

# Challenges and Potential Solutions for Patient Safety in an Infectious-Agent-Isolation Environment:

A Study of 484 COVID-19-Related Event Reports Across 94 Hospitals

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Previous research has shown that patients in infectious-agent isolation are at greater risk for certain types of safety-related events. We conducted a study to explore the relationship between the various types of events that occur in an isolation environment and the associated factors, which may have implications for the likelihood of the event and severity of patient harm. We conducted a query of the Pennsylvania Patient Safety Reporting System (PA-PSRS) database to identify event reports submitted by acute care hospitals between January 1 and September 30, 2020. We identified 484 relevant event reports from 94 hospitals for inclusion in our descriptive study (excluding near-miss events). We measured the frequency of relationship between categories of safety-related event types and 18 categories of associated factors. Among the seven categories of event types, the most frequently identified were skin integrity (141 of 484, 29%), falls (129 of 484, 27%), and medication-related (78 of 484, 16%). Across all 18 categories of associated factors, which had or may have had an influence on the event type, the most frequent were patient's mental status (80 of 484, 17%), staff's time to don personal protective equipment (62 of 484, 13%), and patient's interference with equipment/supplies (45 of 484, 9%). Overall, our results revealed that the frequency of certain associated factors varied considerably from one event type to another, which indicates that the relation between event types and associated factors should guide selection of risk mitigation strategies. We encourage readers to leverage our results along with **Table 9**, which provides a list of challenges identified in an isolation environment and potential solutions. We envision hospital staff proactively and systematically using the information in our manuscript to facilitate their evaluation of the isolation environment and prioritization of risk mitigation strategies.

**Keywords:** *airborne precautions, droplet precautions, contact precautions, ergonomics, human factors, isolation design, isolation room, SARS-CoV-2, coronavirus, pandemic, patient safety, patient harm, risk mitigation*

## Introduction

Based on guidance and recommendations from infectious disease experts, healthcare staff utilize specific strategies to prevent the transmission of infectious agents. In addition to standard precautions, which are used for all patients, transmission-based precautions are used when a patient is known or suspected of being infected or colonized with certain types of infectious agents.<sup>1</sup> Transmission-based precautions—sometimes referred to as isolation or isolation precautions—are typically organized by following three modes of infectious agent transmission: contact, droplet, or airborne.<sup>1</sup>

The primary differences between the types of transmission-based precautions are the forms of personal protective equipment (PPE) donned by staff and the engineering controls applied.<sup>2</sup> For example, a patient under airborne precautions likely will be in an isolation room with the door closed and an active negative air pressure system designed to prevent the infectious agent from moving to other areas of the hospital. Many airborne isolation rooms also

have an anteroom, which provides staff with a location to safely don and doff PPE and creates a buffer between the isolation room and the hallway. Isolation rooms, particularly those designed for airborne precautions, are constructed with considerable emphasis placed on the safety of staff and other patients outside of the room. Unfortunately, there has been a limited amount of research that has explored how isolation rooms could have unintended and adverse impacts on the safety of isolated patients.

Previous research found that isolated patients tend to have lower satisfaction (e.g., negative perceptions of treatment, access to staff, and communication)<sup>3-7</sup> and decreased mental health.<sup>4-6,8</sup> Additionally, studies found that patients in isolation received fewer and shorter-duration visits from healthcare staff<sup>5,9</sup> and patient records were more likely to be inaccurate or missing notes.<sup>3</sup> Finally, research reported that patients in isolation have a greater likelihood of adverse events, including “supportive care failures” (e.g., falls, pressure injuries, fluid or electrolyte disorders).<sup>3,5,10-13</sup> Despite the value of previous research, we were unable to identify any studies that explicitly explored and identified the factors that created risk of patient harm in an isolation environment. For example, it is unclear what aspects of the isolation environment may contribute to a patient fall or delay in detecting a patient fall.

The purpose of our descriptive study was to explore the Pennsylvania Patient Safety Reporting System (PA-PSRS)<sup>†</sup> database to identify safety events that impacted COVID-19-positive or rule-out status patients in an isolation environment. In particular, we sought to identify factors that were associated with or contributed to the occurrence of those safety events. We anticipate that the findings can be used to help hospitals evaluate their isolation environment, identify factors that are of greatest concern, and select strategies to mitigate risk of patient harm.

## Methods

### Data Source and Sample

Data in this study were collected from event reports created by individuals working in hospitals and submitted to the acute care PA-PSRS database. Each event report consisted of responses to many structured fields (e.g., event date, patient age, patient gender, care area) and several free-text narrative fields, which are used to describe the event and actions taken in response. Given the unstructured nature of free-text narrative fields, the quantity and quality of the information varies from one report to another. The responses within the free-text fields of some reports are often concise and none of the reports include access to patients' medical records or other sources of information. Nevertheless, in many reports the information is sufficient to understand and identify the relevant safety-related information.

We conducted a two-phase process to select and identify relevant events for inclusion in the study (note: near misses were excluded from the study). The first phase consisted of a database query, which was conducted in a manner similar to our previous research on safety-related events involving COVID-19.<sup>14</sup> During the database query we applied the following inclusion and exclusion criteria:

<sup>†</sup>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.

- Event dates included: January 1 to September 30, 2020
- Facility type included: Hospital
- Patient status included: Inpatient
- Care area groups<sup>†</sup> included: Intensive care unit (ICU), intermediate unit, labor and delivery, medical/surgical, nursery, obstetrics and gynecology unit, pediatric, pediatric ICU, rehabilitation unit, and specialty unit
- Sample of phrases included in the event narrative: “coronavir,” “corona vir,” “covid,” “cov-2,” “cov2,” or “sars”
- Sample of phrases excluded from the event narrative: “covidien,” “coviden,” or “covidian”

Our query generated an output of 2,285 events, which were then manually reviewed by one researcher. During review, the following criteria were applied to identify reports aligned with the study scope.

**Inclusion criteria:**

- Patient had a COVID-19-positive or rule-out status, which is typically associated with airborne precautions.<sup>15</sup>
- Patient was impacted by a safety-related event. We define “impact” as any instance where an event reached the patient and was not a near miss. Events were included regardless of whether they caused harm.
- Patient was in an isolation room.

**Exclusion criteria:**

- Events reported within the “Laboratory test problem” subtype under the “Error Related to Procedure/

Treatment/Test” event type in the database. These events were excluded because this topic was explored in a previous study that targeted COVID-19 safety-related events.<sup>14</sup> Furthermore, during development of the event coding scheme and a sample review of events, we did not find any laboratory-related events that were within our study scope.

Based on the inclusion and exclusion criteria, we identified 484 event reports for inclusion in our study.

**Variables Coded**

We analyzed two sets of variables. The first set was coded by the event reporter (i.e., facility personnel who submitted the event report to PA-PSRS) and largely consisted of demographic variables (e.g., patient age and gender, event date). The second set of variables was coded by one researcher, based on manual review of the event reports. The primary variables in this study were event type and associated factors.

**Event Type.** Event type consisted of seven mutually exclusive categories. For each event report, the researcher initially determined whether the patient was impacted by one of the following event types: fall, medication related, skin integrity, transfusion related, or an unplanned extubation. If none of those five event types were identified, then the researcher next considered whether the patient’s care was missed, delayed, or interrupted. If none of the aforementioned six event types were identified, then the “other” event type was selected. This coding process was repeated for each of the 484 event reports. See **Table 1** for definitions of the seven event type categories.

**Associated Factors.** This variable was used to identify factors that had or may have had an influence on the event type. Provided that the report contained adequate information, one or more

**Table 1. Categories of Event Type**

The event type was used to identify how the patient was impacted.	
<b>Fall</b>	Patient experienced an “...unplanned descent to the floor (or other horizontal surface such as a chair or table)...” <sup>16</sup>
<b>Medication-Related</b>	Patient was impacted due to a medication not being administered as intended or the medication produced an unintended result.
<b>Skin Integrity</b>	Patient experienced a pressure injury, <sup>17</sup> skin tear, blister, and/or maceration.
<b>Transfusion-Related</b>	Patient was ordered a transfusion; however, the patient was administered the wrong product, had a reaction, or had a dose omission.
<b>Unplanned Extubation</b>	Endotracheal tube was removed due to an unplanned, unintentional, and/or uncontrolled action. <sup>18</sup>
<b>Missed, Delayed, or Interrupted Care</b>	This event type consisted of the following subcategories: 1) Delay in monitoring or failure to maintain monitoring; 2) Delayed or missed bedside assessment/exam; 3) Delay in implementing or failure to maintain appropriate care/treatment; and 4) Delayed or missed consultation.
<b>Other</b>	An event type that was not aligned with the aforementioned six categories of event types.

