeping the number of administered injections high. Providers not only believe injections to be a more effective method of treatment, but they can also derive a certain social status and power from administering injections. Injections act as a tool to demonstrate healthcare providers have a higher knowledge of treatment, medicine and drugs than do non-healthcare providing citizens. This power gives them a 'secret' knowledge of medicine that distinguishes them as professionals offers them a higher social position. Oral drugs are available at drug stores, but injections can only be administered in private practices. Therefore, there is an internal desire to provide more injections to patients as "injections give popularity to the prescriber" (Van Staa et al, 1996).

In Indonesia, there is a very strong public image of Western biomedicine. Historically, the rapid results of neosalvarsan injections from Dutch colonial times helped combat *framboesia tropica* and now, people believe injections are critical for fighting all diseases (Van Staa et al, 1996). Ever since the Western creation of injections and hypodermic needles, "biomedicine was 'injected' into the villages" (Van Staa, 1996). The continuous stream of Western biomedical advertising reinforces its positive reputation. Further, the behavior of health center staff in promoting Western medicine has made it acceptable in Indonesian culture.

From the patient's perspective, patients often feel disappointed if they do not receive an injection when they make visits to their practitioner. In a survey of Indonesian households, results demonstrate a popular demand for injections and show that over half of the injections were provided through explicit request of patients or family members (Van Staa et al, 1996). This patient initiative is very different than what is demonstrated in Pakistan. In most cases, Indonesian individuals desire injections for their "fast action", and the "customary" nature of receiving them (Van Staa et al, 1996). Respondents say "injections are more appropriate", "they are cheaper", "they are more effective" and "I forget to take my medication" (Van Staa et al, 1996). These beliefs likely come from the great support of injections on the provider level. Healthcare providers are responsible for providing appropriate therapy and the patient therefore follows the advice of the specialist because he/she is perceived to be more knowledgeable and powerful.

Any fear around injections is mostly derived from a fear that the medicine will not agree with the body. There is a slight fear of pain, but fear of an allergic reaction is greater (Van Staa et al, 1996). This fear is amplified for young children who are perceived as less strong and believed to be less resistant to allergic reactions. However, healthcare workers are rarely transparent about their fear of adverse reactions in patients. Patients act as passive receivers and rarely refuse injections (Van Staa et al, 1996). Communication is a large issue as healthcare workers rarely provide any explanation around treatment rationale or alternative treatment. In some villages, 90% of the population does not receive any explanation for why they are receiving an injection (Van Staa et al, 1996). There becomes a vicious circle around injections where

healthcare workers provide them because they believe patients expect them and patients want injections because healthcare providers give them.

8.7 Perceived Healing Properties of Injections

In many different cultures within Africa, Southeast Asia and the Middle East, there is a belief that injections have "a very powerful method of restoring or maintaining health" (Van Staa et al, 1996). Healthcare providers and everyday patients share these beliefs. The issues that surround injection use in developing countries are so complex, that adequate training is not enough to solve the array of problems that come from injection misuse and overuse. There is often a lack of knowledge around the potential risks of injections. Further, so much demand encourages informal injection providers to administer injections in a variety of environments, which is dangerous to individuals and larger populations (Van Staa et al, 1996).

The preference and popularity of injections has been reported in a variety of developing countries including India, Thailand, Vietnam, Indonesia, Taiwan, The Dominican Republic, Colombia, Guatemala, Nicaragua, El Salvador, Ghana, Ivory Coast, Gabon, Nigeria, Sierra Leone, Burkina Faso, Cameroon, Mozambique, Uganda Morocco, Tunisia and Ethiopia (Van Staa et al, 1996). In some of these countries, the injection has been viewed as the epitome of Western medicine, in that injections have magical properties that have the ability to miraculously cure diseases.

In Uganda, it is believed that injected medicines are more effective as the medicine goes directly into the blood-stream (Van Staa et al, 1996). Similarly, cultures in Southeast Asia believe that an injection has the ability to enter deeper into the body and can therefore locate and fight the root of the disease. A study in Morocco discusses

the notion that the penetration of the needle during an injection produces the best chance at fighting ‘deep diseases’ (Van Staa et al, 1996). In India, within humoral traditions, injections are classified as ‘hot’ where these injections are believed to be powerful and ‘heating’. The most powerful and effective injections are those that create a great burning sensation.

8.8 Pain as a Cultural Indication of More Effective Healing

Many of the cultures of Southeast Asia and Africa agree that injections are preferred for their direct access to the blood stream. This is of special importance as the blood is thought to have a central role in the process of illness and recovery.

Another explanation for the preference for injections is the relation to pain. In Nicaragua, a very painful injection is considered to be better and stronger. This is because in Nicaraguan culture, pain is associated with stronger healing powers (Van Skaa et al, 1996). Similarly, in Sierra Leone, injections are viewed as the best remedy because the associated pain indicates efficacy (Van Skaa et al, 1996). Further, many Asian therapies involve pain as a means of healing. For example, acupuncture in Malaysia can sometimes be combined with moxibustion, which are smoldering herbs attached to an acupuncture needle or placed directly on the skin. These types of treatment can cause scars, burns and bruises but are not viewed negatively (Juckett, 2005). Unlike the United States, pain is often sought to be a source of healing and recovery. Therefore, injections are not feared for being painful in other cultures. In fact, they may be desired because they are more painful.

Chapter 9: Field Study: First Generation Healthcare Providers

9.1 Methods

Interviewing three first – generation, foreign healthcare providers in order to contrast developing and developed countries.

9.2 Users

- Male born and lived in Iraq (developing country) for 26 years
- Female born and lived in Japan (developed country) for 32 years
- Female born and lived in Korea (developed country) for 26 years

9.3 Insights

Iraq:

In Iraq, there is a culture around seeking healthcare and medication for everything. Given healthcare is extremely cheap and often free, individuals will go the emergency room or doctor for everything; “my people will go to the emergency room for an IV if they are dehydrated because they are too lazy to drink water”. People get excited to see needles because needles are associated with faster recovery. Similarly, intravenous delivery of medicine is always preferred. Patients will always request double the dose of anything prescribed because more medication ‘is better’. This results in significant medication overuse. Patients will specifically request injections or IVs not for the pain, but for the connection to efficacy. Therefore, injections are always welcomed because they are seen as being a worthwhile source of pain; “I would go to the hospital every other day to get a vitamin B complex shot because it makes my brain work better”.

In Iraq there is a great respect for Western biomedicine amongst younger generations, but older generations still prefer herbal and natural methods of treatment. In younger generations, biomedicine is associated with speed and efficacy. Further, Iraqis have great respect for their doctors and for healthcare providers. They would never question anything a doctor suggests and will completely trust them for everything. This reduces any fear associated with injections and needles as needle use only takes place in healthcare environments and are only administered by healthcare professionals that are greatly trusted.

Korea:

In Korea, healthcare is extremely affordable, however individuals prefer self-healing as the first option of treatment. When an individual gets sick, they try and let their body fight the illness. After a couple days, they will seek the help of a healthcare professional but medication is not easily accessed.

Needles are not greatly preferred to oral medication. If they both have the same functionality, there is no reason to prefer an injection. There is no fear around needles as they can only be used in hospitals. Further, Koreans have great respect for doctors and healthcare workers and a patient will completely trust the doctor and his/her advice so if a needle injection is recommended, a patient will not doubt this. Given patients don't see injections to be significantly more effective than oral medication, needle and injection overuse does not appear to be a large issue.

Japan:

In Japan, individuals are highly against putting extra substances in their body. They will always prefer a natural approach to healing and do not use medication unless

it is an extreme situation. Further, anesthetics and epidurals are avoided and the nitris oxide used in dentistry is not sought after. Patients believe that the medication is not worth the side effects and if an individual can go through the process naturally, there is absolutely no need to medicate.

Pain perception and communication is much more hidden in Japanese culture. In the US, patients exhibit extreme expressiveness around pain, however in Japan, people will not openly admit they are in pain. Generally, they are a much more stoic culture. Needle pain or fear is not widely communicated, so pain thresholds are also much higher.

There is little communication between the doctor and the patient around treatment methods or options because of time constraints. Since the cost of medical treatment is so cheap, professionals need to see a lot of patients to make enough money. There is a very short amount of time allotted to each patient, maybe 5 to 10 minutes with the physician. Since the wait time can be 2 or 3 hours, patients sometimes expect injections as a means of treatment and providers often administer them because they are easier and faster. As seen in other cultures, injections are preferred for efficiency and efficacy.

Chapter 10: Consequences of Needle Use In Developing Countries

10.1 Issues around Sterilization

Injection safety is a huge issue in developing countries. The fact there are so many injections administered without real cause is alarming not only on the basis of misuse, but also in fear of medical transmission of HIV and other blood-borne pathogens. Injection safety falls under the category of health systems needing to strengthen safe medical injection, safe disposal of sharps and healthcare waste, safe phlebotomy practices and provision of post-exposure prophylaxis following occupational exposure to HIV.

10.2 Pakistan and Sterilization

Receiving an injection in the developing world is an experience that is laced with risk. Unfortunately, the reuse of contaminated needles/syringes is a commonplace practice (Raglow et al, 2001). These behaviors have lead to the iatrogenic transmission of many life threatening blood borne diseases including “HIV, Hepatitis B, Hepatitis C, Lassa fever and Ebola” (Raglow et al, 2001). With little protocol or regulation, there is no policy to ban the reuse of needles and syringes. It has been reported that there is virtually no system in Pakistan that controls the safe and routine destruction of disposable syringes. More frighteningly, in some developing countries, including Pakistan, there is a black market for medical waste repackaging that resells used needles. Given a virus cannot be seen by the naked eye, there is often no way to tell if a needle is truly sanitized or not.

The method for ‘cleaning’ needles in Pakistan is to wipe or rinse them immediately before injection. In a study performed with 205 individuals, it was observed that needles were cleaned in 49% of injections (Raglow et al, 2001). This method of cleaning was seen as the placement of the needle into a pan of water, wiping the needle with an alcohol swab or soaking in a disinfectant (Raglow et al, 2001). Given commercial alcohol swabs are not accessible, it can be presumed that the swabs used to ‘disinfect’ are either non-sterile cotton balls soaked in alcohol or just a dry cotton ball.

Patient education and awareness for transmission of disease is another issue. While 83% of patients thought a needle could transmit a fatal disease, there was lower awareness for transmission of specific diseases (Raglow et al, 2001). 67% were aware of AIDS transmission and 69% for Hepatitis. However, even though there is awareness for disease transmission, patients still continue to receive injections without question, where only 16% of patients ever refused an injection (Raglow et al, 2001). This suggests that knowledge of specific risks is not enough. This knowledge needs to be combined with schooling in order to successfully influence behavior and reduce the number of unnecessary and risky injections. In a city with high numbers of poverished and uneducated people, public health interventions are key to reducing these behaviors.

Unfortunately, the injections carry significant risk with little or no perceived benefit in many instances. Reuse of needles creates a situation in which the health practioner’s clinic can become “the point of crossover of disease transmission from groups at high risk of acquiring blood borne viruses (e.g. people with multiple sexual partners, prostitutes, men who have sex with men, and intravenous drug users) to those who may otherwise be characterized as low risk groups in the general population”

(Raglow et al, 2001). Therefore, these community health offices become a source for amplification of blood borne epidemics when they should be the sites of healing.

10.3 Needle Sharps Injuries

90% of worldwide reported needle stick injuries happen in developing countries (WHO, Safe Injection Global Needle Work, 2003). This is alarming because many developing countries have a heavy burden of HIV/AIDS and other blood borne infectious diseases (Nsubuga et al, 2005). In developing countries in Sub-Saharan Africa, for example, low expenditure on healthcare and occupational safety and health services disrupts safety and sanitation needs. This coupled with high rates of injections and a high ratio of patients to healthcare workers put healthcare workers at great risk for needle stick injuries and consequently, transmission of blood borne infections (Nsubuga et al, 2005).

In a study performed in Uganda, results indicate that almost 40% of the needle stick injuries, reported in the last year, were related to administration of injections (19% related to injecting a patient and 17% putting up an intravenous line) (Nsubuga et al, 2005). These types of procedures were followed by disposal of the needles, which accounted for 16% of injuries. Further, recapping of used needles, suturing, and cleaning after patient care related to 13% of injuries. Although nurses are discouraged from recapping needles, almost 50% of participants were seen recapping needles.

10.4 Needle Reuse

Today, there are still nurses that will inject patients with a syringe of antibiotics and then reload and inject into the next patient. The syringe was never sterilized, the

needle was never replaced and all the patients become at risk for contracting a deadly disease from the injection that was intended to cure them (pbs.org, Self Destructing Syringes). The World Healthcare Organization estimates that 40% of all injections are given with unsterilized and reused syringes and needles (pbs.org, Self Destructing Syringes). This accounts for 1.3 million deaths and 21.7 new Hepatitis B infections every year as a result of unsafe practices. Money plays a big part of the problem of needle reuse. “In developing countries, you only pay 5 cents for a syringe but their income might be 1 dollar a day. So if you have 20 kids that you vaccinate with one syringe, then you have a doubling of your income. It’s dubious if people will make the right decision” (pbs.org, Self Destructing Syringes). Human behavior is often aware of negative consequences, but some other incentive (ex: money) drives them to make poor decisions that impact morbidity and mortality.

Even if a needle is taken from a sealed package, it is still questionable whether or not the needle is sanitized. In 2009, an investigation was performed in India, and found warehouses filled with syringes and needles recovered by waste-pickers. These tainted needles were then repackaged and sold on the black market (pbs.org, Self Destructing Syringes). In many cases, a syringe can be well packaged, but a closer look will reveal some blood still in the syringe from the previous user. Many of the modern syringes are made of plastic, so even when a needle is replaced, remnants of blood can be retracted into the syringe and passed on. The syringe cannot be sterilized and should never be reused.

Chapter 11: Design Opportunities

11.1 Universal Design Opportunities: United States Patients

Given the issue of pediatric needle fear is largely psychological, the best methods for reducing this fear is in moving attention away from painful stimuli, promising lower pain and being extremely transparent around what is happening to the child.

1. Distraction and Comfort:

Insight 1.1: Medical environments have strong sensory triggers that create fear. If you can replace negative stimuli with positive stimuli, you can aim to reduce fear cues.

Opportunity 1.1: Create positive sensory experiences that relate to tactility, visual cues and smells. Building a more familiar and less clinical experience can result in less procedural fear and provide comfort to the child. Unfamiliar environments provide a child with no control and very little ability to self-cope with the stressful situation.

Insight 1.2: Children respond well to physical closeness and benefit from having a sense of security and control.

Opportunity 1.2: Create comfort through physical closeness that could be achieved through designing a blanket – like products that physically wraps around a child to give him/her a sense of physical security. This could also involve a parent and allow them to hold or comfort their child.

2. Individuality

Insight 2.1: Children respond positively to hearing they are receiving ‘special treatment’ or a special product. Through multiple visits, nurses can become familiar with a patient and learn what works and what does not work, which can be comforting to a child and a parent.

Opportunity 2.1: By creating an apparently unique experience for each child, they can feel more cared for and develop trust for their healthcare provider. If a nurse mentions they are using a special product or a special process for the child, the feel individualized and special.

Insight 2.2: Children are very afraid of how painful the needle will be and will always ask ‘how much will this hurt’.

Opportunity 2.2: If products are designed to lower pain for children and this is communicated to the child, a child may exhibit less stress. It is best not to lie to a child about pain levels, but anything that promotes pain reduction should be positively accepted.

3. Transparency

Insight 3.1: Children become afraid of the unknown and experience more pain in foreign environments.

Opportunity 3.1: A healthcare provider should always provide total awareness for what is happening. Countdowns can help mentally prepare a child. It is not necessary to communicate everything about the entire process, but providing transparency for what is going to happen. It is important to also discuss possible pain, procedure and timing.

Insight 3.2: In developing countries injections are worthy of pain because of perceived efficacy. If this efficacy can be seen in the US, maybe there would be less fear and perceived pain.

Opportunity 3.2: While it is difficult to communicate the importance of certain medical procedures, a parent's positive reinforcement can be helpful. Any positive perception that can be created can reduce fear and resistance.

11.2 Universal Design Opportunities: Developing Countries

Changing behavior and cultural beliefs around efficacy and economic incentives related to injections is going to be difficult. Instead of changing mentality and beliefs, change the process to make it safer. If you can make the needle and syringe part of the solution, you can force the provider not reuse needles.

1. Self Destruction

Insight: Needle reuse is a result of convenience and cost factors. If the syringe is unusable after use, you force behavior to dispose used needles because reuse is not possible.

Opportunity: Create a needle and syringe that 'self – destructs' after single use. If you make reuse impossible by breaking the needle and syringe after use, you can prevent needle reuse and disease transmission. It will be important to keep cost low in order for the product to be successfully adopted.

2. Transparency Around Use Status

Insight: Black markets exist that repackage needles and syringes to make them look new. It is not easy to tell with a naked eye if a syringe is fully sanitized so this creates risk for inadvertent and unknown reuse.

Opportunity: Create a needle that clearly shows use status where is potentially changes color after use so it is obvious to a patient and a doctor that the needle has been used. If you make use transparent, issues around repackaging can be reduced.

3. Forcing User Behavior Changes

Insight: The issue of needle and injection popularity is the result of cultural beliefs, economic incentives and historical ideas of efficacy, so trying to change this mentality will likely not happen through a singular approach.

