Patient Safety Concerns in COVID-19–Related Events

A Study of 343 Event Reports From 71 Hospitals in Pennsylvania

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Abstract

COVID-19 (i.e., coronavirus disease 2019) was declared a pandemic and has had a profound impact on healthcare systems, which may increase the risk of patient harm. We conducted a query of the Pennsylvania Patient Safety Reporting System (PA-PSRS) database to identify COVID-19–related events submitted by acute care hospitals between January 1 and April 15, 2020. We identified 343 relevant event reports from 71 hospitals and conducted a descriptive study to identify the prevalence of and relationships between 13 categories of associated factors and six categories of event outcomes. We found that 36% (124 of 343) of events had more than one associated factor and 24% (83 of 343) had more than one outcome. The most frequently identified factors were Laboratory Testing (47%; 161 of 343), Process/Protocol (25%; 87 of 343), and Isolation Integrity (22%; 74 of 343). The two most frequent outcomes were Exposure to COVID-19 Positive or Suspected Positive Patient (50%; 173 of 343) and Missed/Delayed Test or Result (31%; 108 of 343). Finally, the findings showed that seven of the associated factors had a notable impact on the frequency of Exposure to COVID-19 Positive or Suspected Positive Patient outcome. Overall, we anticipate that the results can be used to identify areas of greatest need and risk, which could help to guide allocation of resources to mitigate risk of patient harm.

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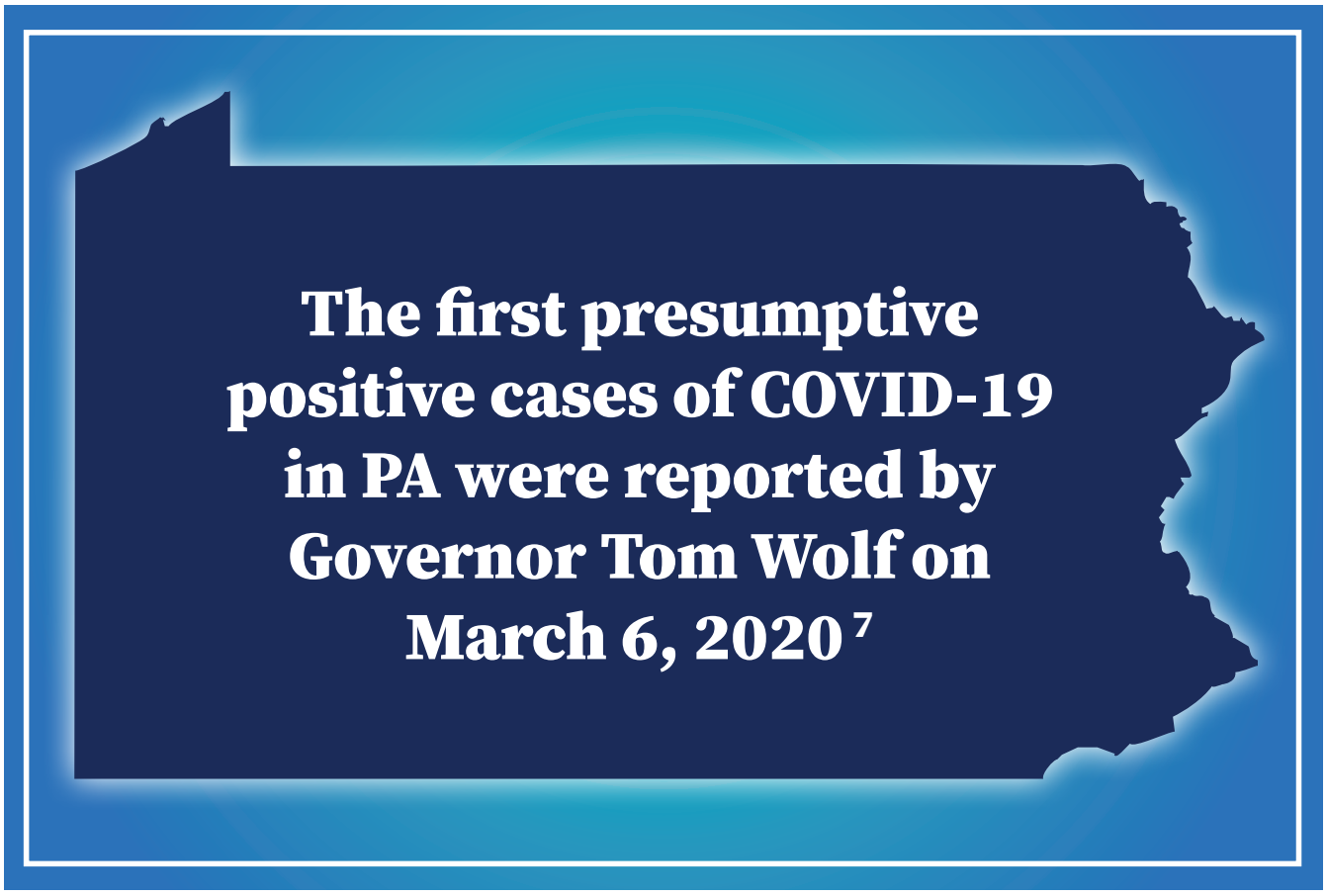
Keywords: *patient safety, associated factors, COVID-19, SARS-Cov-2, coronavirus*

