University of Pittsburgh

Human Factors Analysis: Engineering Equipment for a Simplified Central Venous Catheterization

October 19, 2007

Group: Jennifer Adams, Janet Chan, Evan Hill, Matt Wolf

Purpose: The placement of a central venous catheter (CVC) is a complicated process that creates large amounts of error associated with the procedure. This document is intended to identify those hazards that are directly related to the use of the redesigned CVC device. Identification of potential hazards thereby allows design modifications that minimize the possibility of occurrence.

Device Overall:

The redesigned CVC device will include a needle, pressure sensor, three-way connector piece with visual feedback for vessel entry, an ergonomic support handle, and guide wire. The device will be used to place the guide wire in a patient's Internal Jugular (IJ) vein. The needle will be inserted into a properly prepared and sterilized patient neck until it enters the IJ vein. The pressure sensor will measure the pressure generated by blood in the punctured vessel. When a change in pressure is sensed, the pressure sensor will display a numeric pressure and a color signal to identify whether the clinician has entered the carotid artery (above 30mmHg with a red display) or the IJ vein (below 30mmHg with a green display). The sensor should have an accuracy of ± 4mmHg. Once the needle is in the vein as confirmed by the pressure sensor, in conjunction with the require ultrasound and visual confirmation in a small tube in the handle, the handle can be removed from the connector piece.

The connector contains a one-way valve that prevents blood flow. The guide wire can be inserted through the valve and connector, through the needle, and placed at the correct depth within the patient's IJ vein. The guide wire will have depth markings at 16mm and 20 mm in order for the clinician to visualize the depth of the wire. Following placement of the wire, the needle and connector can be removed from the patient leaving only the guide wire within the patient. The final steps of the CVC placement can then be performed as they currently are.

The entire CVC device, including needle, connector, and handle, will be approximately 15cm long and the guide wire will be 40cm long. The needle diameter will be approximately 1.02mm (18 Gauge) and the guide wire diameter will be approximately 0.8mm. The syringe will be a 5mL syringe with a diameter of approximately 12.1mm.

Numerous conditions warrant the administration of central lines. Patients who have recently suffered from a severe decline in blood pressure often lack pronounced peripheral veins and therefore require central lines to be established to administer fluids or drugs. In addition 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 and can be used for various other patient conditions or treatments. Central lines can be administered to any patient.

The current procedure for the placement of a central venous catheter (CVC) requires multiple steps involving several individual pieces of medical equipment. The clinician must first insert the needle into the blood vessel. The syringe is then removed and a piece of plastic tubing

is connected to the needle in order to test whether the needle is in the vein or artery. Once the needle is in the vein, the guide wire must be thread through the needle and placed at the correct depth within the patient. During this procedure, the needle remains in the patient allowing the possibility for damage to the epithelial layers of the vein as a result of needle movement. Following the guide wire insertion, the clinician must still thread the dilator of the guide wire and into the patient, remove the dilator, thread the catheter into the patient, remove the guide wire, and secure the catheter in place. The complexity of the procedure thus allows for human error leading to additional medical complications, including infection or clotting, resulting from the procedure of CVC placement. Both the patient and clinician suffer repercussions as a result of CVC complications.

The redesigned CVC device will aid in minimizing the complexity of the steps of the procedure and the error associated with incorrect CVC placement. Through the easy to use pressure sensor and more comfortable handle, clinicians will be able to quickly and accurately place the guide wire into the patient while minimizing errors such as arterial catheterization. Infection, clotting, and discomfort will also be minimized by the faster placement and decreased needle movement within the patient.

Device User Interface:

The CVC device must be easy to operate and to teach to use. The device should be comfortable for the clinician to hold while performing the procedure. The size of the entire device should not be too large or heavy for the clinician to use but it must also be large enough that it is easy to manipulate. The clinician must be able to have a clear view of their procedure and therefore the device must not be too large of an obstruction. The pressure sensor should be visible in order that the clinician can see the display. The guide wire marks must be clearly visible to the clinician as well. The clinician must use two hands during the procedure.

The use of this CVC device will proceed simultaneously with other procedures a patient may be experiencing. The CVC placement is a subset of the overall treatment of a patient. Since the procedure is commonly performed, training and proper warning labels must be included with the CVC device. Along with proper CVC technique, training must include the conditions for which the pressure sensor may not be accurate and how to recognize these situations. Labels should explain the indicator signals and the depth markings on the guide wire. Warnings should be placed on the packaging to ensure sterility and to prevent over insertion of the guide wire.

