BIOENG 2150

TEAM OOWIE KAWZOWIE

TEAM MEMBERS

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CLINICAL MENTOR

DR. TRENT EMERICK, MD, MBA

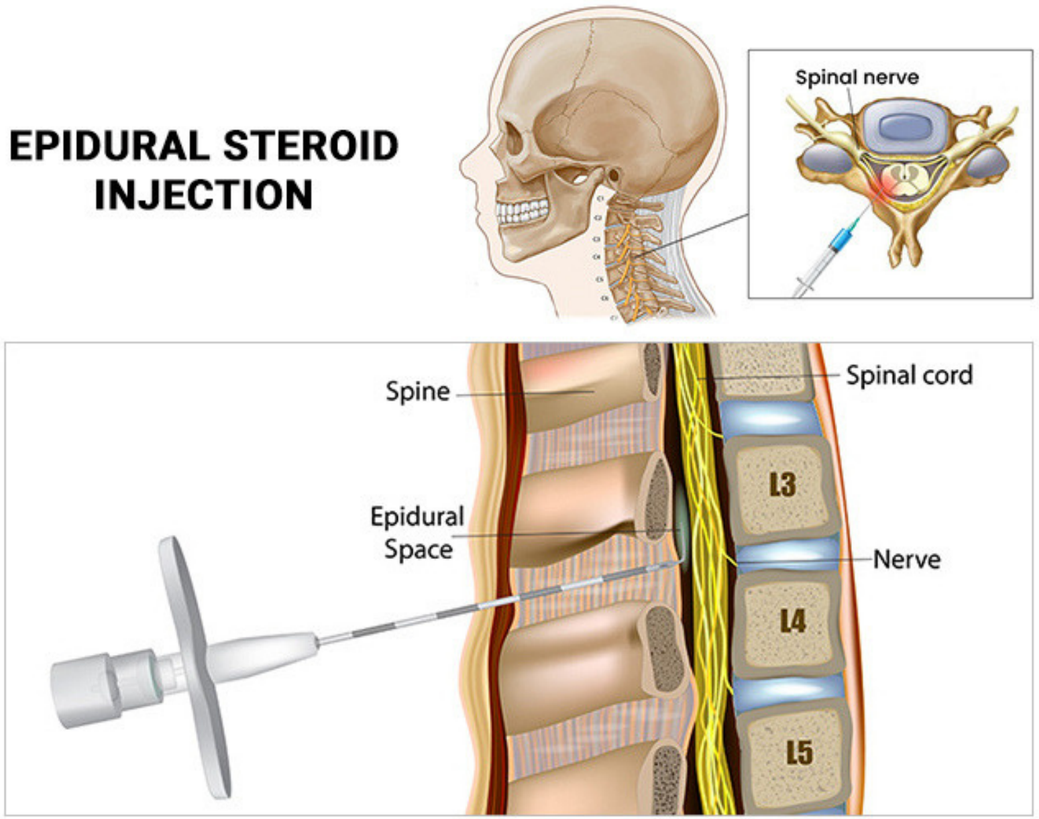
- Anesthesiologist, pain medicine, and addiction specialist
- Associate Professor of Anesthesiology and Perioperative Medicine and Bioengineering
- Fellowship Director, Chronic Pain Medicine
- Associate Chief, Chronic Pain Medicine
- Certified Six Sigma Black Belt (ASQ)
- Director of Quality Improvement and Innovation, Division of Pain Medicine

BACKGROUND

- **Lower back pain** is a very common pain resulting from an injury to the muscles or tendons in the back [1]
- 80% of people have lower back pain at some point in their lives [7]
- Risk factors: age, weight, overall health, disease, etc [1]
- Pain ranges from mild to severe [1]
- Treatment: rest, pain relievers, and physical therapy, cortisone injections or surgical procedures [1]

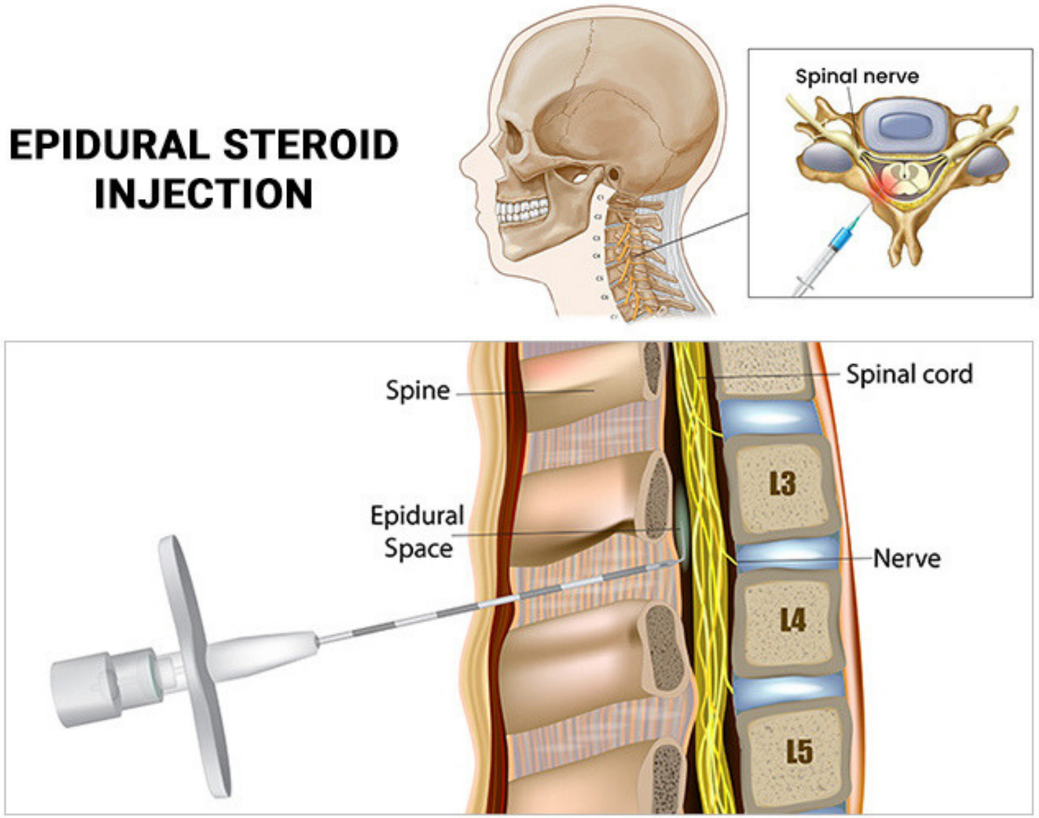
BACKGROUND

- **Lumbar epidural injections** are used to treat lumbar radicular pain, axial low back pain, and neurogenic claudication [8]
- Performed by anesthesiologists, radiologist, neurologists, and surgeons [8]
- 45.2% of all interventional techniques used for managing spinal pain [9]



BACKGROUND

- Annually, an estimate of **10.5 million** epidural injections are administered in the United States [10]
- **Risk of infection** from the epidural needle insertion, such as epidural abscess, or meningitis [10]



Initial Meeting & Ethnographic Study (part 1)

Initial Meeting

- Met with Dr. Emerick to understand unmet needs
- Learned about different machines/tools

Process

Groups of 2 → 2 separate ethnographic studies → Observe & Identify problems

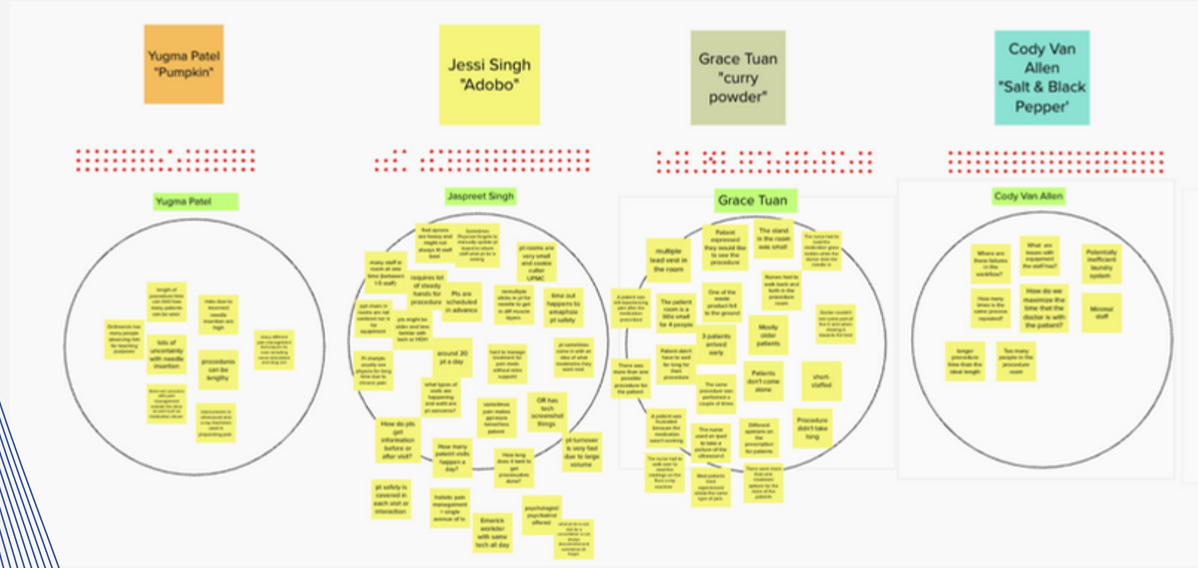
Initial Meeting & Ethnographic study (part 2)

Ethnographic study/Shadowing:

