University of Pittsburgh

Design Brief: Engineering Equipment for a Simplified Central Venous Catheterization

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Purpose: This document is intended to introduce the medical problem as well as the proposed solution. A brief analysis of the objective, constraints and resources are included.

1. Introduction:

Numerous conditions warrant the administration of central lines. Patients who have recently suffered from a severe decline in blood pressure due to blood loss often lack pronounced peripheral veins. Thus central lines must be established to administer fluids or drugs. Certain drugs, such as vasoactive or inotropic drugs, can't be injected peripherally and must be administered through a central line. Central lines are also used to measure central venous pressure as well as many other procedures. The current procedure for the placement of a central venous catheter (CVC) requires multiple steps involving several individual pieces of medical equipment in order to verify entry into the vein. The procedure also involves awkward and often uncomfortable handling of the syringe throughout CVC placement. The complexity of the procedure thus allows for human error leading to additional medical complications, including infection or clotting, resulting from the placement of the CVC. Both the patient and clinician suffer repercussions as a result of CVC complications. In order to decrease the occurrence of complications, we are proposing the design of a device that minimizes the complexity of the CVC placement procedure.

2. Primary Consumer:

The primary consumer will be a mixture of the patient, clinician, and purchasing managers at various hospitals, medical centers, and laboratories. The patient comfort and health must be considered while clinician comfort and ease of use are equally important factors. The purchasing manager will keep in mind both patient and clinician opinions as well as cost and efficiency of the product.

3. Aims and Objectives:

Within the next seven months we aim to completely design, fabricate, and begin testing of the equipment for the simplified CVC kit. Following the design and fabrication of the equipment, the device must meet the following design criteria:

- Provide an accurate indication of whether the needle has entered the vein or artery using a pressure sensor with a display that shows the pressure and indicates red for artery and green for vein.
- Replace the syringe with a more ergonomic handle.
- Provide a small three-way connector piece that connects the needle, handle, and pressure sensor. The three-way connector must allow blood to flow into the handle for visual confirmation but prevent blood flow out when the handle is disconnected.

The guide wire must then also be able to be inserted through the connector from the port where the handle was initially attached.

Following the initial simulation testing of the equipment, the device must meet the following criteria:

- Allow for efficient and desirable use by the clinician. This would be verified by having a clinician perform a CVC using a traditional kit, and then with our improved kit.
- Provide a significant decrease in the amount of CVC placement complications, as verified by a clinician.

4. Constraints:

While the CVC device does involve an invasive procedure, its failure does not necessarily lead to patient death. Our proposed design would be a short term CVC which is listed in the FDA guidance documentation as a Class II medical device. Under the assumption that our device will be substantially similar to current short term CVCs, the following quality system regulation and good manufacturing practices must be adhered to:

- Submission of a 510(k) Premarket Document to the FDA.
- Ensure physical, mechanical, chemical and biological properties are compatible with use in the human body.
- Ensure all procedures allow the device to remain sterile.

The product must be cost effective for prototype production with a $1500 budget. The design should also meet all of the clinician's CVC placement needs thereby including the numerous tools and materials included in current CVC kits. The device must be completely designed and fabricated within seven months.

5. Evaluation of Device:

Testing the device will occur once design and fabrication have been completed. The initial testing will occur at the WISER center. The following parameters will be tested:

- Success rate of the CVC insertion.
- Clinician ease and comfort of use.

The success rate will be measured by the amount of clinicians that place the CVC correctly in a shorter amount of time using the new device compared to using the old technique. Additional testing will include a study of how quickly inexperienced medical students learn the CVC technique using the new device. This data can then be compared to previous data regarding CVC training time for the current method. Finally, the clinician ease and comfort will be tested through a qualitative evaluation filled out by the clinician who will rank various aspects of comfort and ease on a numeric scale.

6. Resources:

- Dr. Joseph Samosky, Ph.D, Director of Research and Development at the Peter M. Winter Institute for Simulation, Education and Research
- The Peter M. Winter Institute for Simulation, Education and Research (WISER)

- Dr. Bill McIvor, anesthesiologist and associate director of medical student programs
- Christine Barton, WISER coordinator of simulation services
- University of Pittsburgh Medical Center (UPMC) staff, clinicians, and researchers