Automated Classification of Computer-based Medical Device Recalls:

An Application of Natural Language Processing and Statistical Learning

Homa Alemzadeh, Raymond Hoagland, Zbigniew T. Kalbarczyk, Ravishankar K. Iyer
Coordinated Science Laboratory, University of Illinois at Urbana-Champaign

BACKGROUND

- **FDA recalls database:** publicly available collection of medical device recalls since 2002.
- **Recalls:** Voluntary actions, taken by manufacturers to correct or remove medical devices that violate the FDA laws.
- Several hundred recalls are reported each year, but only a fraction are related to computer-based medical devices.

EXAMPLE RECALL RECORD

Class 2 Recall
Solar 8000i with Patient Data Module / Transport Pro Monitor

See Related Information

General recall information

Date Posted	November 15, 2010
Recall Status[1]	Terminated on May 17, 2012
Recall Number	Z-0363-2011
Recall Event ID	56461
Premarket Notification 510(K) Number	K071073
Product Classification	Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms) - Product Code MHX
Product	GE Healthcare Transport Pro® Monitor with the CARESCAPE™ Patient Data Module.
Recalling Firm/ Manufacturer	GE Healthcare, LLC 3000 N Grandview Blvd Waukesha, Wisconsin 53188-1615
Consumer Instructions	Contact the recalling firm for information
Manufacturer Reason for Recall	Transport Pro Monitor stops communication with the CARESCAPE Patient Data Module (PDM) after 414 days of continuous run time. This time will equate to different amounts of real time depending on how much the units is actually in service per day. Transport Pro contains an internal timer that is used to control the software and remind users to perform preventive maintenance. When this internal timer
FDA Determined Cause [2]	DESIGN: Software Design
Action	GE Healthcare issued an "Urgent Medical Device Correction" letter dated September 17, 2010 to consignees. The letter was addressed to Hospital Administrator, Head of Biomedical Engineering and Nursing Manager. The letter described the product, Safety Issue, Affected Product Details, Safety Instructions, Product Correction and Contact Information. Service representatives will updates all of the affected Transport Pros with PDM that were distributed. Customers may contact GE at 262-548-2731 about this correction.
Quantity in Commerce	3256
Distribution	Worldwide Distribution: Domestic in the states of AL, AZ, AR, CA,CT, CO, DC, FL, GA, ID, IL, IN, IA, KY, LA, MD, MA, ME, MI, MN, MS, MO, NE, NV, NJ, NM, NY, NC, OH, OK, PA, SC, TN, TX, VA, VT, WA, WI, and WY; and internation in the countries of BRAZIL, BERMUDA, BELGIUM, AUSTRIA, AUSTRALIA, CANADA, CHINA, COLOMBIA, CZECH REPUBLIC, DENMARK, EGYPT, ESTONIA, FINLAND, FRANCE, GERMANY GREECE, INDONESIA, IRELAND, ITALY, JAPAN, JORDAN, KUWAIT, LEBANON, LITHUANIA, MALAYSIA, MAURITIUS, NETHERLANDS, NEW ZEALAND, NORWAY, POLAND, REPUBLIC OF KOREA, SAUDI ARABIA, SINGAPORE, SOUTH AFRICA, SPAIN, SWEDEN, SWITZERLAND, TAIWAN, THAILAND, TRINIDAD 7 TOBAGO, and the UNITED KINGDOM.
Total Product Life Cycle	TPLC Device Report

Device type
Device problem
Recovery action taken by the manufacturer
Number of devices affected by the recall
Device category and medical speciality
Device approval information

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database
510(K)s with Product Code = MHX and Original Applicant = GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES

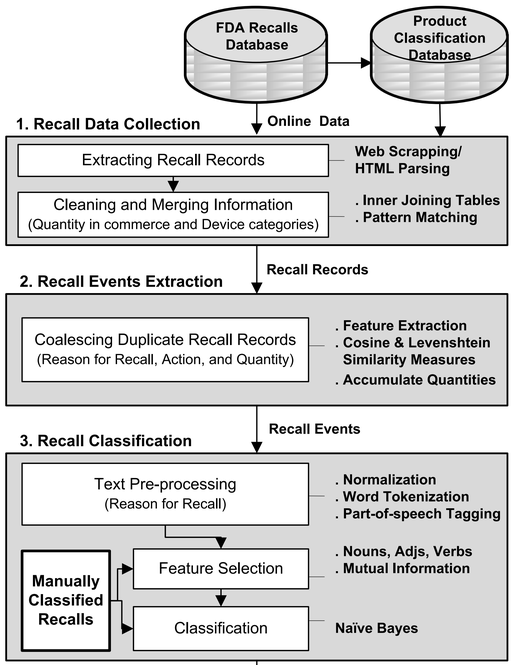
GOALS AND CHALLENGES

- Study of recalls data provides valuable insights on past failures of medical devices and how their future designs could be improved.
- Important fields in the recall records, including *Product Name, Reason for Recall,* and *Action,* are in unstructured text format.
- Identification of causes and impacts of failures requires semantic interpretation of the natural language text.
- Manual review of several thousands records requires significant amount of human effort, and simple keyword searching might not provide accurate results.