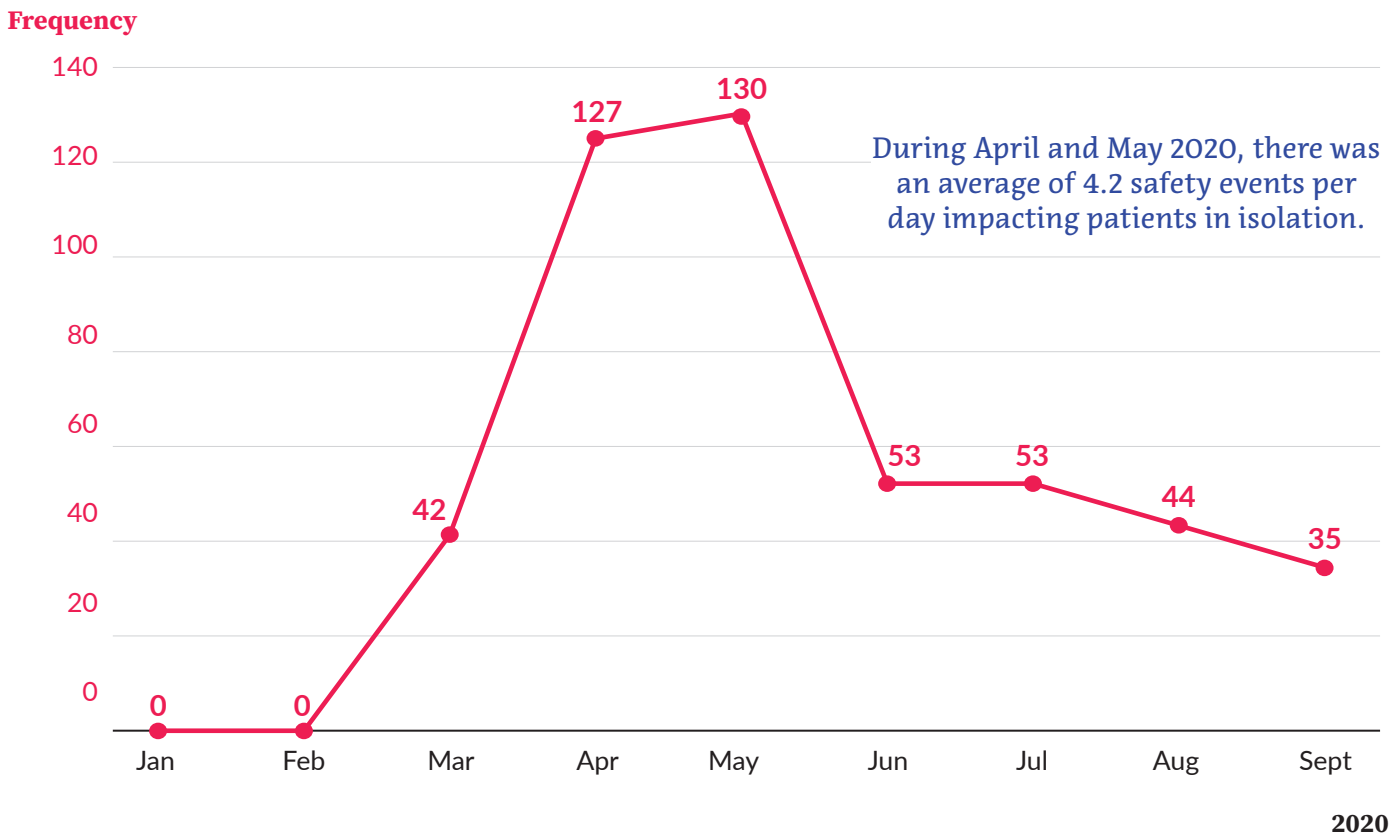
**Note:** Each of the 484 event reports were coded as having only one event type. Note that subcategories for some of the event types will be identified and defined in the results section.

<sup>†</sup> Within PA-PSRS, the event reporter chooses among 179 care areas to indicate the location where an event occurred. In order to simplify our analysis, we sorted each of the care areas into higher-level care area groups.

**Table 2. Categories of Associated Factors**

The associated factors were used to identify the conditions that had or may have had an influence on the event type.		
Environment, Equipment, and Supplies	1. Visualizing patient	Staff were unable to observe or had difficulty observing the patient. This may have been caused by the door being closed or a lack of windows and/or nonoptimal window location. In some cases, video monitoring may have been implemented but the equipment was not functioning properly or may not have provided an adequate view of the patient.
	2. Hearing alarms	Staff were unable to hear a device alarm, such as alarms associated with a bed, chair, ventilator, infusion pump, oxygen monitor, or cardiac monitor. Auditory challenges may have been related to staff distance from patient room, building design, closed door, inadequate alarm volume, or competing noise (e.g., negative air system, alarms from other equipment).
	3. Communication	Communication was limited by environmental conditions. This included situations in which staff were outside the isolation room and had difficulty communicating through the door or window to the patient inside the room, or patients in the isolation room were yelling to request assistance from staff.
	4. Equipment/supplies nonoptimal conditions of use	Equipment and/or supplies did not produce the expected result due to conditions of use. For example, medication tubing was run from an infusion pump on the outside of the room, under an active door, and to the patient inside the room; however, the friction between the tubing and traffic through the doorway caused the tubing to fail. Alternatively, staff chose not to use equipment and/or supplies due to conditions related to the isolation environment. For example, staff did not use a computer and/or scanner inside the isolation room due to concerns of contaminating the equipment.
	5. Equipment/supplies malfunction or broken	Equipment and/or supplies malfunctioned or broke during normal use.
	6. Equipment/supplies use error	Equipment and/or supplies were not used as ordered, used in the wrong context, or were improperly setup or adjusted.
	7. Time to don PPE	Upon arriving to a patient's room, staff were not wearing adequate PPE (e.g., gown, N95 mask or powered air purifying respirator, gloves, eye protection) and were unable to immediately enter the isolation room. Staff had to take time to don PPE before entering the room and were delayed in responding to an urgent need.
	8. PPE unavailable or staff untrained on PPE	PPE was not accessible or staff were not trained on use of PPE, which resulted in staff not entering a patient's room or delayed entry.
Treatment/Care	9. Not ordered/ordered incorrectly	Necessary treatment or care was not ordered or an incorrect order was placed and implemented. This factor involved workflow failures, which may have included issues with inadequate or unclear policy, staff adapting to new processes, information transfer, or care coordination. This factor excluded issues caused by equipment/supplies malfunction or use error.
	10. Ordered but not performed	Necessary treatment or care was ordered but was not implemented. This factor involved workflow failures, which may have included issues with inadequate or unclear policy, staff adapting to new processes, information transfer, or care coordination. This factor excluded issues caused by equipment/supplies malfunction or use error.
	11. New treatment protocol	Patient received a treatment that was relatively new, and the effects and potential reactions may have been unfamiliar or unexpected to some staff.
	12. Refusal to enter patient room or assess in person	Staff refused to enter the isolation room or refused to assess the patient in person and instead indirectly assessed the patient with assistance from other staff or by reviewing the patient's chart.
Communication/Teamwork	13. Staff between departments/units	Failed to communicate or miscommunicated important information about treatment/care.
	14. Staff within department/unit	
	15. Staff and patient	
Patient-Related	16. Mental status	Patient had a mental illness, altered mental status, or developmental disability. This factor included situations in which patients were described as having delirium; <sup>19</sup> dementia; substance withdrawal; <sup>20</sup> an intellectual disability; or demonstrated impulsive, agitated, aggressive, or confused behavior.
	17. Interference with equipment	Patient deliberately manipulated equipment in a manner that interfered with treatment/care. For example, a patient removed chest tubes, intravenous lines, monitoring leads, nasal cannula, nasogastric tube, or endotracheal tube, or turned off their bed alarm.
	18. Other	This included various factors that were not aligned with the above 17 associated factors.

Figure 1. Safety Events Impacting COVID-19 Patients in Isolation by Month, N=484



associated factors were identified per event report. Our study used 18 categories of associated factors, which were sorted into the following five groups: environment, equipment, and supplies; treatment/care; communication/teamwork; patient-related; and other. See **Table 2** for definitions of the 18 associated factors.

