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Failure Modes and Effects Analysis: Off-Label Use of Alaris Infusion Pump for Cerebrospinal Fluid Subarachnoid Drainage

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Abstract— **Communicating hydrocephalus is a medical condition that occurs when there is an imbalance between production and absorption of cerebrospinal fluid (CSF) resulting in increased intracranial pressure. One treatment for the condition involves draining excess CSF. A custom CSF drainage system was designed by clinical staff from Vancouver Coastal Health. The system uses an infusion pump off-label to drain CSF from a catheter inserted into the patient's lumbar spine. A Failure Modes and Effects Analysis (FMEA) of the system was conducted to assess the risk of the therapy from an equipment perspective. The FMEA identified thirty-one device hazards. Highest ranked hazards included operating the device without drug-error reduction system controls, operator error resulting in improper system setup, and potential patient harm due to the device controlling flow rate instead of CSF pressure.**

Keywords— **Failure modes and effects analysis, off-label, infusion pump, hydrocephalus, cerebrospinal fluid**

I. Introduction

The Monroe Kellie doctrine states that the human skull is a rigid box comprised of three components; brain tissue, blood and cerebrospinal fluid (CSF) [1]. Normally the volumes of these components are in homeostasis and the pressure within the skull is constantly maintained within a normal pressure. A small increase in the volume of one component may result in a detrimental increase in intracranial pressure (ICP). Sustained increased ICP may result in global cerebral ischemia and herniation syndromes which could lead to unfavorable neurological outcome and/or death [1]. Communicating hydrocephalus is a condition that occurs when there is an imbalance between production and absorption of CSF resulting in increased ICP [2].

A lumbar drain may be indicated to treat communicating hydrocephalus [2]. The drain is surgically inserted into the subarachnoid space of the lumbar spine which is then connected to a drainage bag via a tubing set. Removal of CSF through the drain reduces the pressure in the intracranial and intraspinal CSF compartments.

The traditional lumbar drain requires a fixed relationship between the patient and the drainage system in order to maintain the desired drainage rate; this presents a significant drawback as it severely limits patient mobility. Additionally, flow rate adjustment is a manual process that requires frequent operator interaction.

To solve these drawbacks, special pumping devices have been commercialized to control the drainage of CSF from the patient. The Möller Medical GmbH LiquoGuard® 7 CSF drainage pump is a pressure-controlled peristaltic pump that is specifically designed to pump CSF from the ventricular system and lumbar area of the patient [3]. The device regulates the pumping rate on the basis of volume or the patient's CSF pressure. The device also allows the patient to move relative to the drainage bag. At the time of the analysis described in this paper, no commercialized CSF pumps were available in Canada due to lack of Health Canada licensing approval.

In the absence of a commercially-available solution, clinical staff at Vancouver General Hospital designed their own drainage system using the BD Alaris infusion pump (the "system"). The system interfaces the infusion pump with the lumbar catheter to remove CSF via the lumbar drain at a controlled rate. An internal procedure (the "procedure") was developed which includes instructions for setting up the system as well as general nursing practice guidelines.

Pump-assisted lumbar drainage is not an indicated use for the Alaris infusion pump. A Failure Modes and Effects Analysis (FMEA) of the system was conducted by the authors (the "assessment group") to assess the risk of the therapy.

II. Method and Materials

A. Apparatus

Figure 1 shows an image of the system as it is setup by clinical staff with the red lines indicating the direction of CSF flow. The system is composed of a Medtronic EDM patient assembly line connected to an Alaris half infusion set and a 1L Medtronic drainage bag. The Alaris set is loaded into a standard BD Alaris 8100 Large Volume Pumping module, and the EDM patient assembly line is connected to the patient's lumbar catheter (surgically inserted into patient). The drainage bag is hung at the top of the IV pole.

B. Drainage Volume Accuracy Testing

The system's drainage volume accuracy was tested by measuring the mass of water pumped through the system over a specified period of time. CSF is composed of 99% water so it was considered to be an acceptable substitute. The actual mass was compared to the theoretical mass given the programmed flow rate. The water was weighed using a calibrated Sartorius Practum 313-1S balance. A graduated cylinder full of water was used to represent the patient's subarachnoid space.

Nine different tests were conducted in total. Three tests were conducted each for the minimum, maximum and median flow rates that are typically ordered by physicians. The height of the spinal catheter, Alaris pump and drainage bag were varied using the catheter as a reference point. For two of the three tests at each flow rate, an 80cm Medtronic closed tip lumbar catheter was placed into a graduated cylinder full of water and then connected to the EDM patient assembly line. For the remaining tests, the catheter was removed and the connection point was directly inserted into the graduated cylinder. Table 4 summarizes all volume accuracy tests and results.

