The Impact of COVID-19 on Medical Device Reporting and Investigation

By Zoe Pruitt, MA*, Christian Boxley, BS*, Seth A. Krevat, MD†, Srijan Sengupta, PhD§, Raj M. Ratwani, PhD‡§, & Allan Fong, MS‡

Corresponding author
MedStar Health National Center for Human Factors in Healthcare
Georgetown University School of Medicine
North Carolina State University

Disclosure: The authors declare that they have no relevant or material financial interests.
This project was funded by the National Institutes of Health (Award Number: 1R01LM013309-01).

DOI: 10.33940/data/2021.9.3
COVID-19 and the resulting pandemic changed nearly every aspect of medicine, including medical device reporting. Medical device reporting is a strategy used by the U.S. Food and Drug Administration (FDA) to monitor medical device safety. The FDA stores submitted reports in the Manufacturer and User Facility Device Experience (MAUDE) database, which serves as a passive tool for postmarket surveillance.1,2 Anyone can submit reports voluntarily, but some entities (e.g., manufacturers, importers, user facilities) are mandatory reporters and must report adverse events.3

The FDA asks mandated reporters to submit reports within a specific time frame, typically 30 days for manufacturers.4 However, in May 2020, the FDA released updated guidance formalizing the government agency’s expectations for adverse event reporting during a pandemic.5 The guidance requests that firms report adverse events when possible but that the “FDA does not intend to object” if reports are delayed due to pandemic-related “high employee absenteeism.”

It is evident that the FDA expected the pandemic to disrupt manufacturers’ overall capabilities to report issues with medical devices. However, it remains unclear exactly which aspects of the reporting and investigative process have been impacted by the pandemic. The goal of this paper is to answer this question. The pandemic presents a multitude of unique factors to the healthcare system and the world, which could impact medical device reporting. These include increased use of specific devices (e.g., ventilators), the moratoriums on elective procedures, patients’ reluctance to seek in-person care, limited travel, and delayed postal service.

MAUDE contains millions of reports about medical devices, and some of these reports include data about the efficacy and safety of medical devices. However, it is difficult to find relevant and actionable signals in the noise. We sought to analyze reports in the MAUDE database that mention COVID-19 or related terms. We used word search and manual review to understand how the COVID-19 pandemic impacted medical device reporting. The resulting reports describe manufacturers’ challenges to investigate medical device events due to the pandemic.

## Methods

Reports submitted between January 1, 2020, and July 31, 2020, were retrieved from the MAUDE database via keyword search. The search period begins in January because this is when COVID-19 was first identified in the United States. Reports were included in the manual review if they contained COVID-19 phrases ("COVID-19", "corona", "coronavirus", "covid-19", "COVID-19", "pandemic") in either the free-text description entered by the reporter or the manufacturing narrative entered by the device manufacturer. The reports with COVID-19-related phrases were categorized using the codebook described in Table 1.

Two coders (ZP, CB) dually coded 10% of the data with the codebook described in Table 1. Coders discussed disagreements when necessary, and a third coder (AF) was included as a tiebreaker when necessary. The inter-rater reliability kappa scores were 0.96 for Relevance to COVID-19 and 0.85 for Patient Care Impact. The inter-rater reliability kappa scores were 0.96 for Relevance to COVID-19 and 0.85 for Patient Care Impact. The inter-rater reliability kappa scores were 0.96 for Relevance to COVID-19 and 0.85 for Patient Care Impact.

### Results

From the 816,476 reports submitted between January 1 and July 31, 2020, 3,500 (0.43%) included phrases related to COVID-19. Of these reports, 4.8% (167/3,500) described adverse events during COVID-19 patients’ treatment, and 30.3% (1,085/3,500) described barriers manufacturers faced investigating malfunctioning devices during the pandemic. 4.9% (172/3,500) of reports were not related to COVID-19. Malfunctions were clinically significant in 85.8% (3,004/3,500) of reports.