During our review of the reports describing a skin integrity event type, we found that many of the associated factors were unique to skin integrity and appeared to have a multifactorial relation (e.g., diet, limited mobility/paralysis, disease process, prone position, device-related friction, obesity). In addition, we observed a very small percentage of skin integrity events that mentioned an associated factor that was aligned with our current coding scheme and/or unique to an isolation environment. As a result, we chose to only analyze the frequency of the skin integrity event type and not explore the complex relation with unique associated factors.

### Descriptive Data Analysis

The variables were measured by frequency and were assessed using a descriptive analysis. A descriptive analysis is an approach where phenomena are identified and patterns are explored to better comprehend and explain the conditions in which the phenomena occur.<sup>21,22</sup> This type of analysis is not used to identify causal relations, rather it is used to characterize the context of the phenomena, point toward possible causal mechanisms, and generate hypotheses. With a descriptive analysis, data are presented in a manner favoring simplicity with minimal statistical adjustments, as opposed to complex statistical modeling or an unnecessarily complex presentation of the data, to help a broader

audience readily comprehend the findings. This type of analysis is often achieved with visual presentations of the data that will allow insights among various combinations of variables.

### Results

#### Patient Sex and Age

Across all 484 event reports, 59% (286 of 484) of patients were reported as male and 41% (198 of 484) were female. Based on the 484 event reports, patient age was an average of 66 years and a median of 68 years (range of 0 to 99 years, 59 years was the 25<sup>th</sup> percentile and 77 years was the 75<sup>th</sup> percentile).

#### Safety Events Impacting COVID-19 Patients in Isolation

All 484 events occurred at acute care hospitals and at least one event was reported by 94 hospitals. Across the 94 hospitals, the average and median events reported were 5.15 and 2.5, respectively (range of events per hospital was 1–60, frequency of 1 event was the 25<sup>th</sup> percentile, frequency of 5 events was the 75<sup>th</sup> percentile, and 12 hospitals reported 10 or more events).

As shown in **Figure 1**, seven of the nine months included in our study had at least one event. There was a sharp increase in events from 0 in January and February to 127 in April. During April and May, there was an average of 4.2 events per day (257 events in 61 days); the rate decreased to an average of 1.2 events per day in September (35 events in 30 days).

**Table 3.** Frequency of Relationships Between Event Types (N=484) and Associated Factors (N=473)

		Event Types							Total
		Fall	Medication	Skin Integrity	Transfusion	Unplanned Extubation	Missed, Delayed, or Interrupted Care	Other	
<b>Total (1 per report)</b>		<b>129 (27%)</b>	<b>78 (16%)</b>	<b>141 (29%)</b>	<b>12 (2%)</b>	<b>34 (7%)</b>	<b>71 (15%)</b>	<b>19 (4%)</b>	<b>484 (100%)</b>
<b>Associated Factors</b>									<b>Total</b>
<b>Environment, Equipment, and Supplies</b>	1. Visualizing patient	10	-	NE	-	1	2	-	<b>13</b>
	2. Hearing alarms	12	1	NE	-	3	3	-	<b>19</b>
	3. Communication	13	-	NE	-	-	1	-	<b>14</b>
	4. Equipment/supplies non-optimal conditions of use	13	9	NE	-	3	3	-	<b>28</b>
	5. Equipment/supplies malfunction or broken	1	-	NE	-	4	10	-	<b>15</b>
	6. Equipment/supplies use error	7	12	NE	-	1	7	2	<b>29</b>
	7. Time to don PPE	48	2	NE	-	8	4	-	<b>62</b>
	8. PPE unavailable or staff untrained on PPE	1	-	NE	-	1	4	-	<b>6</b>
<b>Group Total</b>		<b>105</b>	<b>24</b>	<b>NE</b>	<b>-</b>	<b>21</b>	<b>34</b>	<b>2</b>	<b>186</b>
<b>Treatment/Care</b>	9. Not ordered/ordered incorrectly	-	3	NE	2	-	5	-	<b>10</b>
	10. Ordered but not performed	-	20	NE	1	-	9	-	<b>30</b>
	11. New treatment protocol	-	26	NE	8	-	-	-	<b>34</b>
	12. Refusal to enter patient room or assess in person	1	2	NE	-	-	16	1	<b>20</b>
<b>Group Total</b>		<b>1</b>	<b>51</b>	<b>NE</b>	<b>11</b>	<b>-</b>	<b>30</b>	<b>1</b>	<b>94</b>
<b>Communication/Teamwork</b>	13. Staff between departments/units	-	-	NE	-	-	15	-	<b>15</b>
	14. Staff within department/unit	-	4	NE	-	-	8	-	<b>12</b>
	15. Staff and patient	17	-	NE	-	-	3	-	<b>20</b>
<b>Group Total</b>		<b>17</b>	<b>4</b>	<b>NE</b>	<b>-</b>	<b>-</b>	<b>26</b>	<b>-</b>	<b>47</b>
<b>Patient-Related</b>	16. Mental status	65	-	NE	-	3	6	6	<b>80</b>
	17. Interference with equipment	3	1	NE	-	29	8	4	<b>45</b>
<b>Group Total</b>		<b>68</b>	<b>1</b>	<b>NE</b>	<b>-</b>	<b>32</b>	<b>14</b>	<b>10</b>	<b>125</b>
18. Other		2	7	NE	-	1	4	7	<b>21</b>
Insufficient Information		34	9	NE	1	-	7	6	<b>57</b>

**Note:** The **blue** shaded area at the top of the table identifies the seven categories of event types and the frequency per type. Only one event type was identified in each of the 484 events; however, more than one associated factor may have been identified for each event, which would reflect a situation where more than one factor had or may have had an influence on the event type. The **gold/tan** shaded areas correspond with the associated factors identified throughout the study. The 18 associated factors were sorted into five groups, which include a row identifying the total below each group indicating the overall impact of a group of associated factors. In the right column, the associated factors were summed to reveal the frequency across all seven categories of event type. Overall, 18 different associated factors were explored and the **gold/tan** shaded area shows the impact per category of associated factor and the relationship with each column of event type. Cells with “NE” indicate that the associated factors were not explored. Cells with a - represent a zero frequency per combination of categories.

## Event Types and Associated Factors Impacting COVID-19 Patients in Isolation

The primary results from this study are shown in **Table 3**, which reveal the distribution of 484 event types and 473 associated factors identified from 484 event reports.<sup>‡</sup> Among the 484 reports, skin integrity (141 of 484, 29%), falls (129 of 484, 27%), and medication-related (78 of 484, 16%) were the most frequent event types among the seven categories. In contrast, the least frequent event types were unplanned extubations (34 of 484, 7%) and transfusion-related (12 of 484, 2%).

In the table, the 18 associated factors were sorted into five groups. The environment, equipment, and supplies group was the most frequent (186 of 473, 39%) and patient-related was the second most frequent group (125 of 473, 26%). Across all 18 associated factors, the most frequent were patient's mental status (80 of 484, 17%), staff's time to don PPE (62 of 484, 13%), and patient's interference with equipment/supplies (45 of 484, 9%).

The data in **Table 3** show that the frequency of relation between the event types and associated factors varied from one combination of categories to another. For example, the medication-related event type was most frequently related with the new treatment protocol factor (26 of 78, 33%) and treatment/care ordered but not performed factor (20 of 78, 26%). In contrast, within the unplanned extubation event type, the two most frequently associated factors were patient interference with equipment (29 of 34, 85%) and