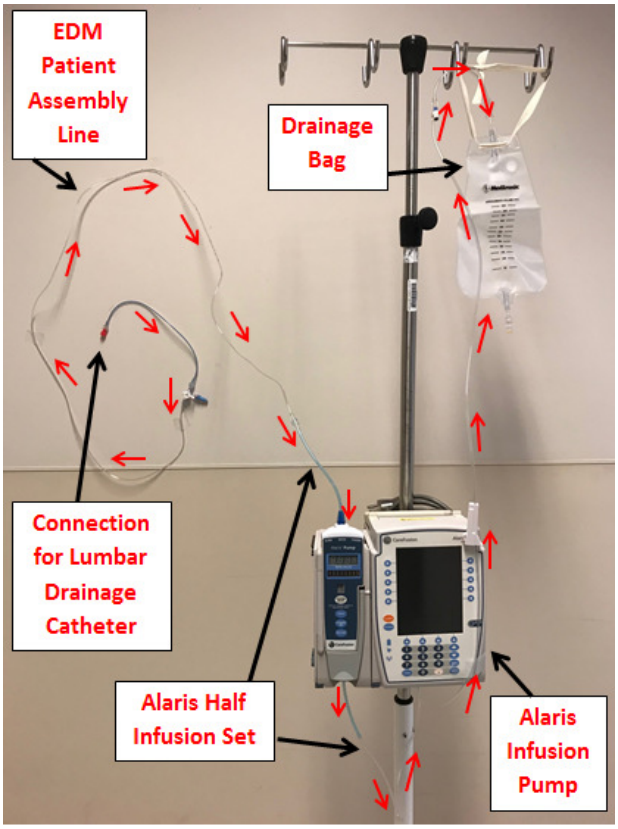

Fig. 1 Alaris Infusion Pump Subarachnoid CSF Drainage System

C. Failure Modes and Effects Analysis

FMEA is a systematic technique used to analyze potential failure risks within a system. Conducting a FMEA involves identifying all possible failure modes and causes in a system and the associated effect of the failure. Each failure mode is classified in risk by assessing the severity, probability of occurrence, and detectability of the failure mode. A standard FMEA procedure was followed for this analysis.

a) Scope

The FMEA was limited in scope to equipment-related failure modes only. The analysis considered the use-case of both setting up the system and the system actively providing therapy.

b) Severity

Severity of harm considers the worst potential consequence of a failure, determined by the degree of injury. Severity was estimated on a conservative basis. Table 1 summarizes the severity scoring criteria.

Table 1 Severity Scoring Criteria

Score	Criteria
1	Negligible – Inconvenience or temporary discomfort
2	Minor – Results in temporary injury or impairment not requiring professional intervention
3	Major – Results in temporary injury or impairment requiring professional intervention
4	Critical – Results in permanent impairment or is life threatening
5	Catastrophic – Results in patient death

c) Probability of Occurrence

The probability of occurrence is the likelihood of a failure occurring. Occurrence was determined based upon the assessment group's understanding of the device and reasonable human reliability. The probability was estimated for one day of therapy. Table 2 summarizes the occurrence scoring criteria.

Table 2 Probability of Occurrence Scoring Criteria

Score	Criteria
1	Improbable: <= 10^{-6}
2	Remote: <= 10^{-5} and >= 10^{-6}
3	Occasional: <= 10^{-4} and >= 10^{-5}
4	Probable: <= 10^{-3} and >= 10^{-4}
5	Frequent: >= 10^{-3}

d) Detectability

Detectability is how well a control can detect either failure cause or its associated failure mode after it has occurred but before the patient is affected. Detectability was estimated based upon built-in device features and the assessment group's understanding of the clinical practice elements. The FMEA only considered explicitly required checks in the procedure and excluded practice that is not documented in the procedure or that is not universally practiced. Table 3 summarizes the detectability scoring criteria.

Table 3 Detectability Scoring Criteria

Score	Criteria
1	Certain to detect
2	Almost certain to detect
3	Moderate ability to detect
4	Low ability to detect
5	Certain not to detect

e) Risk Prioritization Number

The Risk Prioritization Number (RPN) is an index used to identify significant hazards with the system. The RPN is calculated by multiplying severity, probability of occurrence and detectability of a failure mode. The maximum RPN is 125.

e) Assumptions

The following assumptions were made for the FMEA:

- The patient is able to express discomfort caused by the therapy.
- The pump providing the therapy was programmed in basic infusion mode (no drug-error reduction system controls).
- All current risk controls are documented in the existing pump-assisted CSF drainage procedure.
- Short interruptions in the therapy have minimal consequence to the patient's outcome.