Reports indicate challenges some manufacturers had when investigating medical devices during the pandemic. The pandemic made investigating implants uniquely difficult, as restrictions to person-to-person contact limited the type of care patients could receive. Because full-scale investigations into malfunctioning devices may be difficult to perform during the pandemic, the safety issues may go unaddressed and result in future harm to patients.

### Discussion

The COVID-19 pandemic and the myriad of health-care, travel, and shipping challenges it created impacted how manufacturers reported and investigated events involving medical devices.

### Patient Care Impact

Not Clinically Significant

- Reports that describe medical device malfunctions that did not change the patient’s condition or outcome.

### Summary

The COVID-19 pandemic impacted medical device reporting. The FDA asks mandated reporters to submit reports within a specific time frame, typically 30 days for manufacturers. However, in May 2020, the FDA released updated guidance formalizing the government agency’s expectations for adverse event reporting during a pandemic. The guidance requests that firms report adverse events when possible but that the “FDA does not intend to object” if reports are delayed due to pandemic-related “high employee absenteeism.”

It is evident that the FDA expected the pandemic to disrupt manufacturers’ overall capabilities to report issues with medical devices. However, it remains unclear exactly which aspects of the reporting and investigative process have been impacted by the pandemic. The goal of this paper is to answer this question. The pandemic presents a multitude of unique factors to the healthcare system and the world, which could impact medical device reporting. These include increased use of specific devices (e.g., ventilators), the moratoriums on elective procedures, patients’ reluctance to seek in-person care, limited travel, and delayed postal service.

MAUDE contains millions of reports about medical devices, and some of these reports include data about the efficacy and safety of medical devices. However, it is difficult to find relevant and actionable signals in the noise. We sought to analyze reports in the MAUDE database that mention COVID-19 or related terms. We used word search and manual review to understand how the COVID-19 pandemic impacted medical device reporting. The resulting reports describe manufacturers’ challenges to investigate medical device events due to the pandemic.

## Tables

### Table 1. Codebook for the Analysis of COVID-19-Related Reports

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 Treatment</td>
<td>Reports that discuss devices and equipment directly used to diagnose, treat, and prevent COVID-19.</td>
<td>85.8% (3,004/3,500)</td>
</tr>
<tr>
<td>Investigative Delay</td>
<td>Reports that discuss delays to manufacturer’s investigation of a device in any MAUDE report due to COVID-19.</td>
<td>REPORTS Coded as COVID-19 Treatment and Investigative Delay MAUDE Reports Between January 1, 2020, and July 31, 2020</td>
</tr>
<tr>
<td>Patient Care Impact</td>
<td>Reports that mention COVID-19 incidentally, without reference to investigative delays or COVID-19 treatment.</td>
<td>90.3% (3,161/3,500)</td>
</tr>
<tr>
<td>Not Related</td>
<td>Reports that describe medical device malfunctions that did not change the patient’s condition or outcome.</td>
<td>73.1% (1,225/1,676)</td>
</tr>
</tbody>
</table>

### Table 2. Frequency of COVID-19 Treatment and Investigative Delay MAUDE Reports Between January 1, 2020, and July 31, 2020

<table>
<thead>
<tr>
<th>Relevance Categories</th>
<th>Clinically Significant</th>
<th>Not Clinically Significant</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 Treatment</td>
<td>68</td>
<td>99</td>
<td>167</td>
</tr>
<tr>
<td>Equipment to treat COVID-19</td>
<td>25</td>
<td>7</td>
<td>32</td>
</tr>
<tr>
<td>PPE</td>
<td>2</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Investigative Delay</td>
<td>2,936</td>
<td>225</td>
<td>3,161</td>
</tr>
<tr>
<td>Implant</td>
<td>2,748</td>
<td>6</td>
<td>2,754</td>
</tr>
<tr>
<td>Dental</td>
<td>2,080</td>
<td>0</td>
<td>2,080</td>
</tr>
<tr>
<td>Breast</td>
<td>304</td>
<td>1</td>
<td>305</td>
</tr>
<tr>
<td>Neural Stimulator</td>
<td>185</td>
<td>0</td>
<td>185</td>
</tr>
<tr>
<td>Cardiac</td>
<td>75</td>
<td>2</td>
<td>77</td>
</tr>
<tr>
<td>Other</td>
<td>104</td>
<td>3</td>
<td>107</td>
</tr>
<tr>
<td>Glucose Monitoring</td>
<td>37</td>
<td>109</td>
<td>146</td>
</tr>
<tr>
<td>External Infusion Pump</td>
<td>20</td>
<td>28</td>
<td>48</td>
</tr>
<tr>
<td>Catheter</td>
<td>29</td>
<td>9</td>
<td>38</td>
</tr>
<tr>
<td>Stapler</td>
<td>5</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>Other</td>
<td>97</td>
<td>67</td>
<td>164</td>
</tr>
<tr>
<td>Not Related</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Total</td>
<td>3,004</td>
<td>324</td>
<td>3,500</td>
</tr>
</tbody>
</table>

