INNOVATION AT CMI

CLINICAL CONCEPT QUESTIONNAIRE

PLEASE LIMIT RESPONSE TO THREE (3) PAGES MAXIMUM (Arial 11-point type)

Please complete the following form to submit your concept for consideration. (* Required.)

NAME, DEPARTMENTAL AFFILIATION AND CONTACT INFORMATION:*

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BRIEF PROJECT/IDEA TITLE:*

Rotating Medication Vial Holder

DATE:*

12/05/2023

DESCRIPTION OF THE PROBLEM:

Describe the clinical problem or need and your new devices/services that may solve the problem. In what location does the problem occur (OR, ICU, ER, physician office, etc.)? If available, append a drawing, photo, or any other graphical materials that would clarify the problem for the non-physician.

Injection procedures that require the extraction of medication from a glass vial with a needle often require assistance from another healthcare provider to maintain a sterile environment; However, a lack of staffing can hinder the workflow, which leads to unnecessary wait times that lengthen procedure times. Utilizing a device that would allow the procedure to be carried out by an individual rather than using two people for one job would allow for reduced wait times in the clinic or physician's office and would save money by allowing medical assistants to use their time for more position-specific tasks.

The physician performing a procedure where risk of infection is a big concern aims to maintain a sterile environment by avoiding using gloved hands to touch the medication vials directly to withdraw the medication. Therefore, they rely on the use of another person in the room to simply hold the vial so that the medication can be extracted. When such a person is not immediately available, it can prolong procedure times waiting for someone or having to change gloves. There is also risk of compromising the sterility of the procedure if any “shortcuts” are taken for matters of ease. Involving another individual to hold the medication vial also puts them at risk of

needlestick when the physician attempts to insert the needle into the vial they are simply holding in the air with proper stabilization.

This problem occurs in the procedure room inside clinics that provide treatments involving needle injections.

Figure 1: Current approach used in clinics to withdraw medication with the assistance of another person

POTENTIAL IDEAS FOR SOLVING THE PROBLEM:

Describe your ideas for a solution, device, or invention. Have you filed an invention disclosure on this or something similar? Has your idea been disclosed to the public (e.g., via publication or presentation)?

A rotating, wall-mounted, medication vial holder should allow for the healthcare provider to be able to prepare for sterile procedures quickly and efficiently. It is currently designed to hold 4 medications which is one more than the average number of medications used during a procedure. Each vial holder is a different color to add a layer of clarity for the physician in differentiating the order in which the medications are used during the procedure. The vial holder also allows for the visibility of the labels on the vials themselves to allow for a quick confirmation of the medication that is being drawn. The rotating wheel locks into place to prevent unwanted movement when inserting the needle or when drawing the medication. A foot pump allows for control of the rotation mechanism without the use of the physician's hands to limit exposure to the sterile field. The foot pedal can be pumped to rotate the wheel clockwise until the desired orientation is achieved. The rotation is continuously clockwise so that the vial could theoretically be rotated a full 360 degrees in the plane of the wheel. The holders are all designed to orient the vials so that the top of the vial, or the point of insertion, is facing outwards on the wheel. The mechanism of the holder itself mimics that of a water bottle holder used on bikes which employs secure latching to hold the bottle snug and engages the narrower neck to stop it from falling out.

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This allows for the vial to be held securely in any position, even when it is upside down. The holders also provide a flat platform on the side facing the center of the wheel where the bottom of the vial sits. This is to provide an extra layer of support to counteract the force experienced when the needle is being inserted.

This proposed solution has not been filed, but it also has not been disclosed to the public.

HOW IS THE PROBLEM ADDRESSED CURRENTLY?:

Are there any competitors in the field addressing similar problems or needs? What approaches have been tried that you are aware of? How do they differ from your proposed solution?

Currently, some medication vial holders do exist on the market, however, they only are tabletop stands or attachments onto IV stands that hold the vials statically in one orientation with a little extra benefit. Additionally, these stands hold the vials tilted just over a 90-degree angle from vertical (or top facing diagonally downward), whereas this proposed solution allows the vials to be at up to a 180-degree angle from vertical (completely upside down). The existing stand does not hold the vials securely enough for the medication to be withdrawn without touching the vials or stand itself which does not address the problem of maintaining sterility when withdrawing medication. Because it holds the vial in one position facing downwards, it is not optimal for visualizing accurate needle insertion.

HOW IS YOUR APPROACH BETTER?:

Does your proposed solution improve upon the current state-of-the-art? If so, explain how.