III. Results

a) Drainage Volume Accuracy Testing

The system was found to pump less fluid than the theoretical value (i.e. the programmed flow rate), with lower flow rates resulting in greater degrees of inaccuracy. Connecting the spinal catheter to the system caused the expected volume of fluid pumped to further decrease. Varying the height of the catheter, pump and bag had a minimal effect on accuracy. The maximum error resulted in 13.7% less water being pumped through the system than expected. Complete results can be found in Table 4.

b) Failure Modes and Effects Analysis

The FMEA identified thirty-one different device hazards with RPNs ranging from 1 to 100. Table 5 presents a sample of four hazards that were identified through the analysis. Overall, the highest ranked hazards included:

- Operator errors related to operating the device in basic infusion mode (no system controls for rate programming errors).
- Operator errors related to setting up the atypical apparatus used for the therapy.
- Operator errors related to loading the set into the pump.
- Potential patient harm due to drainage being driven by the device-controlled flow rate rather than CSF pressure.

Table 4 Volume Accuracy Testing Criteria and Results

Test #	Number of Tests	Spinal Catheter	Flow Rate (mL/hr)	Length of Test (mins)	Height Spinal Catheter (cm)	Height Alaris Pump (cm)	Height Drainage Bag (cm)	Average Error	Maximum Error
1	3	No	3	60	0	0	0	-9.4%	-13.4%
2	3	Yes	3	60	0	0	0	-10.6%	-13.6%
3	3	Yes	3	60	0	22.9	97.8	-11.2%	-13.7%
4	3	No	6	60	0	0	0	-2.5%	-3.0%
5	3	Yes	6	60	0	0	0	-7.1%	-8.7%
6	3	Yes	6	60	0	22.9	97.8	-7.7%	-7.8%
7	3	No	10	60	0	0	0	-1.3%	-1.6%
8	3	Yes	10	60	0	0	0	-6.3%	-6.9%
9	3	Yes	10	60	0	22.9	97.8	-7.0%	-7.0%

Table 5 Example Hazards from the FMEA of the Custom CSF Drainage System

Function	Potential Failure Mode	Potential Effect(s) of Failure	S	Potential Cause(s) of Failure	O	Current Process Controls	D	RPN
Drain CSF at flow rate ordered by clinical staff	Flow rate less than flow rate ordered by clinical staff	Less CSF drained than anticipated. Therapy doesn't progress fast enough. ICP increases. Increased ICP could result in brain herniation and/or death.	5	Operator error *Set incorrectly loaded into the 8100 module: silicon tubing stretched*	5	None	4	100
			5	Operator error *Operator inputs incorrect flow rate*	4	None	4	80
Detect occlusions in system	Upstream occlusion not detected		5	Upstream pressure sensor is intended for bottle side. Configuration of this system has the upstream pressure sensor on the patient side	1	Occlusion is detected by pump in range of 5 minutes	2	10
Drain CSF for length of time ordered by clinical staff	Therapy administered shorter than expected		5	Battery failure *Capacity insufficient* *Battery capacity overestimated*	4	Device alarm	1	20

S = Severity; O = Probability of Occurrence; D = Detectability

IV. Discussion and Conclusions

The Alaris infusion pump is designed for infusing fluid into a patient. The safety features and thresholds are intended for an apparatus with the patient on the downstream line of the pump, not the upstream line. Additionally, the pump is volume-regulated rather than pressure-regulated. Clinical staff must estimate the flow rate and drainage volume in order to achieve the target pressure reduction. The device is completely unaware of the patient's CSF pressure and will continue to drain CSF at the programmed rate even if the target pressure has been achieved. Considering the risks with the atypical apparatus, the assessment group found the FMEA to be an effective tool for systematically identifying hazards that had potential to compromise patient safety.

The volume accuracy tests proved to be valuable for both the FMEA as well as clinical staff. The Alaris pump calculates the volume infused by multiplying the programmed flow rate by the therapy duration. The device has no ability to measure the actual volume of fluid which flows through the pump. Testing found that the volume infused accuracy was reduced. This was largely attributed to the device not being intended to control flow with a very narrow catheter on the upstream line. This information has been provided to clinical staff and they are now aware that the system will not drain as much CSF as expected based upon the programmed flow rate. Further testing is now required to obtain better data on the system's accuracy. In particular, flow accuracy is known to be reduced during the startup phase of an infusion so testing over a longer period of time is needed. Future tests will ideally follow the international standard for infusion devices, IEC 60601-2-24.

The assessment group was not responsible for evaluating the acceptability of the risks identified with the therapy as these need to be considered in context with risks from the traditional non-pump facilitated drainage systems and differences in therapeutic benefit. However, the group did make recommendations for additional risk controls. The risk controls focused on mitigating the highest ranked hazards which were mostly operator related. Recommendations included:

- Independent double check of apparatus setup and programming.
- One pump with a single channel dedicated to providing CSF therapy. No other infusions to be administered via this pump.
- Labelling the pump with its therapeutic use "CSF Drainage".
- Labelling of all lines.

Following the completion of the FMEA, the LiquoGuard® 7 CSF drainage pump received a Health Canada medical device license. Biomedical Engineering is advocating for an assessment of this device as it is specifically designed for the therapy.

V. Conflict of Interest

The authors declare that they have no conflict of interest.

VI. References

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