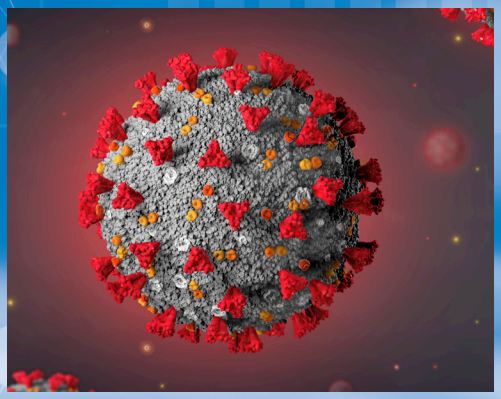
NPSD Data Spotlight

Patient Safety and COVID-19: A Qualitative Analysis of Concerns During the Public Health Emergency



Agency for Healthcare Research and Quality

Patient Safety Listed PSO Organization

Patient Safety and COVID-19

A Qualitative Analysis of Concerns During the Public Health Emergency

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Introduction

The Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) public health emergency (PHE) of 2020 has had dramatic impacts on the healthcare industry worldwide.[1] The transmission of SARS-CoV-2 caused widespread incidence of Coronavirus Disease 2019 (COVID-19), with a wide range of presentations. In some cases, individuals were asymptomatic or presented with only mild symptoms such as fever and cough. Other cases resulted in severe illness or death. As COVID-19 spread throughout communities, the healthcare industry experienced unanticipated changes in demand for services that simultaneously overwhelmed some providers and services in the system, while reducing demand for others.[2] The reorganization of services required to attend to the immediate needs of the PHE pulled resources away from traditional programs for quality improvement and patient safety. Yet patient safety concerns and the need for quality service delivery have remained throughout the PHE. This brief presents one perspective on the COVID-19 PHE and its impact on patient safety concerns in hospitals.

The Agency for Healthcare Research and Quality (AHRQ) implements the Patient Safety Organization (PSO) program for the Department of Health and Human Services (HHS) as mandated by the Patient Safety and Quality Improvement Act of 2005 (PSQIA).[3] Some AHRQ-listed PSOs voluntarily submit data stemming from reports by providers to the Patient Safety Organization Privacy Protection Center (PSOPPC) using the Common Formats for Event Reporting – Hospital (CFER-H) V1.2 and V2.0. The data consist of a set of structured data elements, and unstructured free text that describe the nature of patient safety concerns and the factors contributing to those concerns. The data are not a representative sample of patient safety concerns nationally.

Highlights

- The Agency for Healthcare Research and Quality (AHRQ) Patient Safety Organization (PSO) program has received nearly 5,500 records of patient safety concerns in which the COVID-19 public health emergency (PHE) was included as part of the description of the event or unsafe condition.
- Among a sample of records analyzed, the most common description of the patient safety concern, in 26.6% of records, was that a patient had either tested positive for COVID-19 or was a person under investigation (PUI).
- Procedural issues with COVID-19 testing represented 13.0% of records analyzed. The results indicate a need to close the loop on critical processes, such as testing, during a PHE.
- The exposure of patients and staff to individuals with positive COVID-19 test results was identified in 18.2% of records analyzed. Results indicate opportunities to improve communication for patient transfers, and to ensure proper isolation and personal protective equipment (PPE) usage.
- Patient safety concerns such as falls, pressure injuries, and adverse medication events were reported less often in relation to COVID-19 than policy- and procedure-related concerns.
- Some descriptions point to interactions between staff workloads, policies and procedures, and treatment methods that may have contributed to specific pressure injury incidents.

As part of its response to the COVID-19 PHE, AHRQ performed a pilot study of data collected through the PSO program to answer two questions: First, could the CFER-H data be used for the timely analysis of reports on patient safety concerns.

[1] Allen, S. 2021 global healthcare outlook. Deloitte Insights. 2021, Deloitte Development LLC.
[2] Blumenthal D, Fowler EJ, Abrams M, Collins SR. Covid-19 – Implications for the Health Care System. N Engl J Med 2020; 383:1483-1488.
[3] The HHS Office for Civil Rights enforces the confidentiality provisions of the PSQIA and its implementing regulation.