Introduction

Coronaviruses are a family of viruses that cause a range of respiratory illnesses, ranging from the common cold to severe acute respiratory syndrome (SARS) and pneumonia.[1] In late December 2019, a cluster of pneumonia cases were reported in Wuhan in the Hubei Province of China, and the pathogen was subsequently identified as a novel coronavirus, which was named SARS-CoV-2.[1-3] The associated disease was named coronavirus disease 2019, abbreviated COVID-19.[3]

The virus began to spread quickly in China and then around the world.[2] The first case of COVID-19 in the United States was confirmed on January 20, 2020, in a 35-year-old man in Snohomish County, Washington, who became ill after returning from a trip to Wuhan.[4] Since then, positive COVID-19 cases have been identified throughout the United States.[3] The World



Health Organization (WHO) declared the COVID-19 outbreak a global pandemic on March 11, 2020.[5] Pandemics of respiratory disease are characterized by several distinct phases, beginning with investigation, followed by recognition, initiation, acceleration, and deceleration.[6]

The first two presumptive positive cases of COVID-19 in Pennsylvania were reported by Governor Tom Wolf on March 6, 2020.[7] As of April 15, 2020, there were 26,490 cases and 647 deaths reported by the Pennsylvania Department of Health (DOH).[8] Given the many challenges associated with managing care and treatment for patients with COVID-19 and the burden placed on healthcare systems,[9] we became concerned about how the pandemic may impact patient safety. As a result, we began monitoring the Pennsylvania Patient Safety Reporting System (PA-PSRS)* database and identifying COVID-19–related events occurring in acute care facilities. To better understand the nature of these COVID-19–related events, we designed a descriptive study to identify associated factors and outcomes. We sought to provide timely information that may help healthcare facilities and policymakers better understand how the COVID-19 pandemic has impacted certain aspects of patient safety in Pennsylvania. Additionally, we anticipate that the findings may be used to identify areas of greatest need, which could help to guide allocation of resources to mitigate risk of patient harm.

Methods

Sample

We queried the PA-PSRS database for event reports submitted by acute care facilities between January 1 and April 15, 2020. In the query we applied keyword inclusion filters (e.g., "coronavir" OR "corona vir" OR "covid" OR "cov-2" OR "cov2" OR "sars") and exclusion filters (e.g., "covidien" OR "coviden" OR "covidean") to the free-text narrative fields. Based on the query criteria, the output had a total of 473 event reports.

Subsequently, one author manually reviewed the free-text narrative fields in each of the 473 reports to identify events that are consistent with the scope of the study. Events were included if they met at least one of the following criteria:

- Described a patient who was COVID-19–positive or suspected as positive and included a patient safety concern.
- Described a COVID-19 negative or non-suspected patient, or staff member, who, while in hospital, experienced or expressed concern for a higher than necessary level of risk of exposure to COVID-19.

We excluded event reports in which non-COVID-19 patients were indirectly impacted by the pandemic (e.g., non-suspected patient had a delay in care at an emergency department due to competing demands related to management of COVID-19–positive patients). While these reports reflect an incredibly important topic, we felt that it would be best addressed in a separate study. We also excluded reports that described a hospital-acquired COVID-19 infection, as the Patient Safety Authority issued a program memorandum in concurrence with the DOH on March 27, 2020, advising that acute care facilities are not required to report any COVID-19 infections to PA-PSRS.