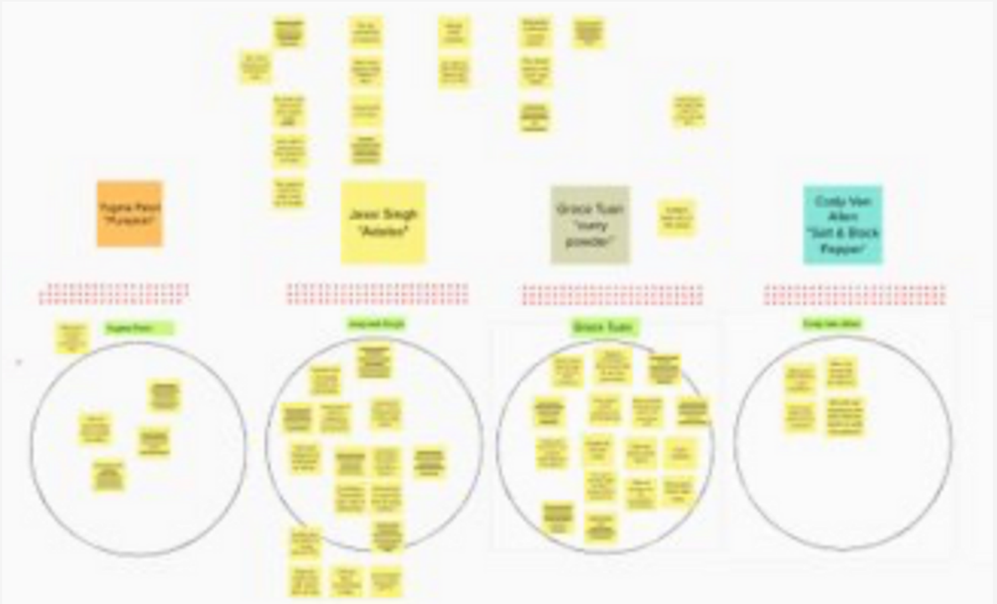
- Observed a few different procedures
  - Most common being the lumbar epidural injection
- Observed without bias
- Find the potential problem we want to solve

AFFINITIZATION

STEP 1: Silent Brainstorming



STEP 2: Eliminating Overlaps



AFFINITIZATION

STEP 3: Multi-picking Method with red dots

STEP 4: Similarity Grouping

AFFINITIZATION DIAGRAM

STEP 5: Create headings for similar groupings

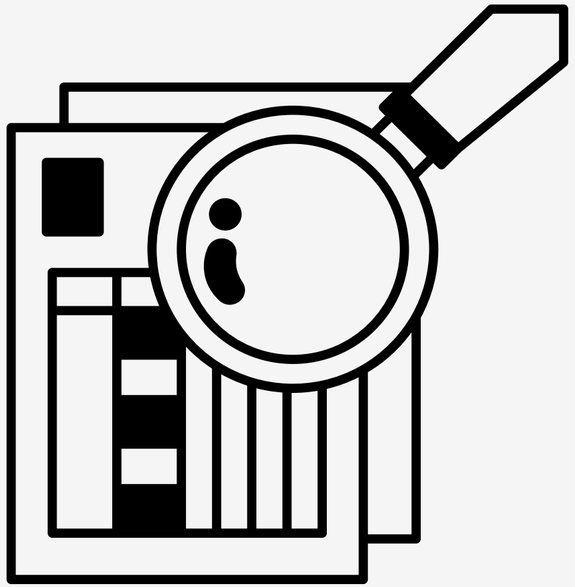
CUSTOMER IMAGE DIAGRAM

1. Doctor Patient Relationship		2. Treatment Approaches		3. Clinic Inefficiencies			4. Procedural Inefficiencies		5. Patient commonalities	
1.1 Understanding individualized patient needs	1.2 Patient Expectations	2.1 Multi-faceted pain management approach	2.2 Holistic pain management	3.1 Limited Staff	3.2 Inefficient organization and documentation	3.3 Patient rooms become crowded	4.1 Ambiguity in needle insertion	4.2 Long procedure/visit times	5.1 Types of patient cases seen	5.2 Patient Scheduling
1.1.1 Patients might be older and less familiar with more modern technology	1.2.1 Patients expressed interest in seeing procedure	2.1.1 Different pain management techniques used	2.2.1 Contact with psychologist or psychiatrist is offered	3.1.1 Patient chairs and BP equipment in room are not sanitized in between patients	3.2.1 Nurse uses iPad to take picture of ultrasound	3.3.1 Too many people in the procedure room	4.1.1 Physician has uncertainty of accuracy when inserting needle	4.2.1 Length of procedure time can limit how many patients can be seen	5.1.1 Patients still experience pain after initial prescribed treatment	5.2.1 Sees 20 patients a day
1.1. 2 Patients often do not come alone, whether it be due to emotional support reasons or for transportation	1.2.2 Patients may come in with an idea of what treatment they want next	2.1.2 Concerned about pain management treatments outside the clinic such as medication abuse		3.1.2 Technician must screen shot things in procedure room	3.2.2 Doctor may forget to update patient board to inform other staff and stay on the same page	3.3.2 Many staff and at one time (1-5 staff)	4.1.2 Ultrasound and X-ray machines meant to guide insertion have limited accuracy	4.2.2 Patient charts can be long since patients may be long term due to chronic pain	5.1.2 Many patients have similar pain cases	5.2.2 Patients are only seen by advanced scheduled appointments
	1.2.3 There may be more than one feasible treatment plan for each patient			3.1.3 Short staffed	3.2.3 Nurse must walk across room to read output of fluoro x-ray machine		4.1.3 Physician must rely on their own steady hands			5.2.3 Patient turnover is fast
					3.2.4 Consultation not always documented so Doctor may forget what to do next		4.1.4 May need multiple needle sticks in patient to get successful insertion			

KEY TAKEAWAYS

- Limited space in the procedure room
  - Those who are in the room usually include: an attending physician, residents and/or fellows that are learning, a nurse, a medical assistant, and the patient
- Require very steady hands for procedures
  - Especially careful with needle insertion during injection as well as when drawing medication
- Staff limitations at times can cause procedural shortcomings
  - Sterility maintenance
  - Prolonged procedure preparation time

WHAT DID WE OBSERVE?



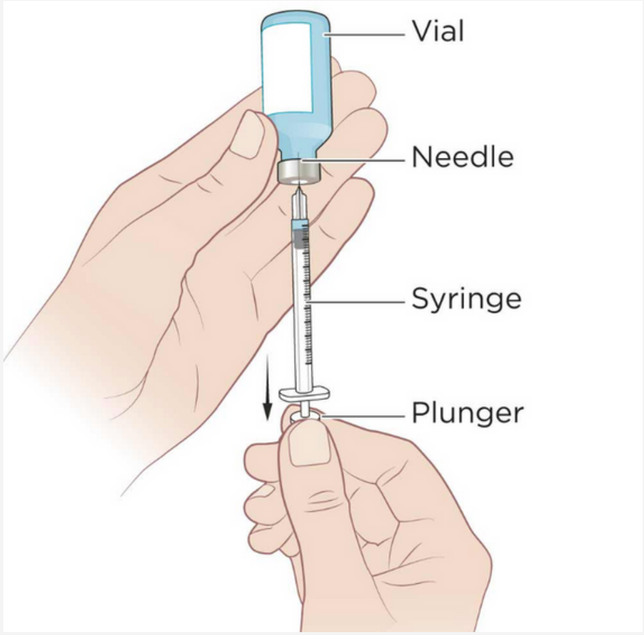
CURRENT PROCESS

Medical Asisstant

Physician

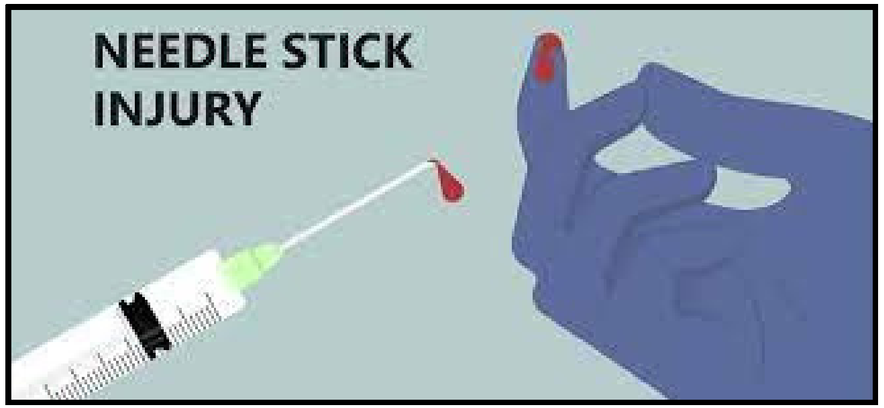
FINDING CLINICAL NEED

- During lumbar epidural steroid injection, the physician needs assistance from a medical assistant when drawing medications to maintain sterility.
- When understaffed, this procedure is prolonged.
- If withdrawn incorrectly or sterility isn’t maintain, it puts patient at risk for deadly infection.
- It puts the medical assistant at risk for needle stick.

