Findings

Medical devices fail routinely, endangering patients and representing a status quo enabled by lax testing requirements for medical device manufacturers. Unfortunately, lax reporting on medical device failures means that it can be difficult to detect a dangerous device on the market. Combining large datasets and statistical analysis, we have given some shape to the response to dangerous devices. Analyzing the International Medical Devices Database (MAUDE) database has revealed that some manufacturers are more prone to deadly device malfunctions than their competitors.

Several statistical tests were performed on the MAUDE dataset to reveal telling information about the fatality rates of medical devices. Maximum and total number of deaths were taken from device reports grouped by the following columns: "DEVICE_REPORT_PRODUCT_CODE" (product code) from MAUDE's "devices" dataset, "GENERIC_NAME" (device name) from MAUDE's "devices" dataset, and "MANUFACTURER_G1_NAME" (manufacturer) from MAUDE's "master" dataset. The top three product codes that reported the highest number of deaths in a single incident (in order) are "ELECTRODE, ION SPECIFIC, SODIUM" products at 52 deaths, "ANALYZER, CHEMISTRY (PHOTOMETRIC, DISCRETE), FOR CLINICAL USE" products at 48 deaths, and "Ige, Antigen, Antiserum, Control" products at 45 deaths. The top three device names with the highest number of deaths in a single incident are the "CLINICAL CHEMISTRY ANALYZER – JJE" at 52 deaths, the "CHEMISTRY ANALYZER" at 48 deaths, and the "IMMUNO-ASSAY ANALYZER" at 45 deaths. The top three manufacturers with the highest number of deaths in one incident are "ROCHE INSTRUMENT CENTER AG" at 52 deaths, "SIEMENS HEALTHCARE DIAGNOSTICS INC." at 45 deaths, and "HITACHI HIGH TECH CORP" at 43 deaths. Roche Instrument Center's clinical chemistry analyzer (an electrode, ion specific, sodium product) was the device with the greatest number of deaths in one single incident.

The top three product codes that reported the greatest total number of deaths (in order) are "Pump, infusion, insulin, to be used with invasive glucose sensor" products at 623,653 total deaths, "Pump, Infusion, Insulin" products at 386,913 total deaths, and "System, Test, Blood Glucose, Over The Counter" products at 380,100 total deaths. The top three device names with the largest number of total deaths are the "CONTINUOUS GLUCOSE MONITOR" at 474,396 total deaths, the "INSULIN INFUSION PUMP / SENSOR AUGMENTED" at 313,947 total deaths, and the "GLUCOSE MONITORING SYS/KIT" at 261,193 total deaths. The top three manufacturers with the highest number of deaths are "MEDTRONIC PUERTO RICO OPERATIONS CO." at 643,691 total deaths, "DEXCOM, INC." at 328,691 total deaths, and "MEDTRONIC MINIMED" at 274,028 total deaths.

Variance analysis was performed on the total number of deaths using product code, device name, and manufacturer as treatments separately using one-way ANOVA. The dataset contained too many observations for the compiler to compute the necessary test statistics, so samples of a 0.001 factor of the true dataset were taken from the dataset. For each test, a minimum of 10 ANOVAs were tested on individually drawn samples. For device names, 10 samples all returned statistically significant F-statistics from their ANOVA tests, giving cause to reject the null hypothesis that all treatment levels (device names) are identical. From this, it can be concluded that at least one device name yields a significantly different number of deaths than the others and that the average number of deaths in a given event does indeed vary across device names. For manufacturers, 9 out of 10 samples returned statistically significant F-statistics for their ANOVA tests, again giving reasonable cause to reject the null hypothesis. This indicates that the average number of deaths has statistically significant variance across (or at least for one) manufacturers . For the product codes, 5 out of 10 of the samples returned statistically significant F-statistics for their ANOVA tests. A further 10 samples were drawn and again only half returned significant F-statistics. Without substantial evidence to reject the null hypothesis, it was concluded that there is not significant variance in deaths per incident across product codes.

