University of Pittsburgh

Initial Hazard Analysis: Engineering Equipment for a Simplified Central Venous Catheterization

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Purpose: The initial hazard analysis serves to identify potential complications associated with device failure as well as general complications of the CVC procedure.

Potential Hazards:

Device Failures:

1. Pressure Sensor Failure:

   - False positive. The pressure sensor indicates pressure below 20mmHg when the needle is not in the vein.
   - False negative. The pressure sensor indicates pressure above 30mmHg when the needle is in the vein.
   - Complete failure. The pressure sensor does not indicate any pressure.

   A false positive could occur if the sensitivity of the sensor is greatly diminished. Thus the high pressure of an arterial puncture would not trigger a high enough potential to measure 30mmHg or higher. A false negative could occur if the sensitivity of the sensor is greatly augmented. In this case the low pressure of a venous puncture would generate a greater than desired electric potential, and measure a pressure of 30mmHg or higher. Complete failure could occur due to faulty electrical connection between the sensor and the indicator, or due to display malfunction. If the pressure sensor fails, arterial catheterization can occur causing a hemorrhage. If an artery is punctured instead of a vein, excessive blood loss could occur. However, this error is usually very detectable and can be ceased in a short period of time by applying pressure to the vessel.
   High Severity

2. Valve Failure:

   If the valve fails, blood loss could occur via the connector. The amount of blood lost would not be severely detrimental however the potential for infection is increased by the presence of blood at the site of CVC insertion.
   Low Severity

3. Mechanical Failure of the Handle, Needle, or Connector:

Any of the parts of the device must be able to withstand mechanical stresses throughout the procedure. The needle, handle, or connector could fail and break during a CVC placement. This would again cause the clinician to restart the procedure after removing the malfunctioning syringe.
Low Severity

Additional Hazards:

- Infections. Once the equipment is exposed to air, especially while gliding through the skin and into blood vessels, pathogens could be introduced into the blood stream or under the skin around the insertion area, which could lead to infections.
  Moderate Severity

- Needle sticks. Since a CVC kit contains multiple pieces with sharp ends for puncturing, improper disposal could lead to accidental exposure to a patient's blood.
  Moderate Severity

- Guide wire insertion. The guide wire can be inserted too far into the patient becoming lost within the patient. Overly inserted guide wires can also puncture the heart walls causing various other medical complications
  High Severity

Causes of Hazards:

Device Failure:

1. Pressure Sensor Failure:

   These hazards could be caused by mechanical failure of the Wheatstone Bridge circuit used to convert the mechanical force of blood pressure into an electric potential. A damaged circuit could affect its sensitivity to mechanical force and generate an incorrect potential. Indicator mishaps could also be due to failure of the electrical components of the sensor. If the connection between the circuit and the display is damaged, the electrical signal could be distorted or completely absent. Also a malfunctioning display would not generate any signal. Both design and manufacturing factors can affect the ability for the sensor to work correctly.
   Moderate Probability

2. Valve Failure:

   Valve failure could be caused by manufacturing error in making the connector. Parts within the device can all be within the tolerance range however the additive affect of multiple parts with error could cause the valve to operate incorrectly.
   Moderate Probability

3. Mechanical Failure of the Handle, Needle, or Connector:

The device materials must be selected and manufactured such that they can withstand the mechanical stress during the procedure. Both design and manufacturing factors can affect the strength and durability of the material throughout use.
Low Probability

Additional Hazards:

Infections can occur due to improper sterilization, contaminated packaging, or environmental conditions (ie: unsterile room). **High Probability**

Needle sticks and guide wire complications can occur as a result of user error. Proper warning labels will be included to alert users of these hazards. **Moderate Probability**