Opportunity: Instead of trying to change beliefs around injections, you can make the process safer through changing products and forcing user behavior to change. If a product forces a change in behavior, then at least you can reduce the risk of one main concern: disease transmission and needle reuse.

Chapter 12: Summary and Conclusions

12.1 Discussion

One of the main questions that was tested during this research was whether or not medical needle fear is a universal condition. After performing primary and secondary data collection, I do not believe needle fear is a universal on the basis of cultural practices and beliefs about pain. Therefore it is not possible to implement one universal design that can single-handedly reduce needle fear worldwide.

United States:

Countless research studies have attempted to determine if pediatric needle fear is largely psychological or if physical pain of needles warrants the level of distress, anxiety and emotional reaction that can be observed. From my observations and synthesis of the secondary data, I see needle fear to be largely psychological where distress is a result of anticipatory fear, procedural fear and fear of pain. The actual physical pain inflicted by a needle from either an injection or a venipuncture stick is rarely the primary source of distress. Clearly needles do inflict a level of pain, as babies who are not cognitively aware of what is happening, will always cry when given an injection. But, as children develop more cognitive awareness for procedural cues, fear becomes less physical and more psychological, starting at age 2. Suddenly children exhibit distress significantly before the needle stick even occurs and become more wary for ‘what is going to happen’. Vaccinations can remain scary as the time gap between immunizations can leave children reminiscent of negative memories and forget about

how little the injection actually hurt; it is always easier to remember the bad than the good in these types of situations.

A second theory for needle related fear is the idea that children do not understand why a needle procedure is necessary. With many medical procedures such as a vaccination, there is no element of 'immediate satisfaction'. It is extremely difficult to communicate to a child that getting a needle prick today could potentially prevent him/her from contracting a disease that will likely inflict significantly more pain in the future. So for a child, the pain of the shot seems widely unnecessary and unfair.

People in the United States seem to be much more open to voicing pain and seeking immediate fixes for any type of body pain. Further, American populations have a much higher perception for pain than other cultures, so perhaps needles do cause more perceived pain for Americans than other populations. It also seems that there is a higher expectation in the United States for healthcare providers to individualize patient care and provide comfort to patients. There is a lot done to make sure patients are as comfortable as possible, whereas in other countries, medical care is less sympathetic.

For a typically healthy child, perhaps needle related procedures are the most painful and invasive experiences, and therefore physical and psychological pain is high. This is hypothesized on the basis that American children who are extremely sick and in chronic pain will not worry at all about the pain inflicted by an IV as this is such a small comparison to their typical state. Further, if they know a needle can make them feel better, any procedure is worth the pain.

Developing Countries:

In developing countries there are such high beliefs around the efficacy of injections, that they are celebrated as being miraculous cures. While physical pain is still associated with needles, the perceived benefits of an injection masks any fear for pain. Therefore I believe that a positive association equates to no fear. Further, there is such a high level of respect that is given to a doctor in many developing countries, that a patient would never doubt what a doctor says. If a doctor communicates the efficacy and efficiency of an injection, a patient will more than willingly accept and will trust that they will feel better immediately. Unlike the United States, where medical devices can have negative connotations, they bring excitement to global populations. Further, as seen in the US, the promise of feeling better is well worth a temporary needle prick. But in developing countries, needles are associated with efficacy on a cultural and historical level.

Pain thresholds have been seen to be higher in developing countries. It seems that in the United States, it is the anomaly to be in pain, and Americans will happily seek medication to reduce any type of pain. Hypothetically, perhaps there are higher expectations in the United States for lower pain, whereas populations in developing countries expect some level of pain at any given time. Therefore the pain of a needle is no big deal and not a fearful concern.

12.2 Conclusion

In designing for populations outside of the United States it is extremely important to be culturally empathetic. Until one realizes the totality of an issue, it will be impossible to create a solution. In the United States it is important to understand that

the meaning for needle fear is not entirely rooted in physiological pain. However, one would not realize this until he / she actually observes patients and talks to the families and providers. Further, when looking at the issue of needle reuse, one can't simply say this is an issue that can entirely be solved through educational practices. Or claim people in developing countries are uneducated about disease transmission.

Educational programs try to teach the dangers of needle misuse, reuse and overuse, however, given the issue is rooted in cultural, socioeconomic and historical factors, imposing US ways of thinking is not always accepted positively. Instead, there needs to be consideration for every aspect of the problem. Therefore, any approach to education or solution implementation needs to be realistic and culturally salient and most importantly, empathetic to existing cultural ideologies.

When I go about designing solutions, I typically try to work off of existing user behavior and create a solution that can be adopted within the way people already operate. However, for the issue of needle reuse, I think the best design solution is actually the opposite. Healthcare providers are aware of the danger of needle reuse and the risk for disease transmission but the incentive for monetary gain disrupts the importance for safety. Many times humans are aware of consequences but continue dangerous practices in the hope the risk will not affect them. Or sometimes an alternative incentive provides more instant gratification than the delayed risk, so the potential for consequences is overlooked. Therefore, sometimes the best solution is in forcing user behavior to change.

As a final thought, I personally believe design has the power to make huge impacts in the lives of individuals. I believe design to be the promising economic and

cultural resource of the 21st century. Within the context of healthcare there is such a great need for universal design, both in a local and global context. I believe a human-centered approach to healthcare can improve patient and provider satisfaction at the local level and can reduce mortality and morbidity at the global level. I think it is time the world turns to the designer to make some revolutionary changes in healthcare and public health. In order to solve some of the world's most urgent global problems, it will require cultural empathy in order to really make a sustainable change.

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OREGON HEALTH & SCIENCE UNIVERSITY

IRB#: 10627

Research Consent Summary

You are being asked to join a research study. You do not have to join the study. Even if you decide to join now, you can change your mind later.

1. The purpose of this study is to learn more about children's fears about receiving an IV placement.
2. We want to learn
    a. What aspects of needle fear is most painful or traumatic and
    b. How to lessen the negative feelings surrounding needle sticks.
3. Everyone who joins the study will be observed during the IV placement and all parents or guardians of the patient will complete a survey.
4. If you join the study, your participation will only occur during this doctor's visit. We will observe you and your child during their doctor's visit and IV placement. You will complete the survey during this visit.
5. There is a risk of breach of confidentiality.

OREGON HEALTH & SCIENCE UNIVERSITY

IRB#: 10627

Research Consent and Authorization Form

TITLE: How can you use human centered design to reduce needle fear in children ages 4-10?

PRINCIPAL INVESTIGATOR:	Jeffrey Koh, MD	(503) 494-1203
CO-INVESTIGATORS:	Kelsey Colpitts, BA	(503) 346-0011

PURPOSE:
"You" means you or your child in this consent form.

You and your child have been invited to be in this research study because your child will be receiving an IV during his or her visit today at Doernbecher Children's Hospital.

The purpose of this study is to learn more about children's fears of IV sticks. We want to learn what aspect of needle fear is most painful or traumatic to children. For example, we want to know if children fear the actual needle interaction, the anticipation, or the discussion about the needle. We will be observing your child while he or she is receiving an IV and then have you fill out a short survey about your child's experience.

This study requires 1 visit to the clinic.

A total of 30 children and their parents or guardians will be enrolled in the study.

PROCEDURES:
After obtaining consent, a research assistant will stay in the room during the IV placement and quietly observe your child. After the IV has been placed, the research assistant will hand you a short questionnaire about your child's experience involving the IV placement. This questionnaire should take no longer than five minutes to complete. Upon completion of the questionnaire, you and your child will have finished the study.

If you have any questions, concerns, or complaints regarding this study now or in the future, contact Jeffrey Koh, MD at 503-494-1203 or Kelsey Colpitts at 503-346-0011.

RISKS AND DISCOMFORTS:
Although we will make every effort to protect your confidentiality, there is a risk of breach of confidentiality.

BENEFITS:
You will not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

ALTERNATIVES:
You may choose not to be in this study.

CONFIDENTIALITY:
We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. The data that we collect will be kept anonymous and no personal health information will be collected.

We will create and collect health information about you as described in the Purpose and Procedures sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including

- The Office for Human Research Protections, a federal agency that oversees research involving humans

Under Oregon law, suspected child or elder abuse must be reported to appropriate authorities.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

OHSU complies with Oregon state requirements for reporting certain diseases and conditions to local health departments.

COSTS:
There will be no cost to you or your insurance company to participate in this study.

Participants will receive $5 for agreeing to participate in the study. We may request your social security number in order to process any payments for participation.

PARTICIPATION:
This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. [*If study has optional components, add:* Some parts of the study are optional. You can choose not to participate in some or all of the optional parts but still participate in the rest of the study.]

If you do join the study and later change your mind, you have the right to quit at any time. [*If study involves PHI, add:* This includes the right to withdraw your authorization to use and disclose your health information.] [*If study has optional components, add:* You can choose to withdraw from some or all of the optional parts of this study without withdrawing from the whole study.] If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study we will leave the room and any information we collected will be destroyed.

You may be removed from the study if your child does not receive an IV.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the

conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

OREGON HEALTH & SCIENCE UNIVERSITY
INSTITUTIONAL REVIEW BOARD
PHONE NUMBER (503) 494-7887
CONSENT/AUTHORIZATION FORM APPROVAL DATE

MAY 12, 2014

Do not sign this form after the expiration date of:
05.11.2015

Subject Printed Name

Parent/Guardian Printed Name | Parent/Guardian Signature | Date

Person Obtaining Consent Printed Name | Person Obtaining Consent Signature | Date

OREGON HEALTH & SCIENCE UNIVERSITY

Child Assent Form

IRB#10627
Use for Children Aged 7-10

TITLE: How can you use human centered design to reduce needle fear in children ages 4-10?

PRINCIPAL INVESTIGATOR: Jeffrey Koh, MD 503-494-1203

CO-INVESTIGATOR: Kelsey Colpitts, BA 503-346-0011

This research study was explained to me. I know how it may or may not help me. I also know that this study will help doctors learn more about fear of needles. To be sure that I know what is going to happen, the investigator will ask me the following:

1. To explain what I will do and what will happen in this study.

2. If I have any questions or want to know anything else about this study or (insert name of condition).

3. To explain some of the good and bad things that might happen to me if I enter this study.

I have thought about being a part of this study. I have asked and received answers to my questions. I agree to be in this study. I know that I don't have to agree to be in the study. Even though I agree to be in it now, I know I may feel differently later on and can ask to stop being in the study. I know that I may talk with my parents and/or doctor about not being in this study at any time.

Name/signature:_____ Date:_____

PPQ#_____

PROPOSED PROJECT QUESTIONNAIRE (PPQ) – PLEASE TYPE
Oregon Health & Science University Research Development and Administration (RDA)
This form must accompany all ☐ Industry funded contracts and ☐ Unfunded protocols submitted for review by the IRB

GENERAL INFORMATION

Principal Investigator (Last name, First name, Degree)	Telephone Number	Mail Code	Email Address
Koh, Jeff, MD	503-346-0011	BTE-2	kohj@ohsu.edu
Contact for questions (Last name, First name) Colpitts, Kelsey	503-346-0011	BTE-2	colpitts@ohsu.edu

School/Unit: SOM **Department:** Anesthesiology & Periop **Division:** Pediatric Anesthesiology

Award Owning Org Name (Name of the org that the Award will be assigned to and that will receive F&A credit unless otherwise specified below):
Please see the OHSU Project-Owning Org Finder Tool.
How can you use human centered design to reduce needle fear in children ages 4-10?

Will F&A be shared by more than one department or unit? * If yes, indicate agreement by having each department/unit head and each internal project PI sign this PPQ. Also include an internal budget showing the distribution of funds requested. ☐ Yes* ☒ No

Project Title (240 characters maximum. Same as project title listed in grant or contract.)
How can you use human centered design to reduce needle fear in children ages 4-10?

Project Short Title (30 characters maximum. Will be displayed in OGA. Must be unique for each OGA Project under an OGA Award)
Reducing needle fear

Award Short Title (30 characters maximum. Will be displayed in OGA.)
Reducing needle fear

Applicant Organization
☒ OHSU ☐ Other*
*If Other, please specify pass-through organization that will issue a subcontract to OHSU: ____

Sponsor: n/a
(Example: NIH, American Heart Association, Acme Co.)

Clinical Research Organization (CRO) (If applicable for an industry sponsored clinical drug / device investigation): ____
See Clinical Research Organization definition.

ACTIVITY AND F&A RATE INFORMATION

Primary location (Building Name) where the work is being performed (See the OHSU Building List): DCH
% of work performed at this location: 75%
Indicate 'Off-Campus' if the work is being performed at a non-OHSU facility.

Is the research primarily Basic or Applied? See Basic/Applied Research Definitions. If the project is not research, select N/A — Please select one: ☒ Basic ☐ Applied ☐ N/A

TYPE OF FUNDING INFORMATION

Contract Type *If funded. Check all that apply*
☒ New – new project not previously funded by this sponsor ☐ Amendment– request for additional funds

COMPLIANCE QUESTIONS
If this project involves humans and/or animals, please indicate applicable IRB Protocol #(s) ____ or IACUC Protocol #(s) ____

1. a. **Does the project involve human subject research?**
Human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains:
- data through intervention or interaction with the individual, or
- identifiable private information.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

a. ☒ Yes ☐ No ☐ Not Sure
To receive a determination on whether this proposal involves human subject research, please login to the eIRB and use the Request for Determination tool.

2. **Will animals be used in the project?**
a. * If yes, will non-human primates be used in the project?
All projects involving animals must be submitted to and approved by the IACUC prior to beginning work on new projects or modifications to existing protocols.

☐ Yes* ☒ No
☐ Yes ☒ No

PPQ, Revised 03/2013

PPQ#_____

3. If this study involves humans or animals, did OHSU personnel design/develop the study protocol? The answer to this question will help determine how to handle the intellectual property terms of the proposal, determine appropriate IRB fees for the study, and allow tracking of this information for reporting and management purposes.	☒ Yes ☐ No ☐ N/A
4. Will this project involve the use of non-recombinant infectious agents or certain biologically-derived toxins (including select agents and infectious proteins, cells, viruses, bacteria, etc.)? See Definition. * If yes, complete the Infectious Agent/Toxin Questionnaire and submit it with this PPQ. -OR- Approved IBC registration #: _____	☐ Yes* ☒ No
5. Will this project involve the use of recombinant DNA (rDNA, includes all recombinant plasmids/vectors/viruses)? * If yes, complete the Initial rDNA Research Classification Form and submit it with this PPQ. -OR- Approved IBC registration # is: _____ -OR- This project was previously determined to be exempt and no changes are proposed that will affect the exempt status ☐	☐ Yes* ☒ No
6. Will this project involve the use of synthetic nucleic acid molecules in cells, organisms or viruses that can replicate or generate nucleic acids that can replicate, integrate into DNA, or produce a toxin lethal in vertebrates with an LD50 of <100ng/kg? For additional information please review the FAQs on the IBC website. *If yes to ANY of the above, complete the IBC Initial Classification Form and submit it with this PPQ. -OR- Approved IBC registration # is:_____ -OR- This project was previously determined to be exempt and no changes are proposed that will affect the exempt status ☐. *If no to ALL of the above, the synthetic nucleic acid molecule portion of this project was determined to be exempt from registration or further review by the OHSU Institutional Biosafety Committee.	☐ Yes* ☒ No
7. Will Biosafety level 3 or Animal Biosafety Level 3 facilities be required for this work? Review list of Risk Group 3 agents at http://oba.od.nih.gov/rdna/nih_guidelines_new.html#_Toc331174058 *If yes, indicate the proposed location for this work. The appropriate Director or Department Chair will be notified. ☐ West Campus, VGTI ☐ West Campus, ONPRC ☐ Central Campus	☐ Yes* ☒ No
ADMINISTRATIVE QUESTIONS	
8. Do any of the personnel listed on this project who have paid or unpaid appointments at OHSU also have paid VA appointments? * If yes, please provide the most recent copy of the memorandum of understanding (MOU), dated within one year. The MOU is not required if the project is industry-sponsored. Note that if this project is funded, an updated MOU that accounts for effort on this project will be required at time of award. If any persons listed on this project have unpaid OHSU appointments and paid VA appointments, please be sure to complete the VA cost-sharing requirements referenced in Question 6 above.	☐ Yes* ☒ No
9. Does this project involve Portland Veterans Affairs Medical Center (PVAMC) resources? * If yes, please have this PPQ signed by the VA ACOS/R&D (Associate Chief of Staff for Research & Development) and prepare a VA PPQ for submission with the OHSU PPQ. In certain cases, the Research Service at the PVAMC will need to obtain the approval of the VA clinical service chief prior to VA signature on the OHSU PPQ. If this proposal includes research related expenses that will be incurred by the VA, you will need to complete a VA Administrative Review prior to VA signature of the OHSU PPQ. Please check all the following VA resources that apply: ☐ VA Space ☐ VA Equipment ☐ VA patients (or their tissue or data)	☐ Yes* ☒ No

10. Which of the following University Shared Resources has been included in your research plan? *(please select all that apply)*

☐ Advanced Computing- Dir. Gliessman	☐ DNA Services – Dir. Keller	☐ Proteomics – Dir. David
☐ Advanced Light Microscopy - Dir. Kaech Petrie	☐ Electronic and Instrumentation Design – Dir. Hunt	☐ Transgenic Mouse Models – Dir. Fedorov
☐ Affymetrix Microarray - Dir. Harrington	☐ Flow Cytometry (main campus) – Dir. Streeter	☒ None of the above
☐ Bioanalytical/Pharmacokinetics- Dir. Koop	☐ Histopathology– Dir. Corless	
☐ Biostatistics- Dir. Mori	☐ Illumina Microarray – Dir. Searles	
☐ Biomedical Informatics- Dir. Logan	☐ Massively Parallel Sequencing Shared Resource – Dir. Searles	

PPQ#_____

APPROVALS & CERTIFICATIONS

All signatures below are required prior to institutional approval of the proposal, with the exception of unfunded IRB studies which do not require Dean/VPR/Provost signature.