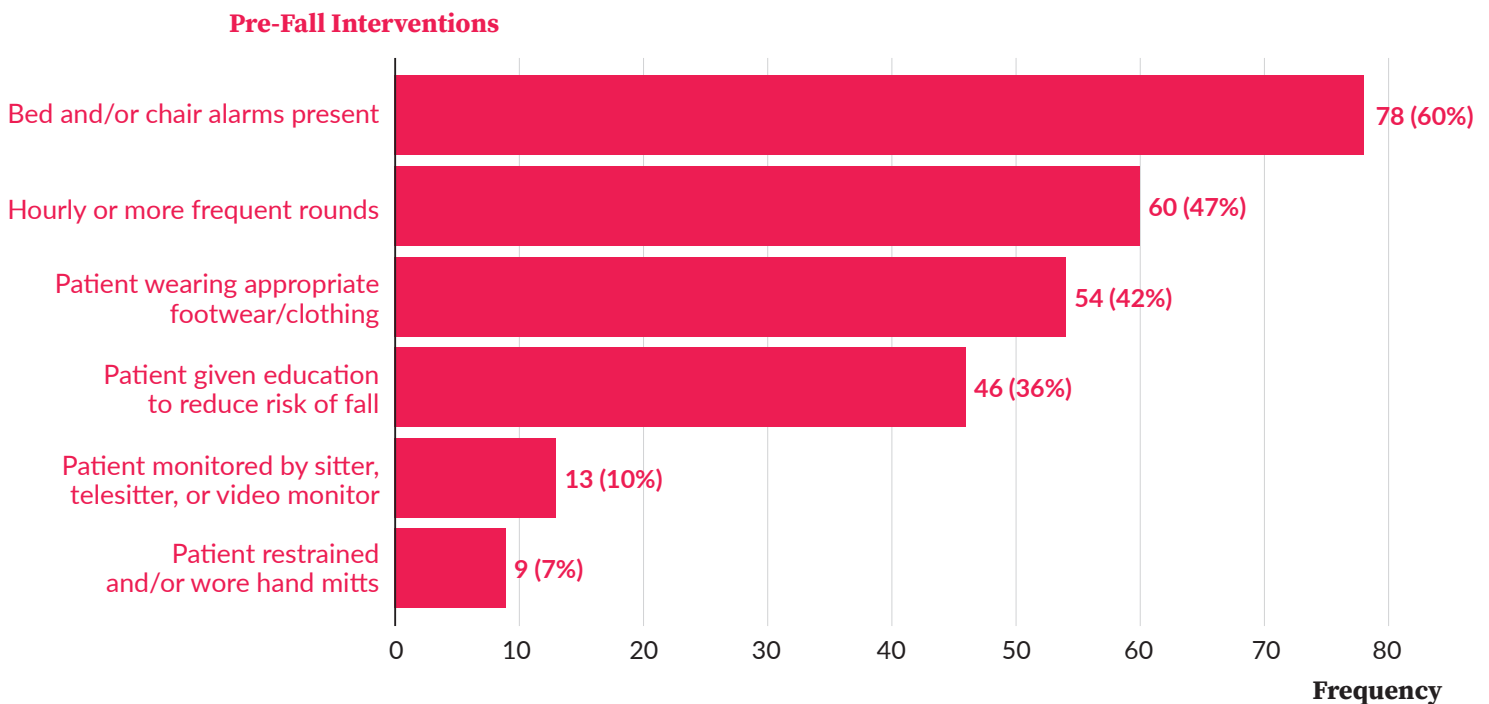
staff's time to don PPE (8 of 34, 24%). These results highlight the importance of exploring the associated factors per event type to better understand the context in which the events occurred. For further exploration into each event type and the relationship with each associated factor, see the subsequent sections.

## Fall Event Type and Associated Factors With Supplemental Findings

**Table 3** shows that the fall event type occurred in 129 of the 484 events and 13 of the 18 associated factors were involved. A majority of the associated factors were related to the environment, equipment, and supplies group (n=105) and the patient-related group (n=68). The categories of associated factors most frequently identified were patient mental status (65 of 129, 50%) and staff's time to don PPE (48 of 129, 37%). To better understand the impact of time to don PPE, we further explored the fall events and found that in 26% (33 of 129) of the events the patient had not yet fallen when staff arrived at the entrance to the isolation room; however, staff were unable to prevent the fall due to time required to don PPE.

We also collected data on the pre-fall interventions that were in place and intended to decrease the likelihood of a fall. **Figure 2** shows that in 60% (78 of 129) of the events a bed and/or chair alarm was implemented and 47% (60 of 129) involved hourly or more frequent rounds. Despite these pre-event interventions, the patient fell in each of the 129 events.

Figure 2. Frequency of Pre-Fall Interventions Across 129 Events That Involved a Fall



**Note:** The results represented by each bar are not mutually exclusive, as many of the events had more than one pre-fall intervention. Percentage was calculated with a denominator of 129.

<sup>‡</sup>The 141 skin integrity events were unexplored for an associated factor and 57 additional events had insufficient information to identify an associated factor, which resulted in fewer associated factors (N=473) than the total number of events (N=484).



In 26% of the fall events the patient had not yet fallen when staff arrived at the entrance to the isolation room; however, staff were unable to prevent the fall due to time required to don PPE.

Within the environment, equipment, and supplies group of associated factors, **Table 3** reveals that falls were frequently associated with inability or difficulty communicating, hearing alarms, and/or visualizing the patient. For example, staff had difficulty or were unable to hear alarms in 9% (12 of 129) of the fall events, which was related to alarm volume being inadequate, doors being closed, and/or noise from negative air pressure systems. Additionally, in 8% (10 of 129) of the events staff had difficulty visualizing the patient from outside of the room due to a lack of windows or placement of the windows. Also, staff had difficulty communicating with the patient in 10% (13 of 129) of the events due to the door being closed, background noise, and/or patients having a hearing impairment. Overall, the frequency of these associated factors indicates a multifactorial relation between the isolation environment and equipment that may create additional challenges when caring for patients.

We also explored each of the 129 fall events to determine how staff detected the fall or were alerted to the patient's impending fall. As shown in **Table 4**, 40% (52 of 129) of the falls or impending falls were detected by the sound from the bed or chair alarm, 4% (5 of 129) were detected by a telesitter or through a video monitor, and 3% (4 of 129) were from a call bell. Collectively, 47% (61 of 129) of the falls or impending falls were detected by an intended method.

**Table 4.** Frequency of Method Used to Detect the Fall or Method That Alerted Staff to the Impending Fall, N=129

Bed or chair alarm	52 (40%)
Unexpectedly found patient on floor	26 (20%)
In-person witnessed fall	14 (11%)
Patient yelling and/or crash sound	13 (10%)
Unknown	8 (6%)
Heart or oxygen saturation monitor	5 (4%)
Telesitter or video monitor	5 (4%)
Call bell	4 (3%)
Patient communication post fall	2 (2%)
<b>Total</b>	<b>129 (100%)</b>

**Note:** Rows of data are mutually exclusive. Percentage was calculated with a denominator of 129.

**Table 5.** Frequency of Subcategories Within Medication-Related Event Type, N=78

Dose omission	30 (38%)
Adverse drug reaction (ADR)	26 (33%)
Extra dose	4 (5%)
Overdosage	4 (5%)
Wrong drug	3 (4%)
Wrong time	3 (4%)
Dose delay	2 (3%)
Underdosage	2 (3%)
Wrong patient	2 (3%)
Drug-drug interaction	1 (1%)
Duplicate therapy	1 (1%)
<b>Total</b>	<b>78 (100%)</b>

**Note:** Rows of data are mutually exclusive. Percentage was calculated with a denominator of 78.

In contrast, 35% (45 of 129) of the fall events were detected by a nonoptimal method. For example, 20% (26 of 129) were detected by staff unexpectedly finding the patient on the floor, 10% (13 of 129) were from staff hearing a patient yelling and/or a crash sound, 4% (5 of 129) were from a triggered heart or oxygen monitor, and 2% (2 of 129) were from patient communication post-fall. Overall, the fall-related findings indicate that prevention and timely detection of falls can be impeded by various conditions associated with an isolation environment.

**Medication-Related Event Type and Associated Factors With Supplemental Findings**

**Table 3** reveals that the medication-related event type was identified in 78 of the 484 events and was related to 11 of the 18 categories of associated factors. Across the 78 medication-related events, the treatment/care group of associated factors (n=51) and environment, equipment, and supplies group (n=24) were the most frequent. Additionally, new treatment protocol (26 of 78, 33%) and treatment/care ordered but not performed (20 of 78, 26%) were the most frequent among the 18 categories of associated factors.

We further analyzed the medication-related events to identify subcategories of the event type. We found that 38% (30 of 78) involved a dose omission and 33% (26 of 78) reported an adverse drug reaction (ADR). Within the dose omission events, 50% (15 of 30) involved an inhaled respiratory medication; within the ADRs, 73% (19 of 26) involved remdesivir. See **Table 5** for additional findings related to the subcategories.

**Table 3** shows that within the environment, equipment, and supplies group of associated factors, equipment/supplies use error (12 of 78, 15%) and equipment/supplies nonoptimal conditions of use (9 of 78, 12%) were the most frequent. Upon further analysis of the events connected with these two categories of associated factors,



we found that 9 events were related to use of an infusion pump, 4 of which involved broken tubing that was run from a pump outside the isolation room, under an active door, and to the patient inside the room. In contrast, one event involved an inaudible infusion pump inside the isolation room. Four events were related to not having a computer or scanner in the isolation room. On the whole, the medication-related events were frequently associated with the conditions of the isolation environment.

