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

Simon Diemert, Scott Low, Paul Moon

March 23rd 2015

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 **1**

2 Methods **1**

2.1 Data Pre-Processing 2

2.2 Data Mining 2

3 Results **2**

4 Discussion **2**

5 Conclusion **3**

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 mechanical, electrical, software, or combination thereof 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 **F**acility **D**evice **E**xperience (MAUDE) database and are publicly accessibly. The MAUDE database contains approximately 3.7 million records dating back to 1991.

Many previous works have focused on analyzing the data in the MAUDE database to extract trends related to specific devices [**?**, **?**]. 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 our knowledge, no work has been published using this new API to acquire a larger set of the data.

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 user [**?**]. Safety analysis of medical devices must consider more than the device, it must also consider how the device interacts with human actors [**?**]. 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 [**?**]. Work by Mason-Blakely and Weber has tailored this model for analysis of software in health care [**?**]. The STAMP EMR model is visible below:

Mason-Blakey and Habibi used the STAMP EMR model was used 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.

2 Methods

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.

2.1 Data Pre-Processing

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.

2.2 Data Mining

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.

3 Results

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.

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

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.

References

[1] Jacqueline Fawcett. On the requirements for a metaparadigm: An invitation to dialogue commentary. 9(3):94–97.