Based on our manual review of the 473 event reports and application of the inclusion criteria, we identified a total of 343 relevant events. The 343 events represent several types of acute care hospitals, including children's hospitals and rehabilitation hospitals. (Psychiatric hospitals and ambulatory surgical facilities were not represented in the final dataset.)

Variables Coded

Across all 343 event reports, we explored two sets of variables. The first set was coded by event reporters (i.e., hospital-designated staff who submitted the reports to PA-PSRS) and included the following demographic and clinical variables: patient age and gender, event classification (Serious Event† vs. Incident‡), and care area group. §

*PA-PSRS is a secure, web-based system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports of patient safety–related incidents and serious events in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Act 13 of 2002). All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

†Serious Event is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services to the patient.[10]

‡Incident is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional healthcare services to the patient.[10]

§Within PA-PSRS, there are 179 care areas to capture the location where an event occurs. To cross-tabulate a more manageable number of category elements with other variables of interest, the authors placed each of these care areas into higher-level care area groups.

Table 1. Factors Associated With Patient Safety Concerns Within COVID-19–Related Events

Associated Factor	Examples
1. Admission Screening 	Admission staff missed or had notable delay in screening the patient for COVID-19 signs/symptoms or recent high-risk travel.
	Admission staff conducted patient screening, but findings were unreliable in identifying patients that warranted COVID-19 testing.
2. Communication 	Staff failed to communicate patient's COVID-19–positive or suspected positive status during handoff to other staff.
	Transport staff failed to notify clinical staff that a COVID-19–positive patient with fall-risk status was returned to the isolation room. While unattended, the patient fell at the bedside.
	The paging system malfunctioned, which delayed staff from consulting infection control about whether COVID-19 testing was warranted for a patient.
	Hospitals failed to notify Emergency Medical Service (EMS) when a patient later tested positive for COVID-19.
3. Imaging 	Portable x-ray unit was not charged overnight, which caused imaging delays for COVID-19–suspected patients.
	Magnetic resonance imaging (MRI) staff members refused to see a patient because of suspected COVID-19–positive status.
	Computerized Tomography (CT) scan was not performed while a COVID-19–suspected patient was in the emergency department, causing a delay in results.
4. Inadequate Disinfection 	Staff performed a CT scan of a COVID-19–suspected patient and failed to prevent other staff and patients from entering the room during the subsequent hour.
	A room previously occupied by a COVID-19–suspected patient was not terminally cleaned prior to admitting a new patient into the same room.
	A thermometer being applied directly to visitors' foreheads was not disinfected between each use.
5. Isolation Constraints 	Staff who were outside an isolation room were unable to hear a device alarm (e.g., ventilator, infusion pump) located inside the room.
	Staff were unable to communicate or observe the patient from outside of an isolation room, preventing timely detection of changes in the patient's health status (e.g., fall, self-extubation, change in level of consciousness).
	Notable time required to attain and don personal protective equipment (PPE), which caused delays in entering an isolation room.
	Error in connecting extended infusion pump tubing from outside of isolation room to the patient, which caused a drug omission.
6. Isolation Integrity 	A non-suspected-COVID-19 patient was assigned a roommate who was suspected to be positive.
	Order for isolation precautions for a COVID-19–suspected patient were not recognized and adopted by staff in a timely manner.
	A COVID-19–suspected patient was placed in a room without a negative-pressure system or the room had a negative-pressure system, but it was not turned-on.
	Staff failed to don (apply) adequate PPE when interacting with a COVID-19–positive or COVID-19–suspected patient or failed to doff (remove) potentially COVID-19–contaminated PPE.
	A COVID-19–suspected patient did not don a mask and was unnecessarily transported through a non-COVID-19 unit.

Table 1. Factors Associated With Patient Safety Concerns Within COVID-19–Related Events (cont.)