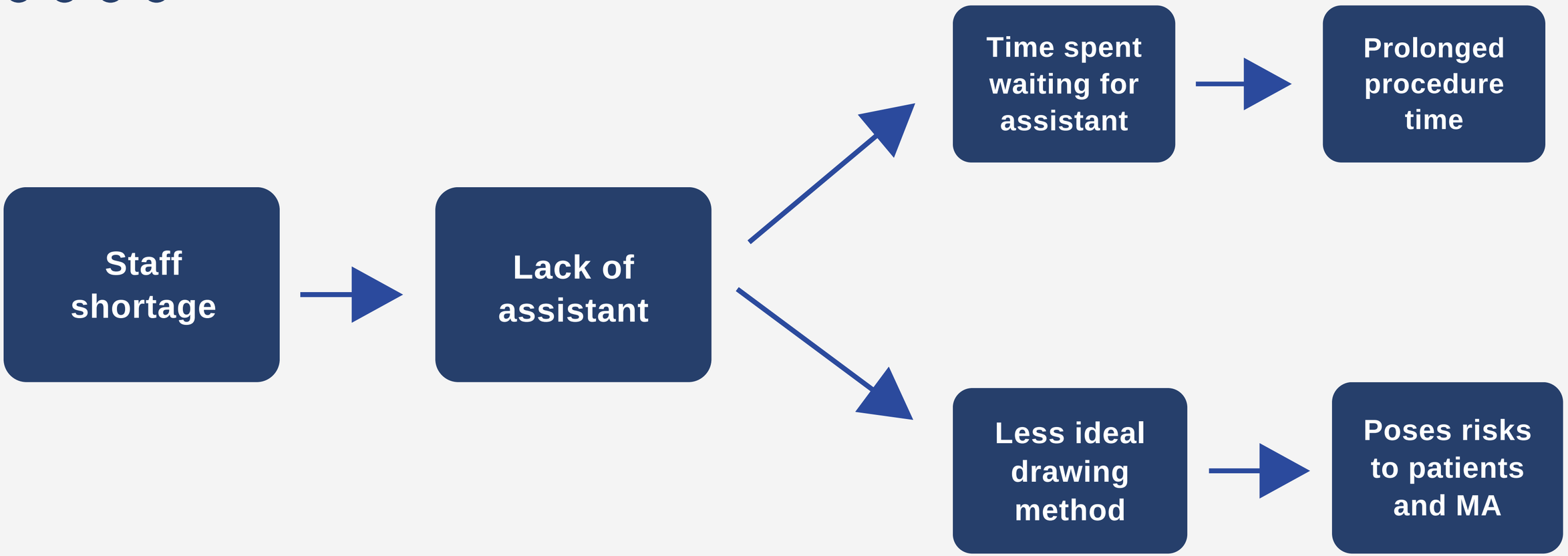


NEEDLESTICK INJURIES

- An estimated of 600,000 to 800,000 needlestick injuries occur annually [6]
- Needlestick injuries are the second most commonly reported incident within the National Health Service (17%) and many of them go unreported[12]
  - Risk of acquiring, HBV (3%), HCV(30%), HIV (0.3%), and 60 more bloodborne pathogens [12]
  - Average of treatment is around $4,352 per case (as of Sep 2022) [13]
  - If infected by bloodborne pathogens, it can cost US$1 million or more in expenditures for testing, follow up tests, lost time and disability payments [13]
- Emotion toll - Stress and fear while waiting for the result



PROBLEM IDENTIFICATION :



PROBLEM STATEMENT

In clinical settings, injection procedures that involve drawing medication from a glass vial often require assistance from another healthcare provider, putting them at risk of needle stick in order to maintain a sterile environment; Staff shortages can hinder the workflow, which leads to prolonged procedure preparation times.

NEEDS STATEMENT

During injection procedures, staff shortages lead to the lack of immediate assistance from medical assistants, which leads to prolonged procedure times. Hence, a method that can provide assistance in holding medication vials while maintaining a sterile environment is needed for the safety of the patients and healthcare professionals.

MORPH CHART

Features/functions									
Accommodate multiple medication vials	multiple holder frames				Sterility				
Minimize residual liquid waste	tilting holder frame	upside down	automatic detection of mL left		independently used				
maintain sterility	shield or guard to protect vial	UV light source shines on septum.	removeable cap over septum		maintain enviornmental safety				
Ensure no accidental "sticks"	clear visibility	labeled medications			modular	Angle adjustment for holder is possible		can be placed at different heights	
Adjustable height	Portable, light weight	wall mount			ease of access				
Keep room organized	labelling for vial holders	automatic record of meds loaded, unloaded	receptacle for disposal of waste/sharps		organization		will not add to clutter		
Angle of retrival							next to physician, over gloves, easy to		

DESIGN CRITERIA

- Maintains sterility
- Assists the physician by making medication drawing preparation shorter and independent
- Easy to operate
- Compact
- Adjustable to ensure ease of retrieval of medication

SOLUTION IDEATION

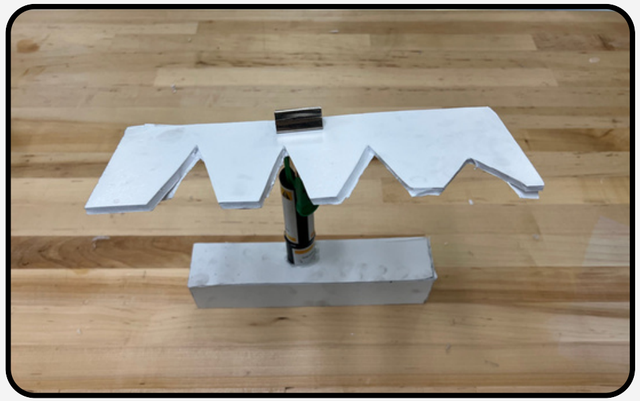
ADDRESSING AN UNMET CLINICAL NEED

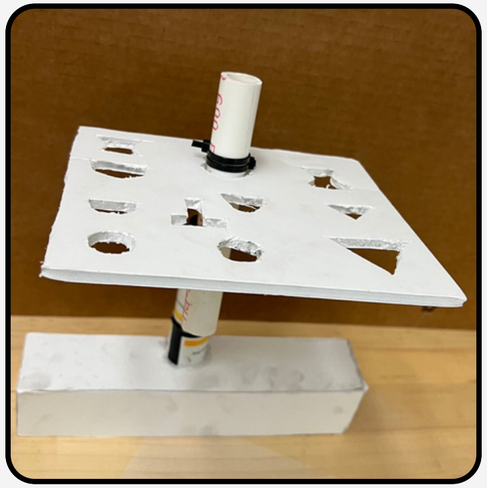
GOAL

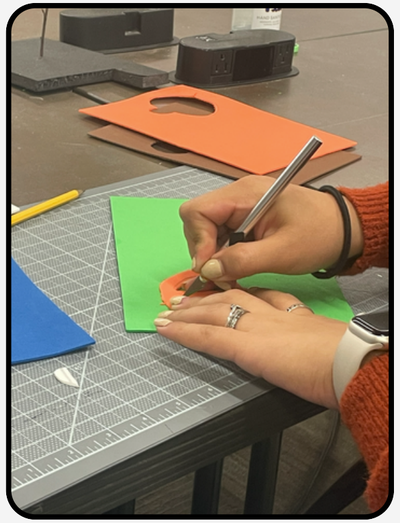
Eliminate the need for an extra set of hands in the procedure room for the sole purpose of holding the medication vial during the procedure.