Next, more focused variance analysis and multiple comparison tests were performed on device names and manufacturers. One-way ANOVA was again run on the variables names, but instead of using the full dataset, only the device names with the 5 highest number of total deaths were used and samples of a 0.01 factor size of the true dataset were taken. For device names, the following treatments were analyzed: "CONTINUOUS GLUCOSE MONITOR", "INSULIN INFUSED PUMP / SENSOR AUGMENTED", "GLUCOSE MONITORING SYS/KIT", "INSULIN INFUSION PUMP", and "INFUSION PUMP". Fewer than half of the 10 samples returned significant F-statistics from their ANOVA tests. Failing to reject the null hypothesis, device names was not pursued for post-hoc analysis. For manufacturers, the following treatments were analyzed: "MEDTRONIC PUERTO RICO OPERATIONS CO.", "DEXCOM, INC.", "MEDTRONIC MINIMED", "LIFESCAN EUROPE, A DIVISION OF CILAG GMBH INTL", and "ANIMAS CORPORATION". Almost all 10 samples returned F-statistics from their ANOVA tests. Rejecting the null hypothesis, post-hoc multiple comparison was performed on these five manufacturer treatment levels.

Tukey's Honestly Significant Difference (HSD) test was run to perform pairwise comparison of the mean number of deaths per incident across the treatment levels. The comparison revealed significant mean differences between "MEDTRONIC MINIMED" and each of the other manufacturers. There was no statistically significant difference between the other four manufacturers. The results can be interpreted as follows: of the 5 medical device manufacturers with the highest number of deaths attributed to them, "MEDTRONIC MINIMED" was statistically different from the rest, while the rest of the comparisons in the analysis were fairly equal. The mean number of deaths per incident reported by Medtronic MiniMed is 1.0002. The variance in deaths per incident across these five manufacturers is demonstrated in Figure 5. Note that column 3 (MEDTRONIC MINIMED) has far more outliers above the mean. This implies that Medtronic MiniMed's variance is characterized by higher deaths per incident than the other manufacturers analyzed.

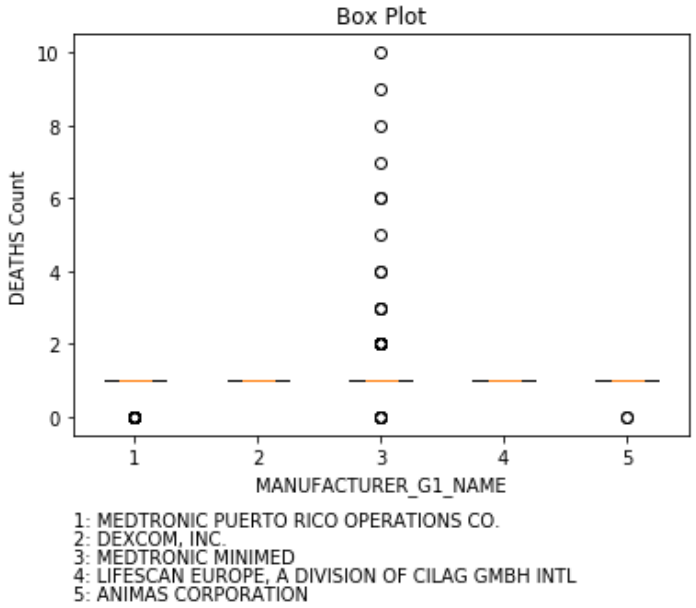

Figure 5: Box plots of deaths per incident across manufactures with most total deaths

The results of these variance analysis and multiple comparison tests prompts further investigation into Medtronic MiniMed as to what features make their mean number of deaths different from other manufacturers with similar numbers of total deaths. Perhaps their data is skewed by several incidents with inordinately high (or low) number of deaths relative to their mean.

Perhaps they have considerably fewer (or more) data points to work with. Perhaps their products are just more prone to deadly failures.