As the PI of this project, I certify that the information submitted is true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and, if a contract is awarded as a result of this proposal, to comply with the terms and conditions of the award, including providing required progress reports. I understand that I am responsible for ensuring that the project is conducted in full observance of the financial, compliance, and administrative requirements described in the **OHSU Roles and Responsibilities in Research** document.

4/16/14

PI / Project Director, Date
Name: Jeff Koh, MD

The signatures of the Division Head, Department Chair and Dean/VPR/Provost indicate that:

- the proposed scientific work is appropriate;
- space and/or resources are, or will be, available;
- budgeted salaries and effort levels are appropriate for the personnel named in the application;
- the budget proposed is sufficient to cover the costs incurred in the study,
- and that roles and responsibilities assigned to the Division Head, Department Chair and Dean/VPR/Provost as described in the OHSU Roles and Responsibilities in Research document will be carried out or appropriately delegated.
- If the project involves resources (faculty, staff, equipment, space) from more than one OHSU Department/School/Unit, each Department Chair/Dean/VPR/Provost should review the proposal and approve it by signing below.

The signature of the VA Research Service does not represent institutional approval. It simply indicates that the VA Research Service is aware of the proposal and the VA review process has commenced. The work cannot begin at the PVAMC without a notification letter from the Associate Chief of Staff of Research stating that the work can begin.

Note: All staff with direct involvement in the design and/or conduct of the project (including, but not limited to, the principal investigator, co-investigators, research assistants/coordinators, and collaborators) must:

- Complete OHSU's Responsible Conduct of Research (RCR) Education
- Have a current OHSU Conflict of Interest in Research Disclosure form on file
- See Requirements for Investigators Outside OHSU

Note: Unfunded IRB studies do not require Dean/VPR/Provost signature.

4/16/14 Division Head, Date Name: Jeff Koh, MD	Department Chair, Date Name: Jeffrey Kirsch, MD	Dean/VPR/Provost, Date Name:
Division Head, Date Name: *(if appropriate)*	Department Chair, Date Name: *(if appropriate)*	Dean/VPR/Provost, Date Name: *(if appropriate)*
VA ACOS/R&D, Date Name:	SON Advisor, Date Name: *(if PI is SON student)*	*Other:*

Observational Checklist

Physical Reactions

- ☐ Body movement away from needle
- ☐ Child squirms and makes lots of motion
- ☐ Child sits calmly
- ☐ Child watches needle procedure
- ☐ Body appears very tense
- ☐ Body appears very relaxed
- ☐ Child faints
- ☐ Child looks away from needle

Psychological Reactions

- ☐ Child asks many questions to the nurse
- ☐ Child asks many questions to their parent
- ☐ Child tries to grab the needle or nurse
- ☐ Child seems agitated upon entry
- ☐ Child seems agitated upon seeing the needle
- ☐ Child responds positively to distraction methods (if applicable)

Emotional Reactions

- ☐ Child cries before the needle stick
- ☐ Child screams
- ☐ Child whimpers
- ☐ Child cries during the needle stick
- ☐ Child cries after the needle stick
- ☐ Child looks for support from parent

Other Observations

Questions for Parents of Children Undergoing Sedation:

Dear participant,
Thank you so much for participating in this survey. All information gained from this survey may be used in a University of Oregon Honors Thesis project titled, "How can you use human centered design to reduce needle fear in children?". By participating in this survey, you are helping inform a design solution to reduce needle fear in children. Thank you for your assistance.

1. Has your child had previous experience with IVs?
    a. Yes
    b. No

2. Is your child afraid of needles?
    a. Yes
    b. No
    c. Don't know

3. How would you rate your child's anxiety on a 0-10 scale in relation to IV placements (0 = no pain, anxiety or fear 10 = unmanageable pain, anxiety or fear etc)

    1 2 3 4 5 6 7 8 9 10

4. When does your child **start** to show anxiety when going to an appointment (that requires an IV)?
    a. Before leaving the house
    b. On the car ride to the hospital
    c. When they enter the doctor's office
    d. Only immediately before the needle start
    e. During the needle start
    f. No previous experience

5. When does your child have the **most** anxiety when going to an appointment (that requires an IV)?
    a. Before leaving the house
    b. On the car ride to the hospital
    c. When they enter the doctor's office
    d. Only immediately before the needle stick
    e. During the needle start
    f. No previous experience

6. What does your child bring to the appointment to feel less anxious?
    a. Stuffed animals
    b. Blankets
    c. Pillows
    d. Video games
    e. Mobile devices or tablets
    f. Other toys
    g. Nothing
    h. Other _____

7. Do you think distractions reduce anxiety related to needle fear?
    a. Yes
    b. No

8. If yes, what type of distraction works best for your child?

9. Generally speaking, what brings comfort to your child?

10. Does your child fear any other medical interactions (going to the dentist, getting immunizations, getting a check up, etc)?
    a. Yes
    b. No
    c. If yes, what procedures do they fear _____

11. How many times a year does your child get medical procedures that require an IV?
    a. 15+
    b. 15-10
    c. 10-5
    d. 5-1
    e. 1 or less

Demographic follow up:

1) Age of your child

2) Gender of your child

Questions for Pediatric Anesthesia Nurses

1. What factors do you feel are the most important in contributing to a patient's anxiety about a needle stick?
    a. Physical factors (the pain from needle sticks)
    b. Psychological factors (patient doesn't know what is happening, bad past experiences, being in a foreign environment, etc)
    c. Both
2. What percentage of your patients cry when getting IV sticks?
    a. 0-25%
    b. 25%-50%
    c. 50%-75%
    d. 75%-100%
3. Please rank your concerns from highest to lowest (related to IV placement)
    a. Patient safety
    b. Nurse safety
    c. Patient comfort
    d. Getting an IV successfully started on the first try
    e. Making sure a patient is aware of what is happening
    f. Other _____
4. When do patients **begin** to show anxiety?
    a. When they enter the patient room
    b. When the needle stick is being discussed/introduced
    c. Immediately before the needle stick
    d. During the needle stick
5. When do patients have the **most** anxiety?
    a. When they enter the patient room
    b. When the needle stick is being discussed/ introduced
    c. Immediately before the needle stick
    d. During the needle stick
6. Do patients like to watch the IV placement?
    a. Yes
    b. No
    c. If yes, what ages tend to watch the IV placement?
7. Is there a method you use to make patients less anxious?
    a. Yes
    b. No
    c. If yes, what do you do?
8. Are distraction methods successful in reducing anxiety?
    a. Yes
    b. No
    c. If yes, what distraction methods are successful?
9. What do patients bring with them to their appointment to feel less anxious?
    a. Stuffed animals
    b. Blankets
    c. Pillows

d. Video games
e. Mobile devices or tablets
f. Other toys
g. Nothing
h. Other _____

10. How many attempts does it take to successfully start the IV?
    a. 1
    b. 2
    c. 3
    d. 4
    e. 5+
11. How involved are parents in helping the child during the IV start?

Demographic follow up

1. How many years of nursing experience do you have?
2. What is your unit assignment?
3. What is your job position?

Questions and Answers for First Generation Foreign Healthcare Providers

1. **What country are you from?**
    a. Iraq
    b. Japan
    c. Korea
2. **How long did you live in your country?**
    a. Japan: 32 years
    b. Korea: 26 years
    c. Iraq: 26
3. **What culture do you most closely align yourself with?**
4. **How does your culture perceive pain?**
    a. Japan: people don't want any extra substances in their body
        i. Prefer a more natural approach
        ii. Don't use epidural
        iii. Prefer not to use anesthetics or extra things in the body
        iv. Vaccination is preference
        v. Against medication use
    b. Not worth side effects
    c. Just go through the process and if it is not necessary then try to avoid it
        i. Last resort
    d. Won't say their pain
        i. US people are very expressive
    e. More stoic culture
    f. Iraq:
        i. Culture, always seeking healthcare whenever
        ii. Always want an IV to rehydrate
        iii. Free and cheaper healthcare
        iv. Get excited when they see the needle
            1. Intravenous needle means really positive thing
            2. Don't like pills
                a. They specifically ask for an injection
            3. Ask at the dentist for double dosage
            4. Don't specifically like the pain but they get excited about the needle
                a. Way over medicated
            5. It's the way it is that they want to feel better sooner so they want injection
                a. Welcomed
    g. Korea:
        i. Try to self heal themselves
        ii. If they get sick, mild, they try and let their body fight it themselves

1. After maybe a couple days then they will take medication
2. Afraid to give them medicine
    a. Let them fight themselves
    b. Give it a couple days and see what happens
3. Super cheap to go the hospital

iii. No needle fear
1.

h. Is communicating pain shameful?
i. Do you think there is a higher threshold for pain in the US or in your country?

5. How does your culture view western biomedicine (positively or negatively?)

a. Korea: positive to new medication and new medical development
    i. Willing to try and accept the new techniques that are being implemented
b. Japan: positive perception
    i. Still more behind than Western culture
        1. America moves much faster than other countries
c. Iraq: generational
    i. Grandmother: tend not to like western medicine
        1. Herbalist was the way to go
        2. Treats high blood pressure with garlic and lemon juice
    ii. Younger: like Western medicine
        1. You can see results must faster than herbals
    iii. Viewed as a positive thing

6. Is there a cultural preference for injections as the preferred method of treatment?

a. Japan: injections because of efficacy and efficiency
    i. Older doctor and dentist
        1. Stay in their old habits
        2. Can't provided updated information
b. Korea: personally, pills
    i. If you can choose, view functionality the same
        1. Take it yourself
c. Iraq: Would go every other day to get Vit B complex injection
    i. Makes your brain work better
    ii. There is pain but it is worthwhile because it has benefits

7. Where does this fear come from – fear of pain, fear of disease transmission, fear of adverse reactions?

a. Japan: pain is the most fear, a little around disease transmission
    i. No communication between the doctor and the patient
        1. No time to communicate
        2. Cost of medical cost is so cheap, so as a professional you need to see a lot of patients to make more money

3. Short time allotted
4. Each patient is only given 5-10 minutes with the physician
    a. Wait 2 or 3 minutes
    b. Easier and faster to provide an injection

b. Iraq: no fear at all around needles, only can get one at a doctors facility so no fear around any needle use
    i. No one would be injecting themselves directly
c. Korea: no fear around needles at all
    i. Can only get an injection in a hospital
    ii. Respectful culture of the doctor (Same in Iraq)
        1. Older generation
        2. Trust everything that a doctor says
        3. Tons of respect for the doctor
        4. Want patient to trust and listen to the doctor
        5. Don't ask any questions
            a. Follow blindly
        6. Do exactly what they are told
        7. No fear because of this trust
        8. Listen and respectful of doctor and dentist
        9. Any healthcare provider

8. Is there more fear in pediatric populations?

a. Korea: little kids don't want to go to hospital because they are afraid
b. Japan: no difference between the US and Japan
    i. Less Nitris use because they don't want extra substance in their body
    ii. Patient will decline
c. Iraq: kids are ok if they are aware of what is happening
    i. Communication about what is happening
    ii. Kids more afraid about going to the dentist
    iii. Still use child restraint
        1. Last resort

GLOBAL NEEDLE USE

Identifying design opportunities through a cultural understanding of medical needle use, fear and pain within the United States and Developing Countries

Claire Pilgrim Sakaguchi

A CREATIVE THESIS

Presented to the Department of Product Design
and the Robert D. Clark Honors College
in partial fulfillment of the requirements for the degree of
Bachelor of Science

June 2014

Claire Sakaguchi for the degree of Bachelor of Science
in the Department of Product Design to be taken June 2014

INTRODUCTION

DESIGN BRIEF

INTRODUCTION:

10% of the global population exhibits some level of medical related needle fear, but meaning and cause for phobia presumably varies greatly by culture (Deacon et al, 2006). In the United States, 90% of pediatric populations are believed to exhibit some level of fear around procedures that involve a needle (Taddio et al, 2012). As a result, various consequential behaviors include healthcare avoidance, negative memory creation as well as conditioned anxiety responses. In understanding the meaning of fear within the United States, psychological, physiological and emotional factors must be examined in pediatric populations.

In developing countries, however, needles are not viewed as frightening objects and instead have positive connotations. Injections are welcomed by populations and are the preferred method for treatment and therapy. In order to understand the preference for injections, one must understand the cultural beliefs around efficacy, the economic interests of providers and the poor communication that exists between patients and providers (Van Staa et al, 1996). As a result, injections are administered in unnecessary quantities and because of poor policy and regulation within healthcare systems the consequence of blood-borne disease transmission becomes a source of fear for global populations.

For both user groups, it is important to understand the cultural and behavioral implications for various types of fear. Through primary and secondary research, my final outcome will produce design opportunities which aim to decrease morbidity, mortality and cost in cross-cultural contexts.

PROBLEM STATEMENT:

Is medical needle fear a universal condition and therefore, is it possible to leverage universal design to create a cross-cultural solution?

OBJECTIVES:

- Understand user behavior around needle use
- Understand cultural perception of needles
- Understand sources of fear around medical needle use

- Analyze use case scenarios around needle use for both end users and healthcare providers
- Analyze user personas for needle use
- Analyze existing methods of reducing fear
- Analyze consequences of user behavior, fear or preference for injections

- Identify design opportunities for reducing needle fear
- Identify constraints for universal design
- Identify trends within user groups

DESIGN BRIEF

REQUIREMENTS:

- A global and cross-cultural understanding of the meaning of needle fear
- Research using interdisciplinary approaches: anthropologic, psychological, cultural, historical, economic

USER GROUPS:

- Pediatric populations within the United States
- Adult populations within developing countries

METHODS:

PRIMARY

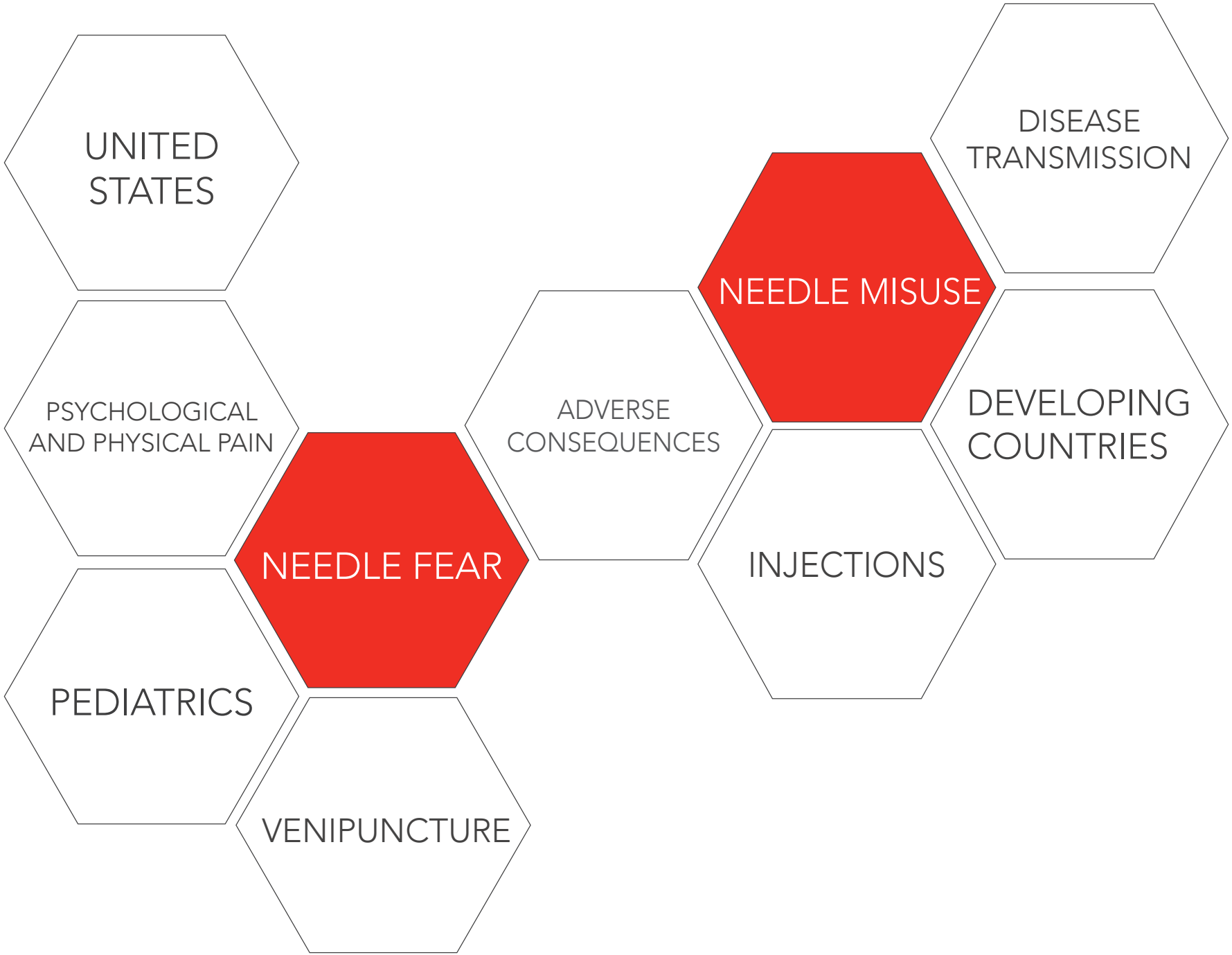
- **Observation**: Pediatric populations undergoing intravenous cathetar placement at Doernbecher Children's Hospital (Sedation Unit)
- **Observation**: Pediatric populations undergoing routine vaccination at Oregon Health & Science University
- **Interview**: First generation foreign individuals in understanding global needle use & pain perception
- **Interview**: Pediatric nurses around vaccination fear
- **Survey**: Pediatric anesthesia nurses around venipuncture needle fear