Associated Factor	Examples
7. Knowledge Deficit 	Staff were unaware of what would be considered adequate PPE to prevent exposure and proper PPE doffing technique.
	Medical residents were untrained and unprepared to interact with a suspected-positive patient.
	Laboratory employees were unclear about adequate sources for COVID-19 specimen (e.g., endotracheal aspirate) or how to handle and manage specimens.
8. Laboratory Testing 	Specimen collection delay or poor collection technique.
	Specimen was mislabeled, without a label, mishandled, misplaced, erroneously disposed, or processed with a delay.
	False negative or false positive result.
	Specimen had to be recollected.
9. Medication 	A COVID-19–suspected patient was prescribed or used an inappropriate drug delivery device (e.g., drug treatment via nebulizer), which may aerosolize the virus particles.
	Patient missed drug treatment because breath-actuated inhalers were incompatible with mechanical ventilation and the patient's drug treatment was not switched to a compatible device.
	Staff did not complete medication reconciliation for a COVID-19–suspected patient due to fear of infection, which resulted in errors in drug treatment.
10. Patient 	COVID-19–suspected patient failed to inform staff of their COVID-19–positive status.
	COVID-19–suspected patient manipulated equipment or device.
	COVID-19–suspected patient behaved erratically and aggressively toward staff.
	Non-suspected patients left the facility against medical advice to avoid potential exposure to COVID-19.
11. Process / Protocol 	Staff failed to use a sign-in sheet before entering an isolation room and the observer of the isolation rooms failed to manage and uphold protocol for monitoring staff interactions with COVID-19–positive patients.
	Patient's status was changed to COVID-19–positive or COVID-19–suspected, but isolation and PPE signage were not placed on patient's door.
	COVID-19–positive or COVID-19–suspected patients were discharged to home without isolation instructions.
12. Resource Availability 	Challenge with availability of a resource due to its shortage, malfunction, or being soiled.
	Types of resources included infrastructure (e.g., isolation room); medical equipment (e.g., x-ray, CT scanner, negative air system, ventilator, heart monitor); medical supplies (e.g., curtains); disinfection supplies (e.g., bleach wipes); PPE (e.g., eye protection, N95 mask, full-face shield); and staff (e.g., phlebotomist).
13. Other 	Staff failed to recognize that a patient developed signs and symptoms of COVID-19 while in hospital.
	Physician deferred or ICU refused to accept a patient due to their COVID-19–suspected or COVID-19–positive status.
	Limited positioning of COVID-19 patient led to pressure injuries.

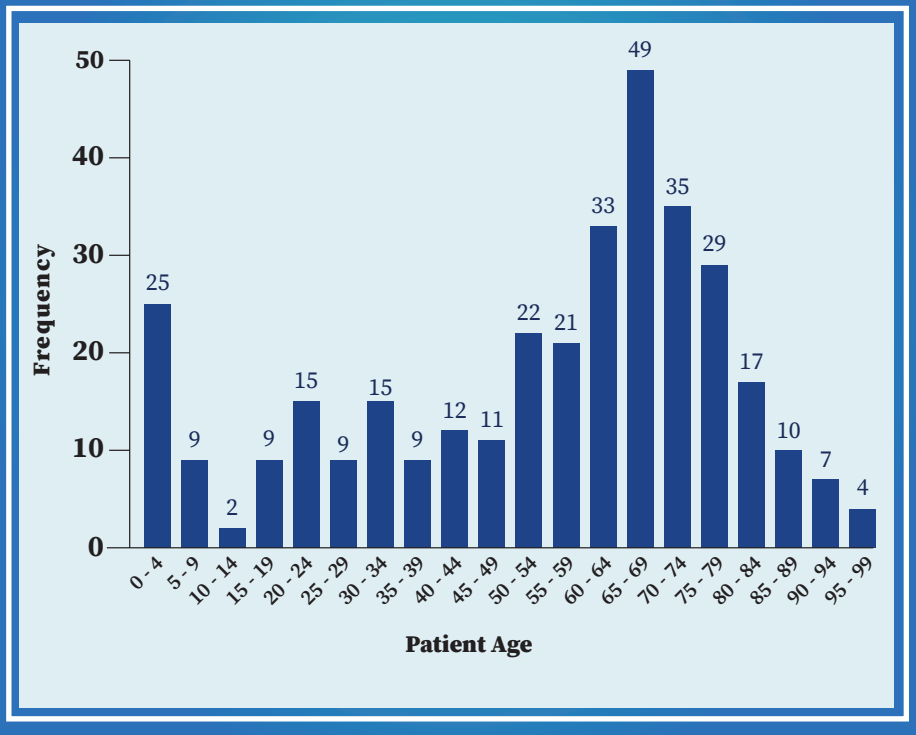
Table 2. Outcomes From COVID-19–Related Events