### Results

From the 816,476 MAUDE reports, 3,500 (0.43%) included COVID-19 phrases, of which 167 (4.8% of 3,500) were coded as COVID-19 Treatment, 3,161 (90.3% of 3,500) were coded as Investigative Delay, and 122 (3.4% of 3,500) were unrelated to COVID-19. See Table 2 for details. Reports that included COVID-19 phrases peaked in May 2020, with 1,207 (34.5%) reports. The distribution of reports over time can be found in Figure 1.

### Reports Coded as COVID-19 Treatment

Of the 167 reports coded as COVID-19 Treatment, 122 (73.1%) related to COVID-19 tests or COVID-19 antibody tests, 32 (19.2%) described issues with equipment used in the treatment of COVID-19, and 17 (7.8%) related to personal protective equipment (PPE). Malfunctions were clinically significant in 61 (36.5%) of 167 COVID-19 Treatment reports.

### COVID-19 Tests

The 122 (73.1% of 167) reports about COVID-19 tests describe three different issues: the validity of testing, discomfort in the nostril after testing, and the tip of the swab breaking off inside the patient’s nose during a test.

..."A customer reported three samples producing a target 2 positive result with a very low ct value, which then tested negative on repeat. The customer was suspicious of the original results and did not report out results for these three samples..."
Of the reports coded as Investigative Delay, delays in investigatory procedures, preventing implants from being removed. Multiple reports mentioned that COVID-19 halted implant removal procedures. This delay impacted the facility’s speed and manufacturer investigations.

“The patient was scheduled for a revision, however, the surgery was deemed non-essential and was canceled due to COVID-19.”

Implants Reaching the Patient

The dental implant reports made up more than half of the total reports in the dataset (59.4%, 2,080/3,500), and all of the reports described events that were clinically significant. All of the dental implant reports were classified as clinically significant because the dental implants did not perform as expected (i.e., nonosseointegration), requiring them to be explanted. Some reports also included information at the implant site.

“As per complaint, after a clinical procedure, a dental implant displayed a failure of osseointegration and the implant was explanted.”

During the pandemic, some explantation procedures were canceled or delayed. The delay of an explantation procedure can have many different effects on the patient’s health depending on the type of implant, the severity of the malfunction, and the patient’s overall health. Several reports emphasized that the lack of an explantation procedure placed the patient in an unsafe situation that could lead to future harm.

“The patient’s explantation surgery was delayed because of COVID-19 restrictions. Because of this, the patient’s right tissue expander was implanted in the patient for longer than 6 months, which is contraindicated in the IPL.”

Reports describe patients with malfunctioning implants who consequently no longer received symptom relief. The options for fixing the implants, and getting the patient’s treatment plan back on course during the lockdown, were few and far between.

“The patient reported that she fell on an icy walkway three weeks ago and since her INS has not been working for her symptom control. She has been extremely happy with her symptom so the lack of symptom control made it pretty obvious that something was wrong. She went to a local urgent care provider today and had two impedance checks done and both came up with black across the screen. She is scheduled for a lead revision after the COVID-19 is over...”

Implants and In-Person Patient Care

The 2,754 (87.1% of 3,161) dental implant reports appeared to be due to a bulk submission of reports from a single manufacturer. The manufacturer narratives contain similar stock language that directly references the FDA guidance for reporting in a pandemic. Some manufacturers stated that they were storing the nonfatal serious injury data, intending to submit a follow-up report.

