Medical Device Recall Prediction Using MAUDE Reports

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Medical devices are commonly used by patients worldwide. However, they can be subject to malfunction when they are in use. This can lead to injury, bodily harm, or even death. To combat this, a device recall is usually instituted after enough instances of harm. Although recall prevents any further damage from occurring, patients who were affected before the recall's enforcement remain so. This prompts the question: can medical device recall be predicted earlier to identify dangerous devices before they cause harm? To do this, the researcher has created a model with Python that is trained on data from the Manufacturer and User Facility Device Experience (MAUDE) database. MAUDE is a form of post-market surveillance that houses medical device reports (MDRs). MDRs describe individual incidents of device-related injury or harm, and have a textual adverse event description field, which will be used in the model to predict the devices that have the greatest risk of recall. Previous attempts have been undertaken, most notably Ensign, 2016. However this work is limited due to age and a lack of public availability. This project has been successful in creating an accurate model (accuracy scores >95%) to predict ICD Lead recall. ICD Leads were selected to create this model due to their common usage, appearance in previous research, and to minimize workload while increasing model performance. The code for this project is publicly available as a GitHub repository, and results show this approach's feasibility as a form of post-market surveillance.