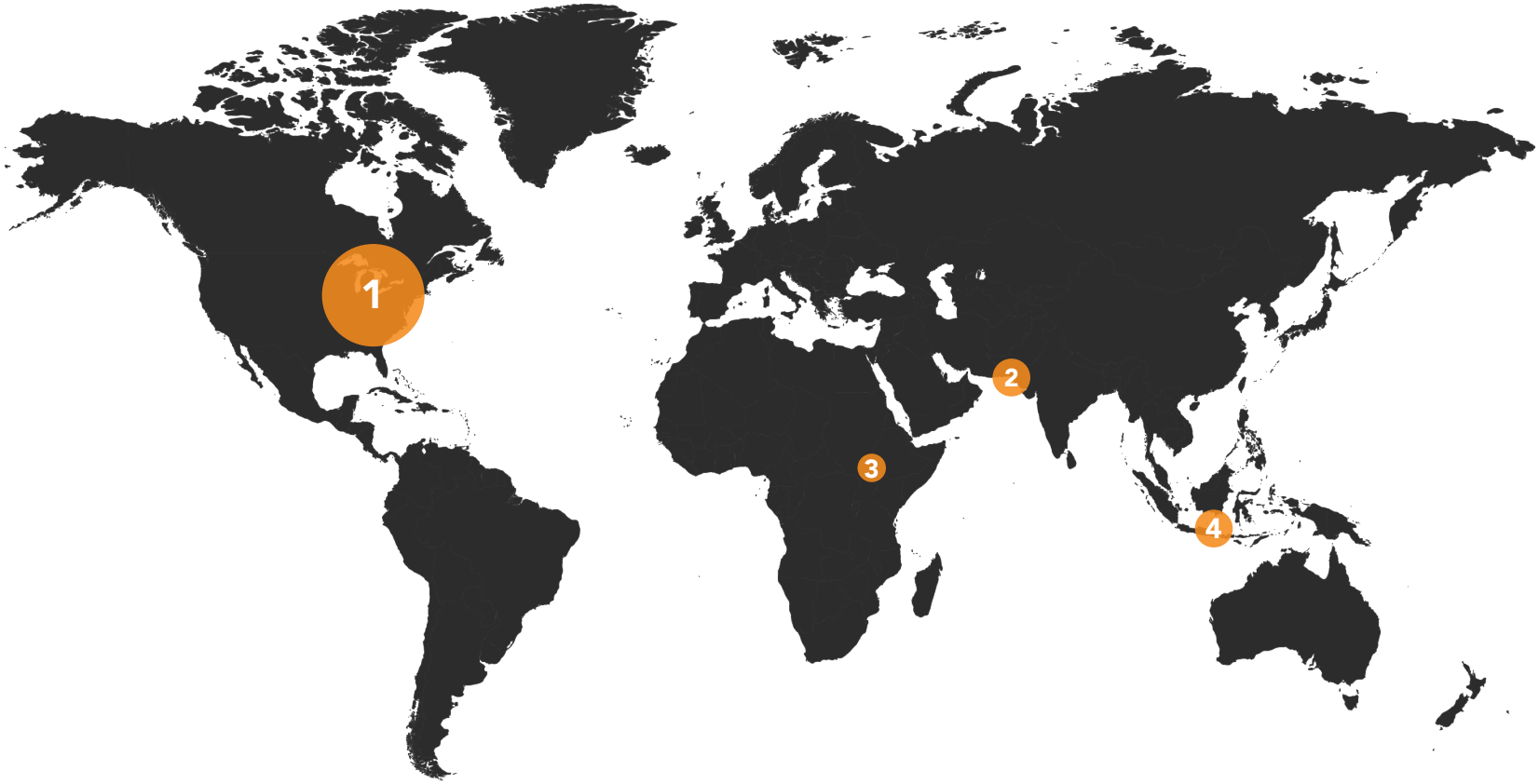
SECONDARY

- Review of primary (peer reviewed) literature

The purpose of this work is to determine if the condition of needle fear is universal across populations in the United States and developing countries and if meaning for fear is consistent. As a designer, one must identify user behaviors, consumer insights and market opportunities when beginning the design process. Without full awareness for a project's user needs and problems, a successful design cannot be conceived. Compounded issues of culture, socioeconomics, history, physiology and psychology are important factors to evaluate when understanding complex issues such as global needle use, fear and pain. Interdisciplinary lenses will need to be used in research. As a final outcome, design opportunities, trends and constraints will be presented based on primary and secondary research findings.

JOURNEY MAP


UNITED STATES
DISEASE TRANSMISSION
NEEDLE MISUSE
PSYCHOLOGICAL AND PHYSICAL PAIN
ADVERSE CONSEQUENCES
DEVELOPING COUNTRIES
NEEDLE FEAR
INJECTIONS
PEDIATRICS
VENIPUNCTURE



CROSS CULTURAL PERCEPTION OF NEEDLES

1. UNITED STATES OF AMERICA: [NEGATIVE] Needles are feared by pediatrics for physical pain and the emotional distress they inflict. But in the US, a majority of modern medicine is dependent on the hypodermic needle for medical testing, vaccine delivery and/or drug therapies, so avoidance behavior can be detrimental.

2. PAKISTAN: [POSITIVE] Doctors will almost always recommend an injection with patients having little knowledge or input to what is happening. Doctors may offer special mixtures of injectable medication, for example an antibiotic, mixed with an antimalarial, a steroid and/or vitamin B12.

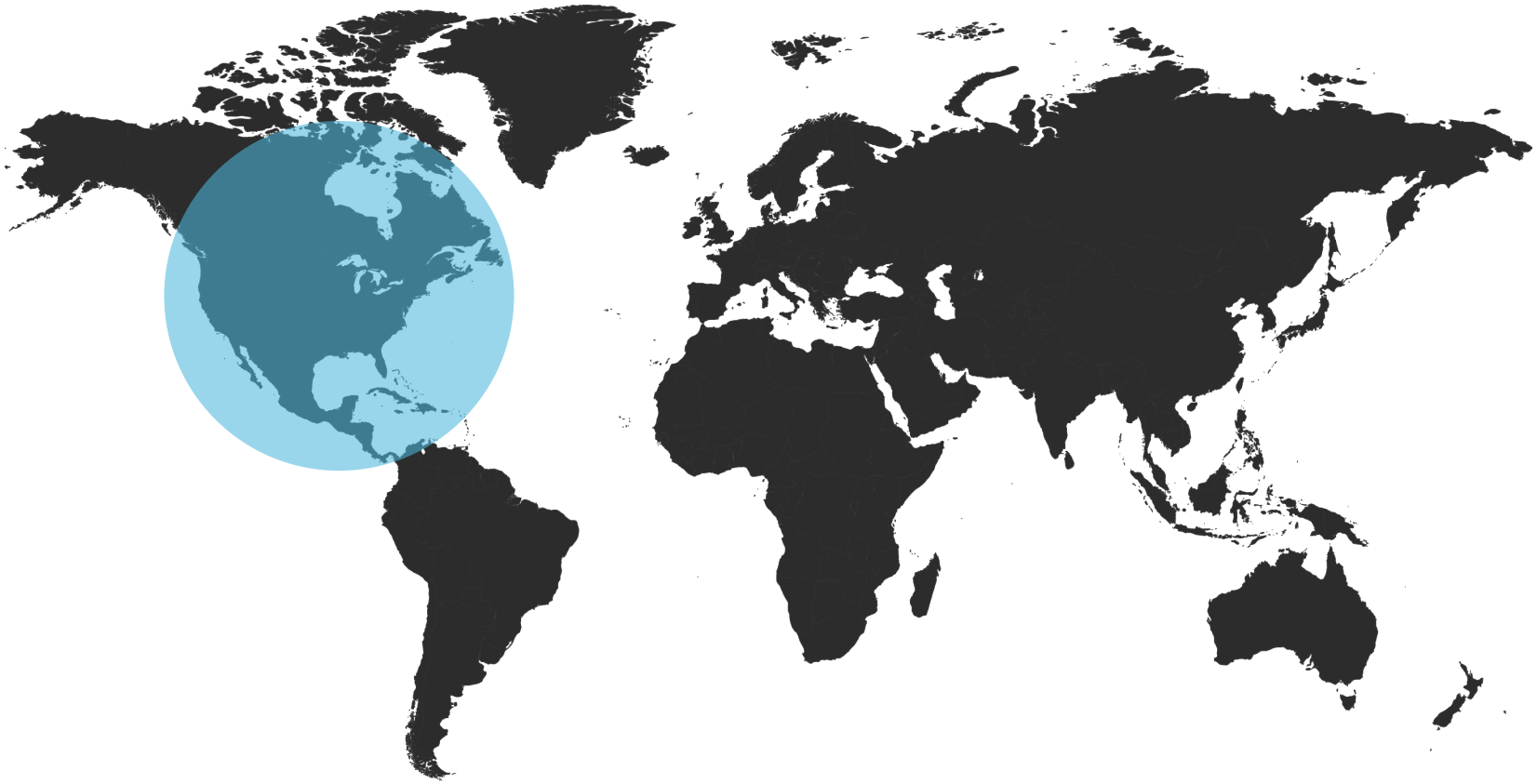
3. UGANDA: [POSITIVE] Injections are preferred by providers because they will provide higher profits. Injections are preferred by patients because they are believed to be more effective and more efficient.

4. INDONESIA: [POSITIVE] Injections are administered by providers because they bring popularity to the administrator. Patients are only satisfied if an injection is provided because injections are believed to cure all diseases as seen historically with *neosalvarsan* injections.

CROSS CULTURAL PERCEPTION OF PAIN

1. United States of America: Report high levels of pain even with stronger pain medication.
2. Nicaragua: Pain is associated with stronger healing powers and a painful injection is believed to work better.
3. Sierra Leone: Injections are viewed as the best remedy because the associated pain indicates efficacy.
4. Ghana: Lower self reported pain levels within HIV patients when compared to US patients (even with weaker pain medication).
5. Nigeria: Pain is seen as a shameful sign of weakness.
6. Ethiopia: Lower self reported pain levels within HIV patients when compared to US patients (even with weaker pain medication).
7. India: Indian students presented a higher threshold for pain tolerance, and a lower rate of overall reporting of pain, than students from the United States.
8. Philippines: Self-induced pain is believed to be a pathway into the divine.
9. Malaysia: Pain is often sought to be a source of healing and recovery.

NEEDLE FEAR IN THE UNITED STATES



The concept of needle fear in the United States is frequently observed in medical settings and refers to a fear of medical procedures that require the insertion of a needle into one's body (Andrews et al, 2010). Needle fear can be mild where only minimal levels of fear, anxiety and aversion can be observed. Or needle fear can be severely disabling and sometimes life threatening, as in cases of pathologic needle phobia and instances where vasovagal (fainting) responses occur (Kettwich et al, 2007 and Deacon et al, 2006). Needles used in medical contexts can refer to injecting liquids (often medicine), intravenously delivering liquids or for taking blood from the body. These medical practices can greatly improve the health and survival of individuals and are considered significant medical advances for patient health. However, literature suggests 10% of individuals (USA), in medical settings, report an "excessive" fear of needles (Deacon et al, 2006). This fear can consequently trigger avoidance behavior, distress and/or impairment, which can adversely impact and restrict important aspects of an individual's life (Deacon et al, 2006).

curious and sensitive

- 7 years old
- American

JASMINE

Jasmine is a 7 year old girl living in Portland, Oregon. She is a healthy kid and does not make too many trips to the doctor and has only been to the emergency room one time. She recalls this experience in a very negative manner and ever since, has been terrified of going to the doctor. She believes every trip to the doctor means a shot or needle stick which gives her a huge amount of distress and fear. She likes to know exactly what is going to happen which means she wants to know how much it is going to hurt, where the needle is going and what it is doing. She always holds her mom's hand during needle sticks and immunizations and will only start crying if physical pain is extreme.

PROVIDER PERSONA UNITED STATES

efficient and direct

- 30 years old
- Nurse Practioner
- American

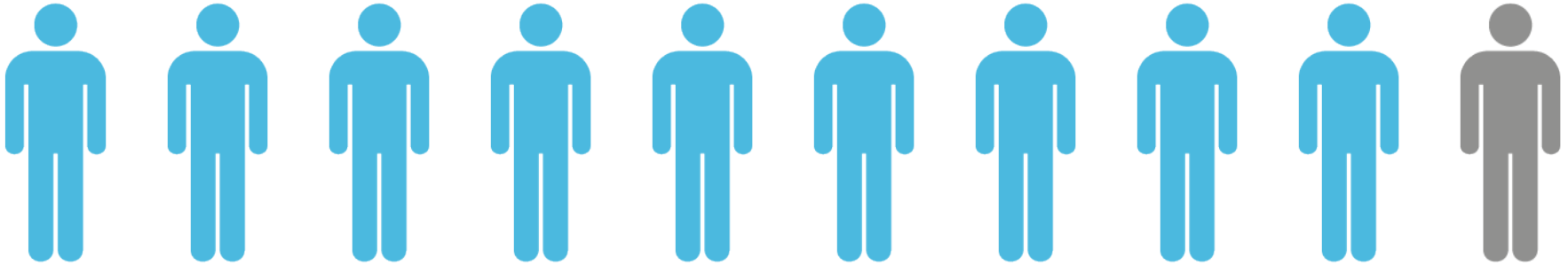
AMANDA

Amanda is a 30 year old nurse practioner living in the United States. She has been a nurse practioner for 7 years and works specifically at the pediatrics clinic. She is fully aware that pediatrics exhibit severe distress around injections and venipuncture procedures. When a child is in severe pain and distress and begins crying, this creates distress for Amanda because she doesn't want to be the source of pain for a child. She tries to be completely transparent and let children know exactly what is happening, when it is happening and how much it will hurt because she knows the kids have alot of anticipatory fear. Sometimes she tries to talk to the child when the procedure is happening in order to keep the child distracted.