“Non-fatal serious injury stored due to COVID-19 pandemic in accordance with FDA guidance ‘postmarketing adverse event reporting for medical products and dietary supplements during a pandemic’ published March 2020...”

Reports also describe difficult situations where an implanted harmer patients. In one such case, the patient believed they could not receive care due to the moratorium on elective procedures.

“I...now due to COVID-19, we are reluctant to go to hospital to replace or remove. Managing with oral antibiotics and reducing dose...”

Many hospital facilities in lockdown did not accept patients for elective procedures, preventing implants from being removed. In one instance, the report describes dispatching a service engineer to evaluate a malfunctioning device. However, the service engineer could not travel to the user facility to evaluate the device due to travel restrictions.

“One field service engineer was dispatched but due to the lockdown in France because of the COVID-19 virus the unit will be inspected at a later date...”

Limited Capabilities of Manufacturers

Some manufacturers referenced halted investigations due to limited capabilities, though the reports do not thoroughly describe the cause of the limited capacity (e.g., employee absenteism, stay-at-home orders).

“Due to the COVID-19 pandemic, the investigation for this event will be delayed. We will however, send the follow-up report as soon as our laboratory services are able to return to normal.”

Shipment of Devices

Reports mentioned devices being returned to manufacturers, which required manufacturers to evaluate the devices and related events from the available information, such as device history or a report by a user facility. Some manufacturers decided not to accept devices for analysis at all to mitigate employee exposure to COVID-19.

“Following WHO declaration of a global health emergency situation due to the outbreak of corona virus sars-cov-2, it was decided to refrain from shipping of samples to support limiting the spread of the virus. In order to adapt to the global situation in the best possible way. The samples have not been investigated...”

Discussion

Our analysis attempted to understand how the COVID-19 pandemic impacted medical device reporting by analyzing reports in the MAUDE database that mention COVID-19. From reports between January 1, 2020, and July 31, 2020, that mention COVID-19, 4.8% were coded as COVID-19 Treatment and described the medical devices used in the treatment, diagnosis, and prevention of COVID-19. In comparison, 90.3% of those reports were coded as Investigative Delay and described the barriers manufacturers face while investigating malfunctioning devices during the pandemic.

The themes found in the reports are aligned with trends appearing elsewhere in healthcare during the pandemic. Research suggests that approximately 41% of Americans avoided or delayed medical care due to the pandemic. Additionally, elective procedures deferred in the summer of 2020 have created a surgical backlog across the world. One question after the pandemic is how patients, including those impacted by malfunctioning devices, will be given the care they need. Individual facilities will likely bear the responsibility of scheduling missed appointments and procedures. As cases fall, some patients will likely schedule necessary
appointments on their own. However, a proactive approach would see facilities reaching out to their patients to encourage them to reschedule missed procedures, appointments, and yearly exams. 

Challenges With Investigating Malfunctions

For some manufacturers, the pandemic made investigating malfunctioning devices more challenging compared to their standard approach. Impacts were uniquely impacted because a doctor’s visit or procedure is sometimes required to alter or replace an implant, and pandemic prevention measures emphasized limiting person-to-person contact. Reports described patients, especially those with increased risk factors for developing severe cases of COVID-19, who were hesitant to meet with their doctor in person. Simultaneously, government healthcare facilities canceled elective procedures, preventing implants from being replaced or extracted. This confluence of events created an environment where patients were not receiving medical care, and malfunctioning implants were particularly vulnerable to investigative neglect.

Investigators may not have been able to investigate devices thoroughly and may lose data about the malfunction over time. In the FDA’s guidance document, the government agency stipulates that manufacturers submit reports “within six months of the restoration of the adverse event reporting process to their pre-pandemic state.” Although it is unclear precisely what this timeframe means, it does suggest that manufacturers will likely be delaying investigations for, at a minimum, several months. Such a long delay brings into question how manufacturers will investigate a backlog of uninvestigated devices and whether those investigations will be fruitful after such a long hiatus. Additionally, because many of these reports were unable to be thoroughly investigated, preventable adverse events may have occurred and may continue to occur due to a lack of postmarket surveillance.