PRETOTYPING

6 rounds

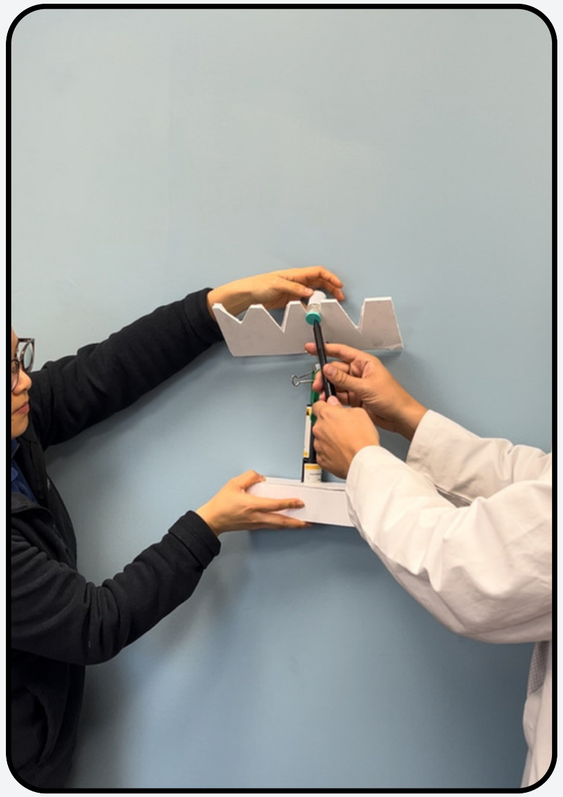


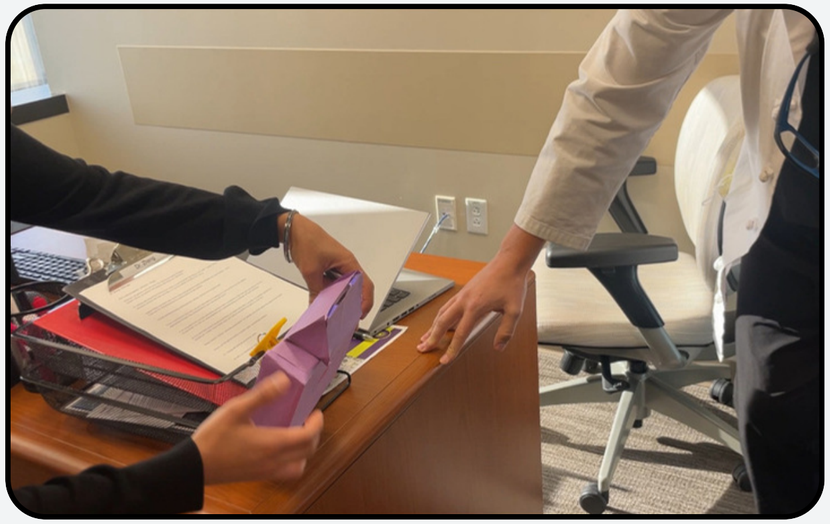




FEEDBACK

4 rounds

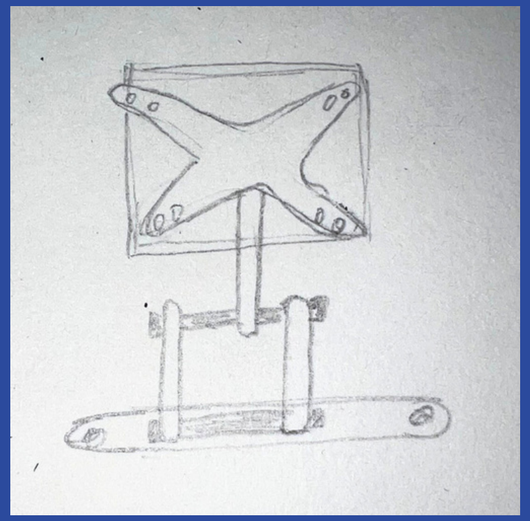


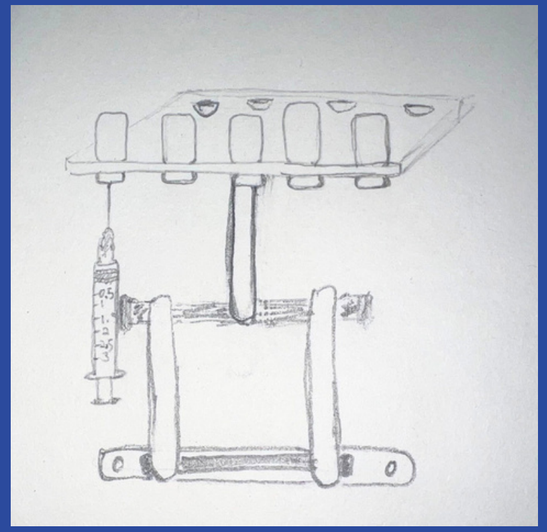


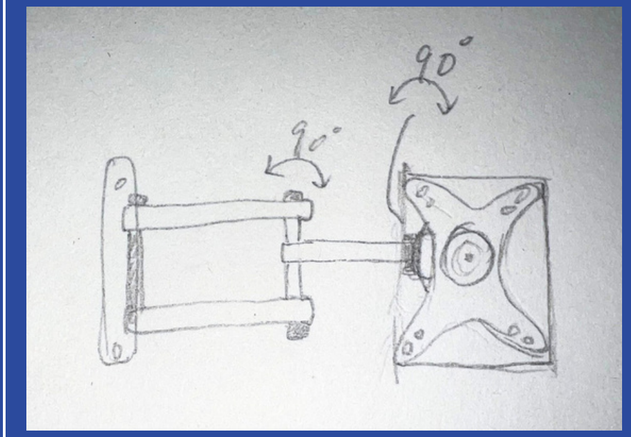
Design #1

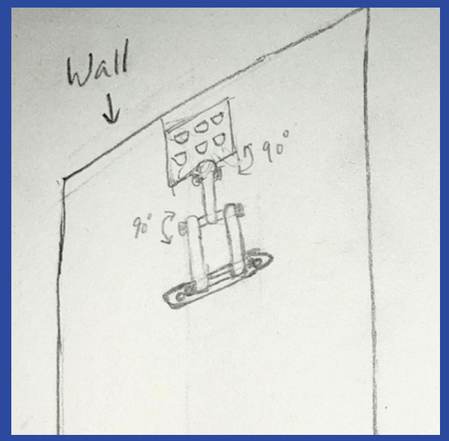
The Vial Holder

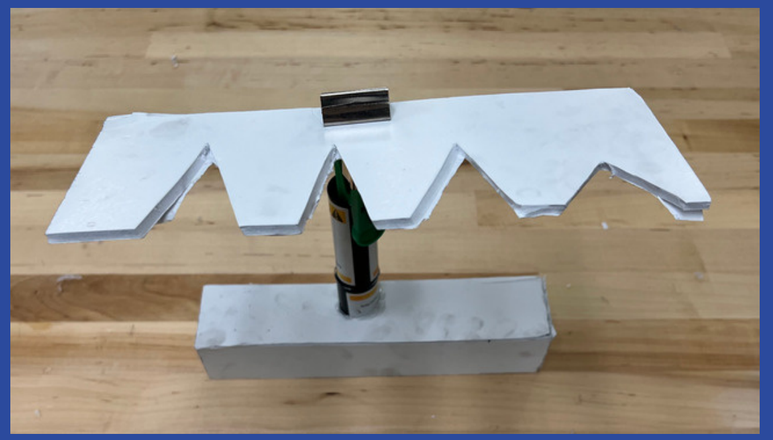
SKETCHES & PRETOTYPE

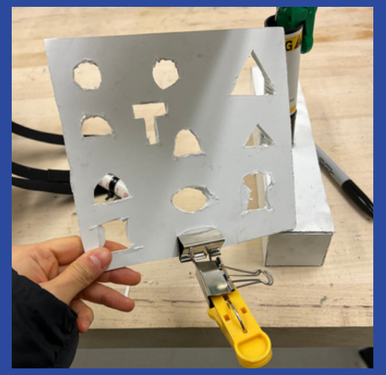


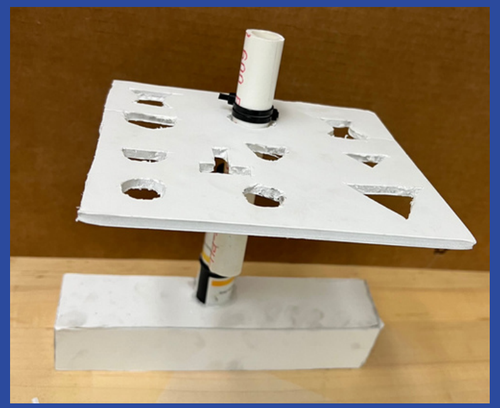


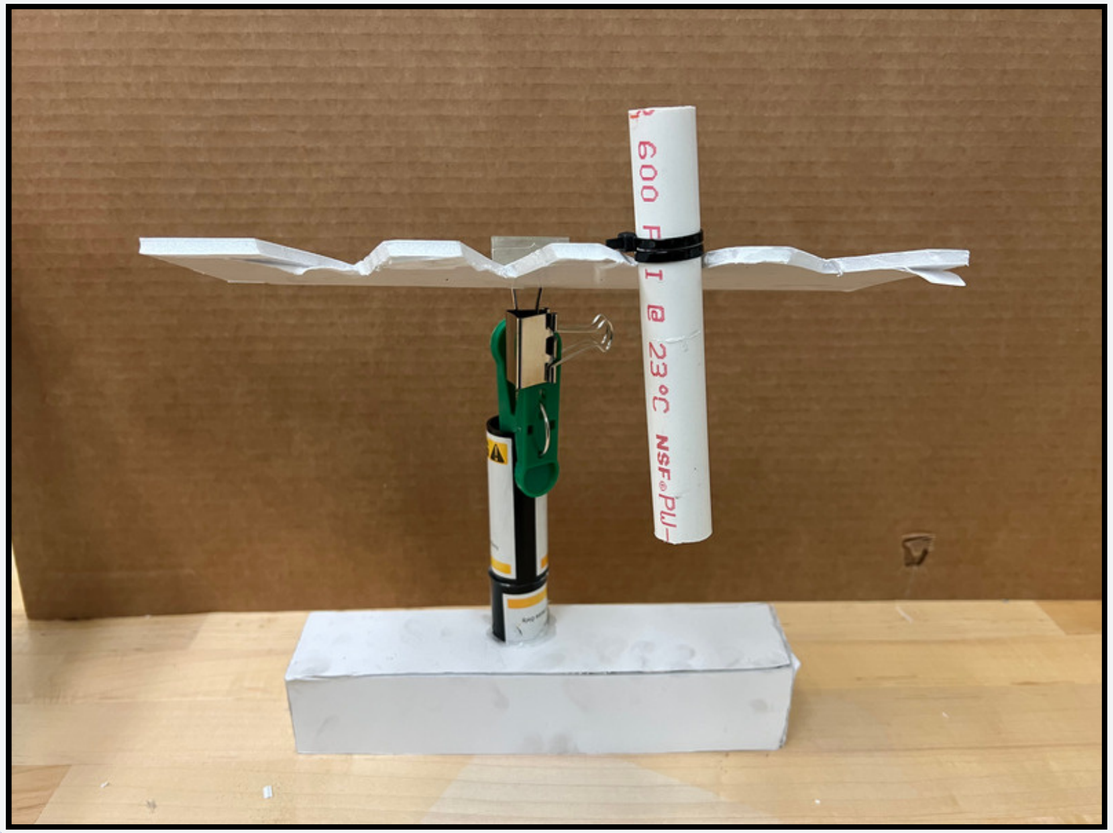