NEEDLE FEAR IN THE UNITED STATES

10% of the adult population has some fear associated with needles

90% of young children have severe distress during needle interactions

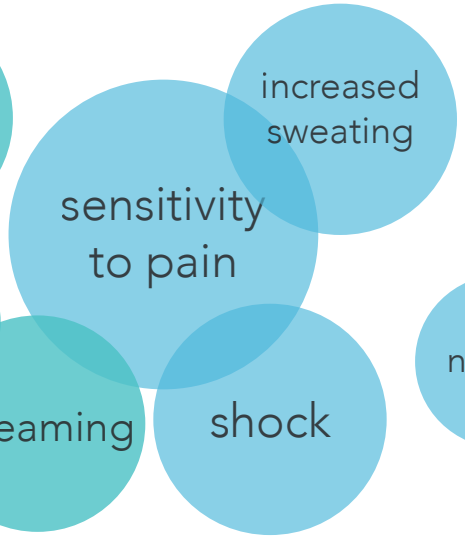


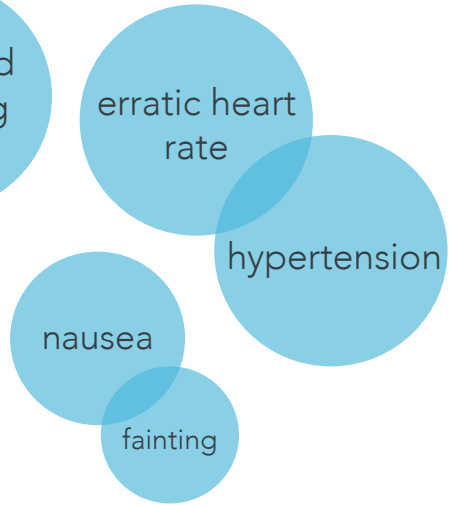
USER BEHAVIOR IN THE UNITED STATES

PSYCHOLOGICAL | PHYSIOLOGICAL | EMOTIONAL

EMOTIONAL RESPONSES

PHYSICAL RESPONSES





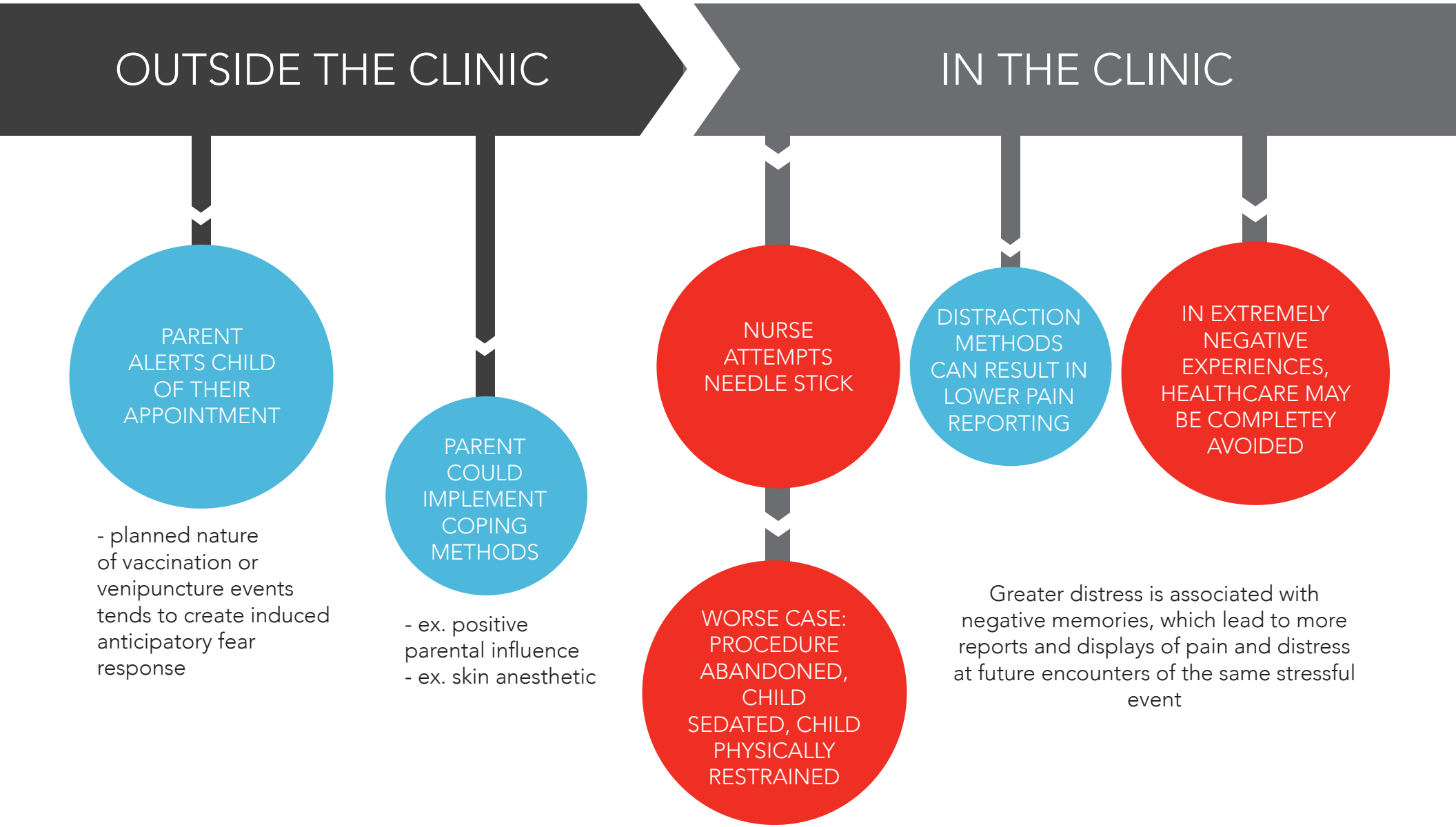
CONSEQUENCES

- total healthcare avoidance
- increased fear in follow ups
- child restraint practices
- sedation of the child
- negative memory creation
- conditioned anxiety response

PSYCHOLOGICAL INSIGHTS

kids want to know **WHAT IS HAPPENING**	how much is this going to **HURT**	**WHEN** is it going to happen?
PROCEDURAL FEAR	FEAR OF PAIN	ANTICIPATORY FEAR

UNITED STATES PATIENT PROCESS [PEDIATRIC VENIPUNCTURE]



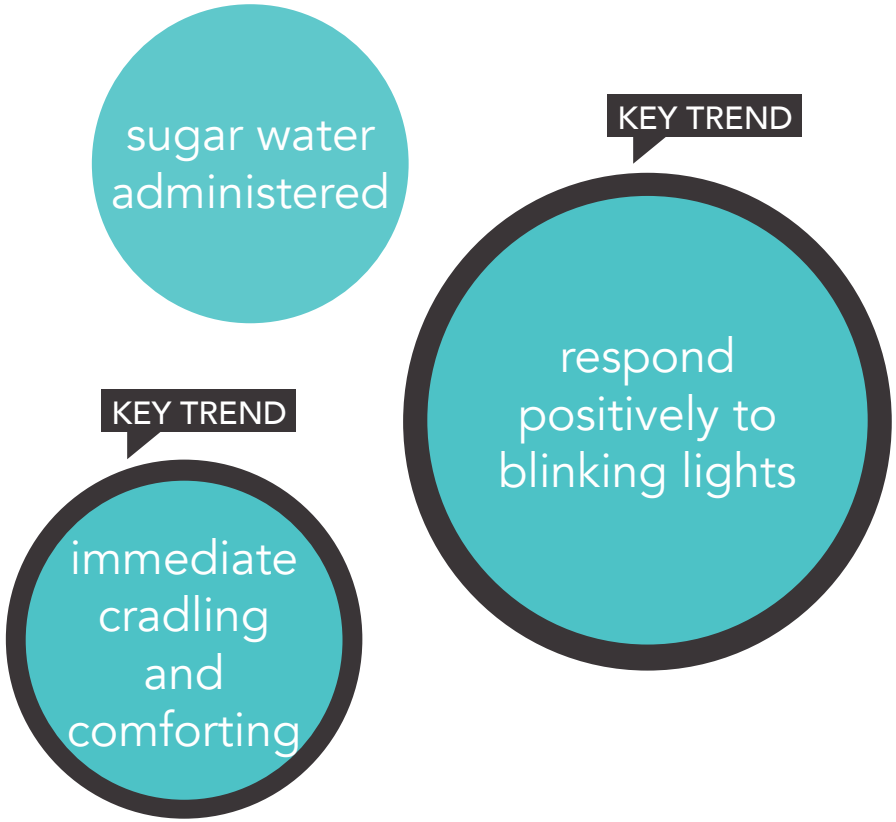
** SIZE AND RED COLOR DENOTES OPPORTUNITY FOR NEGATIVE CONSEQUENCE: **FEAR AND MEDICAL NON COMPLIANCE**

0-1 YEAR OLD TRENDS

+ user observation performed at Oregon Health & Science University Pediatric Clinic
+ observed ~15 vaccinations administered to 7 children aged 10 months to 13 years

PAIN PREVENTION TECHNIQUES

* size connotes success



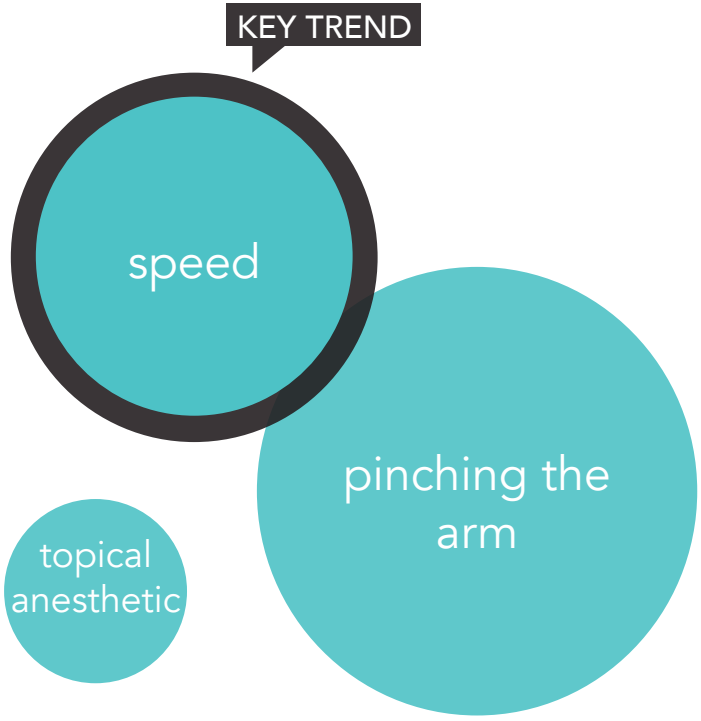
RELATED BEHAVIORS CONSIDERATIONS

10 - 13 YEAR OLD TRENDS

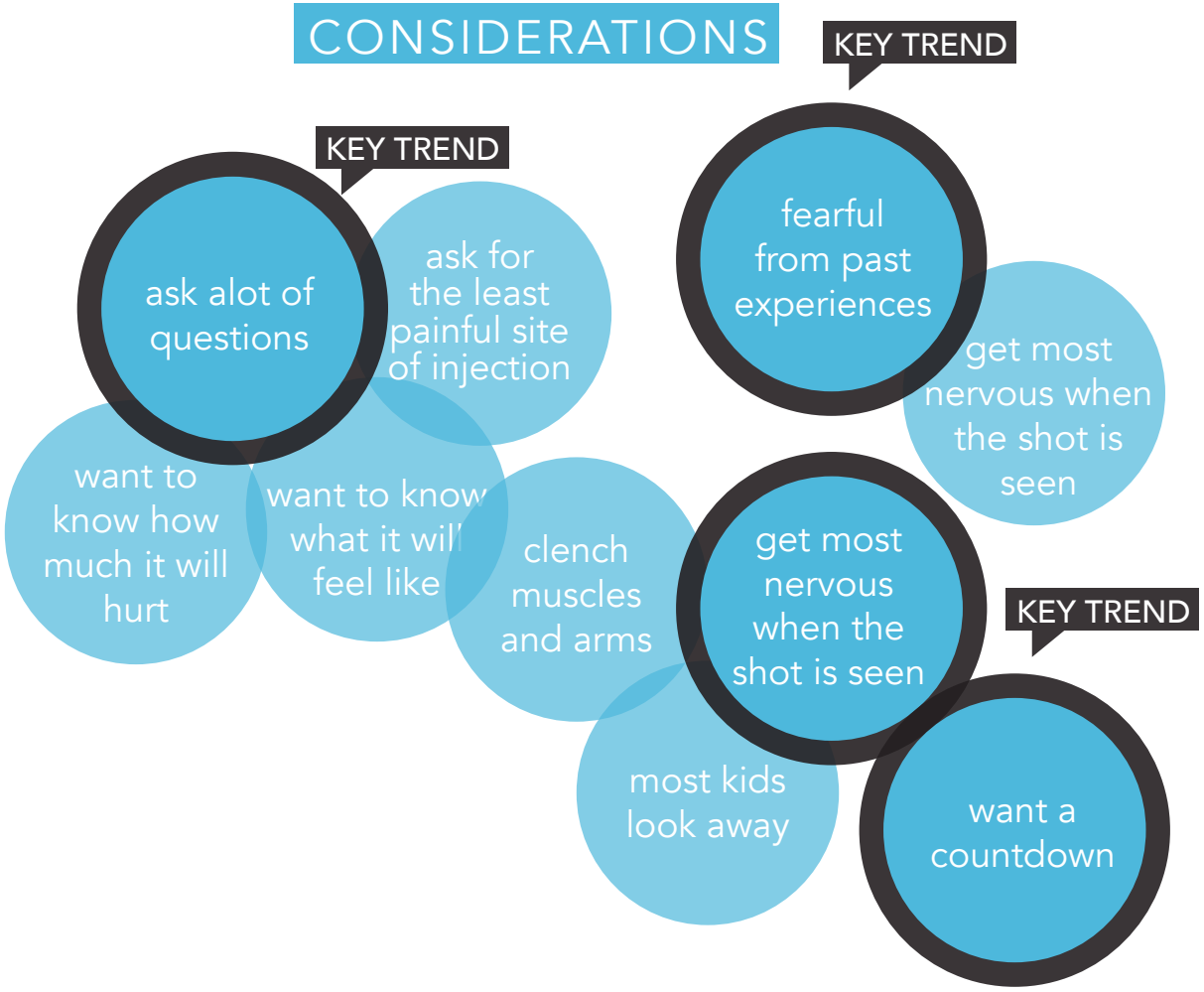
+ user observation performed at Oregon Health & Science University Pediatric Clinic
+ observed ~15 vaccinations administered to 7 children aged 10 months to 13 years

PAIN PREVENTION TECHNIQUES

* size connotes success



RELATED BEHAVIORS CONSIDERATIONS



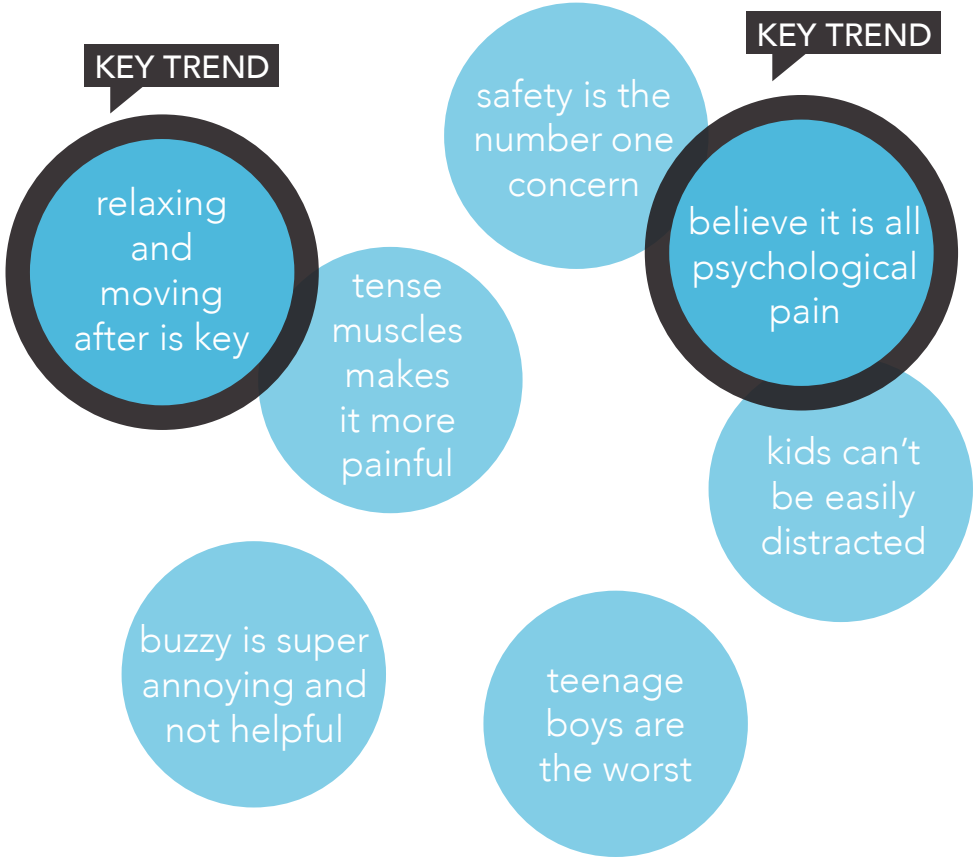
WHAT THE NURSES SAY

+ user observation performed at Oregon Health & Science University Pediatrics Clinic
+ observed ~15 vaccinations administered to 7 children aged 10 months to 13 years

PAIN PREVENTION TECHNIQUES

* size connotes success

RELATED BEHAVIORS CONSIDERATIONS



PEDIATRIC SEDATION

+ user observation performed at Oregon Health & Science University Pediatric Sedation Unit

USER POPULATION

5 girls age 4 - 12 years old

All hospitalized at least 1x in the last year.
Up to 4 hospital visits in the last year.

PHYSICAL PAIN

(3 / 5) CALM DURING IV STICK

(2 / 5) VOICED PAIN DURING IV STICK

PATIENT OBSERVATION

(5 / 5) WATCHED IV PLACEMENT AND DID NOT LOOK AWAY

ANTICIPATORY FEAR

Only one patient cried prior to the procedure.

(4 / 5) CALM BEFORE THE PROCEDURE

(1 / 5) SCREAMED AND CRIED BEFORE THE PROCEDURE

** patient was given Versed (midazolam) to calm them

Experienced patients appear to exhibit significantly lower fear and pain around needle procedures.