Second, to what extent can the unstructured free text collected through the CFER-H be leveraged to generate meaningful understanding about patient safety concerns as they relate to the COVID-19 PHE. The results are not intended to be a systematic analysis of how COVID-19 contributed to patient safety concerns. Rather, the intent is to understand the capacity of the unstructured text to inform our understanding of these patient safety concerns.

All results are aggregated and paraphrased to maintain the non-identification of data and anonymity of the contributing providers and PSOs. The data used for this analysis include reports on patient safety concerns with initial report dates between March 10, 2020 and October 18, 2020. The initial report date represents the date a provider completed the Healthcare Event Reporting Form and entered the data into the provider system. The results presented in this report, therefore, are indicative of events that occurred during the first seven months of the COVID-19 PHE, and they are not a reflection of the current state of affairs.

Results

Table 1 presents the summary results of analysis for the *Description of the Event or Unsafe Condition* or the *Description of Additional Details of Event or Unsafe Condition* reported using the CFER-HV1.2 and V2.0 systems. Of the 320 records analyzed, 19 (5.9%) explicitly identified patients as having a negative COVID-19 test result and are not considered further in this analysis. With respect to the timeliness of reporting, the analysis identified that the average time between a provider entering the report into their system and submission to the PSOPPC was 146.8 days, or just under five months, with a standard deviation of 31.0 days.[4]

The most commonly reported type of event was the identification of a patient with a positive test result or a patient under investigation (PUI) for COVID-19 (n = 80; 26.6%). For these records, the description of a positive test result or PUI status was the entirety of the unstructured text provided. No other patient safety event was identified in the record (e.g., fall, pressure injury, medication event, etc.).

Given that no specific patient safety concern was identified in the free text for these reports, the structured data was analyzed further. Nearly all of these reports were submitted under the event type category of *Healthcare-Associated Infection*. The reports generally included demographic data about the patient (typically patient age and sex), provided a location in the facility, and often included data on contributing factors (typically categorized as *Human Factors*). The report date, or the date that the event is reported into a system by a provider, indicated that all 80 records with this limited information were reported between March 2020 and May 2020. During the initial outbreak of the COVID-19 PHE, when little information was known about the nature of the virus and its mode of transmission, these records may represent providers who reported COVID-19 positive cases as a patient safety concern out of an abundance of caution. There is no evidence in these reports that any other type of patient safety concern occurred.

The second most common type of patient safety concern identified in the data was related to a COVID-19 test not being performed, ordered, or sent properly (n = 39; 13.0%). These descriptions of events included:

- Improper screening or failure to ask screening questions
- Failure to collect swab
- Miscommunication between staff on testing procedures
- Lack of feedback from the lab on test results

[4] The median number of days between a provider entering the report into their system and the submission of that report to the PSOPPC was 147.5 days.

- Patient failures to obtain proper COVID-19 test prior to arrival for procedure

Table 1. Summary Description of Patient Safety Concerns

Summary Description	Number of Records	Percentage of Records
Positive COVID-19 Test Result or PUI	80	26.6%
COVID-19 test not performed/ordered/sent	39	13.0%
Patient incorrectly transferred/discharged	29	9.6%
Staff or patient exposure	26	8.6%
Other	26	8.6%
Medication	17	5.6%
Fall	16	5.3%
Device	14	4.7%
Pressure injury	10	3.3%
Blood	10	3.3%
Proper PPE	9	3.0%
Against medical advice	6	2.0%
Altercation	5	1.7%
Perinatal	4	1.3%
Surgery	4	1.3%
Death	2	0.7%
Environmental services issue	2	0.7%
Delayed treatment	1	0.3%
Contraband	1	0.3%
Total	**301[a]**	**100.0%**

[a] There were 19 reports in the sample that explicitly identified the patient as receiving a negative COVID-19 test result. These reports have been excluded from further analysis.

In eight of the 39 records (20.5%), the delay in COVID-19 testing was described as directly being linked to delays in patient care. In several cases, specimens collected for testing were either lost in transit to the lab, or the results were not communicated back to the submitting provider, requiring additional testing be performed after significant delays. Additionally, nearly half of the records reviewed related to testing (n = 16) noted a failure of the patient to obtain a test in advance of a procedure.