1. Exposure to COVID-19–positive or suspected-positive patient*
2. Fall
3. Missed/delayed care or treatment
4. Missed/delayed test or result
5. Wasted resource
6. Other

*This outcome includes events where a patient and/or staff member experienced or expressed concern for a higher-than-necessary level of risk of exposure to COVID-19

The second set of variables were coded by one of the study authors who manually reviewed the free-text narrative field in each event report and identified one or more *associated factors* that had implications for patient safety. Our coding scheme consisted of 13 categories of associated factors, which are described in **Table 1.** Additionally, while reviewing each report we identified one or more *outcomes* related to each event. Our coding scheme of outcomes included six categories, which are listed in **Table 2.**

Figure 1: Distribution of Patient Age in Years



During our review of the event reports, additional data were coded to better understand the nature of the events. For example, we collected data on whether the challenges with personal protective equipment (PPE) involved donning or doffing (i.e., applying or removing) and whether it involved the patient or staff. Throughout this descriptive study, all variables were measured, analyzed, and compared by frequency or percentage of occurrence.

Results

Patient Age and Gender

Within the sample of event reports, 53% (181 of 343) of the patients were reported as male and 47% (162 of 343) were female. The median patient age was 62 years and the interquartile range was 35–72 years (25th and 75th percentile). (See **Figure 1** for the distribution of patient age.)

Event Classification (Serious vs. Incident) and Care Area Group

The reports revealed that 1% (5 of 343) of the events were classified as Serious, which included one patient death. The remaining 99% (338 of 343) of events were classified as Incidents. The reports also revealed that the events occurred across 19 care area groups. Events were most frequently associated with the following care area groups: Emergency Department (26%; 88 of 343), Medical/Surgical Unit (22%; 75 of 343), Intensive Care Unit (17%; 59 of 343), Laboratory (7%; 25 of 343), and Specialty Units (6%; 20 of 343).

Hospitals

Across the 343 event reports, we found that all 71 acute care hospitals submitted at least one report and a median of two reports per hospital (maximum of 29 reports for an individual hospital). Also, events were reported by hospitals of various sizes, but a majority were from those with more than 300 beds (58%; 200 of 343).

Table 3. Frequency of Associated Factors by Care Area Group and Across All 343 Event Reports

Care Area	Laboratory Testing	Process/ Protocol	Isolation Integrity	Commun-ication	Medication	Other	Resource Availability	Isolation Constraints	Knowledge Deficit	Patient	Inadequate Disinfection	Admission Screening	Imaging	Grand Total
Administration	1	1												2
Emergency	61	10	13	11	4	8	3		4			1	2	117
ICU	22	15	11	8	8	12	6	4	3	5				94
Imaging/Diagnostic		6	7	6			3			1	3		2	28
Intermediate Unit	4	7	9	6	1		4	1						32
Labor and Delivery	4			1										5
Laboratory	24	2		1										27
Med/Surg	23	27	19	12	18	7	3	13	3	1	1		1	128
Nursery	1													1
OB/GYN Unit		1	1											2
Other	2	1	1	1	1	1			1		1			9
Outpatient/Clinic	6	1	1			2								10
Pediatric	3	1		2		1	1							8
Pharmacy						1								1
PICU	3	1		1		2								7
Psychiatric Unit		1	1	1										3
Rehab Unit	1							1		1				3
Specialty Unit	5	11	9	5	4	2	1				2	1		40
Surgical Services	1	2	2	1			1			1	1	4		13
Grand Total	161	87	74	56	36	36	22	19	11	9	8	6	5	530

Note: The grand total below each column represents the number of events that were impacted by each associated factor. The grand total at the end of each row reflects the sum occurrence of all associated factors across all events, by care area group.

Variables Based on Manual Review of Event Reports

In this section, we report results related to event-associated factors and event outcomes. The findings are based on all 343 event reports.

