Analysis of Medical Device Failure Reports from the MAUDE Database: A Data Mining Approach

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Abstract

Lorem Ipsum is simply dummy text of the printing and typesetting industry. Lorem Ipsum has been the industry's standard dummy text ever since the 1500s, when an unknown printer took a galley of type and scrambled it to make a type specimen book. It has survived not only five centuries, but also the leap into electronic typesetting, remaining essentially unchanged. It was popularised in the 1960s with the release of Letraset sheets containing Lorem Ipsum passages, and more recently with desktop publishing software like Aldus PageMaker including versions of Lorem Ipsum.

Contents

1 Introduction

Modern medicine relies heavily on technology to support the delivery of treatments and care. These technologies are described by the umbrella term "medical devices" which encompasses any combination of mechanical, electrical, software devices that are used in medical care. The implications of these devices failing can range from minor annoyances to death. Adverse events related to medical devices in the United States are reported to the Food and Drug Administration (FDA). These reports are stored in the **Ma**nufacturer and **U**ser Facility **D**evice **E**xperience (MAUDE) database and are publicly accessible. The MAUDE database contains approximately 3.7 million records dating back to 1991.

Previous works have focused on analyzing the data in the MAUDE database to extract trends related to specific devices [4]. However, many of these analyses have been conducted using a manual review process that does not lend itself well to analyzing the large number of records available in the MAUDE database. The FDA has recently made the data accessible via its openFDA API which allows programmatic access to the data. To the best of our knowledge, no work analyzing data obtained from this new API has been published.

Health care is a complex domain that requires medical devices to interact with humans in increasingly complicated ways. There are many examples of adverse medical events that were caused by a combination of a device and human users. Horsky conducted an analysis of such an event [1]. Safety analyses of medical devices must consider more than just the device. They must also consider how the device interacts with human actors [2]. Leveson has presented general a model for analyzing the behaviour of complex sociotechnical systems called the STAMP model. The STAMP model describes a system as a feedback control loop with a controlled process being actuated and sensed by a human actor [3]. Work by Mason-Blakely and Weber has tailored this model for analysis of software in health care. This model is shown in Figure 1 below [5].

Mason-Blakey and Habibi used the STAMP EMR model to classify 350 adverse event reports related to software in the MAUDE database (not yet published). This classification was conducted by manually inspecting the natural language summary of each event. A number of different classes (related to the STAMP EMR model) were assigned to each record depending on the reviewer's understanding on the adverse event and how it fits into the STAMP EHR model. The categories used were:

- Care Provider
- Point of Care Sensor
- Point of Decision Display
- Point of Care Actuator
- Point of Decision Control

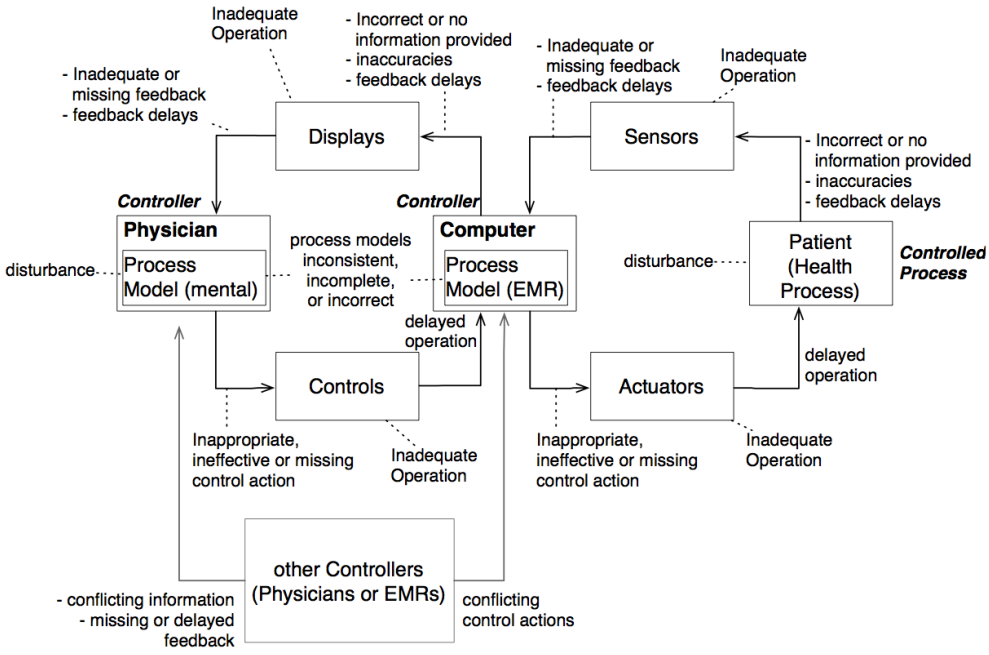

Figure 1: STAMP - EMR model from [5]
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- Medical Device Decision Support (MDDS)
- Technical Process

In this project the MAUDE database was examined algorithmically using standard data mining techniques. Two different approaches were used to analyze data from MAUDE database: i) analysis of the meta-data for each record to predict the outcome of the event (injury, death, etc.); ii) analysis of the natural language description of the adverse event in an attempt to classify the outcome of each record (as outlined in the STAMP EMR model). The remainder of this paper is structured as follows: section 2 describes the methods used to collect and analyze this data; section 3 presents results; and section 4 provides a discussion of results and outlines strengths and weaknesses of the aforementioned approaches.

2 Methods

2.1 Approach I: Meta Data Analysis

2.1.1 Data Collection

2.1.2 Data Pre-Processing

2.1.3 Data Analysis

2.2 Approach II: Record Categorization

2.2.1 Data Collection

2.2.2 Data Pre-Processing

2.2.3 Data Analysis

3 Results

3.1 Approach I: Meta Data Analysis

3.2 Approach II: Record Categorization

4 Discussion

Lorem Ipsum is simply dummy text of the printing and typesetting industry. Lorem Ipsum has been the industry's standard dummy text ever since the 1500s, when an unknown printer took a galley of type and scrambled it to make a type specimen book. It has survived not only five centuries, but also the leap into electronic typesetting, remaining essentially unchanged. It was popularised in the 1960s with the release of Letraset sheets containing Lorem Ipsum passages, and more recently with desktop publishing software like Aldus PageMaker including versions of Lorem Ipsum.

5 Conclusion

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