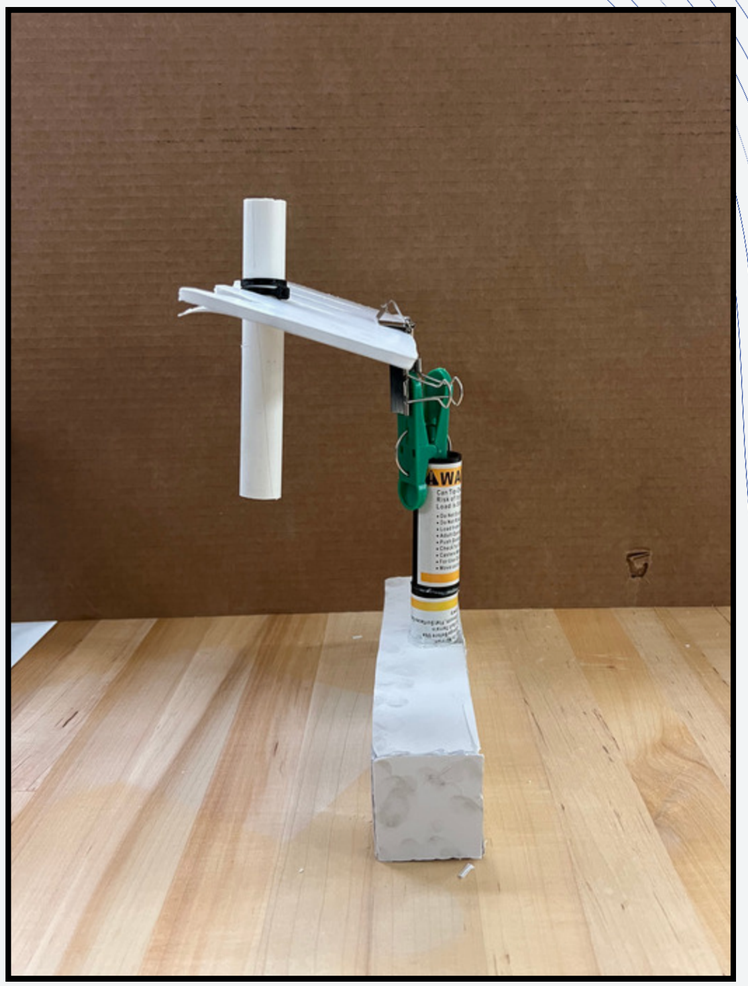








Front View

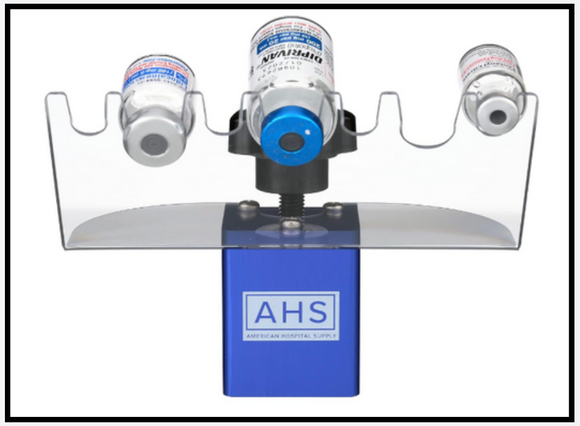


Side View

Clinical Mentor Feedback

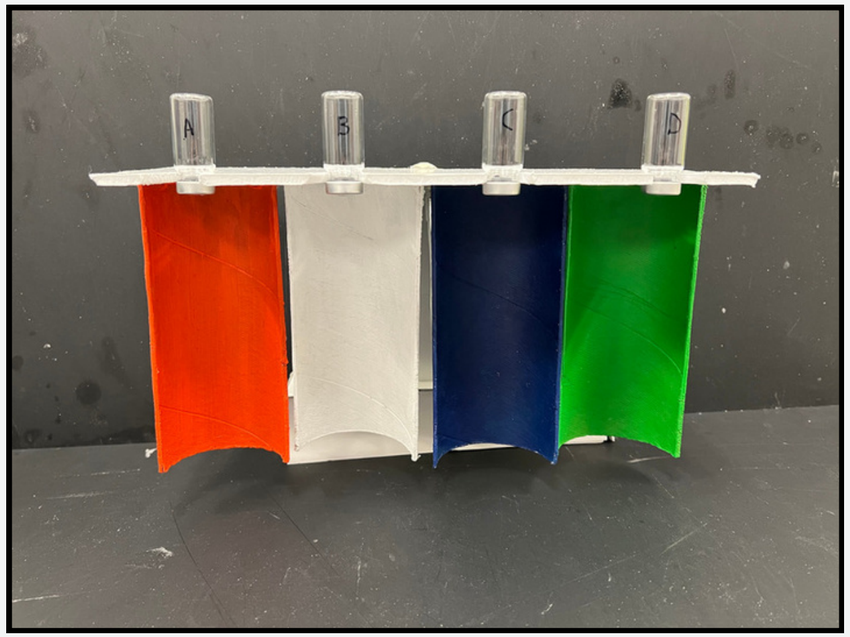
- How does it differ from the existing device?
- How does it maintain sterility
- Less experienced physicians need a safe and stable way to insert the needle into the glass vial

Existing device



Design #2

The Vial Guide

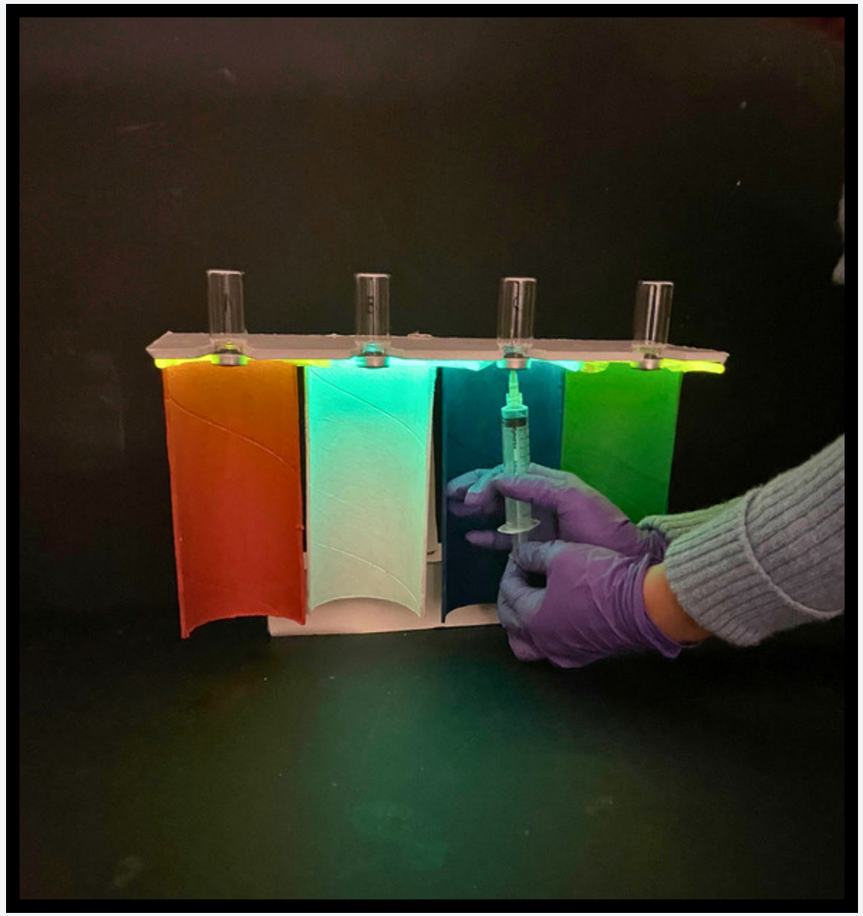


Front View

Video Demonstration

Design #2
2nd Iteration:

The Vial Guide

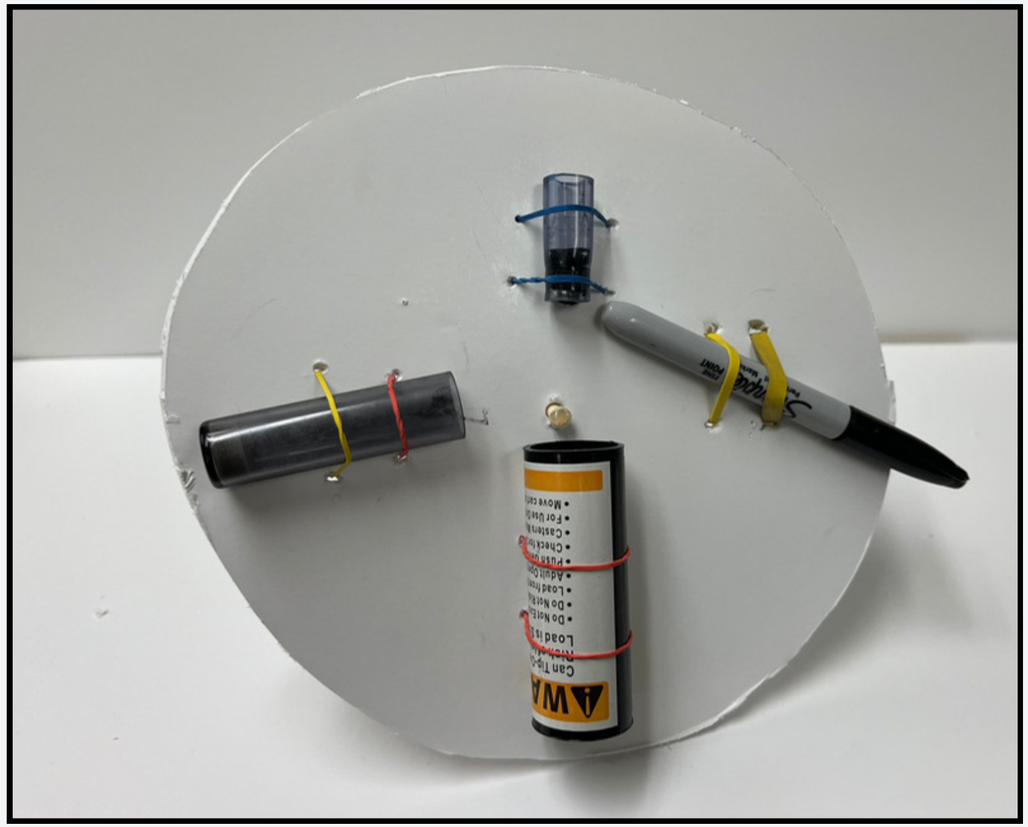


Front View

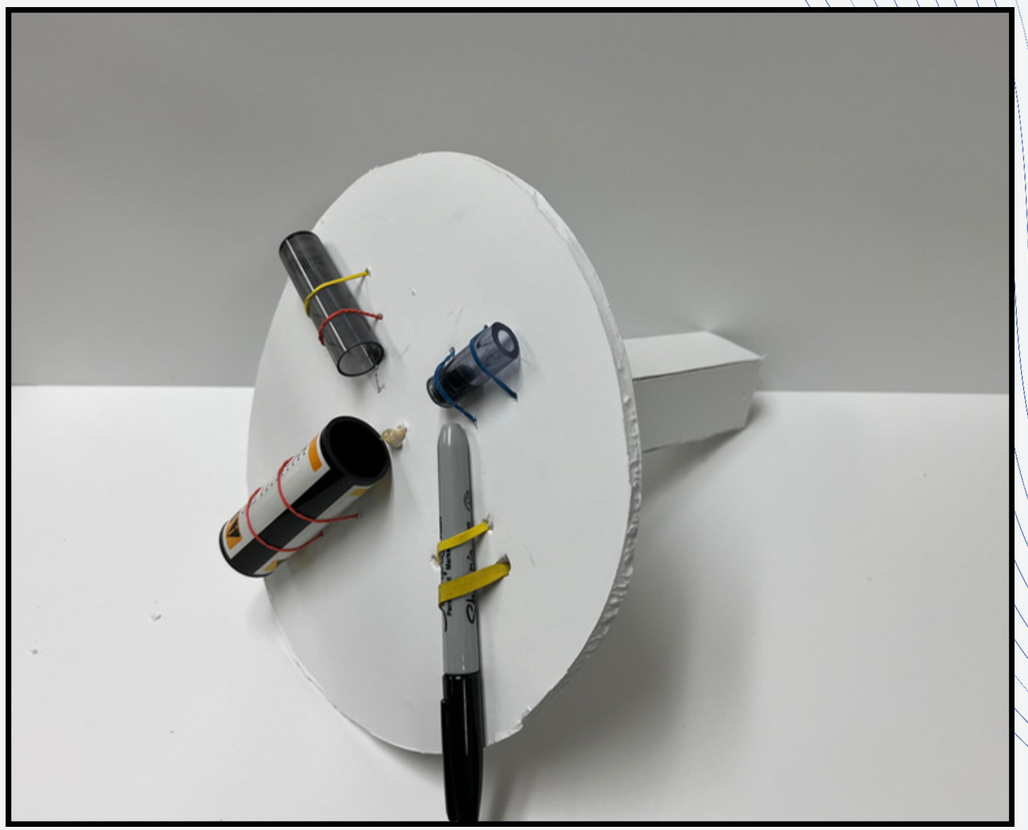
Improvement:
UV sterilization between procedures

Design #3

The Vial Spinner



Front View



Side View

FEEDBACK

- Believes it can assist the physician, the preparation process and reduce the need for hiring an extra medical assistant
- Lower risk of needle sticking
- Reduce human error due to unsteady inexperienced hand
- Has market value as it could save hospital the cost
- Could potentially save up to 25 min a day -> extra 1 or 2 patients

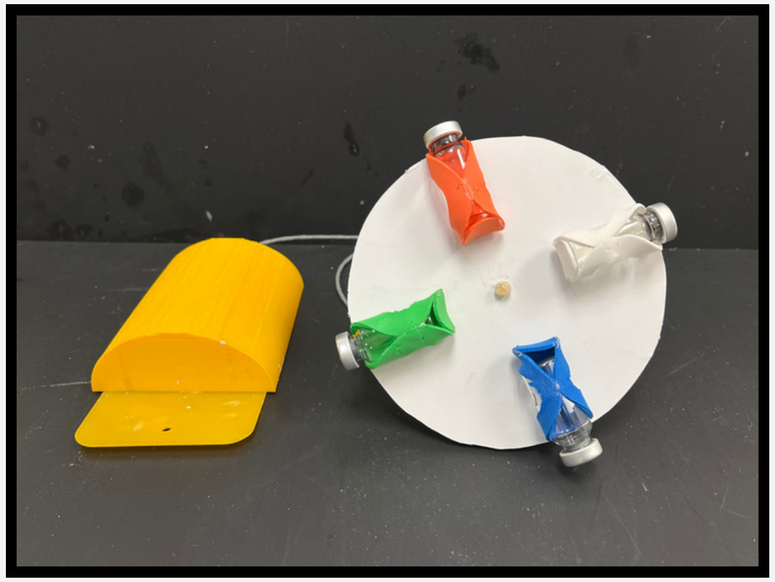
FEEDBACK

Suggestions:

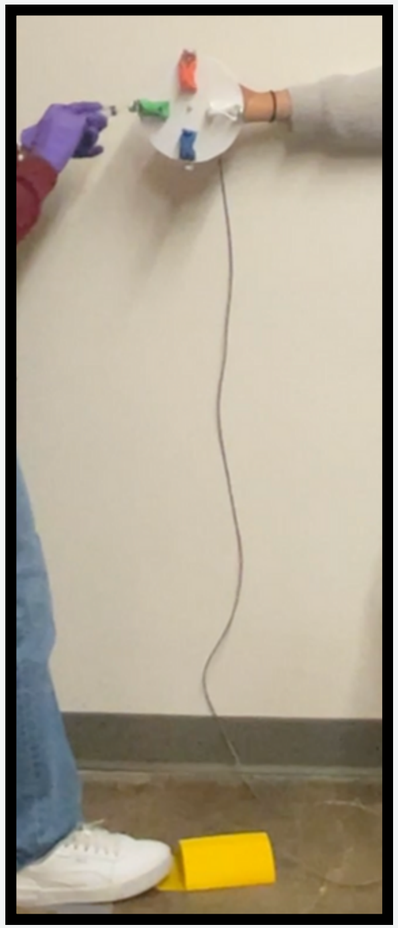
- Color code four common vials used
  - (B,G,O,W- local anesthesia, numbing, contrast, saline)
- FDA regulations regarding foot pedal
- Device is easy to clean
- Shorten mounting support
- Reduce diameter of wheel
- Labels on the vials need to be seen

Design #2
2nd Iteration:

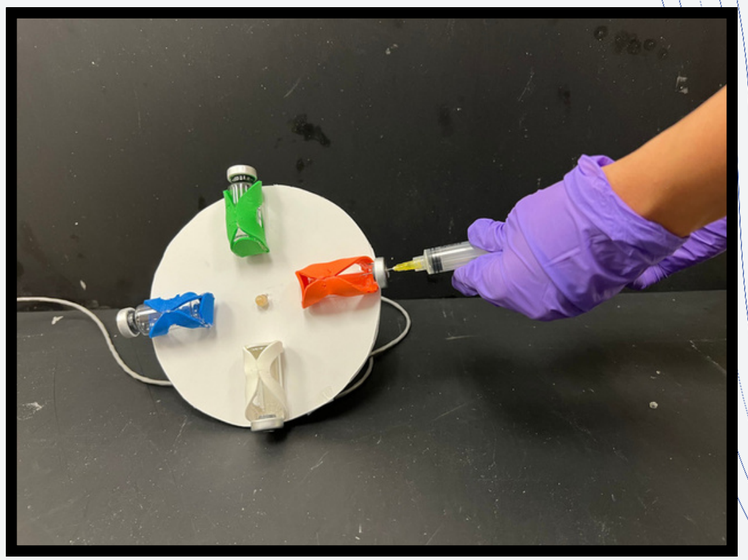
The Vial Spinner



Front View
(close-up)

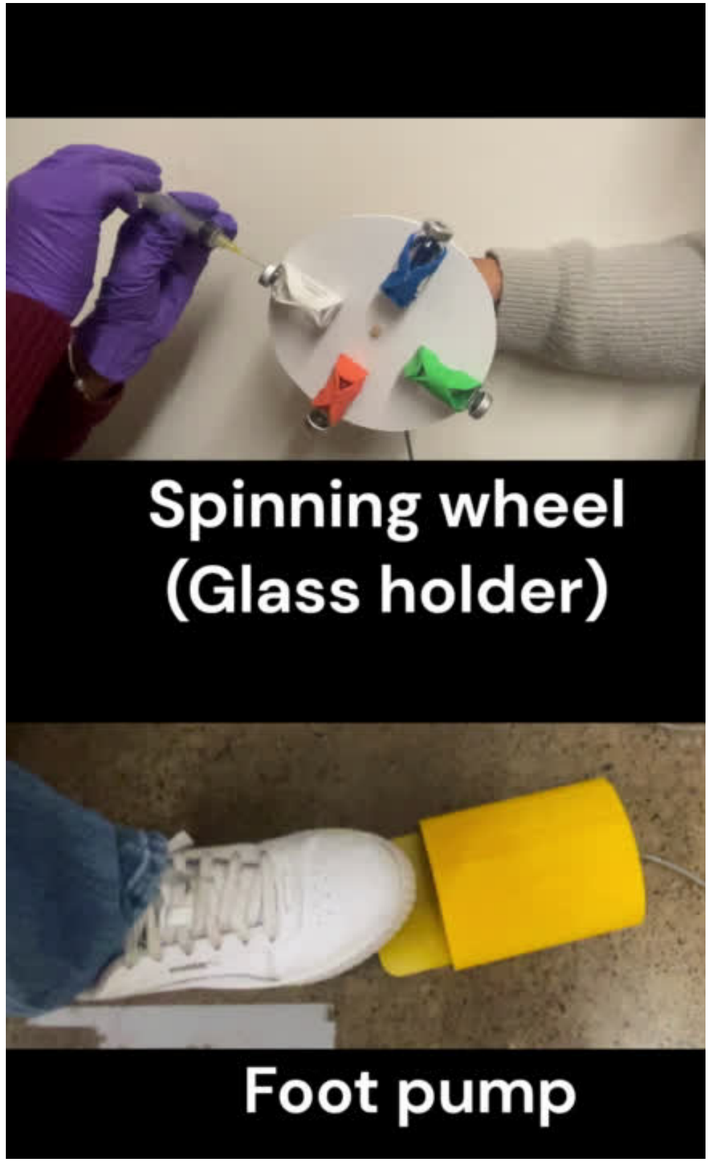


Front View



Front View
(contextual)

VIDEO DEMONSTRATION



STAKEHOLDER ANALYSIS CHART

Stakeholder	*Needs*	*Wants*
Healthcare Providers	Safe, Adds to PR/OR flow	Adjustable, Holds Many Vials
Hospital/Clinics	Modular , Medication Fits Securely	efficient, Optimization of PR/OR, < procedure length/personnel needed in procedure
Insurance	Lower cost for device	N/A
Regulatory Agencies (FDA, JCAHO)	Compliance w/ Regulations	N/A
Patient Families	Ease of Use, Safe	Low Cost, Easily Adaptable
Manufacturer	Must have manufacturability and utilize < expensive materials	Easy to adapt for future release of product
Patient	Safe, Durable	Low Cost, Shorter Procedure