Potential patient and staff exposure to individuals testing positive for COVID-19, or PUI, presented another large group of patient safety concerns identified in the records. Within this group, 29 records (9.6%) were associated with the transfer or discharge of a patient such as:

- Patients transferred between units without masking or testing
- Patients transferred between units without notifying the receiving unit
- Failure to follow visitation restrictions (e.g., allowing multiple visitors for a single patient)
- Patient discharge without providing test results

Transfer-related concerns often involved the failure to notify the receiving unit that a patient was being transferred. In some instances, receiving units did not have beds or staffing available to receive the

patient, or the unit had been designated for treating patients that did not align with the transfer patient's COVID-19 status (e.g., positive or negative test results). In addition, there were another 26 records (8.6%) in which individuals were exposed to patients or staff identified as testing positive for COVID-19. In several instances, the exposure occurred because staff were not following PPE protocols, such as removing exposed PPE before treating non-COVID-19 patients or wearing PPE when working with patients who had positive test results. In other cases, the exposure occurred with an asymptomatic individual, and was later identified when the individual tested positive.

Of the 301 records analyzed, another 26 (8.6%) identified a cluster of other patient safety concerns associated with delays in care associated with the following:

- Lab staff being unable or unwilling to draw labs on patients who tested positive for COVID-19 or were PUI
- Lost lab specimens and results
- Improper screening of patients on presentation
- Incomplete, incorrect, or missing documentation

Policies and procedures have changed rapidly throughout the COVID-19 PHE for front-line staff, and the effective communication of those changes played a role in some instances where care delays occurred. In other instances, the increased workloads experienced by hospital staff and laboratories may have also contributed to miscommunications and errors in order entry, specimen handling, and accurate documentation.

In total, approximately two-thirds of the records analyzed identified a patient safety concern due to a patient testing positive for COVID-19, being PUI, or due to operational challenges associated with delivering care in the PHE. After accounting for records identifying patients' testing status for COVID-19, nearly 40 percent were associated with policy- and procedure-related issues such as closing the loop on the testing process to ensure timely results are obtained, improving communication and patient transfer protocols, ensuring that staff understand and follow proper safety protocols, and completing all documentation in a timely and accurate manner.

Descriptions of Events or Unsafe Conditions

The CFER-H technical specifications capture 10 types of patient safety concerns (e.g., falls, device, medication). Prior to drawing the sample of 320 reports for in-depth review, the unstructured free text data for all records submitted to the PSOPPC since the beginning of the COVID-19 PHE were searched for a reference to COVID-19. This search yielded a sample of 5,498 reports. The vast majority of records with descriptions that included references to COVID-19 fell into the *Other* event type, or *Healthcare-Associate Infections* (n = 5,097; 92.7%). Of the remaining 401 records, most contained descriptions of patient safety concerns that happened to patients who were positive for COVID-19, but they did not include information or otherwise indicate that the disease caused, contributed to, or exacerbated the patient safety concern. There were, however, several notable descriptions of events where the COVID-19 PHE played some role in the patient safety concern described.

The results presented in this section of the report are based on analysis of the 301 reports that were sampled for in-depth review.

Device Events

Among the device or medical/surgical device concerns (n = 14; 4.7%), the most commonly described incident was a device failure or malfunction, often associated with a ventilator. Additionally, several incidents were described where backup devices were unavailable due to use with other patients. In a

smaller set of records, device events occurred because of user error in operating the device, or because a device was used with the wrong patient.

Pressure Injury

Among the pressure injury events (n = 10; 3.3%), several records identified the development of pressure injuries due to the interaction between patient pronation and poor patient mobility. Four records identified the development of multiple pressure injuries to the lips, tongue, ears, and cheeks from patients placed in a prone position. Reporters identified staff workload as a factor that prevented assisting patient mobility. The remaining pressure injuries were identified across multiple other contact points such as the coccyx, buttocks, and feet.

Blood and Blood Product

Among the blood and blood product concerns (n = 10; 3.3%), there were three incidents involving an adverse reaction to a transfusion. Additional near misses occurred when the wrong blood product (e.g., fresh frozen plasma versus COVID-19 convalescent plasma) was either entered into the ordering system incorrectly or delivered by the blood bank. Two additional concerns described situations where too few units of blood were ordered and where blood product was wasted because the bag broke or the unit was left out unattended overnight.