Device Use:

The CVC device is intended solely for placement of IJ vein catheters. After opening the package in a sterile environment, the clinician should connect the handle to the three-way connector, then the pressure sensor to the connector and finally the needle to the connector. After removing the needle sheath, the clinician can begin the procedure. Following the use of the device, the entire device must be discarded.

The clinician will be standing behind the patient’s right shoulder during this procedure. The clinician must insert the needle into the IJ vein using ultrasound, visual confirmation in the connector, and the pressure sensor to confirm entry in the vein. The support handle should then be removed leaving the needle and connector in place. The guide wire will then be thread through the valve in the connector, through the needle and into the patient. After the guide wire

is placed correctly, the needle and connector should be completely removed from the patient and the guide wire should be left in place.

Device User Population:

The CVC device is intended solely for use by skilled and trained clinicians. Clinicians placing central lines face a multitude of complications as a result of the complexity of CVC placement. They require a device that minimizes the error associated with performing the procedure. The clinicians are also already highly trained and require a device that is similar in technique to the current method of CVC placement. Through further training specific to the redesigned CVC device, the clinician will learn how to understand the display, when to use another method to test blood vessel pressure, how to attach the connector and assure valve operation, and how to insert the guide wire. The training will serve as both an introduction to a modified CVC device and also a refresher session on placing central lines. The device should not be used by anyone who is not a clinician and anyone who has not been specifically trained on the use of the CVC device.

Device Use Environments:

The CVC device is intended solely for use in a hospital. It should be used as a part of a CVC kit which will contain the additional materials required for completion of the CVC placement. The parts of the device should be autoclave sterilized prior to packaging and should remain in a mostly sterile environment. The device should be operated at room temperature and is able to withstand temperatures up to 80^{o}C without mechanical or electrical failure. Operating rooms may be crowded depending on their size and the number of people in them at a given time. The other components of the CVC kit will be present next to the clinician. A drape will cover the patient during the majority of the procedure. The device should not be used outside of a hospital setting, in an overly heated room, or in an unsterile hospital setting.

Use Related Hazards:

Currently, there are numerous use related hazards associated with the placement of a CVC. These include arterial catheterizations, infections, over insertion of the guide wire, and needle sticks with contaminated needles. While these hazards are not able to be entirely eliminated by the new design for a CVC device, they can be minimized.

The possibility for arterial catheterizations is the most serious concern in the design of the CVC device. Perforating the artery with a needle is easily corrected by application of pressure to the site for 5-10 minutes. However, completely catheterizing the artery has the potential to cause the patient to hemorrhage and result in many other complications. The risk of the entire procedure is greatly increased if the patient has their artery catheterized. Often arterial catheterization occurs when a clinician is unable to complete the additional task of checking the pressure in the tubing. It can also occur when the arterial blood pressure is so low that it mimics that of venous blood pressure. The incorporation of the pressure sensor within the initial step of inserting the needle should minimize the possibility of arterial catheterization. The pressure sensor will recognize pressure values using a threshold of 30mmHg in order to indicate arterial

or venous entry. This should help to eliminate most improper catheterizations which result from low arterial pressures.

Infections are the most common complication associated with the placement of a CVC. While the repercussions of an infection are not usually as severe as those of an arterial catheterization, the patient could have further complications as a result of the infection and the infection creates great discomfort. Infection can be attributed to many causes. Often infections are due to unsterile environments, packaging, or use. Multiple insertions, overly long exposure of the materials to contamination, or improper procedure can also lead to CVC infections. The main method of eliminating this complication is through clinician training. The redesigned CVC device helps to minimize the chance of infection through three main methods. The first is through the more ergonomic support handle that allows a stable and comfortable grip to insert the needle, thus preventing multiple insertions. The second way to minimize infections is through the connector valve. The valve prevents blood loss, which can contaminate the insertion site and provide a surface for bacteria to grow. Finally, the device minimizes infections through increasing the speed of CVC placement thereby minimizing exposure of the materials to potential contaminants.

Over insertion of the guide wire is a rare incident that can occur if the clinician pushes the guide wire too far into the patient. The guide wire can be lost or may perforate the heart walls. While rare, these risks are severe and could lead to major complications. Clinicians must be trained on the proper way to handle the guide wire while inserting the dilator and catheter. The depth markings on the guide wire should help to minimize over insertions.

Probable hazards associated with the redesigned CVC syringe include misinterpretation of the display, failure to see the display, or inability to properly set up the three way connector. Arterial insertion or multiple injections could result from misuse or misinterpretation of the display. Inability to properly set up the connector could result in a poorly inserted guide wire or having to restart the procedure. Potential hazards should be minimized through design specifications in order to reduce the amount of complications associated with CVC placement. The hazards are rated with respect to severity and probability of occurrence.