Associated Factors

As shown in **Table 3**, the 13 associated factors had varying impact on the 343 COVID-19–related events submitted to PA-PSRS. We found that 36% (124 of 343) of events had more than one associated factor, for a total of 530 occurrences of associated factors across all 343 events. Overall, the most frequently identified associated factors were Laboratory Testing (47%; 161 of 343), Process/

Table 4. Frequency of Subcategories Within the Laboratory Testing Associated Factor

Mishandled	52
Re-Collection Required	45
Mislabeled or Missing Label	31
Post-Collection Processing Delay	30
Collection Delay	15
Misplaced or Erroneously Disposed	11
False Result	11
Order Error	6
Order Delay	6
Specimen Not Collected Due to Restrictive Criteria	3
Poor Collection Technique	2
Other	7
Total	**219**

Note: Across the 161 events with a Laboratory Testing associated factor, we identified 12 subcategories of this factor. The subcategories were not mutually exclusive, which is why the total of 219 is greater than the 161 events with a Laboratory Testing associated factor.

Protocol (25%; 87 of 343), and Isolation Integrity (22%; 74 of 343). **Table 3** also shows that the frequency of the associated factors varied by care area group. For example, the Laboratory Testing factor was most frequently related with the Emergency Department, and the Process/Protocol factor was most frequently linked with the Medical/Surgical Unit.

To provide further insight into the 161 events with a Laboratory Testing associated factor, we coded those events according to 12 subcategories, which were not mutually exclusive. As shown in **Table 4**, the following subcategories were the most frequent across the 161 events: Mishandled (52 of 161), Re-Collection Required (45 of 161), and Mislabeled or Missing Label (31 of 161).

We also explored the 74 events with an Isolation Integrity associated factor and found that 44 of those events described staff, patients, and/or visitors failing to correctly use PPE. More specifically, staff failed to don PPE in 23 of the events and failed to doff potentially contaminated PPE in 3 events. Also, we found that COVID-19–positive or suspected-positive patients were not wearing PPE in 22 events and visitors failed to use PPE in 2 events. These findings suggest that there are notable challenges with use of PPE for both staff and patients.

Event Outcomes

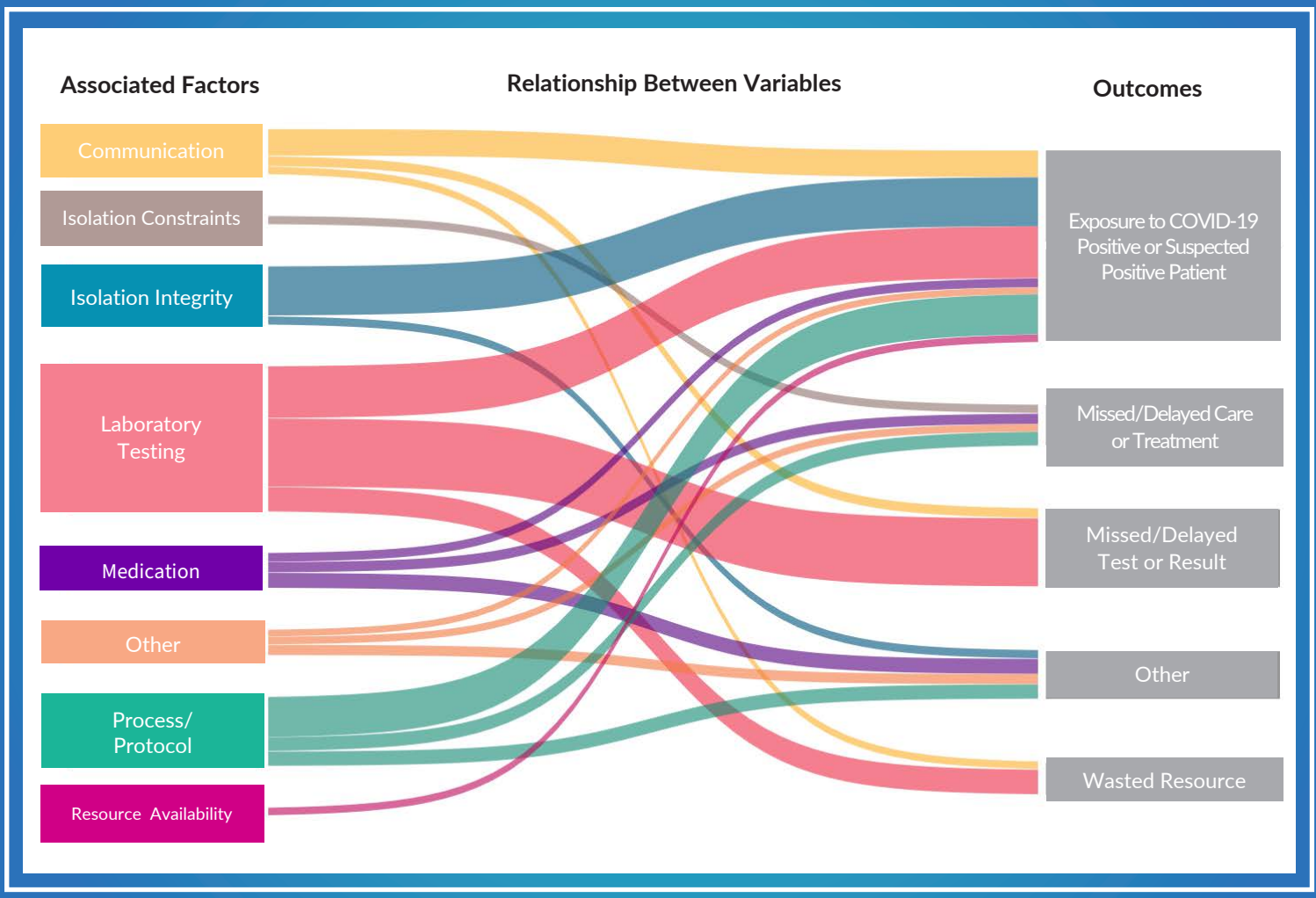
During our manual review of the 343 event reports, we identified six types of event outcomes. We found that 24% (83 of 343) of events had more than one outcome, for a total of 442 outcomes identified across all 343 events. **Table 5** shows that the two most frequent outcomes were Exposure to COVID-19 Positive or Suspected Positive Patient (50%; 173 of 343) and Missed/Delayed Test or Result (31%; 108 of 343). Additionally, **Table 5** reveals that