This proposed solution improves the current approach in multiple ways. Firstly it rotates to allow the vial of interest to be in the orientation the healthcare provider desires for needle insertion and can then be rotated to allow the syringe to be underneath the vial allowing complete extraction of the medicine from the vials. Our approach doesn't only provide a stand to hold the vials, but it also addresses the nuances in medication extraction. It provides a way for the vials to be held securely so that the medication can be extracted without the clinician having to touch anything on the device or vial with his gloved and sterile hands in order to promote the maintenance of a sterile environment. The foot pump allows the physician to have control over the position of the wheel without using their hands and having to change gloves. With this, the physician can select the orientation of the wheel for which the vial is held in the optimal position for the insertion point to be visualized and allow for more accurate needle insertion. This is crucial for ensuring that the needle does not come in contact with an unsterile surface and increases the risk of infection for the patient. Then, the physician can rotate the wheel again to position the vial and needle into the optimal upside-down position for drawing the medication to avoid air bubbles and encourage the more natural downward pulling motion for the syringe.

TARGETED NEED:

What are the characteristics and magnitude of the target market (i.e., number of patients, incidence, and prevalence). Does the problem manifest itself differently in various locations (domestic, international)?

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Our target market applies to any physician or practice that requires the use of needle injections during procedures that require a high level of sterility. Procedures requiring lumbar epidural injections are a major example of this. These are performed by many types of physicians including anesthesiologists, radiologists, neurologists, and surgeons, and the procedure on average uses 3 medications/injections. Annually, an estimated 10.5 million epidural injection procedures are administered in the United States (Li et. al 2020). 42.5% of all interventions used for the treatment of spinal pain are epidural injections (Manchikanti et. al 2016). Any physician performing epidural injections, or other similar high-risk needle injection procedures, could stand to benefit from this solution to improve their workflow and provide a smoother procedural experience for the patient. Having an assistive device like this is even more crucial for environments, such as countries with underdeveloped healthcare systems, where staff shortages are a prevalent problem.

CLINICAL IMPACT:

How would patients benefit? What would be the impact on clinicians and the health care system in general?

This solution would have very prevalent benefits for all involved. For the patients, it would decrease the time a procedure would take, resulting in shorter wait times. It would also help to alleviate the role that physician error may play in increasing the risk of infection for patients during procedures.

For clinicians, because the procedure times are shortened and assistants can be better utilized for fulfilling other tasks, the clinician would be able to take on additional patients per day. Over a year of being able to accept additional patients, an additional tens to hundreds of thousands of dollars of profit can be made for the physicians and healthcare system overall that otherwise would not be feasible.

WHAT IS YOUR NEED FOR ENGINEERING ASSISTANCE?

Materials selection and clinical testing are points of assistance that are required for this proposed solution. Our current prototype is made using low-resolution materials, such as foam core, to visually simulate the concept behind the functionality. We would like to find the ideal plastic material for the device that would allow for the vials to be held securely in place but also be easily taken in and out of the holder. The material also needs to undergo mechanical testing to ensure that it can withstand the weight of the vials and the force from needle insertion. We would also like to test the ideal mechanism for rotation with the foot pedal, whether that be a motor or pressure pump.

Clinical testing with various physicians that perform procedures requiring extremely sterile needle injections would be integral to improving our design. Our idea has thus far been developed based on the general preferences indicated by one clinician and would benefit from the input from multiple other physicians to see if more modularity needs to be included in the design in order to address the differing preferences of clinicians.

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HOW WOULD CMI GRANTS BE USED?

CMI grants would be used to develop a high-resolution prototype and develop a more complete production procedure. Then it would be utilized to fund the clinical testing to determine any changes that would need to occur for this device.

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OTHER BACKGROUND INFORMATION:

List any other helpful background information concerning the problem or need and possible solutions.
(i.e., papers, articles, patents)

Currently, there is a South Korean Patent for a device that can hold medications and rotate medication vials. However, this is part of a drug delivery system. There are patented test tube holders and devices that can hold vials but none were found with this modular design.

In an initial search of articles and patents, we found several devices that incorporated ideas we had used in the past. These ideas included a rotating test tube holder and a medical vial holder (both are not FDA-regulated). Additionally, a rotating medical device patent was found in South Korea but it was used as a medical drug delivery device and is not as a medication holder. However, we also located IV patents that allow you to place test tubes or vials onto an IV stand. These types of devices do not allow for sterile ideal access and medication extraction. Our particular design we did not find any existing patents or intellectual property that infringes on existing devices or ideas.