PEDIATRIC SEDATION // INSIGHTS

+ user observation performed at Oregon Health & Science University Pediatric Sedation Unit
+ observed 5 sedations of girls age 4 - 12

- children that watch the IV stick seem to exhibit less fear and are more accepting of the procedure

- children that have had multiple hospital visits in the last year display no fear or pain

- if a parent discusses negative past experiences, the child reacts much more negatively

- positive reinforcement through receiving a stuffed animal helps a child feel less distress

- children that are interested in the procedure are much less fearful

- warm blankets make a child feel more comfortable

- topical anesthetic and TV distraction can help prevent kids from feeling any pain

- kids that know exactly what is happening cope much better = “expert patient”

PEDIATRIC ANESTHESIOLOGY NURSES

Survey from 8 nurses at Oregon Health and Science University

FEAR RELATED TO IV PLACEMENT

60% Psychological and physical factors

40% Psychological factors

37.5 % 25-50% of patients cry

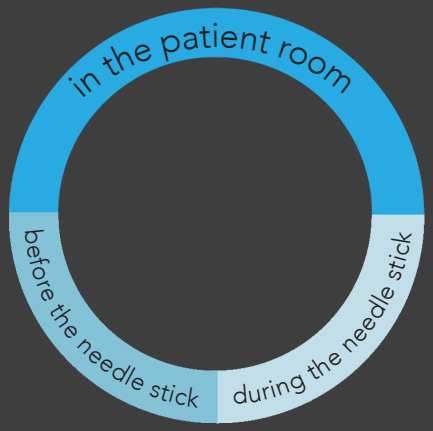
37.5 % 50-75% of patients cry

25% 75-100% of patients cry

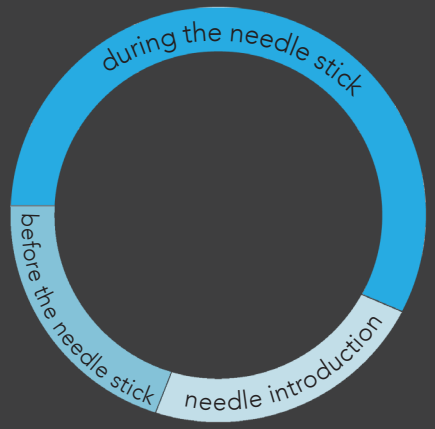
60% Watch IV stick

40% Do not watch IV stick

WHEN ANXIETY BEGINS



WHEN THERE IS THE MOST ANXIETY



100% OF NURSES SAY DISTRACTION METHODS ARE EFFECTIVE IN REDUCING FEAR

METHODS TO REDUCE FEAR

SINGING COLD

DISTRACTIONS

MAKING A PLAN WITH FAMILY

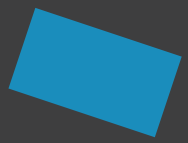
TV AND TOYS TALKING

REWARDS

ENCOURAGING WORDS

WHAT KIDS BRING TO THEIR APPOINTMENT

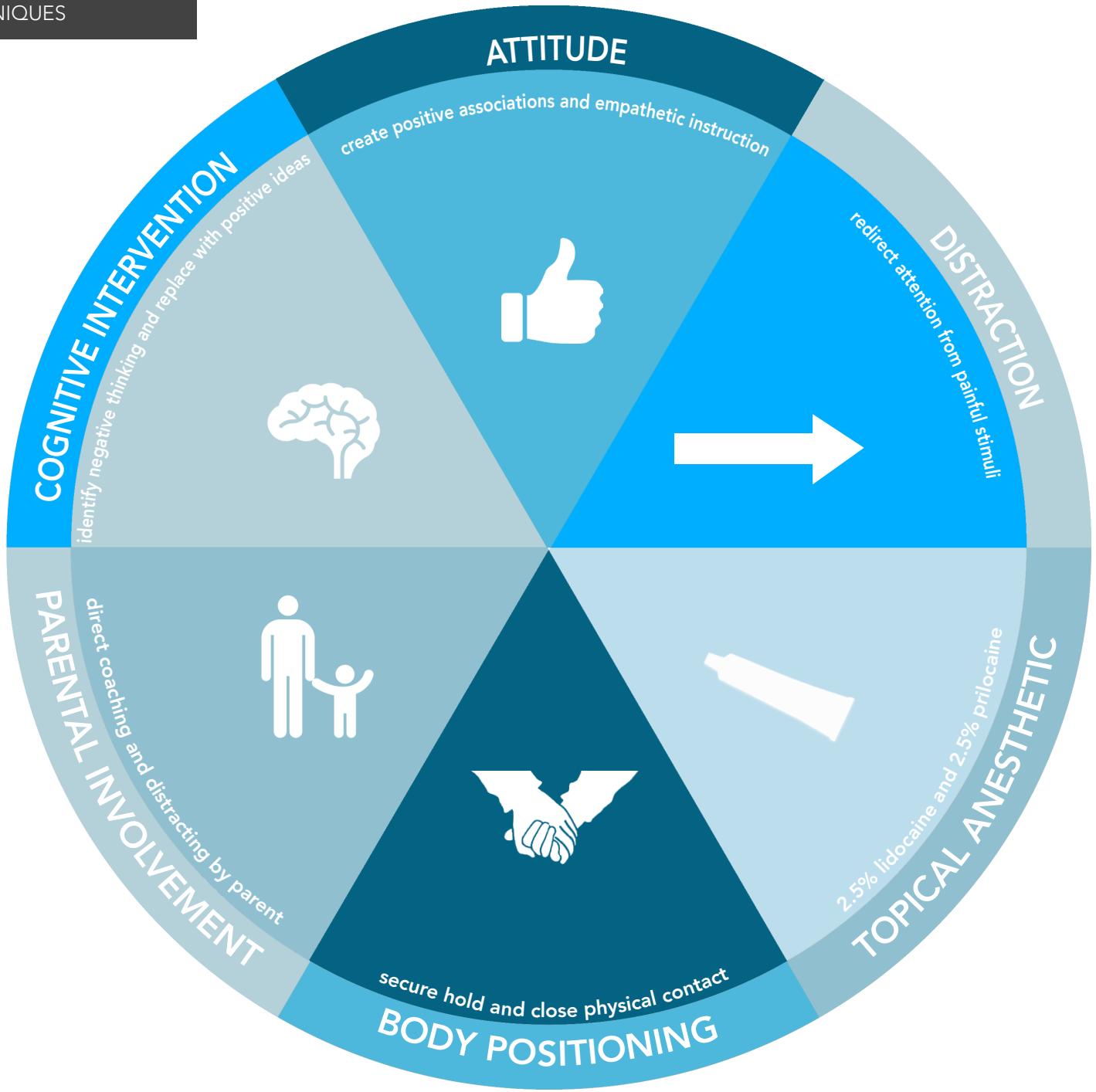
STUFFED ANIMALS



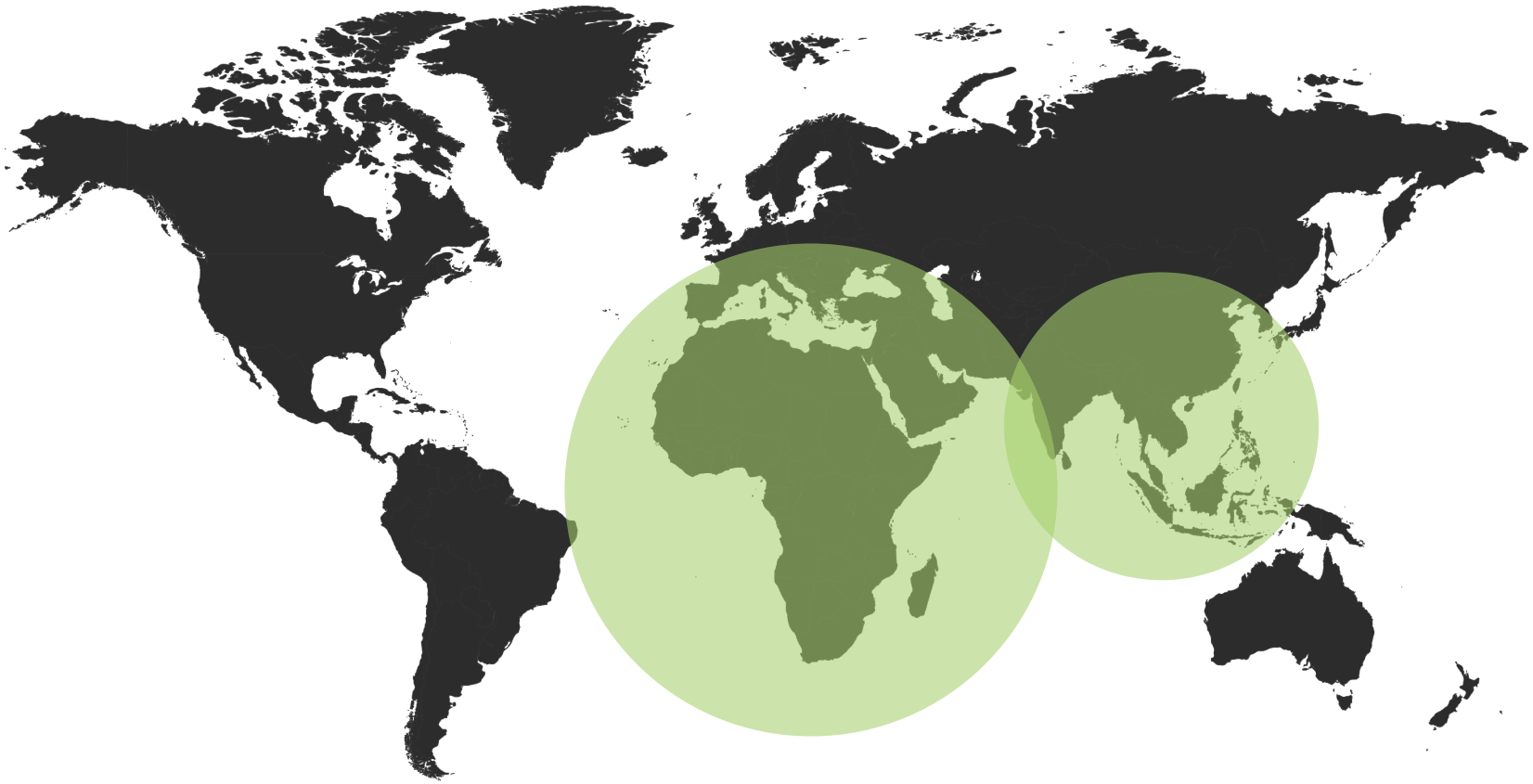
BLANKETS

MOBILE DEVICE OR TABLET

COPING TECHNIQUES



NEEDLE USE IN DEVELOPING COUNTRIES



Within the United States, there is great amount of fear around medical needle use, but most of this fear is attributed to pain that can be inflicted, both physically and psychologically. Americans, especially pediatrics, demonstrate great levels of anticipatory fear and distress when receiving medical treatment that involves a needle. Although the development of the hypodermic needle and other injection devices are Western creations, it seems this notion of needle fear is also a Western created condition. According to primary literature, this fear and distress is not greatly reported in other populations. Instead, many cultures in developing countries show a huge popularity around medical needles, specifically injections. Any fear that is derived from needles in global contexts is less associated with pain and more so with larger consequences including sterilization and contamination issues.

spiritual and health conscious

- 21 years old
- Indonesian

CINTA

Cinta is a 21 year old girl living in Jakarta, Indonesia. She is very spiritual and has strong beliefs around healing and higher powers. She is a health conscious individual and is a strong believer in the power of therapeutic injections. She has great respect for her doctor and will never doubt their suggestions. She typically expects some sort of injection on every visit because her grandmother always talked about how effective and miraculous injections were for curing diseases in the past. If she doesn't receive an injection on her visit, she will likely try a different doctor. She isn't afraid of the pain and thinks that it is a sign of stronger and faster healing.

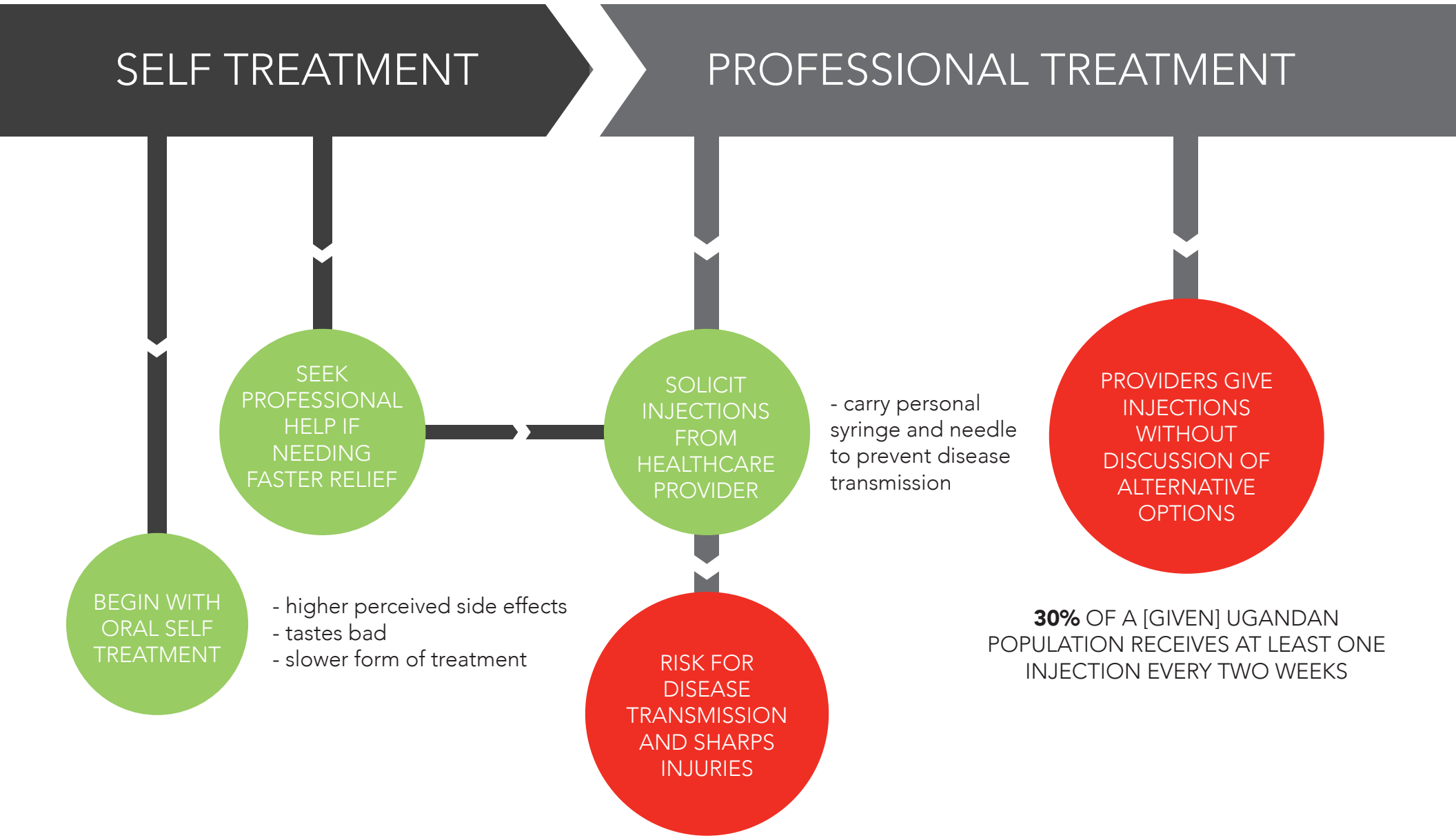
family to feed

- 45 years old
- Ugandan
- Medical provider

LUZIGE

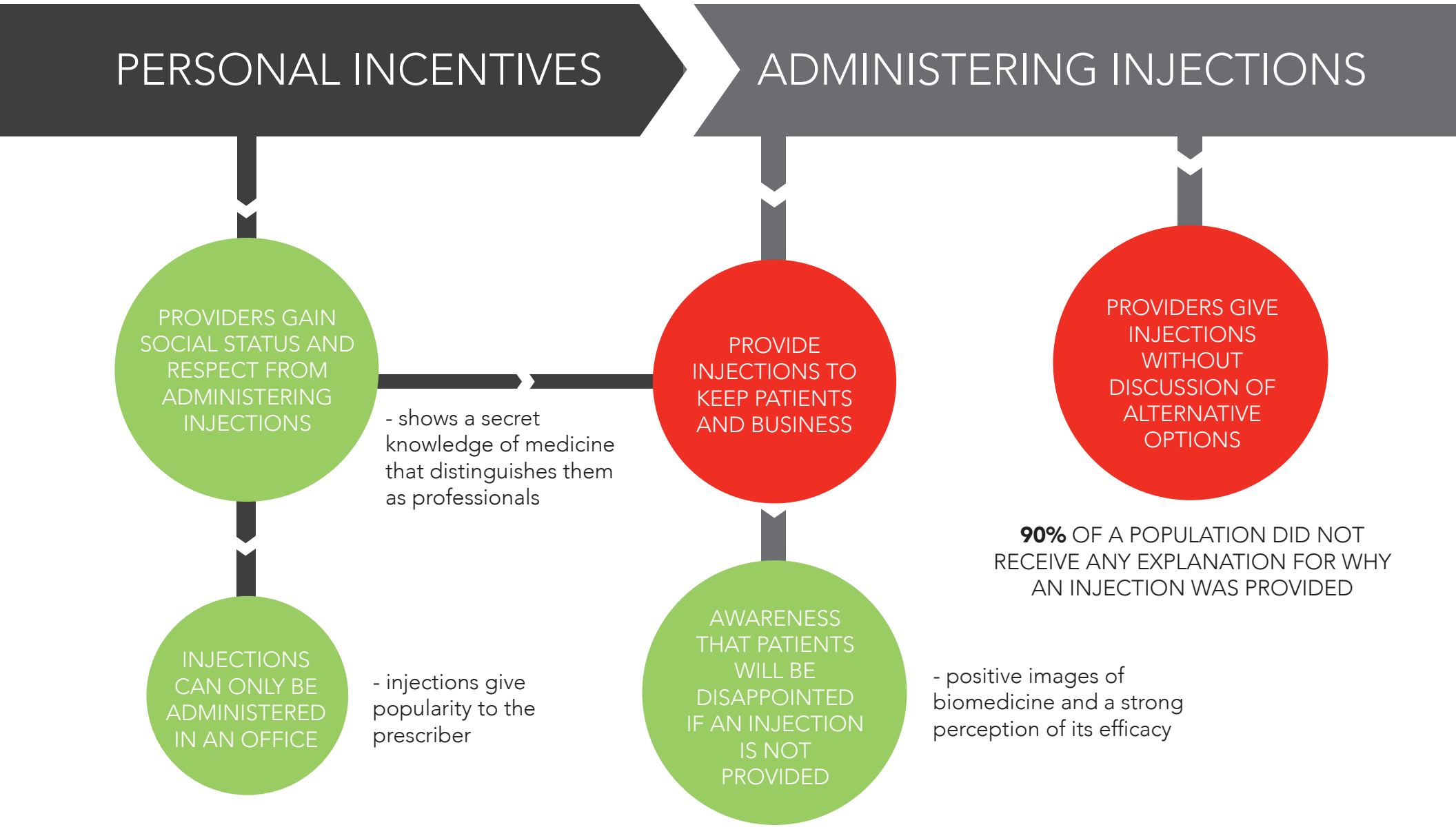
Luzige is a medical provider in the village of Ruhiira, Uganda. He became a medical provider because he has a personal desire to help patients achieve wellness and a healthy life. But, at the same time, he has 4 children at home that he has to feed and is pleased his profession can make a little more money than most. When Luzige administers injections, he can make significantly more money when compared to providing oral therapy. He does believe injections fight diseases better and will almost always offer that as the primary choice of therapy. He is aware that needle contamination is a big issue and practices sterilization as best he can. Many of his patients carry their own syringe and needle with them in attempt to prevent the spread of HIV/AIDS. Luzige is fearful of contracting the disease as a result of a needle sharp injury, but believes the monetary benefits of administering injections to be worthwhile.