### Skin Integrity Event Type and Supplemental Findings

**Table 3** reveals that skin integrity was the most frequent among the seven categories of event type (141 of 484, 29%). As mentioned previously, we did not explore associated factors for the skin integrity events. We did, however, analyze the skin integrity events to identify the frequency of subcategories. **Figure 3** shows that the most frequent subcategories were stage 1–4 or unstageable pressure injury (82 of 141, 58%) and deep tissue injury (43 of 141, 30%).

### Transfusion-Related Event Type and Associated Factors With Supplemental Findings

As conveyed by **Table 3**, 2% (12 of the 484) of the event reports had a transfusion-related event type and all identified associated factors were within the treatment/care group. Across 11 of the 12 transfusion-related events, the associated factors involved were treatment/care not ordered or ordered incorrectly, ordered but not performed, or new treatment protocol (one event provided insufficient information to identify an associated factor).

We further explored the 12 transfusion-related events to identify event subcategories and the product type involved. Convalescent plasma was involved in 11 of the 12 events, including adverse reactions (8 of 11), erroneous administration of fresh frozen plasma in place of convalescent plasma (2 of 11), and an omission (1 of 11). Overall, transfusion-related events were a small portion of the total sample of 484 events.

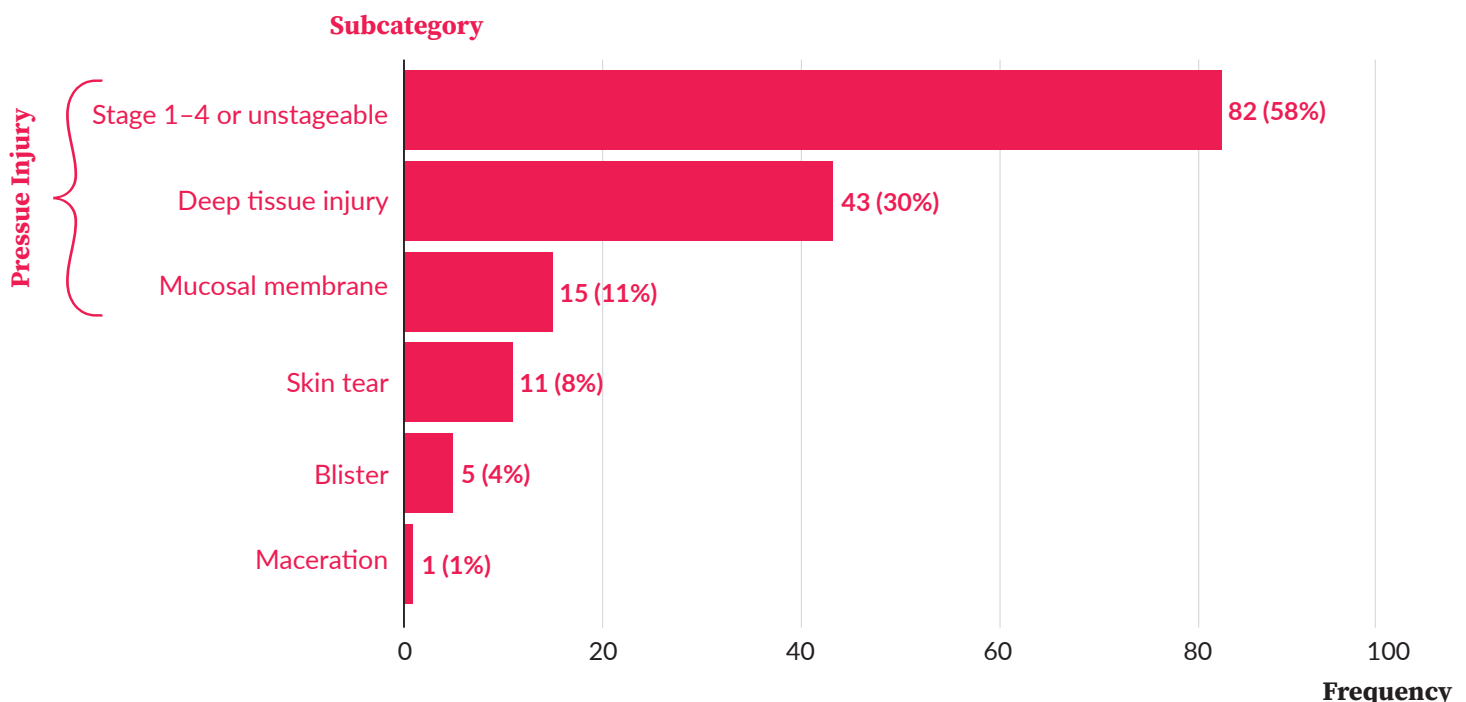
### Unplanned Extubation Event Type and Associated Factors With Supplemental Findings

**Table 3** shows that 7% (34 of 484) of the events had an unplanned extubation and involved 10 of the 18 categories of associated factors. Among the associated factors, nine of the 10 categories were within the patient-related group or environment, equipment, and supplies group. Across all 34 unplanned extubation events, the two most frequent categories of associated factors were patient interference with equipment (n=29) and staff’s time to don PPE (n=8).

We further sorted the unplanned extubation events into three subcategories.<sup>23,24</sup> As revealed by **Table 6**, 85% (29 of 34) involved a patient self-extubation (deliberate action by the patient), 12% (4 of 34) were related to a device malfunction (e.g., cuff leak), and 3% (1 of 34) were related to staff causing an accidental extubation (e.g., tube caught on bedrail when repositioning patient).

Given that a majority of the unplanned extubations involved a patient self-extubation, we further explored that subcategory to better understand the conditions in which they occurred. In 41% (12 of 29) of self-extubation events the patient was restrained.

Figure 3. Frequency of Subcategories Within Skin Integrity Event Type, N=141



**Note:** The results represented by each bar are not mutually exclusive, as each event may have reported more than one type of skin injury. Also, these results do not represent the total number of skin injuries across all patients, as some patients had more than one injury per subcategory. Percentage was calculated with a denominator of 141.

**Table 6.** Frequency of Subcategories Within Unplanned Extubation Event Type, N=34

Patient self-extubation	29 (85%)
Device malfunction	4 (12%)
Staff accidental extubation	1 (3%)
<b>Total</b>	<b>34 (100%)</b>

**Note:** Rows of data are mutually exclusive. Percentage was calculated with a denominator of 34.

**Table 7.** Frequency of Method Used to Detect the Self-Extubation or Method That Alerted Staff to the Impending Self-Extubation, N=29

Unspecified	12 (41%)
Ventilator alarm	9 (31%)
In-person witnessed self-extubation	6 (21%)
Unexpectedly found patient self-extubated	1 (3%)
Heart monitor	1 (3%)
<b>Total</b>	<b>29 (100%)</b>

**Note:** Rows of data are mutually exclusive. Percentage was calculated with a denominator of 29.



In 41% (12 of 29) of the self-extubation events the patient was restrained.

In 21% (6 of 29) of the self-extubation events the patient had not yet extubated when staff arrived at the entrance to the isolation room; however, staff were unable to prevent the self-extubation due to time required to don PPE.

In 14% (4 of the 29) of the self-extubations, staff had challenges in detecting the problem due to inability or difficulty hearing the ventilator alarm or visualizing the patient.

Additionally, in 21% (6 of 29) of the self-extubation events the patient had not yet extubated when staff arrived at the entrance to the isolation room; however, staff were unable to prevent the self-extubation due to time required to don PPE. Also, in 14% (4 of the 29) of the self-extubations, staff had challenges in detecting the problem due to inability or difficulty hearing the ventilator alarm or visualizing the patient.

We also explored the 29 self-extubation events to determine how staff detected or were alerted to the impending self-extubation. As conveyed by **Table 7**, 31% (9 of 29) were detected by a ventilator alarm and 21% (6 of 29) were witnessed in person. Unfortunately, 41% (12 of 29) of the self-extubation reports failed to specify how staff detected the event.

**Missed, Delayed, or Interrupted Care Event Type and Associated Factors With Supplemental Findings**

**Table 3** shows that 15% (71 of 484) of the event reports involved a missed, delayed, or interrupted care event type. Given the breadth of conditions in which this event type can occur, we sorted the events into four subcategories, which are shown in **Table 8**. This table reveals that the four event type subcategories range in frequency from 10 to 38, with delay in implementing or failure to maintain appropriate care/treatment as the most frequent (38 of 71, 54%).