Medication or Other Substance

Of the 17 (5.6%) safety concerns involving medications or other substances, 14 were related to either an incorrect dose (e.g., overdose, extra dose, or missed dose), or an incorrect medication provided to a patient. In two instances, adverse reactions to medications used to treat COVID-19 were identified. In one instance, the reporter indicated the lack of a medication used to treat COVID-19 as the patient safety concern.

Analysis of Structured Data Elements in COVID-19 Related Reports

Among the 301 reports analyzed, the structured data elements were also reviewed to determine whether they provided additional meaningful information. The results of the analysis indicate that the structured data elements submitted by PSOs and their contracted providers are highly specific to the PSO submitting the data. The PSO program relies on voluntary data submission. Thus, while analysis of the structured data elements showed that a limited number of data elements are available for each event type, these are not always submitted by all contributing PSOs.

PSOs generally provided data elements for the location in the facility where the event occurred and contributing factors to the events reported. For incidents that involved a patient, the PSOs reported patient age and sex for 26 (8.6%) records, with race and ethnicity not being reported for any records. The extent of harm to the patient and expected duration of harm were also reported with moderate consistency.

Within each event type module, there were also a limited number of structured data elements that were reported consistently. These included the following data elements:

- Blood and blood product

    - Type of blood product
    - Description of incorrect action
- Device
    - Reuse of a single-use device
    - Unique device identifier
- Fall
    - Assisted or unassisted fall
    - Type of injury as a result of fall
    - Risk assessment prior to fall
    - At risk of fall
- Healthcare-associated infection
    - None
- Medication and other substance
    - Incorrect action
    - Stage the event originated
- Perinatal
    - Type of perinatal event
    - Patient affected by perinatal event
    - Gestational age
- Pressure ulcer
    - Most advanced stage of pressure ulcer
    - Stage on admission
    - Admission skin inspection documented
    - Pressure ulcer prevention intervention in place
    - Secondary patient morbidity
- Surgery or anesthesia
    - Characteristics of surgical adverse outcome
    - Incorrect action for surgical invasive procedure

Descriptions of Other Contributing Factors

The technical specifications for the CFER-H V1.2 and V2.0 data allow users to report *Contributing Factor(s)* for an event, using structured data categories for environment, staff qualifications, supervision and support, policies and procedures, data, communication, human factors, and other reasons. When other reasons is selected as a contributing factor, the reporter may provide unstructured text to describe what the contributing factor was. Analysis of 124 records for which “COVID-19” was referenced in the Contributing Factors unstructured text, yielded the following as the most commonly referenced issues:

- COVID-19 related
- PPE related
- Knowledge deficit (coupled with COVID-19 related)
- Negative pressure room
- Isolation policy issue
- Chain of command related

- Education or instruction deficit
- Handoff
- Shift change
- Refuse to provide Bilevel Positive Airway Pressure device (BPAP) on COVID-19 negative patient
- Positive COVID-19
- Exposure to associate who tested positive for COVID-19
- Patient unable to get COVID-19 testing

Most of the responses provided as unstructured text on contributing factors were short phrases like those cited above. These descriptions contain less information than the *Description of the Event or Unsafe Condition*, because of the brevity of the text. There were, however, a limited number of responses that provided additional explanatory information. Some of these explanatory statements were related to fall and pressure ulcer events, while others were provided with records form the other event category. Table 2 presents text that paraphrases the data information submitted.

Table 2. Paraphrased text describing other contributing factors for a limited number of records

Type of Event	Descriptive Text About the Event Referencing COVID-19
Fall Event	COVID-19 precautions cause a delay in care due to donning PPE.
Pressure Ulcer Event	Very busy environment due to COVID-19 crisis and less time and attention paid to repositioning.
Pressure Ulcer Event	Patient is critically ill, intubated, COVID-19 positive, in multisystem organ failure, NSTEMI[5], requiring pressors, sedation; due to COVID-19 precautions and periods of hemodynamic instability, unable to provide frequent repositioning.
Other Event	Too many things do. Train new staff, perform stat COVID-19 testing for surgery/ED, process ED samples. Many areas for errors to occur especially with increase in test volume.
Other Event	Due to COVID-19, Dr. canceled patient's procedure and follow-up appointment.
Other Event	High influx of pre-op/procedural COVID-19 testing and insufficient manpower to complete in a timely manner.
Other Event	RPh[6] didn't check pump because patient was PUI for COVID-19 to reduce risk of transmission.