PROPOSED APPROACH

Recalls Data Analysis Flow:

- **Collection of data from online databases**
- **Extraction of unique recall events and calculating number of affected devices**
- **Identification of computer-related recalls**



$$MI(R_k, C_r) = \sum_{i,j \in \{0,1\}} P(R_k = i, C_r = j) \log_2 \frac{P(R_k = i, C_r = j)}{P(R_k = i).P(C_r = j)}$$

$$Class(R) \propto \underset{c \in \{0,1\}}{argmax} \left[log\, P(c) + \sum_{1 \le i \le M} log P(k_i|c) \right]$$

Fault Classes	Example Related Keywords
Software	software, application, function, code, version, backup, database, program, bug, java, run, upgrade.
Hardware	board, chip, hardware, processor, memory, disk, pcb, disk, electronic, electrical, circuit, leak, capacitor, transistor, resistor, short-circuit.
Other	error, system, fail, verification, self-test, reboot, web, robotic, calculation, document, workstation.
Battery	battery, power, supply, outlet, plug, power-up, charger, discharge.
Input/ Output	sensor, alarm, message, screen, interface, monitor, connect, button, scanner, key, speaker, wireless.

Categorized Computer-related Recalls

- FDA Recall Number
- Recall Class
- Date Posted
- Product Name
- Recalling Firm / Manufacturer
- Reason for Recall
- Manufacturer Recovery Action
- FDA Medical Specialty
- FDA Product Code
- Device Category - Name
- Device Category - Class
- FDA Submission (Approval) Type
- Number of Recalled Devices
- Fault Class
- Failure Mode
- Recovery Action Category

Fault Class	Example Computer-related Recall Events: Reason for Recall	Summary of Action	Failure Mode	Num. of Records	Num. of Devices
Software	Software interface problem; when connected to the main system, the instrument is not recognized by the system which makes it nonfunctional. Risks are loss of operability; delay in surgery; and loss of dexterity.	Urgent letter was issued to customers, instructing them to return the product.	Device Operation Failure	1	11
Hardware	Failure to deliver Shock; a defective capacitor may cause the delay or non-delivery of the defibrillating shock which may result in failure to resuscitate the patient.	The firm issued instructions to customers on how to return their device and will exchange the recalled defibrillator with a replacement.	Treatment Interrupt/ Therapy Failure	1	1,794
Battery	Insulin pumps exhibit an intermittent loss of power due to loss of contact between battery cap and canister, resulting in device resetting, which may result in failure to administer insulin therapy and hyperglycemia.	The recalling firm issued notification to the patients o inform them of the problem and that they needed to replace the battery.	Treatment Interrupt/ Therapy Failure	5	7,152
Input/ Output	Speakers on patient monitors may fail; causing absence of audible alarms and delaying patient treatment.	The firm sent notification and instructions to customers on actions to take while awaiting their replacement speaker assemblies.	Alarm/ Message Error	2	21,654

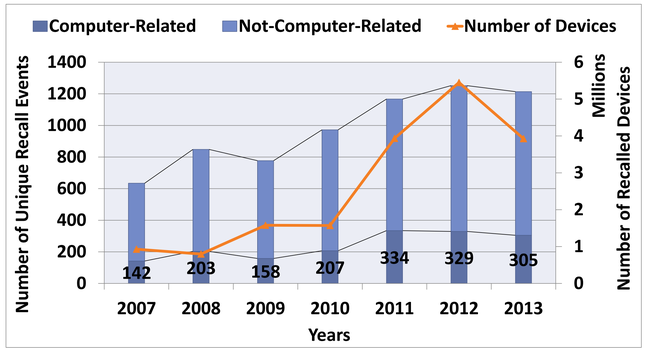
RESULTS

Classification accuracy:

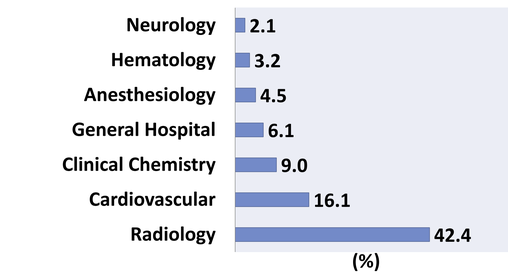
- **Training set: 5,354** recall events (2006-2011)
- **10-fold cross-validation** on the training set:
  - Sensitivity **87%**, specificity **88%**, and F-Score **77%**
- **Testing on new recalls data** (2012 – 2013) manually verified:
  - Sensitivity **93.8%** and specificity **95.8%**

Sample analysis using the proposed approach:

- A total of **16,881** records were submitted during **2007-2013.**
- About **6,864 (40.7%) unique** recall events were identified.
- A total of **1,678 (24.4%)** of recall events were **computer-related**.
- Computer-related recalls affected around **18,189,751 devices.**



- About **58% of computer-related** recalls were related to **radiology** and **cardiovascular** devices.



CONCLUSIONS

- Analysis of recalls descriptions using natural language processing and statistical learning techniques provides accurate automated identification of the computer-related recalls.
- The proposed approach enables faster analysis of larger sets of recalls data, in order to better understand the causes and impacts of failures in computer-based medical devices.

See also: H. Alemzadeh, R. K. Iyer, Z. Kalbarczyk, J. Raman, "Analysis of Safety-Critical Computer Failures in Medical Devices," *IEEE Security and Privacy, vol. 11, no. 4, pp. 14-26, July/August 2013.*