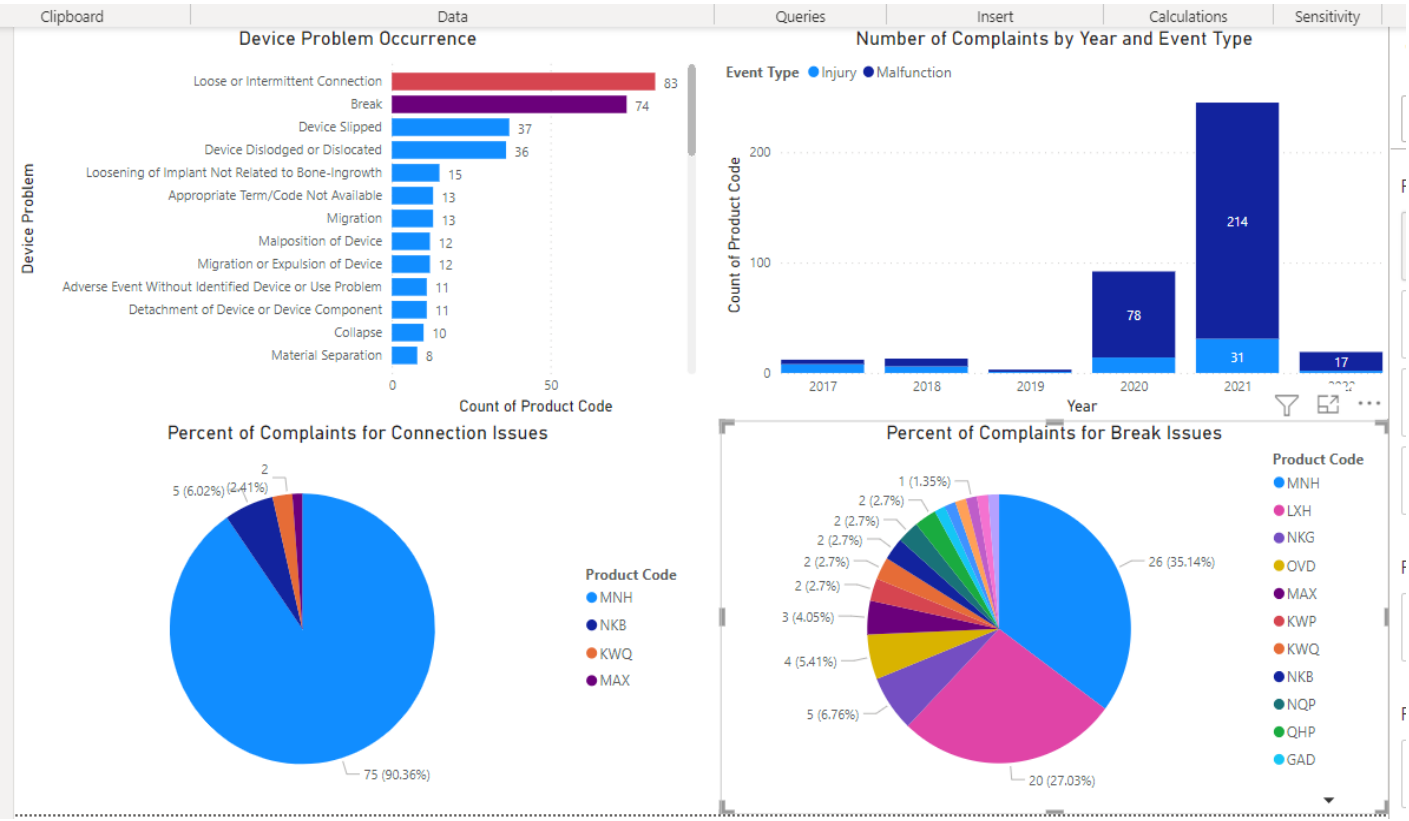

This Dashboard represent medical device product malfunction by type of malfunction and by the device code of the medical product.

This document represents the presentation I would give while discussing my Dashboard.

The medical industry has relied on hardware to correct joint, bone and musculoskeletal pathology. As advances in hardware technology progressed, there are instances when a hardware device will malfunction either during the surgical procedure or post-operation. It is the responsibility of the manufacturer to monitor medical devices after the device has been approved for use and has been utilized in medical practice.

The “Device Problem Occurrence” graph represents the type of malfunction and number of events per problem category. For example “Loose or Intermittent connection” occurred 83 times and was the most represented issue in the problem category. The second most common was “Break” seen 74 times. In third and fourth place was “Device Slipped” with 37 occurrences and “Device Dislodged or Dislocated” with 36 occurrences. The other nine problem categories were half or less common than the fourth place problem category.

The second graph which is labeled “Number of Complaints by Year and Event Type” demonstrates that malfunction of the medical device was much more common than an injury resulting in damage to the medical device. You can also see that between 2017 to 2019, there

was less complaints versus 2020 and 2021. This could be due to several factors including an increase in production and sales of the most common problematic medical device or a switch to an inferior material or manufacture process.

The products represented in this Dashboard seem to be associated with the musculoskeletal system and involves an Orthopedic Surgeon performing the procedures in an operating room. The most common risks following hardware implantation or removal are infection, nerve damage, re-fracture, the risks of anesthesia use and blood clot formation. As we look closer at the devices with the highest complaints, we look to see what exactly was the problem which caused a malfunction to occur.

The third graph titled “Percent of Complaints for Connection Issues” shows that the device with product code MNH was the most problematic. After reviewing the Event Text which included the Event Description, we found that the most common problem was loose locking which occurred 69 out of 75 complaints with connection issues.

The fourth graph titled “Percent of Complaints for Break Issues” demonstrates that out of 74 complaints of equipment breakage, 26 were the MNH product code and 20 were the LXH product code. Upon further review of the complaints it is noted that MNH had 15 rod breakage failures and 11 screw breakage failures. For the LXH breakages, the point of failure was distributed evenly between categories which included Tip of Rod, Tip of K Wire, Tip of Screwdriver, Tip of Screw just to name a few.

In conclusion, the product code MNH had the most amount of complaints in the top two categories in Device Problem Occurrences. This could be due to the number of MNH units is much more that the other units and therefore has more opportunities for malfunction in the population. Another possibility is that the manufacture process for MNH units has been changed to an inferior process that results in more malfunctions or a change in the materials of the MNH units. A thorough investigation must be done to better understand the reason for this outcome.