UGANDA PATIENT PROCESS



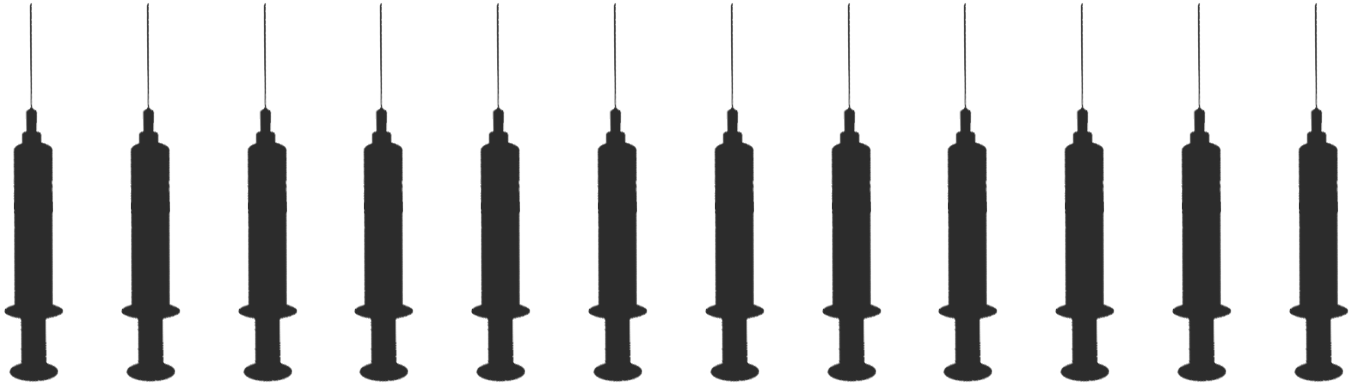
** SIZE AND RED COLOR DENOTES OPPORTUNITY FOR NEGATIVE CONSEQUENCE: **DISEASE TRANSMISSION AND OVERUSE**

INDONESIA PROVIDER PROCESS

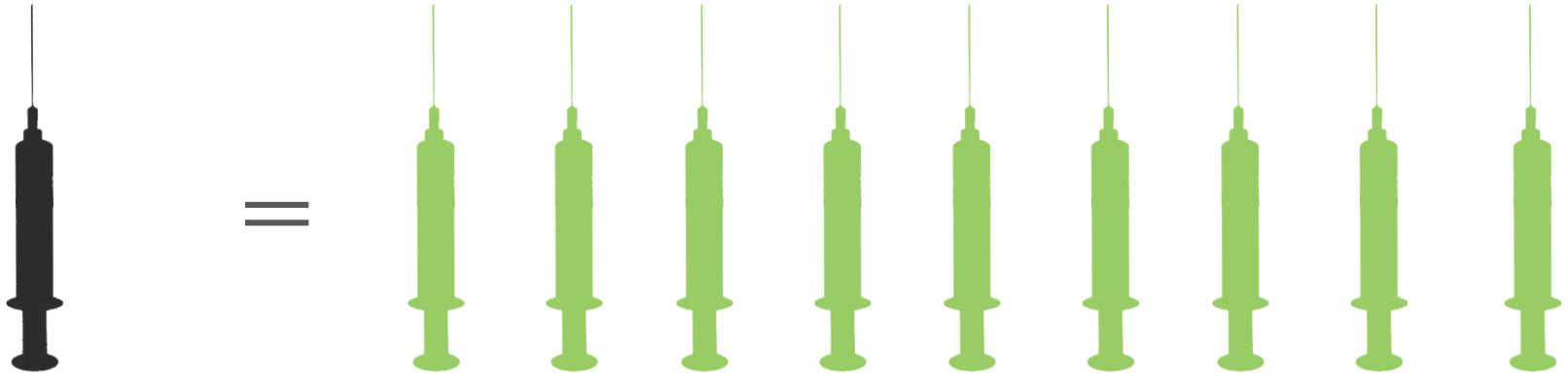


** SIZE AND RED COLOR DENOTES OPPORTUNITY FOR NEGATIVE CONSEQUENCE: **INJECTION OVERUSE AND MISUSE**

NEEDLE USE IN DEVELOPING COUNTRIES



x 1 billion. injections given every year (global)

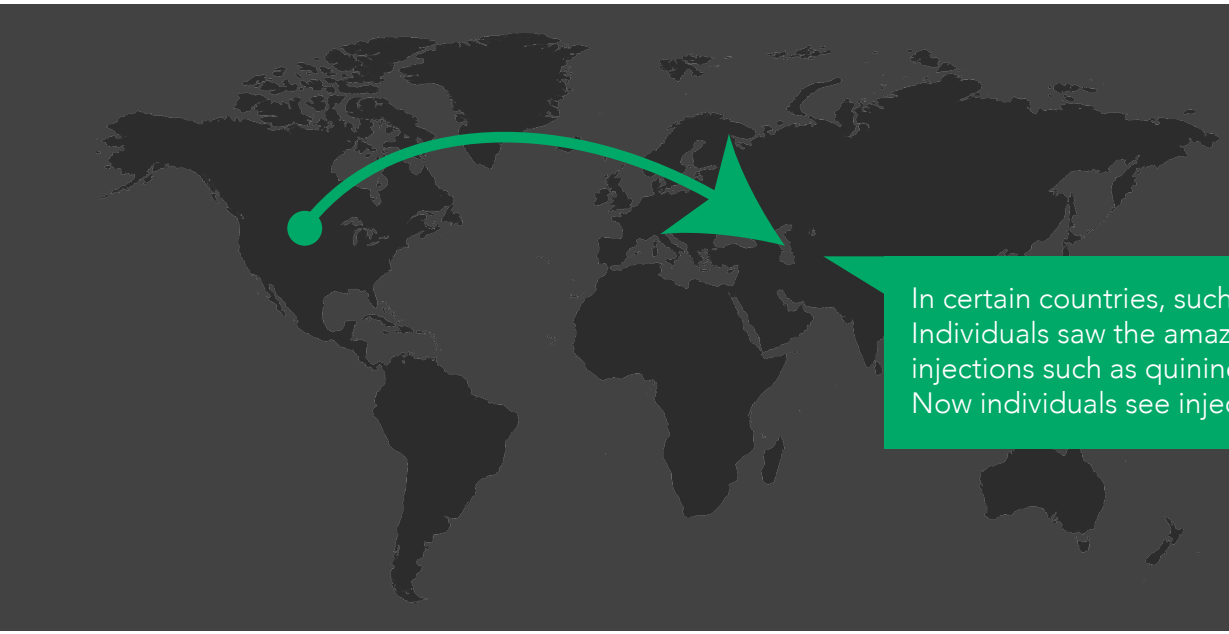


for every 1 immunization injection

9 therapeutic injections are administered

NEEDLE PREFERENCE IN DEVELOPING COUNTRIES

CULTURAL | HISTORICAL | SOCIOECONOMIC



HISTORICAL

In certain countries, such as Indonesia, biomedicine is highly regarded. Individuals saw the amazing cures there were achieved through injections such as quinine to treat malaria and penicillin to treat jaws. Now individuals see injections as necessary to treat all diseases.

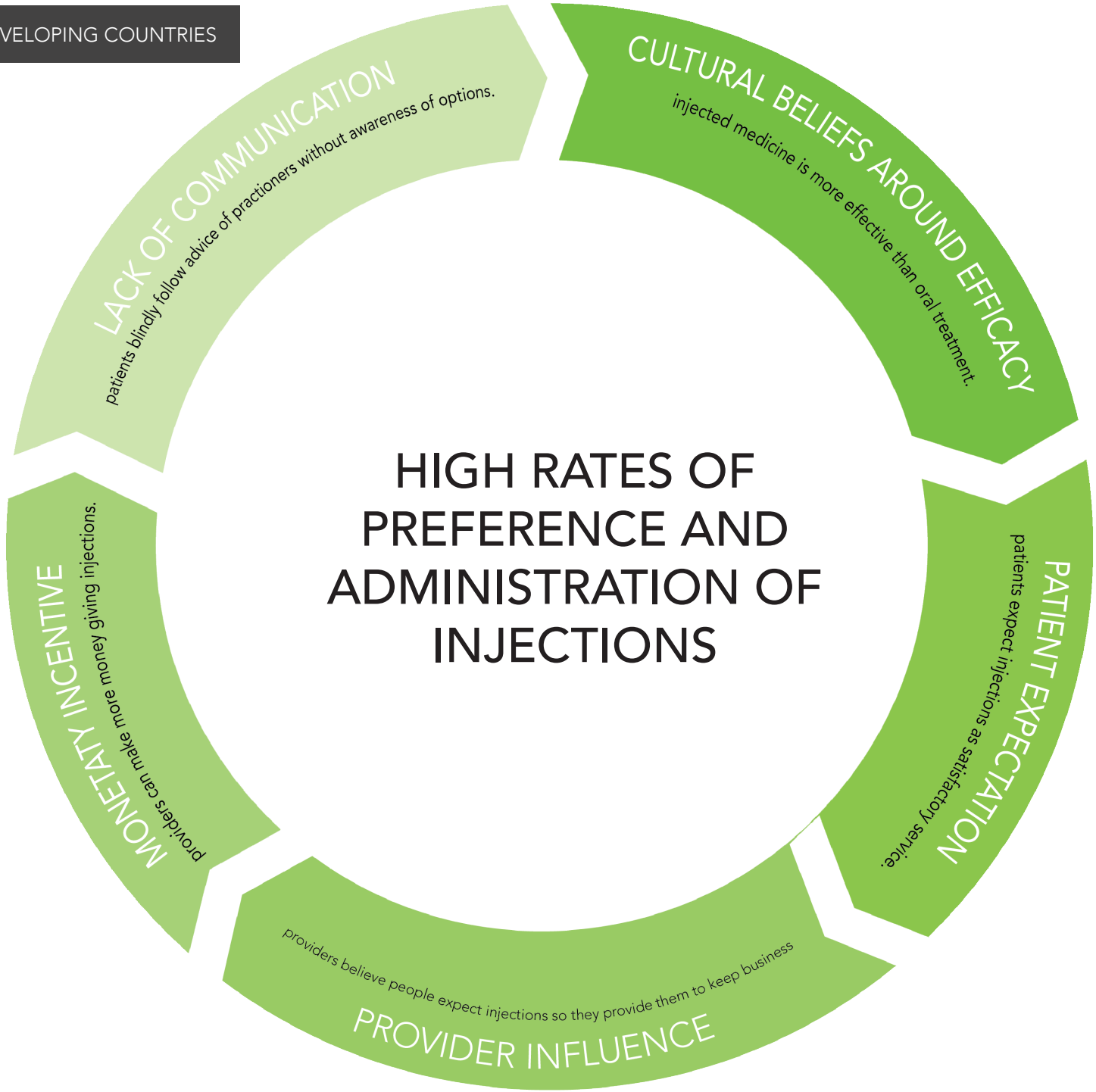
SOCIOECONOMIC

A full treatment of chloroquine tablets earns a profit of **240** Ugandan shillings.

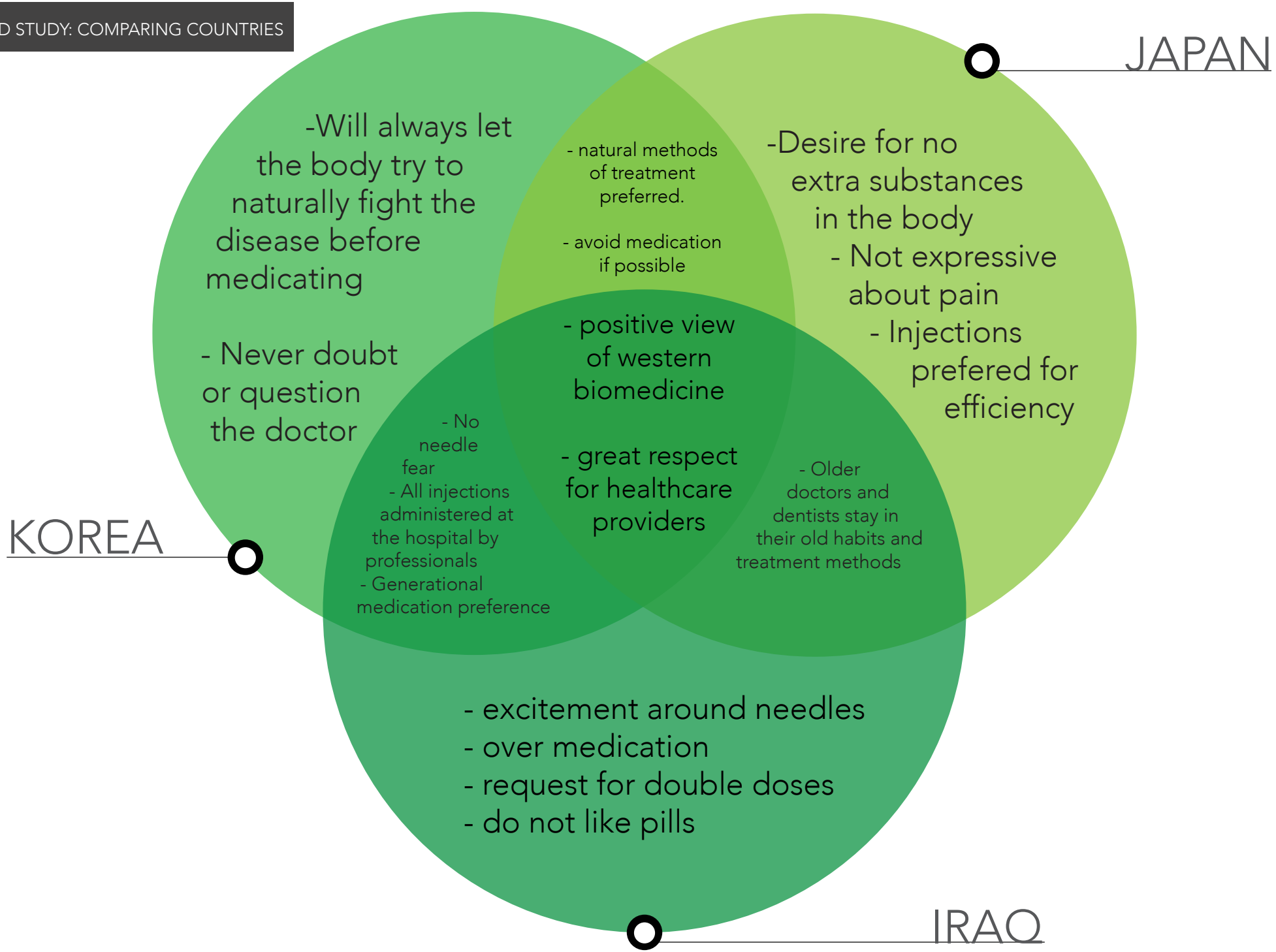
A full treatment of injections to treat malaria costs **2000** Ugandan shillings.

CULTURAL

- **EFFICACY**: injected medicine goes directly to the blood stream.
- **HUMAN PHYSIOLOGY**: oral medication is compared to food, which eventually leaves the body.
- **EPIDEMIOLOGY**: diseases are centered in the blood.
- **EFFICACY:** injections seem more effective as they can attack the disease directly at its source.