The descriptions presented in Table 2 are consistent with the findings obtained from analysis of the *Description of the Event or Unsafe Condition* text. The results highlight how the COVID-19 PHE may contribute to patient safety concerns by increasing both the volume of work to perform, and the speed with which the policy and procedure environment is changing.

Conclusions

The results contained in this report provide insight into the ability of the CFER-H data to provide timely information, and the capacity of the unstructured free text data to provide useful information. The results also help inform some aspects of the healthcare industry's preparedness for future PHEs.

The reports submitted to the PSOPPC related to COVID-19 took, on average, just under five months between reporting and submission. While this time frame may be timely with respect to the consideration of longer-term policy- and decision-making, it is not likely to be sufficient for rapid responses to emerging issues such as a global pandemic. In contrast, the AHRQ Network of Patient Safety Databases analysis of all PSO data submissions through December 31, 2019 identified that the median time between provider reporting and submission to the PSOPPC was 1.6 years. In comparison, this result indicates that those PSOs and providers who were reporting patient safety concerns related to COVID-19 were doing so more than three times more rapidly than had previously been observed. This suggests that the PSO community has the capacity and capability to increase the timeliness and velocity of reporting, in at least some circumstances.

[5] Non-ST-elevation myocardial infarction (a type of heart attack).
[6] Registered Pharmacist

The qualitative review of the unstructured free text also resulted in the identification of several meaningful findings. Even among a small sample of 301 records, distinct patterns began to emerge that speak to how the COVID-19 pandemic may have impacted some patient safety concerns and offer insights into how the healthcare industry might improve processes for care delivery. The results obtained from this small sample of reports suggests that a more robust analysis of the unstructured free text data, using tools such as natural language processing and taking advantage of the more than 2.1 million records currently held by the PSOPPC, could potentially yield valuable insights for improvement in patient safety.

The most frequently described patient safety concern was the statement that a patient had tested positive for COVID-19 or was PUI. During the early stages of the PHE, less was known about the modes of transmission for COVID-19. In light of such uncertainty, the diagnosis of a patient as positive for the disease presents concern for how best to prevent transmission to other patients and staff.

Many of the patient safety concerns reported where COVID-19 was identified in the description of the event were policy- or procedure-related events, such as improper or lost specimens and test results, poor communication related to patient transfers, and the inadvertent exposure of patients and staff to individuals with a positive test result. These policy- and procedure-related events are more likely to occur in a rapidly changing environment, and when staff are experiencing higher than normal workloads. Drawing from these findings, the healthcare industry has an opportunity to identify critical processes related to current and future PHEs and implement policies and procedures to reduce failures at each step of the process.

Among this sample of reports, patient safety concerns that are typically not associated with the COVID-19 PHE (e.g., falls, pressure injuries, perinatal events, venous thromboembolisms, surgery and anesthesia events, etc.) were reported substantially less often than policy- and procedure-related concerns. When these types of patient safety concerns were reported, they were often described as a patient safety event that occurred to a patient with COVID-19, rather than as an event that was caused or made worse by COVID-19. Some descriptions, however, point to interactions between staff workloads and treatments involving patient pronation that may have contributed to specific pressure injuries by limiting the ability of staff reposition patients in a timely manner.

The COVID-19 PHE required the healthcare industry to identify and implement rapid changes in the delivery of care and to triage patients in order to leverage resources for those in greatest need. Drawing on data submitted to the AHRQ PSO program about patient safety concerns where COVID-19 was referenced in the description, this brief examines the nature of the relationship between the PHE and the types of concerns being reported. The findings point to a need for the industry to develop better preparedness for identifying and implementing PHE-specific adaptations in a complex system, such as maintaining the accuracy and completeness of critical care processes (e.g., screening and testing), developing communication systems to effectively disseminate and implement changes across all levels of staff, and identifying areas in which the PHE may interact with changes in the system to negatively impact patient care.