KEY STAKEHOLDER ANALYSIS CHART

Stakeholder	*Needs*	*Wants*
Healthcare Providers*	Safe, Adds to PR/OR flow	Adjustable, Holds Many Vials
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IMPACT ON STAKEHOLDERS

Cost

Manufacturers

- Invest in new infrastructure

Hospitals

- Invest in device

Physicians

- Familiarize workflow with device

IMPACT ON STAKEHOLDERS

Benefits

Hospitals

- Reduced time investment per procedure
    - Opportunity for more procedures per week

Healthcare Providers

- Decreased time investment per procedure
- Decreased reliance on others

I

IMPACT ON STAKEHOLDERS

Impact

Patients and caregivers

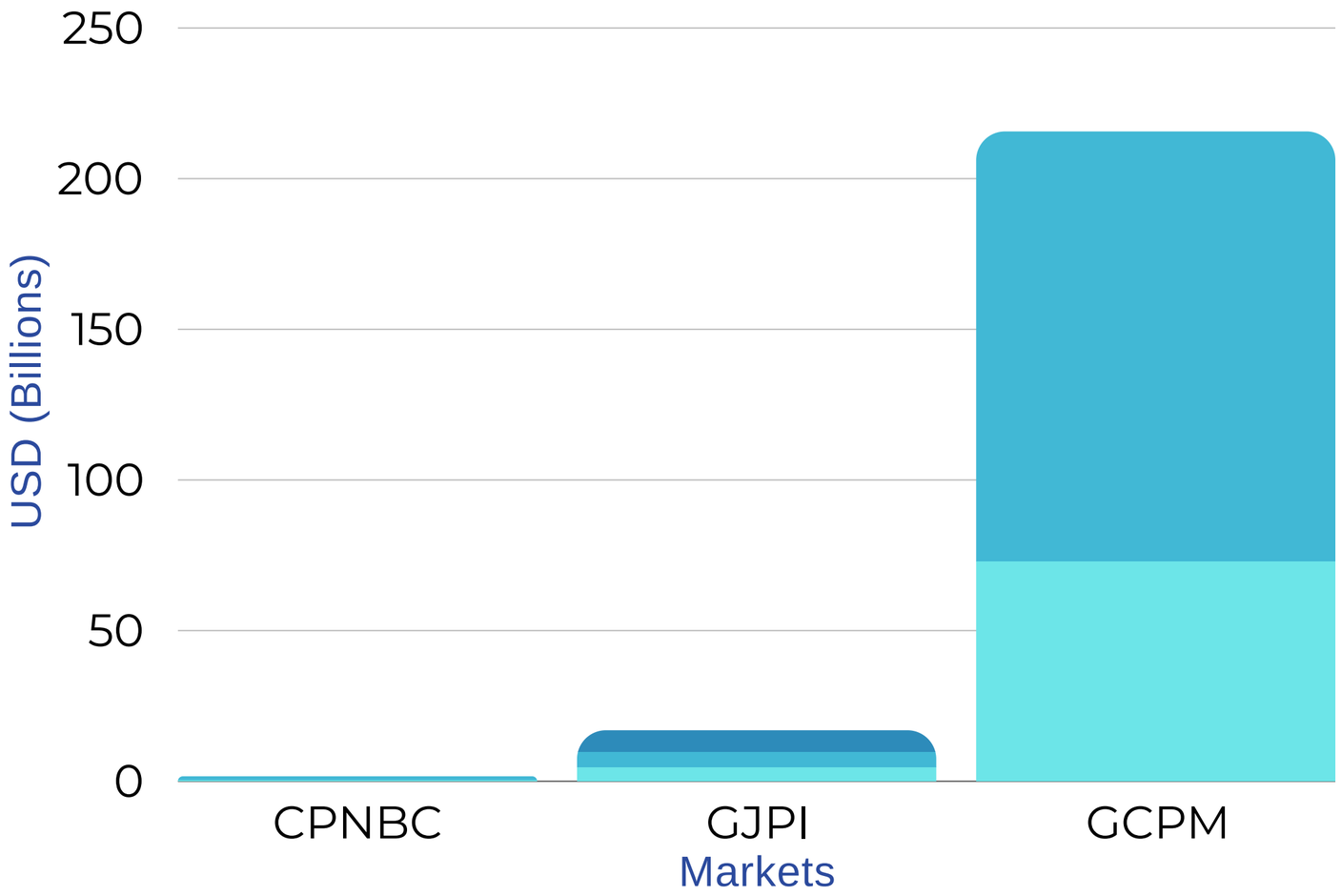
- Positively impacted by safer procedure

Physicians and hospitals

- Higher ratings of patient satisfaction
- Increased revenue stream
- Increased patient visits per day

MARKET ANALYSIS

- Continuous Peripheral Nerve Block Catheter (CPNBC)
  - Predicted CAGR of 6.1% from 2023 to 2033
- Global Joint Pain Injections (GJPI)
  - CAGR of 10% from 2022 to 2023
  - Predicted CAGR of 8.6% from 2023 to 2027
- Global Chronic Pain Market (GCPM)
  - Predicted CAGR of 6.9% from 2023 to 2033



MARKET ANALYSIS

- The average length of a Lumbar Spinal injection falls around 25 minutes
- Predicted to save a conservative average of 25 minutes per day (2 minutes per procedure with 10-15 procedures)
- Allow time for an additional patient to be seen per day
- Additional patient can on average provide between $1,000 to $1,560 extra profit per day
- Over the course of a year this would provide between $260,312 and $405,808 per clinic

Sources:

COMPETITIVE ANALYSIS

AHS vial holder

T1me vial syringe support

Insulin Vial holder

None of these fulfil the same roll that our product is attempting to fill

MEDICAL DEVICE FDA REGULATION

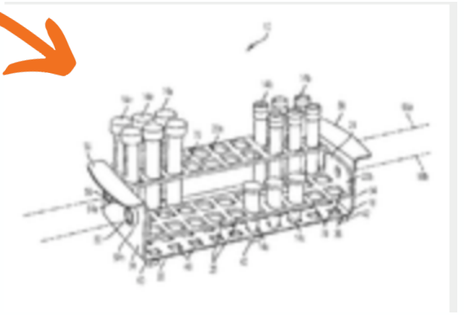
- Class I Medical Device
  - low to moderate risk to the patient and/or use
  - a premarket notification application and FDA clearance is not required before marketing the device in the U.S [8]

- FDA Center for Devices and Radiological Health (CDRH) is responsible for approving new medical device designs
  - New medical devices must be SAFE and EFFECTIVE for users
  - Human Factors testing and assessment NECESSARY
  - ASSURES COMPLIANCE with product and manufacturing requirements [9]

PATENT RESEARCH

Rotating Medical Device Holder

Adjustable Test Tube (US9776188B1)

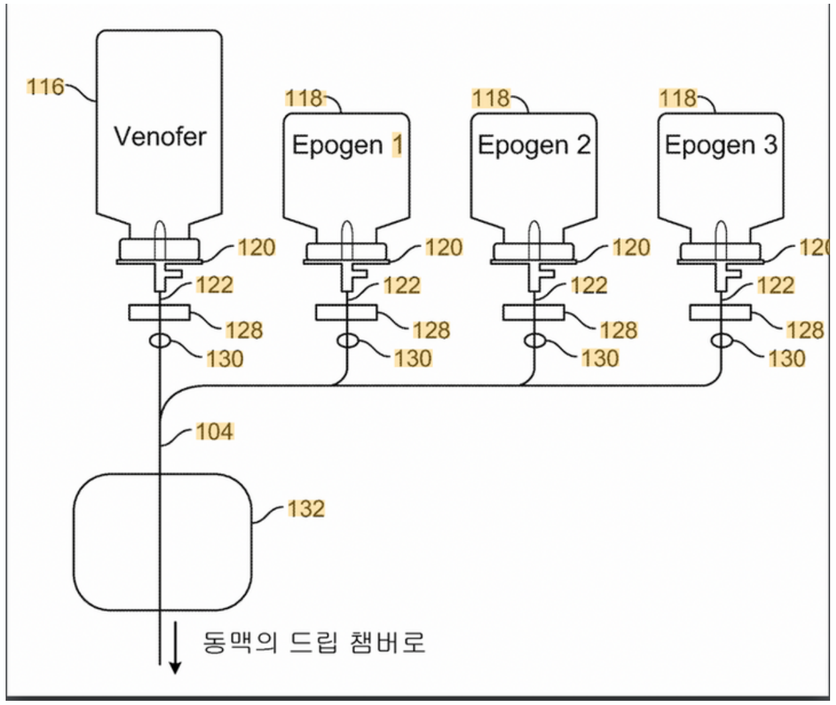


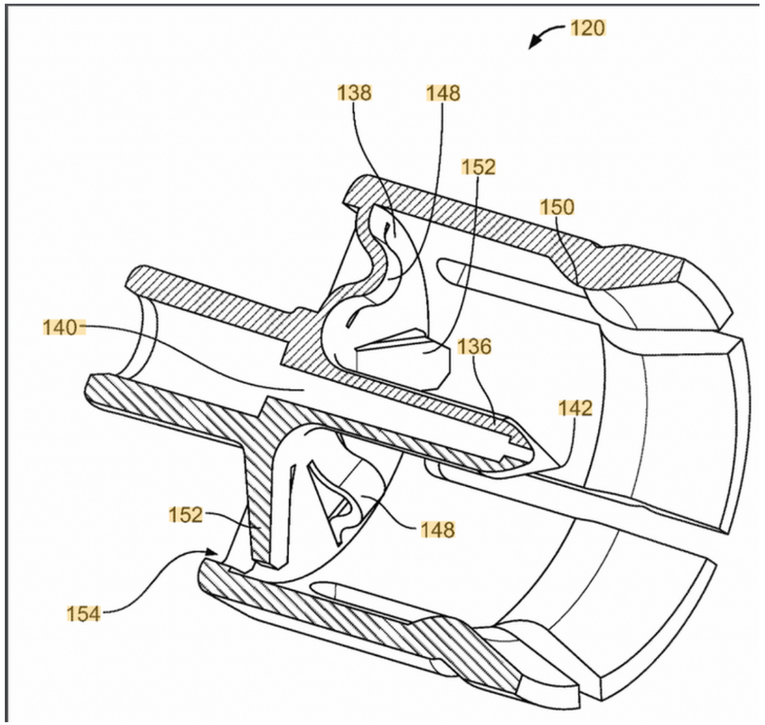
Moutable Test Tube Holder France no image (WO1993019318A1)