LACK OF COMMUNICATION
patients blindly follow advice of practioners without awareness of options.
CULTURAL BELIEFS AROUND EFFICACY
injected medicine is more effective than oral treatment.
PATIENT EXPECTATION
patients expect injections as satisfactory service.
PROVIDER INFLUENCE
providers believe people expect injections so they provide them to keep business
MONETARY INCENTIVE
providers can make more money giving injections.
HIGH RATES OF PREFERENCE AND ADMINISTRATION OF INJECTIONS

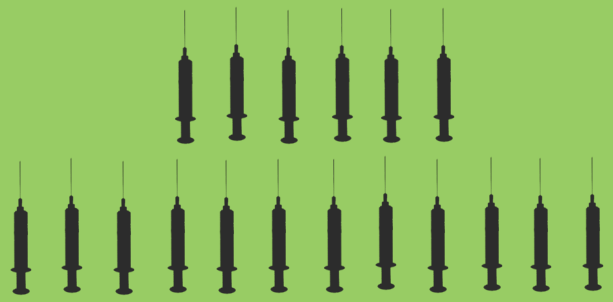
FIELD STUDY: COMPARING COUNTRIES



NEEDLE REUSE IN DEVELOPING COUNTRIES

40% of injections in developing countries are given with unsterilized, reused syringes and needles (WHO)

Traditional syringes cost **$.03**



Auto disable syringes cost **$.15**

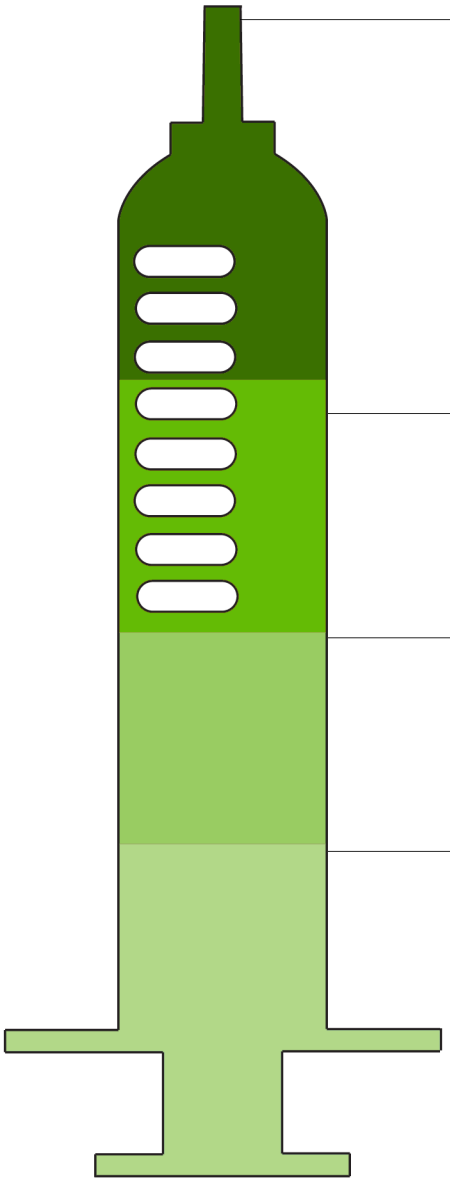
1.3 million deaths occur each year as a result of the unsafe practice

&

21 million hepatitis B infections

5 - 10% of injections are immunizations

90 - 95% are for curative purposes



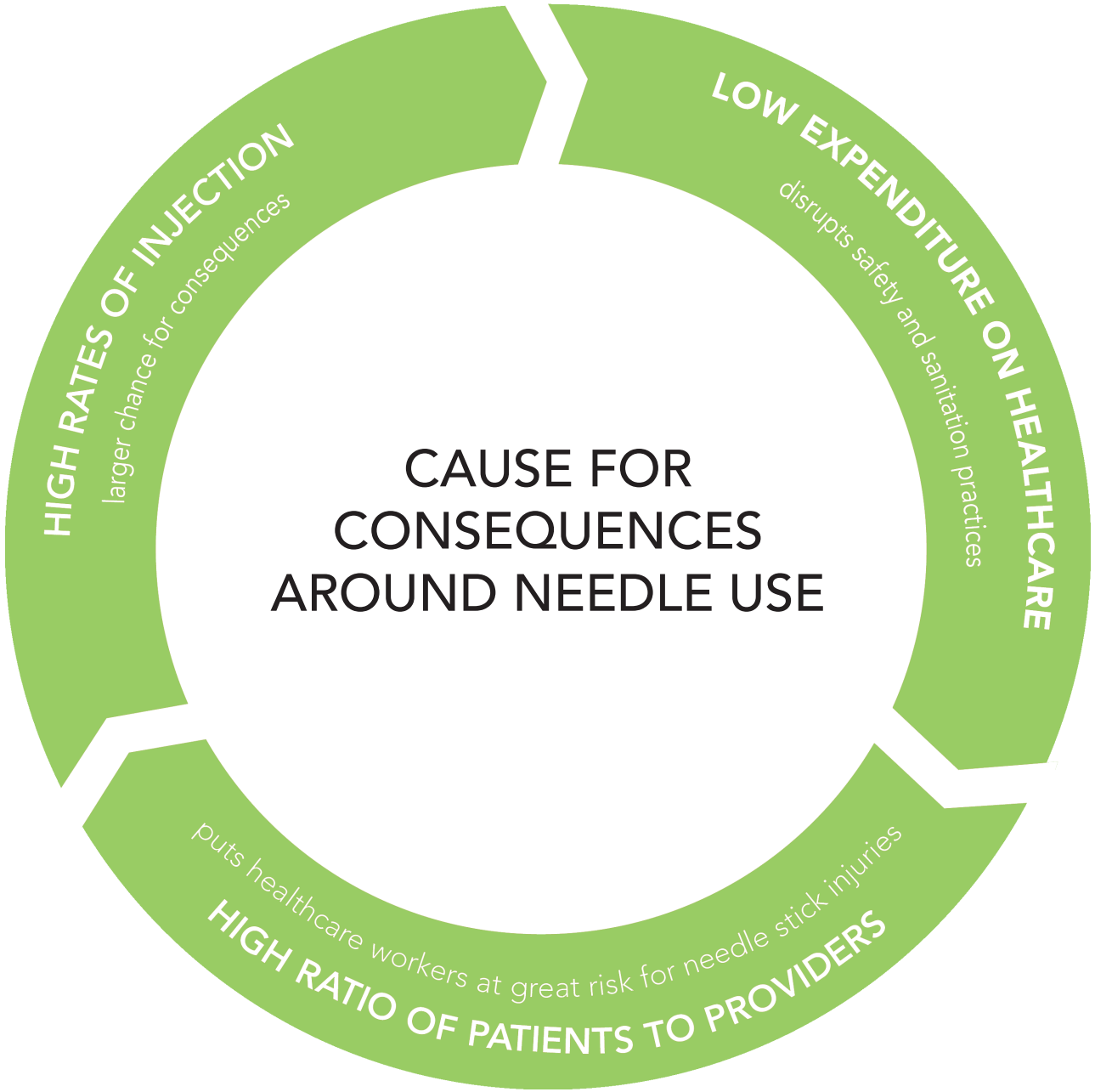
BLOODE BORNE DISEASE TRANSMISSION: needle reuse and improper sterilization practices create risk for transmission of blood borne pathogens including HIV, Hepatitis B, Hepatitis C, Lassa fever and Ebola. Further, hospitals become sites for the point of crossover of disease transmission from groups at high risk of acquiring blood borne viruses (e.g. people with multiple sexual partners, prostitutes, men who have sex with men, and intravenous drug users) to those who may otherwise be characterized as low risk groups in the general population.

STERILIZATION: in rural areas in developing countries there is little protocol and policy for healthcare practices. In rural villages in Pakistan for example, sterilization can entail wiping a needle with a dry cotton ball, rinsing it in a pan of water or wiping it with alcohol, but there is no way to identify a truly sanitized needle.

NEEDLE SHARPS INJURIES: 90% of worldwide - reported needle stick injuries happen in developing countries. In developing countries in Sub-Saharan Africa, for example, low expenditure on healthcare and occupational safety and health services disrupts safety and sanitation needs.

NEEDLE REUSE AND BLACK MARKET: In some developing countries, including Pakistan and India, there is a black market for medical waste repackaging that resells used needles. Further, needle reuse is common in countries with limited economic resources and where there is high demand for injections.

CONSEQUENCES FOR NEEDLE FEAR DEVELOPING COUNTRIES



DESIGN: CONSTRAINTS, INSIGHTS AND OPPORTUNITIES

TARGET USER: **Children Ages 4 - 10**

DESIGN OPPORTUNITY: Reducing anticipatory fear, procedural fear and fear of pain.

Given the issue of pediatric needle fear is largely psychological, the best methods for reducing this fear is in moving attention away from painful stimuli, promising lower pain and being extremely transparent around what is happening to the child.

DISTRACTION AND COMFORT

Create a positive sensory experience:
- Visual
- Tactile
- Auditory

INSIGHT: medical environments have strong sensory triggers that create fear. If you can replace with positive ones, you can reduce fear.

Create comfort through physical closeness:
- Parental Involvement
- Blanket - like products to give child a sense of comfort and physical security

INSIGHT: children respond well to physical closeness and benefit from having a sense of security and control.

INDIVIDUALITY

Creating a unique experience for each child
- Special products or processes to make child feel cared for
- Awareness for individual needs and fears

INSIGHT: children respond positively to hearing they are receiving 'special treatment' or a special product.

Using Products to suggest lowered pain
- Special products or processes that suggest and encourage lower physical pain
- Not lying to child, but using product to promote pain reduction

INSIGHT: children are very afraid of how painful the needle will be and will always ask 'how much will this hurt'.

TRANSPARENCY

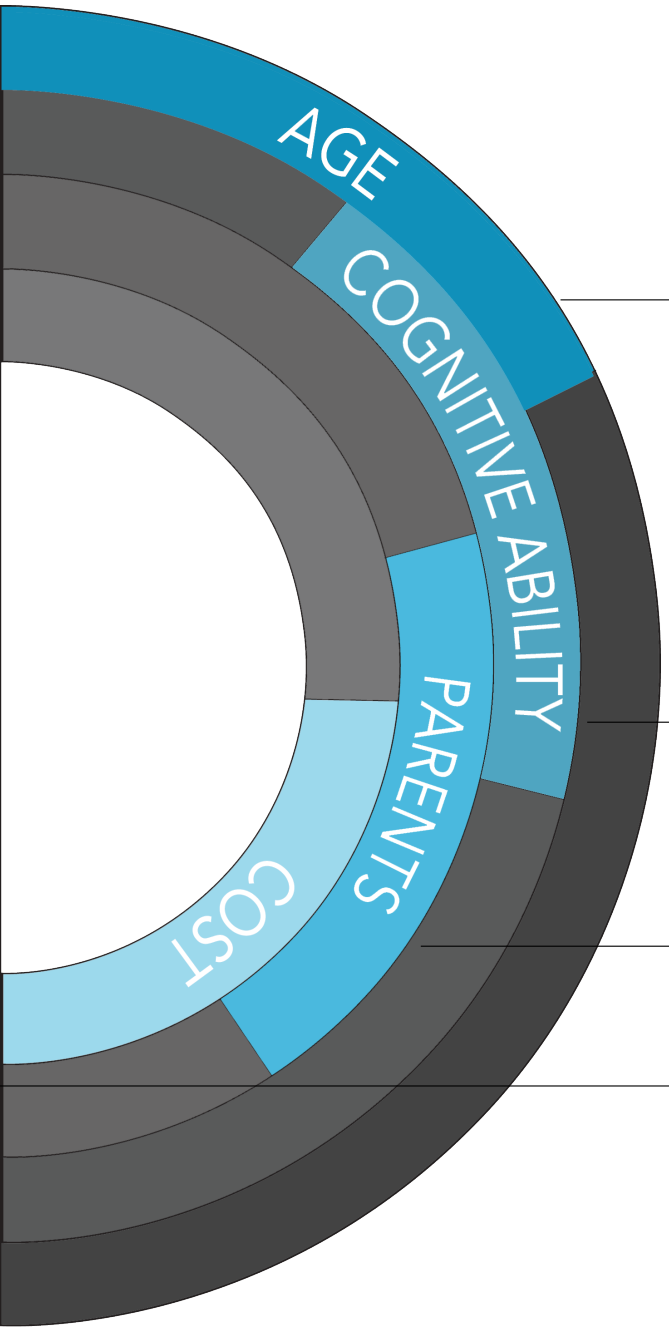
Creating total awareness for what is happening
- Being completely open and honest with what is happening
- Talking about possible pain, procedure and timing

INSIGHT: children become afraid of the unknown and experience more pain in unknown environments.

Communicating importance and benefits
- Highlighting the long term importance
- Positive perception by parents can reduce fear and resistance

INSIGHT: in developing countries injections are worthy of pain because of perceived efficacy. If this efficacy can be seen in the US, maybe there would be less fear and perceived pain.

DESIGN CONSTRAINTS UNITED STATES



AGE: age is a huge dependant for determining what type of intervention or distraction could be effective. Older children will be harder to distract and will be more questioning of the interventions. Further, age has been consistently shown to co-vary with needle pain and fear where ratings decrease with an increase in age. So choosing the most 'at-risk' user group is important.

COGNITIVE ABILITY: an individual's cognitive ability influences how he/she perceives, understands, remembers and reports pain and distress. Therefore, it is important to consider this in design solutions where any design correctly correlates to a user group's cognitive ability.

PARENTS: parents will be an important facilitator in using and/or accepting a new product. While the child is the direct user, the parent will be the consumer and will ultimately decide whether or not to buy the product.

COST: cost will be an important factor as anything too expensive will be harder to adopt by both the parent and healthcare provider. It will be important to determine if the parent or the healthcare provider/facility will be the consumer for the product and if the promise of reducing needle fear is a worthy investment.

TARGET USER: **Adults in Developing Countries**

DESIGN OPPORTUNITY: Self - destruction and transparency around use status.

Changing behavior and cultural beliefs around efficacy and economic incentives related to injections is going to be difficult. Instead of changing mentality and beliefs, change the process to make it safer. If you can make the needle and syringe part of the solution, you can force the provider not reuse needles.

SELF - DESTRUCTION

Creating a needle and syringe that self destructs after single use:

- Makes reuse impossible by breaking the needle and syringe after use
- Prevents needle reuse and disease transmission
- Keep cost low and equal to reusable syringes in order for product to be adopted

INSIGHT: needle reuse is a result of convenience and cost factors. If the syringe is unusable after use, you force behavior to dispose used needles because reuse is not possible.

TRANSPARENCY AROUND USE STATUS

Creating a needle that clearly shows use status:

- Needle changes color after use
- Use status is obvious to patient and doctor and is irreversible
- If you make use transparent where the needle clearly looks used after use, issues around needle repackaging can be reduced.

INSIGHT: black markets exist that repackage needles and syringes to make them look new. It is not easy to tell with a naked eye if a syringe is fully sanitized so this creates risk for inadvertent and unknown reuse.

FORCING USER BEHAVIOR CHANGES

Cannot easily change cultural beliefs around efficacy:

- Instead of trying to change beliefs around injections, make the process safer through changing products
- If a product forces a change in user behavior, then at least you can reduce the risk of one main concern: disease transmission and needle reuse

INSIGHT: the issue of needle and injection popularity is the result of cultural beliefs, economic incentives and historical ideas of efficacy, so trying to change this mentality will likely not happen through a singular approach.

DESIGN CONSTRAINTS DEVELOPING COUNTRIES

CULTURE: culture is a huge consideration for design. The meaning for needle and injection overuse is extremely different in developing countries than in the US. Further, perhaps each individual country needs to be considered on its own, not as a lump of all developing countries under the same design intention. The high rates of needle use in developing countries is a result of cultural perceptions of efficacy, pain and patient-doctor relationships so changing these perceptions may be challenging. Instead, an intervention or new product may be more effective at fixing *one* part of the problem.

COST: financial expenditure on healthcare, training and education programs is already extremely limited so design needs to be extremely cost effective and possibly integrated into existing structures, programs or aid groups.

HISTORY: given injections are historically believed to be a cure-all for diseases, it will be difficult to change this mentality and cultural belief and needs to be an important consideration.

EDUCATION: educational programs try to teach the dangers of needle misuse, reuse and overuse however, given the issue is rooted in cultural, socioeconomic and historical factors, imposing US ways of thinking are not always accepted positively. Instead, there needs to be considerations for every aspect of the problem. Therefore, any approach to education needs to be realistic and culturally salient and most importantly, empathetic to existing cultural ideologies.

UNITED STATES

Needle fear in the United States is **psychological** where there is anticipatory fear of pain and therefore procedural fear and emotional distress.

Children have **9x** more fear than adults

The United States has lower **pain tolerance** and greater **expression of pain** compared to developing countries.

Because there are fewer cultural beliefs around efficacy of injections, there is a lower preference and greater fear.

DEVELOPING COUNTRIES

Fear around procedure is attributed to the fact 40% of injections are given with unsterilized, reused needles. Therefore, fear is due to concern for disease transmission. But awareness around risk is low and not communicated.

Pain is viewed more **positively** in developing countries and is associated with higher efficacy.

Needle overuse in developing countries is a result of **cultural beliefs around efficacy**, socioeconomic incentives and doctor-patient relationships.

Strong associations with efficacy make injections more desireable and worthy of pain.

THANK YOU.

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