Appendix A. Methodology and Limitations

Methodology

The data for this analysis was acquired through the AHRQ PSO program, and the patient safety work product (PSWP) voluntarily submitted by PSOs to the PSO Privacy Protection Center (PSOPPC). The PSWP is submitted using the AHRQ Common Formats for Event Reporting – Hospital (CFER-H) V1.2 and V2.0 technical specifications for patient safety concerns, and it covers events with initial report dates from March 10, 2020 through October 18, 2020. The initial report date represents the date a provider completed the Healthcare Event Reporting Form and entered the data into the provider system. The patient safety concerns submitted to the PSOPPC for analysis include data elements containing descriptions of the event in the reporter's own words: the *Description of the Event or Unsafe Condition* (data element 15) and *Description of Additional Details of Event or Unsafe Condition* (data element 87 in CFER-H V1.2 only). Additionally, when asked to indicate the factors contributing to the event or unsafe condition, the *Contributing Factor(s) for Event* (data element 105) may be reported as "Other Contributing Factor", and unstructured text may be submitted to elaborate on the nature of the contributing factor. These unstructured text data elements comprise the data used for this analysis.

The unstructured text in the *Description of the Event or Unsafe Condition*, *Description of Additional Details of Event or Unsafe Condition*, and *Contributing Factor(s) for Event* were analyzed during a pilot study in September 2020 to identify records where the word "covid" was used, including "covid", "covid19", "covid-19", and "covid- 19". During the pilot study, 3,558 records were identified, and 100 were randomly sampled for qualitative content analysis to identify the nature of the patient safety event that occurred. In November 2020, the pilot study was expanded to identify records that included the terms "covid", "ncov", "cov2", "sars", "pneumonia", or "severe acute respiratory".[7] The expanded review identified a total of 5,498 patient safety concerns reported between March and October 2020. From these records, an additional 220 records were randomly sampled, stratified by the *Category(s) associated with the Event or Unsafe Condition* (data element 21). The combined data from these two samples were used to obtain the results displayed in Table 1. From the expanded review of patient safety concerns in November 2020, the results in Table 2 were obtained from a sample of 124 records out of the 318 (5.7% of 5,498) for which the *Contributing Factor(s) for Event* included free text associated with the "Other Contributing Factor" response. Table 3 presents the number of records classified as belonging to each event or unsafe condition category identified in the database as well as the number sampled for analysis.

[7] The term "pneumonia" yielded a substantial number of records that were unrelated to COVID-19. Additionally, the term "severe acute respiratory" was used in one record that was unrelated to COVID-19. Because of these issues, records identified using only these terms were removed from the sample; however, records which also included the terms "covid", "ncov", "cov2" and "sars" were retained for analysis.

Table 3. Number of Records by the Category(s) Associated with the Event or Unsafe Condition

Category of Event or Unsafe Condition	Number of Records Identified	Number of Records Sampled
Blood or blood product	12	12
Device of medical/surgical supply	35	8
Fall	69	17
Healthcare-associated infection	1,775	73
Medication or other substance	98	17
Perinatal	37	15
Pressure ulcer	74	12
Surgery or anesthesia	76	34
Venous thromboembolism	0	0
Other	3,322	132
Total	**5,498**	**320**

Methodological Limitations

The sampling was completed in two stages for this analysis, using different criteria for inclusion at each stage. While the data sampled reflect the diversity of descriptions for patient safety concerns, the data may not be representative of all patient safety concerns submitted to the PSOPPC. Furthermore, because of the voluntary nature of data submission by PSOs and their providers, the database held by the PSOPPC is not representative of the population of patient safety concerns in the United States. Rather, the data presented here represent a cross-section of patient safety concerns submitted by a subset of PSOs and providers. Data obtained from other sources, other PSOs, or other providers are likely to yield different results. It is unknown to what extent the results of this analysis generalize to the broader population. Furthermore, the records analyzed for the description of the patient safety concern, and the records analyzed for contributing factors are not the same records. This analysis cannot, therefore, connect the two sets of results together to draw broader conclusions about the relationships between these data elements. Finally, because the data must be non-identified prior to presenting the results, the analysis requires paraphrasing text and aggregation of results which prevents direct presentation of the text submitted by PSOs and their providers.

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