

Introduction

Cook Medical invents, manufactures, and delivers medical devices to the healthcare systems around the world.

“Serving patients is a privilege, and we demand the highest standards of quality, ethics, and service in all that we do”.

This project aims to create database linkages between product that is non-conforming due to raw material failures or due to manufacturing failures, with work orders and finished product, and attempt to correlate non-conforming product with environmental and other factors.

Nonconformance

What is it?

- Products that do not meet Cook Medical’s manufacturing quality standards
- Each nonconformance found is logged to keep track of product manufacturing failures.

Why is it important?

- Nonconformances can affect the company in different areas:
 - Production speed
 - Financial impact
 - Timely patient access to product

Nonconformance Questions

1. What are the overall top 5 products that result in the most non-conformances?
2. For each of the top 5 products, what are some of the other aspects of the nonconformance?
3. How do manufacturing sites compare across nonconformances?

Results

Question 1 Figures:

The Top 5 Nonconforming Products

Product (RPN Prefix)
K-JETS
HNB
SILICONE
MA
IGTF

Figure 1. These are the five products with the most nonconformance quantities.

Top Nonconforming Product Each Month

Date	Product (RPN Prefix)
1/2021	K-JETS
2/2021	K-JETS
3/2021	K-JETS
4/2021	SILICONE
5/2021	K-JETS
6/2021	K-JETS
7/2021	K-JETS
8/2021	K-JETS
9/2021	K-JETS
10/2021	K-JETS
11/2021	K-JETS
12/2021	SILICONE
1/2022	K-JETS
2/2022	K-JETS
3/2022	K-JETS
4/2022	K-JETS
5/2022	K-JETS
6/2022	K-JETS
7/2022	HNB
8/2022	K-JETS
9/2022	IGTF
10/2022	K-JETS
11/2022	HNB
12/2022	K-JETS

Figure 2. These are the top products with the most nonconformances each month in the data gathered.

Question 3 Figures:

Number of Nonconformances by Category Code at Each Manufacturing Site

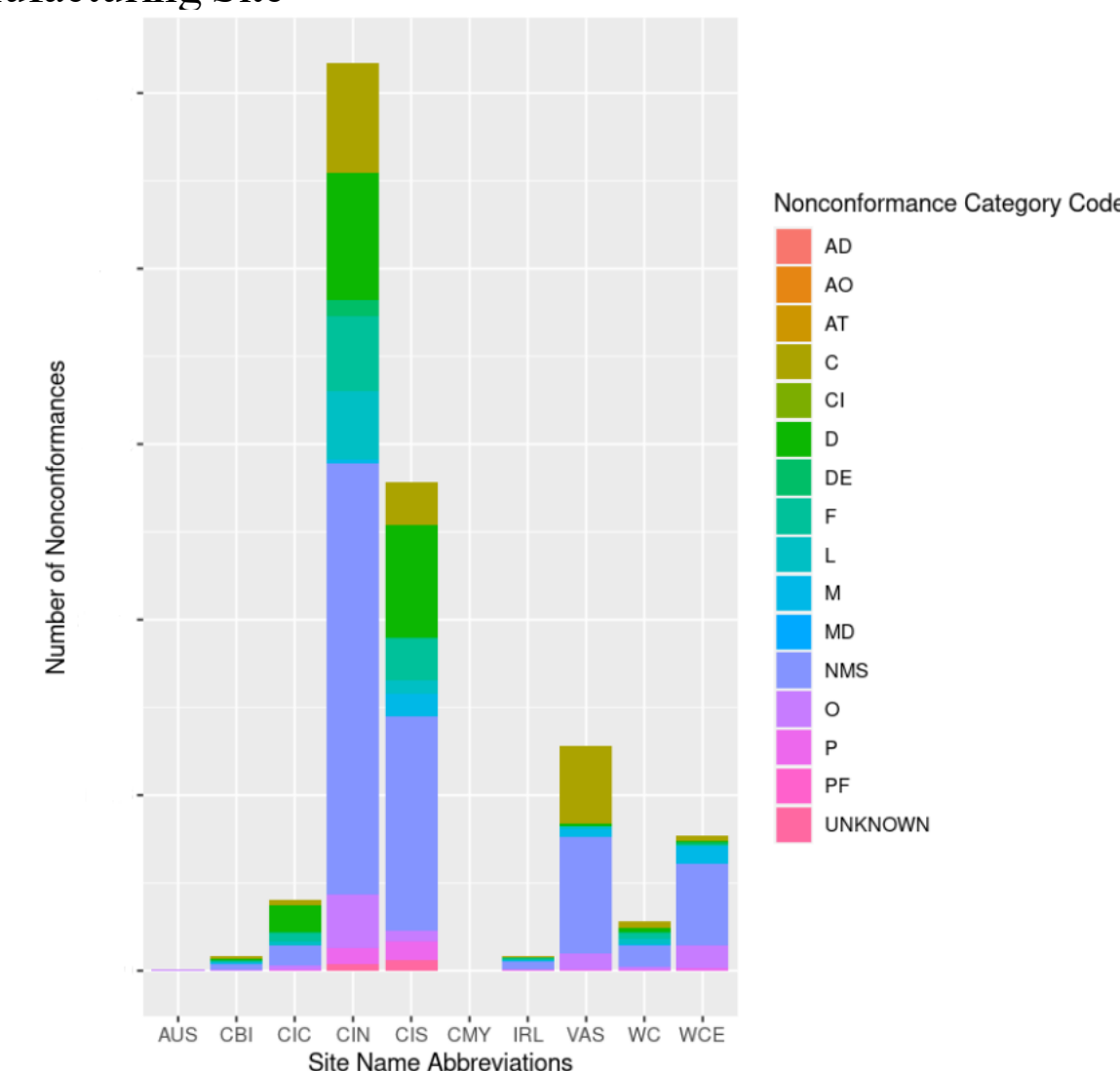


Figure 5. For each nonconformance category code, we display the number of a nonconformances at each site. There are some category codes that are not used at every site.

Question 2 Figures:

The Top 5 Nonconforming Products and Nonconformance Category Codes

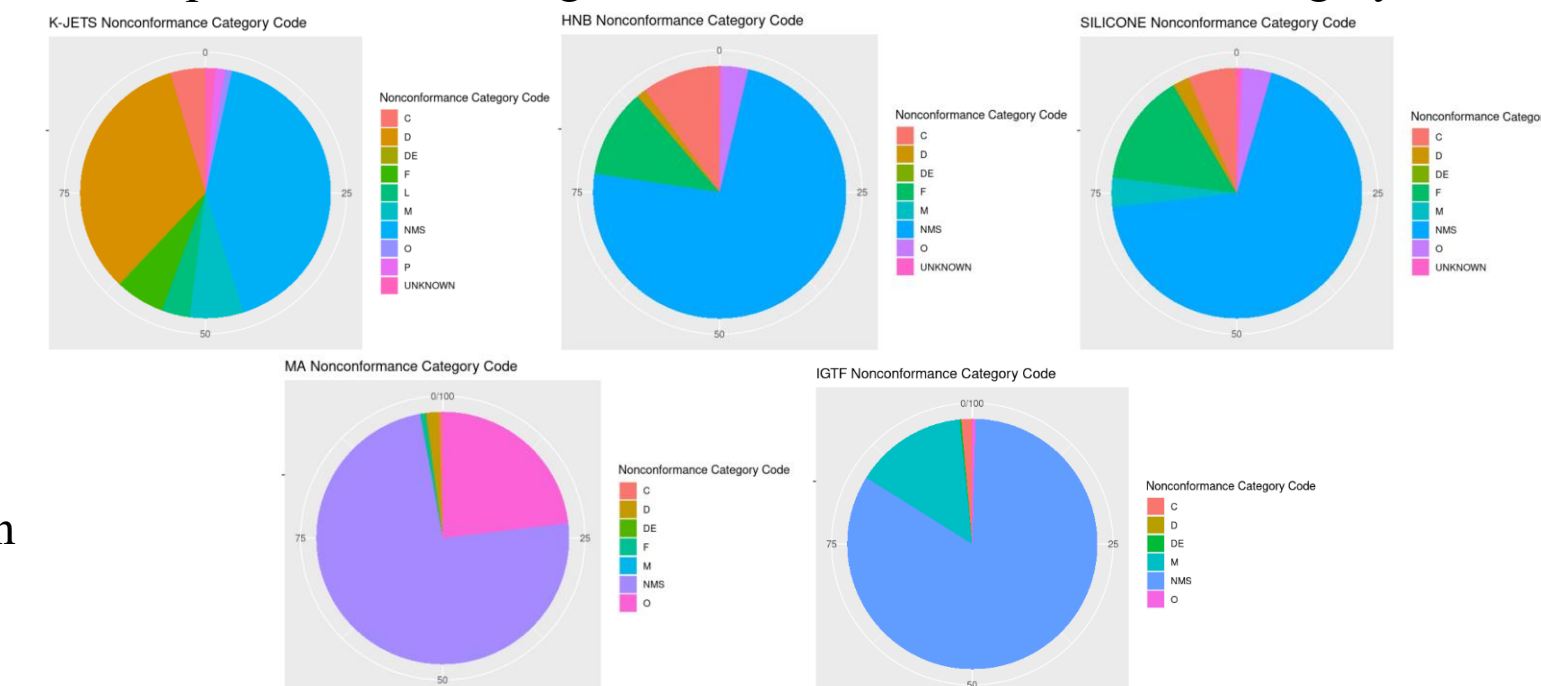


Figure 3. For each of the top five quantities from Figure 1, the proportions of nonconformance category codes.