Backlog of Uninvestigated Devices

It is important that manufacturers and the FDA address the backlog of uninvestigated devices so that unsafe devices can be identified and removed from the market. Additional guidance from the FDA may be necessary to guide the manufacturer investigations of previously uninvestigated reports. The guidance could include a system for prioritizing which report and device investigations should take priority moving forward and how to follow up with patients who were impacted by the malfunctioning device. Furthermore, future research should investigate strategies that manufacturers used to successfully investigate devices during the pandemic to provide examples of how postmarket surveillance can be resilient during crises in the future.

Limitations

A limitation to this study is that medical device reporting is historically low. In 1996, as seen from 0.5% of medical device errors were reported. This dataset does not represent all reasons manufacturers may delay an investigation and we cannot tell how many medical device reports remain uninvestigated. The counts of reports identified in the database do not correspond to the counts of events in the world.

Consequently, certain conclusions cannot be made based on this dataset. For example, the large number of dental implant reports does not indicate that dental implants are causing a disproportionate number of adverse events. Because our research is limited to reports with COVID-related phrases, and not all dental implants cannot make any conclusions about patients aside from the manufacturer’s use of language in their reporting. Comparing report numbers year to year should also be avoided as a fluctuation in the number of reports submitted to MAUDE can be based on a myriad of different factors from decreased reporting, improved device usability, changes to individual manufacturer and facility reporting strategies, and the pandemic.

Conclusion

Aspects of the pandemic, such as travel bans and shipping policies, made it difficult for some manufacturers to investigate devices via traditional means. The nature of some devices, such as implants, also made facility and manufacturer investigations more challenging to perform. This change is a window into the novel patient safety issues arising in response to the pandemic. The lack of full-scale investigations into malfunctioning devices may lead to safety issues going unaddressed and harming additional patients in the future. It is currently unclear how uninvestigated malfunctions will be addressed after the pandemic.

References

7. U.S. Food and Drug Administration. Postmarketing Adverse Event Reporting For Medical Products And Dietary Supplements During A Pandemic; 2020-3.

About the Authors

Zoe Pruitt (zoe.m.pruitt@medstar.net) is a human factors specialist at the MedStar Health National Center for Human Factors in Healthcare. She holds a Master of Arts in human factors and applied cognition from George Mason University. Her research interests include applying a human factors lens to the usability of medical devices and analyzing patient safety event databases for emerging trends.

Christian Boxley is a senior research associate at the MedStar Health Research Institute and holds a Bachelor of Science in psychology from the University of Delaware. He has project experience managing, analyzing, and visualizing large datasets using programming languages such as Python and SQL and software tools such as Excel and Tableau. Mr. Boxley’s current research involves analyzing trends and themes in patient safety event data.

Seth A. Krevat is assistant vice president for Safety at Medstar Georgetown University Hospital. He is a board-certified attending physician, Medstar Georgetown University Hospital. As assistant vice president for Safety, Dr. Krevat is responsible for the patient and staff safety and risk reduction programs. He focuses on understanding, coordinating, and measuring the performance of internal and external safety requirements in the acute and non-acute care arenas.

Sejian Sengupta is an assistant professor in the Department of Statistics at North Carolina State University. He received his bachelor’s and master’s degrees in statistics from the Indian Statistical Institute and his doctorate in statistics from University of Pittsburgh. His research interests include statistical network analysis, bootstrap and related resampling/subsampling methods, and patient safety.

Raj M. Ratwani is the director of the MedStar Health National Center for Human Factors in Healthcare, vice president of Scientific Affairs at the MedStar Health Research Institute, and an associate professor of Emergency Medicine at Georgetown University School of Medicine. He has extensive experience applying human factors principles and theories from cognitive science to improve healthcare delivery, focusing on the design, development, implementation, and use of digital healthcare technologies.

This article is published under the Creative Commons Attribution-NonCommercial license.