Table 5. Frequency of Event Outcomes by Care Area Group and Across All 343 Event Reports

Care Area	Exposure to COVID-19 Positive or Suspected Positive Patient	Missed/ Delayed Test or Result	Other	Wasted Resource	Missed/ Delayed Care or Treatment	Fall	Grand Total
Administration		1		1			2
Emergency	43	43	3	16	13		118
ICU	30	15	14	9	10		78
Imaging/Diagnostic	9	2			1		12
Intermediate Unit	13	2	4	2	2	1	24
Labor and Delivery	2	2		1			5
Laboratory	15	7	5	1			28
Med/Surg	30	16	19	12	14	8	99
Nursery		1					1
OB/GYN Unit	1						1
Other	3	1	1	1	1		7
Outpatient/Clinic	2	7				1	10
Pediatric	1	3	1	1	1		7
Pharmacy			1				1
PICU	1	3	1	1			6
Psychiatric Unit	1			1			2
Rehab Unit		1			2	1	4
Specialty Unit	14	4	5	2	1		26
Surgical Services	8			1	2		11
Grand Total	173	108	54	49	47	11	442

Note: The grand total below each column represents the number of events that were impacted by each Outcome. The grand total at the end of each row reflects the sum occurrence of all Outcomes across all events, by Care Area Group.

Figure 2. Relationships Between Associated Factors and Outcomes



Note: The thickness of lines between the event-associated factors and outcomes reflects the frequency of the relationship identified across event reports. The figure only shows relationships that were identified in 10 or more event reports. Five associated factors and one outcome were excluded from the figure due to an infrequent relationship with other variables.

the two aforementioned outcomes were most frequently associated with the Emergency Department.

To better understand the Exposure to COVID-19 Positive or Suspected Positive Patient outcome, we reviewed each of the 173 reports to identify the person who was potentially exposed to COVID-19 (note: more than one person may have been exposed in each event). Across all 173 events, we found that staff were potentially exposed in 162 of the events, patients in 22 events, visitors in 2 events, and unknown persons in 6 events. Overall, the event reports indicate that staff were at greatest risk for exposure to COVID-19.