The Top 5 Nonconforming Products and Department Type

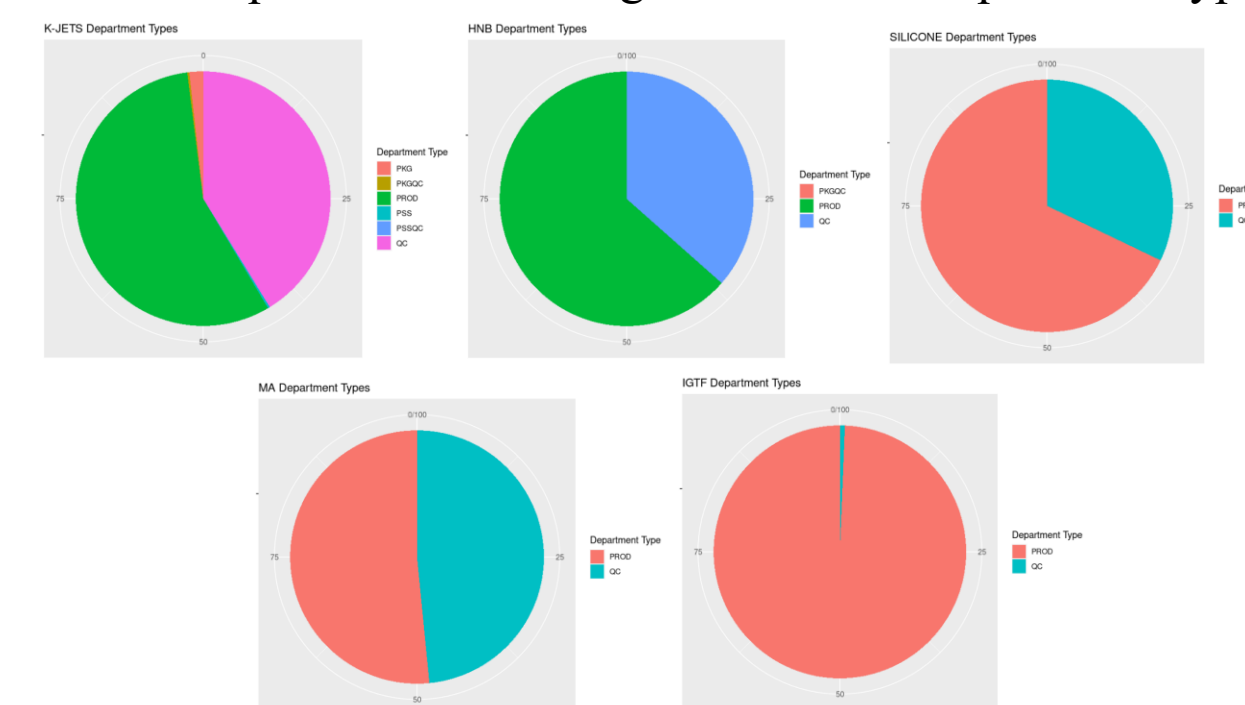


Figure 4. For each of the top five quantities from Figure 1, the proportions of department types.

Number of Manufacturing Sites Using Each Nonconformance Category Code

Nonconformance Code	Number of Sites
AD	2
AO	2
AT	2
C	9
CI	2
D	9
DE	9
F	8
L	9
M	9
MD	2
NMS	9
O	9
P	9
PF	1
UNKNOWN	5

Figure 6. For each nonconformance category code, these are the number of sites that utilize the code. There are some codes that are used at almost every site and there are also codes that are only used at one or two sites.

Discussion

Figure 1 displays the top five nonconforming products over a two-year period. This information could be useful in narrowing down which products may need improvements to their production process. Figure 2 shows that the top nonconforming product of every month is a part of the top five from Figure 1, so there are no outliers in any month. Figures 3 and 4 give insight to where the majority of nonconformances are found in department types and category codes. We research this further in Figure 5 by examining these category codes at each manufacturing site, where we see that most of the sites have the same category with the most nonconformances. In Figure 6, we see that not every manufacturing site uses the same nonconformance category codes, there is a range in the number of sites for each code. Uniformity could be improved across sites for easier analysis.

Interactive Dashboard

Another aspect of our project is creating an interactive dashboard that gives further information to Cook Medical. This dashboard allows Cook engineers to analyze specific factors (location, process, etc.) and look at figures to decipher where and why NCs are occurring.

Acknowledgments

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