Since our device presents minimal harm or risk to patients or during usage of the device, it is classified as a Class I device. This means that crutches are a class I device thus exempt from the 510k pathway and GMP requirements. After FDA approval of the device, we would aim to sell the device to hospitals and private practices. We would primarily aim to sell this device to those who deal with pain management and sports medicine as they require independent, fast, sterile Lumbar Spinal Injections to treat patients and our device could assist with workflow.

Clinical Department Chair or Division Head:*

Trent D. Emerick, MD, MBA

Note: Please attach any additional supporting documents to the application.

☐ I agree that the Chair and/or any department committee assembled by the Chair deem the topic to be of important clinical significance.*

For Administrative Use Only

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Administrator Signature:

References:

Li P, Hou X, Gao L, Zheng X. Infection Risk of Lumbar Epidural Injection in the Operating Theatre Prior to Lumbar Fusion Surgery. J Pain Res. 2020 Aug 26;13:2181-2186. doi: 10.2147/JPR.S261922. PMID: 32922068; PMCID: PMC7457848.

Manchikanti L, Pampati V, Hirsch JA. Retrospective cohort study of usage patterns of epidural injections for spinal pain in the US fee-for-service Medicare population from 2000 to 2014. BMJ Open. 2016 Dec 13;6(12):e013042. doi: 10.1136/bmjopen-2016-013042. PMID: 27965254; PMCID: PMC5168679.

Figures:

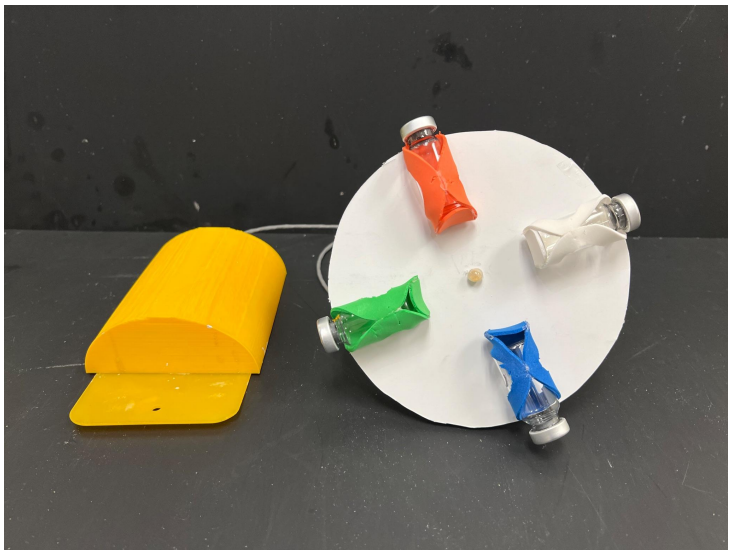

Figure 1: Rotating vial holder prototype with foot pedal pump

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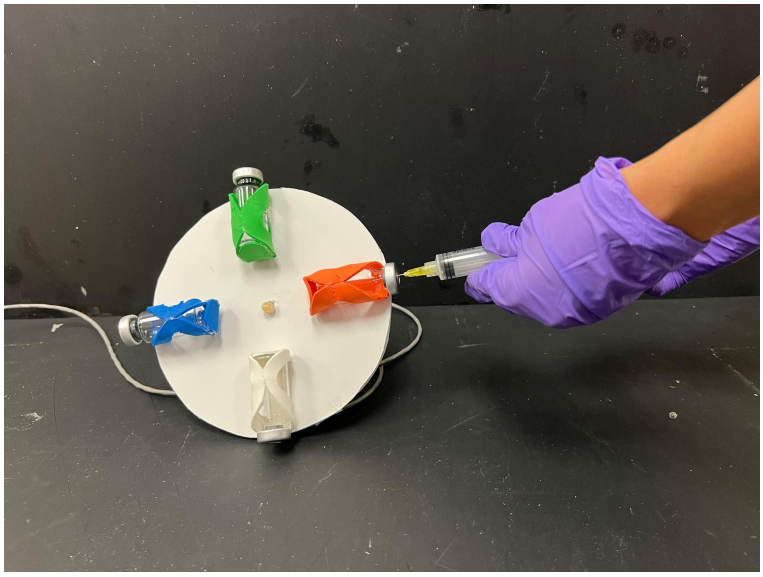

Figure 2: Vial holder mechanism holding simulated vials with a needle being inserted

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