As conveyed by **Table 8**, the event type subcategories were related with either three, four, or five of the associated factor groups, indicating that these events were influenced by a diverse set of associated factors. Across all four of the event type subcategories, the most frequent groups of associated factors were environment, equipment, and supplies (n=34) and treatment/care (n=30). Across all 18 categories of associated factors, the most frequent were refusal to enter patient room or assess in person (16 of 71, 23%), communication/teamwork between departments/units (15 of 71, 21%), and equipment/supplies malfunction or broken (10 of 71, 14%). Across the 10 events associated with the equipment/supplies malfunction or broken factor, 6 events involved a ventilator machine or circuit and 2 events involved a heart monitor.

**Other Event Type and Associated Factors With Supplemental Findings**

**Table 3** reveals that the “other” category of event type was identified in 4% (19 of 484) of the events. These included intravenous site complications (6 of 19), patients attempting to leave or leaving against medical advice (4 of 19), and patient self-harm (2 of 19). Only five of the 18 categories of associated factors were represented among these 19 events, including other (n=7), patient mental status (n=6), and patient interference with equipment (n=4).

**Table 8.** Frequency of Relationships Between Subcategories of Missed, Delayed, or Interrupted Care Event Type (N=71) and Associated Factors (N=108)

		Subcategories of Missed, Delayed, or Interrupted Care Event Type				Total
		Delay in monitoring or failure to maintain monitoring	Delayed or missed bedside assessment/exam	Delay in implementing or failure to maintain appropriate care/treatment	Delayed or missed consultation	
<b>Total (1 per report)</b>		<b>12 (17%)</b>	<b>10 (14%)</b>	<b>38 (54%)</b>	<b>11 (15%)</b>	<b>71 (100%)</b>
Associated Factors						Total
Environment, Equipment, and Supplies	1. Visualizing patient	1	-	1	-	2
	2. Hearing alarms	1	-	2	-	3
	3. Communication	1	-	-	-	1
	4. Equipment/supplies nonoptimal conditions of use	1	-	2	-	3
	5. Equipment/supplies malfunction or broken	3	-	7	-	10
	6. Equipment/supplies use error	2	-	5	-	7
	7. Time to don PPE	-	-	4	-	4
	8. PPE unavailable or staff untrained on PPE	-	1	2	1	4
<b>Group Total</b>		<b>9</b>	<b>1</b>	<b>23</b>	<b>1</b>	<b>34</b>
Treatment/Care	9. Not ordered/ordered incorrectly	-	1	4	-	5
	10. Ordered but not performed	2	1	6	-	9
	11. New treatment protocol	-	-	-	-	-
	12. Refusal to enter patient room or assess in person	2	4	3	7	16
<b>Group Total</b>		<b>4</b>	<b>6</b>	<b>13</b>	<b>7</b>	<b>30</b>
Communication/Teamwork	13. Staff between departments/units	4	1	6	4	15
	14. Staff within department/unit	-	1	6	1	8
	15. Staff and patient	1	1	1	-	3
<b>Group Total</b>		<b>5</b>	<b>3</b>	<b>13</b>	<b>5</b>	<b>26</b>
Patient-Related	16. Mental status	4	-	2	-	6
	17. Interference with equipment	3	-	5	-	8
<b>Group Total</b>		<b>7</b>	<b>-</b>	<b>7</b>	<b>-</b>	<b>14</b>
18. Other		1	2	1	-	4
Insufficient Information		-	3	3	1	7

**Note:** The **blue** shaded area at the top of the table identifies the four subcategories of the Missed, Delayed, or Interrupted Care event type and the frequency per subcategory. Only one subcategory was identified in each of the 71 events; however, more than one associated factor may have been identified in each event, which would reflect a situation where more than one factor had or may have had an influence on the event type. The **gold/tan** shaded areas correspond with the associated factors identified throughout the study. The 18 associated factors were sorted into five groups, which include a row identifying the total below each group. This group total indicates the overall impact of a group of associated factors. In the right column, the associated factors were summed to reveal the frequency across all four subcategories of the event type. Overall, 18 different associated factors were explored and the **gold/tan** shaded area shows the impact per category of associated factor and the relationship with each column of event type subcategory. Cells with a - represent a zero frequency per combination of categories.

**Table 9. Challenges and Potential Solutions for Patient Safety in an Infectious-Agent-Isolation Environment**

Associated Factors	Challenges	Potential Solutions
<b>Environment, Equipment, and Supplies (Associated Factors 1–8)</b>	<p>1. Visualizing patient</p> <p>Delayed detection of patient's change in condition or urgent need due to inability or difficulty visualizing patient.</p> <ul style="list-style-type: none"> <li>• Doors closed to maintain isolation precautions.</li> <li>• Lack of window or inadequate placement of window.</li> <li>• Lack of video monitoring equipment or quality (e.g., resolution, video angle, zoom).</li> </ul>	<p>Increase efficiency of care and timely detection of patient's change in condition or urgent need.</p> <ul style="list-style-type: none"> <li>• During a high volume of patients with a specific infectious agent, provide care in a negative air pressure wing or ward,<sup>26,27</sup> which will allow individual room doors to remain open.</li> <li>• Proactively install new doors with windows or retrofit existing doors by adding a window. When modifying the environment ensure conformity with current Life Safety Codes.<sup>28-30</sup></li> <li>• Use video monitors<sup>31,32</sup> when there are no windows or existing windows provide an inadequate view.</li> <li>• Arrange items in the patient room to allow optimal visibility from the window or video monitor.</li> <li>• Install a temporary clear plastic door kit which will allow greater visibility of the patient while the original door remains installed and active. When modifying the environment ensure conformity with current Life Safety Codes.<sup>28-30</sup> Note that use of a temporary plastic door may reduce the likelihood of certain safety concerns, but may introduce other unintended consequences.<sup>33-38</sup></li> </ul>
	<p>2. Hearing alarms</p> <p>Delayed detection of patient's change in condition or urgent need due to inability or difficulty hearing alarms (e.g., bed, chair, ventilator, infusion pump, oxygen monitor, cardiac monitor).</p> <ul style="list-style-type: none"> <li>• Doors closed to maintain isolation precautions.</li> <li>• Dense building design/construction of hospital impedes sound travel from inside of room to hallway.</li> <li>• Competing noise on unit (e.g., negative air pressure system, other alarms).</li> <li>• Alarms not set to adequate volume.</li> <li>• Alarm not designed to produce adequate decibels.</li> </ul>	<p>Increase efficiency of care and timely detection of patient's change in condition or urgent need.</p> <ul style="list-style-type: none"> <li>• Follow alarm management policies to eliminate unnecessary alarms (competing noise).<sup>39-41</sup></li> <li>• Where possible, have alarms transmitted to the nurse's station or to other remote monitoring staff.</li> <li>• Adopt technology that will allow an alarm to be transmitted to a mobile device.</li> <li>• Transmit alarm sound to accessory speaker immediately outside of patient's room.</li> <li>• Employ a visual signal device immediately outside of patient's room to minimize competing noise in the unit.</li> <li>• When appropriate, use independent double check<sup>42,43</sup> of alarm settings and connections.</li> <li>• If necessary, adjust alarm to maximum volume.</li> <li>• Consider moving the device to outside of patient's room so the device can more easily be monitored (e.g., infusion pump<sup>33-38</sup>). Note that placement of infusion pumps or other devices on the outside of the room may reduce the likelihood of certain safety concerns, but may introduce other unintended consequences.<sup>33-38</sup></li> </ul>
	<p>3. Communication</p> <p>Communication is difficult or limited within the patient's room or between a person inside of the room and a person outside the room.</p> <ul style="list-style-type: none"> <li>• Communication difficulty between patient and staff, who are at doorway or outside of room.</li> <li>• Face mask or powered air purifying respirator (PAPR) impedes clear communication with patient and/or staff.<sup>44</sup></li> <li>• Communication difficulty between staff and patient due to inability to visualize staff's face and name badge.</li> </ul>	<p>Improve ease of communication within the patient's room or between the inside and outside of the room.</p> <ul style="list-style-type: none"> <li>• Utilize mobile or hallway phones to contact patient's bedside phone, as opposed to attempting to communicate through a window or closed door.</li> <li>• Create a list of patients' room phone numbers for clinicians and other staff.<sup>45</sup></li> <li>• Adopt hands-free voice-controlled device or smart speaker so patients can request assistance and communicate with staff from anywhere in the room.</li> <li>• Use visual signs or reusable marker boards.</li> <li>• Use bedside tablets that allow patient to make simple requests via touch screen that is relayed to staff via mobile or central device.<sup>46</sup></li> <li>• Utilize a consistent system for displaying staff name and role on outside of PPE.<sup>44</sup></li> </ul>

Continuation of Table 9. Challenges and Potential Solutions for Patient Safety in an Infectious-Agent-Isolation Environment