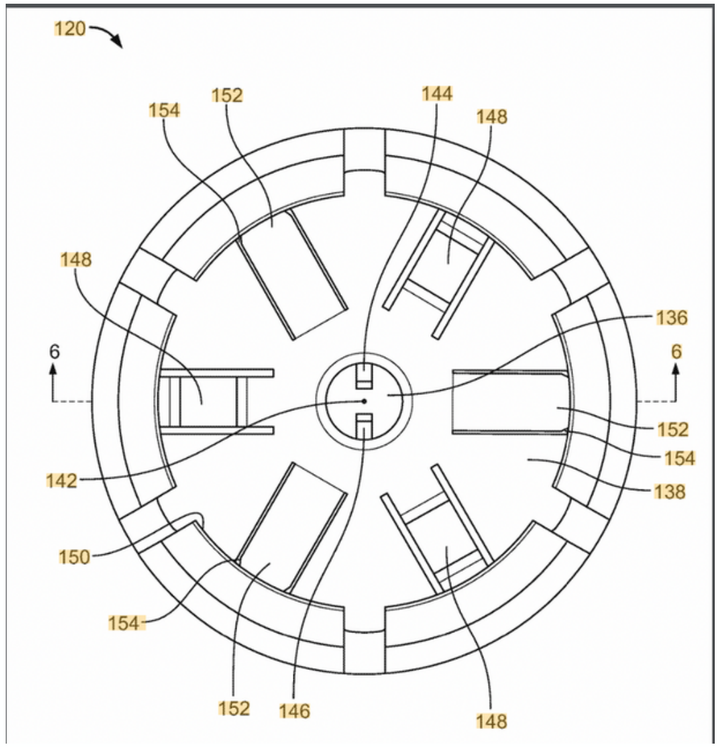
Non-FDA Regulated

Medication Holder

SOUTH KOREAN PATENT







REGULATORY PROCESSES

FDA

- Register Device
- Create Medical Device Listing
- Comply w/ FDA Labeling
- Comply with Quality System Regulation [8]

JC, FORMERLY JCAHO

While not a formal regulatory agency, many organizations may choose to receive accreditation from it. Maintains standards for sterility and cleanliness in environments of care. Foot pedals must be raised to prevent staff tripping hazards and retain cleanliness within an operating or procedure room.

OSHA

While this is not a medical device, this device would need to ensure it does not endanger employees of an organization.

INITIAL HAZARD ANALYSIS

Item	Potential Hazards	Hazard Description	Hazard Rating		
			S	F	R
1	Needle	• Needle contacts an unwanted surface and poses risk of infection to patient	III	II	III
		• Risk of needlestick to user	II	I	II
2	Device Malfunction	• Medication vial may fall and shatter resulting in sharp glass that could cut healthcare professional or patient	II	I	II
		• Wall mounting may fail and cause device to fall and injure healthcare professional or patient	II	I	I
3	Material	• Material failure resulting in device cracking or breaking	I	I	I
		• Plastic degradation due to repeated sterilization	I	II	II
4	User Error	• Clinician drops needle and injures himself/someone	II	I	I
		• Medication label may be partially hindered and clinician may misread and use wrong medication if not careful	III	I	II

DETAILED HAZARD ANALYSIS

Mitigation/Controls	Corrected Hazard Rating		
	S	F	R
• Sterilize device before each procedure	I	II	II
• Provide proper training and manual to users	I	I	I
• Ensure vial is securely fastened before procedure begins	II	I	I
• Ensure device is sturdily mounted at the start of the day	I	I	I
• Conduct mechanical testing on device to determine weight limit guidelines	I	I	I
• Conduct testing to determine acceptable term of use before replacement required	I	I	I
• Provide proper training and manual to users	I	I	I
• Ensure vial is positioned with label visible to user	II	I	I

PRODUCT DISTRIBUTION PATHWAYS

- The main pathways would consist of:
  - Direct sales to clinics or hospitals
  - Online sales
  - Contracts with large healthcare networks like UPMC or AHN

REEXAMINE GOALS

- Maintains sterility
- Provides assistant to the physician by making medication drawing preparation shorter
- Easy to operate
- Compact
- Adjustable to meet physicians’ preference

FUTURE DIRECTIONS

- Obtain feedback from more healthcare facilities on our final prototype
- Finalize vial holding mechanism
- Materials research for the entire system
- Develop a high fidelity prototype and testing an air pump to rotate the wheel
- Clinical testing

FUTURE DIRECTIONS

- Design and prototype a foldable mounting support
- Market research into height and angle adjustability of the device.

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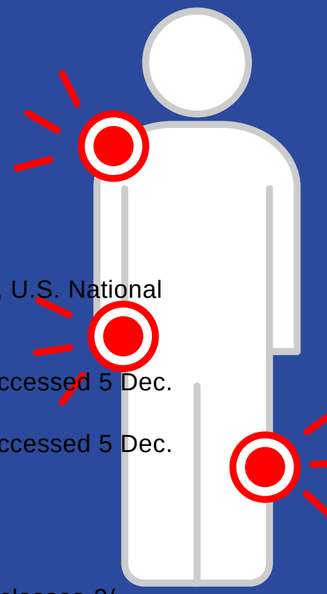

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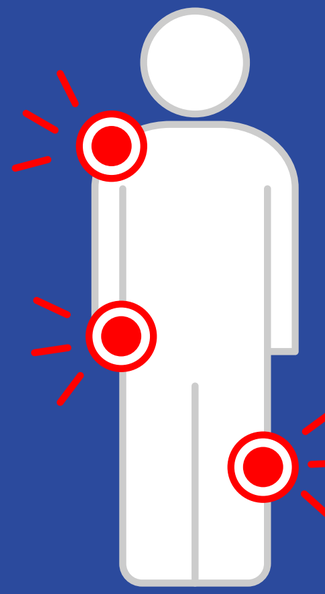

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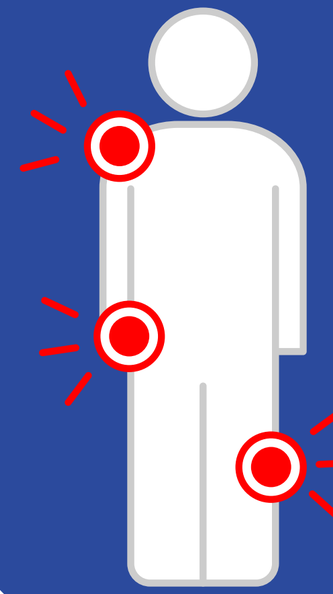

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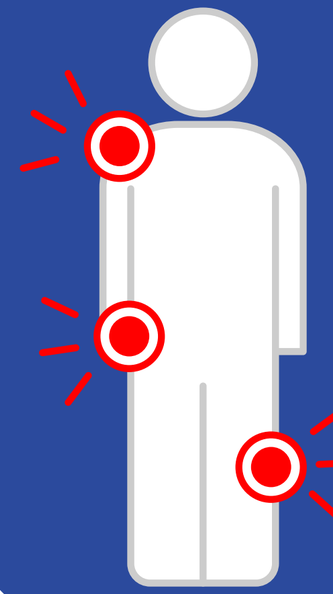
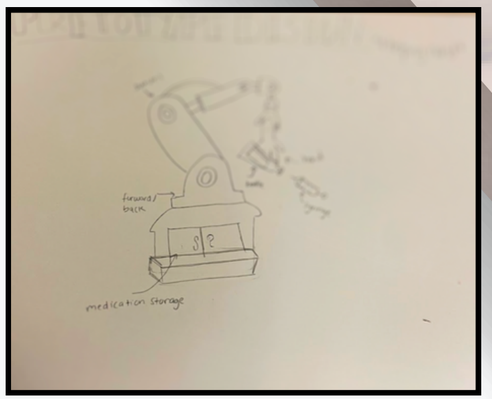
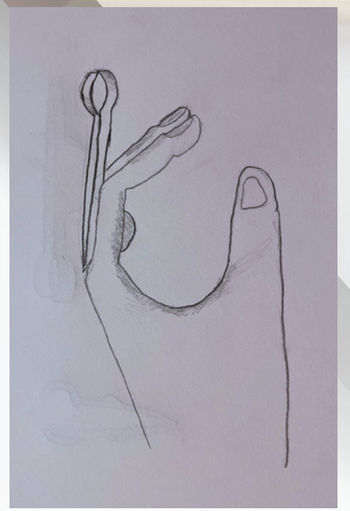


QUESTIONS?

APPENDIX 1.1

Other Design Ideas





7 Chronic Pain Management Techniques

7

EPIDURAL STEROID INJECTIONS

FACET JOINT INJECTIONS

MEDIAL BRANCH NERVE BLOCKS

RADIOFREQUENCY ABLATION*

SACROILIAC JOINT INJECTIONS

SYMPATHETIC NERVE BLOCKS

REGENERATIVE THERAPY INJECTIONS*