Relationships Between Associated Factors and Event Outcomes

In **Figure 2**, the thickness of lines between the associated factors and outcomes represents the frequency of the relationship identified across event reports. For example, the thickest line in **Figure 2** is between the Laboratory Testing factor and the Missed/Delayed Test or Result outcome, as this was the most frequently occurring relationship (29%; 100 of 343). As another example, the third most prevalent relationship was between the Isolation Integrity factor and the Exposure to COVID-19 Positive or Suspected Positive Patient outcome (21%; 72 of 343).

Figure 2 also reveals that there were 19 different relationships between eight categories of associated factors and five outcomes (note: the figure only shows relationships that were identified in 10 or more event reports). Six of the associated factors had an influence on two or three outcomes. Additionally, the figure shows that the five categories of outcomes were each influenced by two or more asso-

ciated factors. In particular, the Exposure to COVID-19 Positive or Suspected Positive Patient outcome was related to seven of the eight associated factors.

Discussion

COVID-19 is caused by a novel virus. As with any novel virus, understanding its life cycle, mode and ease of transmission, and impact on people is paramount to an effective infection prevention and control program. Infectious disease experts are working hard to better understand this virus; however, information is evolving and more research is needed. Given the current knowledge gap, we sought to provide insight into how COVID-19–related events are impacting patient safety.

In our descriptive study, we explored factors with an influence on outcomes that have implications for patient safety. Taking into consideration the novelty and broad impact that COVID-19 has had on healthcare facilities, we chose to explore a relatively high-level set of variables that would capture the challenges encountered across all care areas in a facility. As you may expect, we found that the occurrence of associated factors and outcomes varied by care area. Furthermore, we found a rather dynamic and complex relationship among the associated factors and outcomes. For example, several of the outcomes had a notable relation with four or more associated factors. This type of finding conveys the potential difficulty of developing a comprehensive solution, which likely will require a multidisciplinary and individualized approach at the local level. Considering the differences from one facility to another, it is difficult for us to make sweeping recommendations. Instead, we urge facilities to use our findings to help guide their prioritization of efforts and resources when developing solutions and an implementation plan.

Even though COVID-19 is a novel virus, foundational patient safety strategies remain applicable in addressing this emerging concern. As a result, we urge readers to reference experts and literature on the following topics: using standard precautions,[11] providing infection prevention education for all staff,[11-13] continued tracking and trending of COVID-19–related events to aid in learning about strengths and areas for improvement,[14,15] and reassessing your organization's pandemic preparedness plan.[16,17] For more information about development and refinement of a pandemic preparedness plan, see resources offered by the Centers for Disease Control and Prevention (CDC) and WHO.[16, 17]

Limitations

Events classified as Incidents must be reported to PA-PSRS in a timely manner, typically within 90 days of occurrence. Given the timeliness of this article, it is likely that some of the Incidents that occurred from January 1 to April 15, 2020, have yet to be reported to PA-PSRS. Furthermore, the pandemic has placed a notable burden on healthcare facilities; therefore, delayed reporting of events may have occurred due to competing demands.

As a result, we caution readers against using our findings as a reflection of the absolute frequency of events across Pennsylvania. Readers should also note that the findings reflect events during the onset and early stages of the pandemic. It is likely that challenges experienced across Pennsylvania will evolve over time and our findings may not reflect the challenges encountered in the future. Finally, while our findings come from both urban and rural areas, and small and large hospitals, it is unclear to what extent our findings are representative of healthcare facilities beyond those included in our sample.

Conclusion

Following the first confirmed case of COVID-19 in Pennsylvania, facilities began submitting patient safety reports to PA-PSRS related to management of this emerging infection. Events in our analysis most often took place in the Emergency Department, on a Medical/Surgical Unit, or in the Intensive Care Unit. The most common associated factors were laboratory testing (e.g., mishandling of a specimen or the need to recollect a specimen), process/protocol (e.g., COVID-19–positive patient was discharged without isolation instructions) and isolation integrity (e.g., failure to don or doff PPE appropriately). The most frequent outcome was exposure to a COVID-19–positive or COVID-19–suspected patient. Although most events identified in our analysis were not Serious Events, the data highlight potential areas of focus for healthcare facilities as they develop best practices to safely care for patients amidst concerns about the potential spread of COVID-19.

Notes

This analysis was exempted from review by the Advarra Institutional Review Board.

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