Associated Factors	Challenges	Potential Solutions
<b>Environment, Equipment, and Supplies (Associated Factors 1–8)</b>	<p>4. Equipment/supplies nonoptimal conditions of use</p> <p>Equipment and/or supplies did not produce the expected result due to the conditions of use. Alternatively, staff chose not to use equipment and/or supplies due to conditions related with the isolation environment.</p> <ul style="list-style-type: none"> <li>• Wireless signal insufficient for reliable video monitoring.</li> <li>• Staff not taking the computer and/or barcode scanner into patient's room due to concerns for time required to disinfect the equipment.</li> <li>• Infusion pump on outside of patient's room with tubing run under an active door; however, the friction between the tubing and traffic through the doorway caused the tubing to fail.</li> </ul>	<p>Improve conditions of using equipment/supplies to produce the expected result.</p> <ul style="list-style-type: none"> <li>• Work with telecommunications teams to optimize and boost wireless signal to produce reliable video monitoring.</li> <li>• Use dedicated scanning equipment for the unit. If this is not an option, then create a robust protocol to verify patients and medication.</li> <li>• If infusion pump is on outside of patient room:<sup>33-38</sup> 1) ensure a robust process is in place to verify patient and correct medication; 2) continue to assess the IV site and patient prior to and during medication administration; 3) use a robust protocol to verify correct medication tubing between the medication bag and the patient; 4) verify that extended tubing will be compatible with the medication; and 5) protect tubing run under an active doorway or create sealable access portal for the tubing to pass through the wall. Note that placement of infusion pumps or other devices on the outside of the room may reduce the likelihood of certain safety concerns, but may introduce other unintended consequences.<sup>33-38</sup></li> </ul>
	<p>5. Equipment/supplies malfunction or broken</p> <p>Equipment and/or supplies malfunction or breakage during normal use.</p> <ul style="list-style-type: none"> <li>• The following are examples from our study: Urgent response call button, heart monitor, oxygen monitor, ventilator machine, and components of ventilator circuit.</li> </ul>	<p>It is often difficult to anticipate a malfunction or breakage; therefore, timely detection and well-designed remediation plans are essential.</p> <ul style="list-style-type: none"> <li>• Implement a process that promotes employee reporting of equipment/supplies malfunction or breakage, including near misses.</li> <li>• Implement a process that would detect whether the breakage or malfunction applies to other inventory and implement a backup plan for alternative equipment or supplies.</li> <li>• Perform routine inspections and preventative maintenance.</li> </ul>
	<p>6. Equipment/supplies use error</p> <p>Equipment or supplies were not used as ordered, were used in the wrong context, or were improperly setup or adjusted.</p> <ul style="list-style-type: none"> <li>• The following are examples from our study: Failure to connect a monitoring device, failure to adjust the setting of a device (oxygen monitor, bed alarm sensitivity, alarm volume, infusion pump drug library), failure to turn a device on, and failure to properly setup a device (infusion pump channel swap).</li> </ul>	<p>Solutions will vary depending on the type of equipment or supplies involved.</p> <ul style="list-style-type: none"> <li>• Identify situations at high risk for a use error and ensure that staff have a reliable process to manage risk, including use of independent double checks<sup>42,43</sup> of equipment and supplies.</li> <li>• Consider purchasing new equipment or supplies that are designed to prevent the use error.</li> <li>• If purchasing new and better designed equipment is not an option, then consider consulting a human factors expert to assist in developing a solution specific to the use error.<sup>47</sup></li> </ul>
	<p>7. Time to don PPE</p> <p>Upon arriving to a patient's room, staff were not wearing adequate PPE. Staff had to take time to don PPE before entering the room and were delayed in attending to an urgent need.</p>	<p>Reduce PPE don time or reduce response time to patient call, which will allow for additional time to don PPE.</p> <ul style="list-style-type: none"> <li>• Consider developing a negative pressure wing or ward<sup>26,27</sup> so that staff can remain in partial or full PPE.<sup>48,49</sup> Staff should consult an infection preventionist or the Centers for Disease Control and Prevention to determine when PPE should be replaced.</li> <li>• Use a sitter in the anteroom or hallway with visibility into the isolation room and donned in full PPE.</li> <li>• If staff must don and doff PPE throughout their shift, then establish an efficient and standardized sequence of managing PPE to reduce response time.<sup>44</sup></li> <li>• Identify ways to reduce response time between patient call and arriving to the room (e.g., forego answering patient call at nurse's station and instead immediately go to patient's room).</li> </ul>
	<p>8. PPE unavailable or staff untrained on PPE</p> <p>Staff not entering a patient's room or delayed entry due to PPE being unavailable or staff untrained on PPE.</p> <ul style="list-style-type: none"> <li>• Nonclinical teams unprepared to don PPE for an isolation environment (e.g., security department)</li> </ul>	<p>Train all relevant staff to use PPE and ensure that PPE is readily available.</p> <ul style="list-style-type: none"> <li>• During times of limited resources, develop and communicate clear policies to prioritize use and reduce PPE consumption, which may include restricting patient access to certain groups of staff.<sup>38,50</sup></li> <li>• Anticipate other hospital teams needing training and supplies when responding urgently.</li> <li>• To further reduce PPE consumption, create a sealable access panel that allows passage of supplies into the room.</li> </ul>

Continuation of Table 9. Challenges and Potential Solutions for Patient Safety in an Infectious-Agent-Isolation Environment

Associated Factors		Challenges	Potential Solutions
Treatment/Care (Associated Factors 9–12)	9. Not ordered/ordered incorrectly	Necessary treatment or care was not ordered, or an incorrect order was placed and administered.	Identify processes that are unique to a specific patient population and/or an isolation environment. <ul style="list-style-type: none"> <li>• Redesign workflow to prevent or reduce the likelihood of an error.</li> <li>• If unable to redesign workflow, identify transition points where an error is most likely and create salient alerts to prompt staff to avoid an error.</li> <li>• Establish a robust communication system to ensure that all staff are informed of changes or uncommon nuances of the current workflow.</li> </ul>
	10. Ordered but not performed	Necessary treatment or care was ordered but was not implemented. <ul style="list-style-type: none"> <li>• For example, in our study one of the more common types of challenges involved respiratory medication that was omitted due to concern for aerosolizing the SARS-CoV-2 virus.</li> </ul>	Identify processes that are unique to a specific patient population and/or an isolation environment. <ul style="list-style-type: none"> <li>• Redesign workflow to prevent or reduce the likelihood of an error.</li> <li>• If unable to redesign workflow, identify transition points where an error is most likely and create salient alerts to prompt staff to avoid an error.</li> <li>• Establish a robust communication system to ensure that all staff are informed of changes or uncommon nuances of the current workflow.</li> </ul>
	11. New treatment protocol	Patient received a treatment that was relatively new, and the effects and potential reactions may have been unexpected or unfamiliar to some staff. <ul style="list-style-type: none"> <li>• Patient reaction less predictable.</li> <li>• Monitoring ability impacted by the isolation environment.</li> </ul>	Ensure staff are aware and updated on known symptoms associated with a reaction to a new treatment protocol and adopt a process for more closely monitoring patients. <ul style="list-style-type: none"> <li>• Communicate often and consistently.</li> <li>• Manage new and changing information to avoid cognitive overload.</li> <li>• Develop cognitive aids, such as checklists and visual guides (infographics), to place at the point of care to assist staff with administration and monitoring protocols for unfamiliar treatments.</li> <li>• Designate adequate time to train staff on new treatment protocols.</li> </ul>
	12. Refusal to enter patient room or assess in-person	Staff refused to enter the isolation room or refused to assess the patient in person and instead indirectly assessed the patient with assistance from other staff or by reviewing the patient's chart.	To prevent an omission of care or a lower quality of care, implement processes to ensure that all patients receive high-quality care. <ul style="list-style-type: none"> <li>• Develop clear policies that guide all levels of staff and identify those who are expected to directly interact with patients in isolation. Ensure that the policy addresses instances where staff refuse to care for a patient in isolation.</li> <li>• Create tangible actions to address staff's concerns about direct interaction with patients in isolation.</li> <li>• Create a policy and process to minimize unnecessary staff entrance into the patient room, which may include use of telehealth equipment or portable video conferencing tools that would allow staff to communicate and visualize the patient from outside of the isolation room.<sup>37</sup></li> <li>• See <b>Associated Factor 8: PPE Unavailable or Staff Untrained on PPE</b> section for relevant information.</li> </ul>
Associated Factors		Challenges	Potential Solutions
Communication/Teamwork (Associated Factors 13–15)	13. Staff between departments/units	Failed to communicate or miscommunicated important information about treatment/care. <ul style="list-style-type: none"> <li>• Shifting workflows and complexity of care.</li> <li>• Limited staff face-to-face interaction between departments.</li> <li>• Communication difficult or limited by environmental conditions.</li> </ul>	<ul style="list-style-type: none"> <li>• Limit distractions during hand-offs and allow time for teams to communicate key information.</li> <li>• Use standardized communication tools (e.g., situation, background, assessment, recommendation—SBAR)</li> <li>• Evaluate mobile communication devices and applications that could enhance ability to communicate.<sup>51</sup></li> <li>• Clarify roles and adopt a team approach for managing workflow.</li> <li>• See <b>Associated Factor 3: Communication</b> section for information about improving ease of communication within the patient's room or between the inside and outside of the room.</li> </ul>
	14. Staff within department/unit		
	15. Staff and patient		

