Evaluating Systems with Multiple Processes Using STPA: A Case Study in a Medical Intensive Care Unit

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Abstract: This paper evaluates the use of STPA in a heatlhcare setting specifically a complex setting involving controllers participating in multiple processes at one time. This is a scenario that has not been explored with STPA before but is the status quo in most healthcare systems. In an intensive care unit, the process of providing care to patients is comprised of many processes including drug delivery, lab draws, radiological imaging, bedside procedures, physical therapy, and far more. The interactions of these procedures support patient care but also increase risk in healthcare delivery in ways that need to be considered.

1 Introduction

Risk analysis in healthcare today commonly involves the application of Failure Mode Effects Analysis to various processes, including prescribing and running intravenous drug infusions [Ap04] and drawing lab samples [WRY06]. The approach to performing an FMEA in a healthcare setting is relatively constant regardless of the process being analyzed. The authors map the process of interest and analyze each step for severity of failure, likelihood of failure, and the ability of the system to detect the failure before harm occurs. They use these measures to locate risky steps in the process to target for corrective action. However, besides issues with the underlying assumptions in FMEA, highlighted in [Le11], healthcare is faced with another issue in using FMEA for risk assessments. These analyses in healthcare look only at one process at a time. In the Intensive Care Unit, for example, there can be many processes occurring simultaneously – medications are being ordered and given, labs are being drawn and sent for analysis, images are being taken, and invasive procedures are being performed. To do an analysis of an ICU as a whole using FMEA would involve performing a separate analysis on each of these processes. However, even this would provide an incomplete assessment of the risk of care delivery in this unit. Each FMEA assumes that the process is carried out independent of every other process. These processes though are all a part of the larger ICU system and have the potential to interact. This creates a compelling case for using a

hazard analysis technique that can look at the system as a whole. This work seeks to use the Systems-Theoretic Process Analysis as a way of integrating these multiple processes into one hazard analysis.

2 Methods

This work was all performed in the setting of an 8-bed Medical Intensive Care Unit at a large academic medical center. The Institutional Review Board of the Beth Israel Deaconess Medical Center granted this work approval as protocol #2014P-000020. Data collection was completed by observation of the workflows of nurses and physicians during weekday hours as well as through unstructured interviews. These observations were used to perform STPA as outlined in [Le11].

3 Selected Results

3.1 Identifying Accidents and Hazards

The major hazards for an intensive care unit include not treating the patient appropriately for their diagnosis or giving them an iatrogenic injury or infection that was not present when they were admitted. These correspond to the possible accidents, which include death or disability due to the disease, the treatment, or an acquired injury or infection.

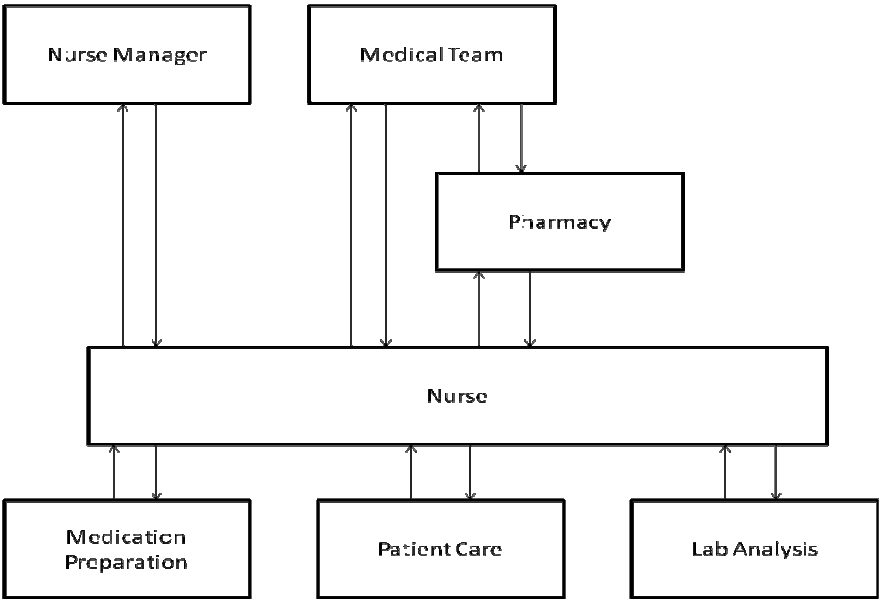

Figure 1: Simplified (Top-Level) Hierarchical Control Structure for ICU

3.2 Step 1: Unsafe Control Actions

The nurse (RN) has nine unique control actions from five different processes: lab testing, medication administration, patient positioning and other direct patient care, infection prevention, and patient monitoring. Using Step 1 tables 25 unsafe control actions were identified from these 9 control actions.

3.3 Step 2: Causal Factors

One interesting unsafe control action was the nurse mislabeling a lab specimen, either with the wrong patient identifiers or the wrong details about the tests ordered. In this ICU the process was to draw the sample and then print a label at a central printer which was affixed to the tube and sent to the lab. A step 2 scenario was the delayed operation of printing and labeling the specimen leading to the nurse forgetting potentially which patient the specimen came from. This could occur very easily in drawing a drug trough level, which is drawn just before the next dose of that medication is administered. A common scenario involves the nurse drawing the lab specimen, putting it down, and administering the drug. Administering the drug can take several minutes during which the nurse may not recall that the specimen needs to be labeled, leading to the potential for mislabeling the test tube. This is an example where a safe control action, administering the medication, can contribute to an unsafe control action, mislabeling or not labeling the lab specimen.

4 Discussion

The scenario where one process interacts in a risky manner with another process is not an uncommon scenario in a complex setting like an ICU. The FMEA completed on lab draws identified a failure mode of not putting the time on the label with a root cause listed as „time of collection not recorded“ [WRY06]. Because of this as the root cause the recommended control was to add more training. This analysis looked at blood draws as an independent process, so they never identified the clash found with STPA, which as a causal scenario would lead to implementation of very different controls to promote patient safety. This ability to handle multiple processes in one analysis is an important strength of STPA because these interactions are clinically important. STPA performs the analysis at the level of the controller, not at the level of the step in the process, allowing this flexibility in analysis and consideration of these interactions.

References

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