Continuation of Table 9. Challenges and Potential Solutions for Patient Safety in an Infectious-Agent-Isolation Environment

Associated Factors		Challenges	Potential Solutions
Patient-Related (Associated Factors 16–17)	16. Mental status	<p>Patient had a mental illness, altered mental status, or developmental disability.</p> <ul style="list-style-type: none"> <li>Differences in type of mental status likely will produce different types of behavior and risks.</li> <li>Different behavior management strategies might be required to address different forms of risk.</li> <li>Limited or no visitors permitted may reduce timely detection of altered mental status and risky behavior.<sup>52</sup></li> </ul>	<p>Establish a protocol for identifying and managing patients with mental status challenges.</p> <ul style="list-style-type: none"> <li>Identify presence of mental illness, altered mental status, or developmental disability and communicate status during hand-off.</li> <li>Identify underlying cause of altered mental status and use the diagnosis to guide choice of treatment.</li> <li>When appropriate, consult behavioral health staff to help manage patients.</li> <li>When appropriate, consider treatments for an acutely altered mental status. For example, staff may address delirium with a combination of treatments, including pain management, patient-family communication, sedation management, and optimizing sleep-wake schedule.<sup>53</sup></li> <li>Communicate with family and/or friends about patient’s behavioral tendencies that may indicate an antecedent to risky behavior.</li> <li>Adopt video-chat technology (e.g., tablet) that allows patients to easily communicate with family and friends outside of the hospital.</li> </ul>
	17. Interference with equipment	<p>Patient deliberately manipulated equipment in a manner that interfered with treatment/care.</p> <ul style="list-style-type: none"> <li>For example, we identified instances where patients self-extubated<sup>54</sup> or removed catheters, intravenous lines, or monitor leads.</li> </ul>	<p>Identify high-risk patients and periods of time when there is an elevated concern for interference with equipment and identify strategies to reduce risk.</p> <ul style="list-style-type: none"> <li>Assign sitters to high-risk patients.<sup>55</sup></li> <li>Optimize sedation and management of delirium.</li> <li>Anticipate times when patients are high-risk for self-extubation, such as during sedation weaning, and create a plan for monitoring during those times.</li> <li>When appropriate, use soft wrist restraints and/or hand mitts.</li> <li>During rounds, check and verify that monitoring leads, cables, catheters, and intravenous lines are intact and connected to the patient and device.</li> </ul>
Associated Factors		Challenges	Potential Solutions
18. Other		<ul style="list-style-type: none"> <li>Staff roles and responsibilities were overextended due to baseline staffing patterns being inadequate for the situation. For example, a sitter had the role of monitoring staff entering and exiting the isolation room, restocking PPE, and simultaneously monitoring the patient in isolation.</li> <li>Staff fatigue and emotional stress.</li> <li>Staff from different units were unfamiliar with the process of caring for patients in an isolation environment.</li> </ul>	<ul style="list-style-type: none"> <li>Adjust staffing patterns to account for a surge of patients that require complex medical care.</li> <li>Hold daily leadership and unit-based huddles to discuss operational and clinical challenges, which may help to reduce the burden placed on staff.</li> <li>Hold leadership rounds to actively inquire about staff fatigue and workplace stress level.</li> <li>Promote use of staff support systems and dedicated space for breaks and quiet moments.</li> </ul>

## Discussion

### Implications of Findings

Previous studies have shown that patients in an isolation environment are at greater risk for certain types of safety-related events.<sup>3-5,9-13</sup> Our study expanded upon previous research and revealed that the frequency of certain associated factors varied

considerably from one event type to another. For example, we observed that a greater percentage of factors within the environment, equipment, and supplies group were related to the fall and unplanned extubation event types than to medication-related or transfusion-related event types. Overall, we expect this information will help to identify situations in an isolation environment with greatest risk of patient harm and prioritize safety solutions.

## Challenges and Potential Solutions to Reduce the Likelihood of Safety Events Impacting Patients in Isolation

In the field of patient safety, we strive to learn from previous safety-related events and identify strategies to proactively reduce the likelihood of future harm. With this mindset, we developed **Table 9**, which outlines specific challenges in an isolation environment and potential solutions to mitigate risk of patient harm. The list of challenges in **Table 9** corresponds with the 18 categories of associated factors from our study.

The potential solutions outlined in **Table 9** were identified through the following four methods: mitigation strategies noted in the hospitals' event reports, interviews of six staff (patient safety officer or clinical leader) from various hospitals in Pennsylvania, review of literature, and creative thinking. We chose to provide this list of potential solutions in an effort to advance patient safety in an isolation environment; nevertheless, we encourage readers to critically review these potential solutions prior to implementation because most have not been assessed for efficacy nor the risk of unintended outcomes. The potential solutions listed in **Table 9** are largely oriented toward situations that are unique to an isolation environment. We also encourage readers to reference existing best practices for long-standing patient safety issues (e.g., falls, medication errors, skin integrity<sup>25</sup>).

When reviewing and prioritizing the challenges and potential solutions listed in **Table 9**, readers should also leverage data from **Table 3** and **Table 8** to inform their decision. For example, readers could use **Table 3** to identify the most frequent associated factors, such as patient mental status or staff time to don PPE, and consider prioritizing the corresponding challenges listed in **Table 9**. During the prioritization process readers should also consider many other variables, including the following: degree of patient harm prevented, likelihood of solution effectiveness, monetary cost, immediacy of rollout, and degree of staff buy-in.

## Limitations

We caution readers against interpreting our findings as being representative of the absolute frequency of events across Pennsylvania, as some events may go unreported. Many of our findings and recommendations will be applicable to patient care that involves droplet precautions,<sup>56</sup> other infectious agents beyond SARS-CoV-2, and non-pandemic periods of time. Nevertheless, we acknowledge that our findings will not be representative of all situations that involve an isolation environment. For example, it is possible that we identified a higher percentage of skin integrity events in patients infected with SARS-CoV-2 than would be found with other infectious agents that require patients to be in isolation. Our inclusion of skin integrity events in the study provides context for the distribution of event types occurring in an isolation environment; however, our exclusion of associated factor data for skin integrity limits our understanding of the conditions influencing the likelihood of a skin integrity event. Nevertheless, the lack of associated factor data does not change our interpretation of the findings described throughout the study. Finally, we suspect that most of the 484 events in our study involved airborne precautions; however, event reports did not reliably identify the type of precautions applied. As a result, we did not report the type of precautions in place or explore the relation between the type of precautions, event type, and associated factors.

## Future Directions

We anticipate that many of our findings and information in the discussion section could be used to guide development of a risk assessment tool, which would facilitate a systematic evaluation of patient safety in the isolation environment and guide hospitals in their redesign or development of isolation rooms. We also envision that our findings may spur and help prioritize future research by human factors scientists who would analyze the usability of equipment/supplies in an isolation environment.

## Conclusion

The findings show that patients in isolation were frequently impacted by safety events and the events were frequently influenced by factors related to the environment, equipment, and/or supplies. In particular, we found that events were frequently associated with staff's time to don PPE, equipment/supplies use error, equipment/supplies nonoptimal conditions of use, and inability to hear alarms. The most frequent among the seven event types identified in our study were skin integrity (e.g., pressure injury, skin tear), fall, and medication-related. Overall, our results revealed that the frequency of certain associated factors varied considerably from one event type to another, which indicates that the relation between events and associated factors should guide selection of risk mitigation strategies. We encourage readers to leverage our results along with **Table 9**, which provides a list of challenges identified in an isolation environment and potential solutions. We envision hospital staff proactively and systematically using the information in our manuscript to facilitate their evaluation of the isolation environment and prioritization of risk mitigation strategies.

## Note

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

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