Ventilator-Related Adverse Events: A Taxonomy and Findings From 3 Incident Reporting Systems

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BACKGROUND: In 2009, researchers from Johns Hopkins University's Armstrong Institute for Patient Safety and Quality; public agencies, including the FDA; and private partners, including the Emergency Care Research Institute and the University HealthSystem Consortium (UHC) Safety Intelligence Patient Safety Organization, sought to form a public-private partnership for the promotion of patient safety (P5S) to advance patient safety through voluntary partnerships. The study objective was to test the concept of the P5S to advance our understanding of safety issues related to ventilator events, to develop a common classification system for categorizing adverse events related to mechanical ventilators, and to perform a comparison of adverse events across different adverse event reporting systems. METHODS: We performed a cross-sectional analysis of ventilator-related adverse events reported in 2012 from the following incident reporting systems: the Pennsylvania Patient Safety Authority's Patient Safety Reporting System, UHC's Safety Intelligence Patient Safety Organization database, and the FDA's Manufacturer and User Facility Device Experience database. Once each organization had its dataset of ventilator-related adverse events, reviewers read the narrative descriptions of each event and classified it according to the developed common taxonomy. RESULTS: A Pennsylvania Patient Safety Authority, FDA, and UHC search provided 252, 274, and 700 relevant reports, respectively. The 3 event types most commonly reported to the UHC and the Pennsylvania Patient Safety Authority's Patient Safety Reporting System databases were airway/breathing circuit issue, human factor issues, and ventilator malfunction events. The top 3 event types reported to the FDA were ventilator malfunction, power source issue, and alarm failure. CONCLUSIONS: Overall, we found that (1) through the development of a common taxonomy, adverse events from 3 reporting systems can be evaluated, (2) the types of events reported in each database were related to the purpose of the database and the source of the reports, resulting in significant differences in reported event categories across the 3 systems, and (3) a public-private collaboration for investigating ventilator-related adverse events under the P5S model is feasible. *Key words: ventilator; adverse events; human factors; patient safety; public-private partnership; common taxonomy.* [Respir Care 2016;61(5):621–631. © 2016 Daedalus Enterprises]

Introduction

In 2009, researchers from Johns Hopkins University's Armstrong Institute for Patient Safety and Quality; public agencies, including the FDA; and private partners, including the Emergency Care Research Institute and the University HealthSystem Consortium (UHC) Safety Intelligence Patient Safety Organization sought to form a public-private partnership called the public-private partnership for the promotion of patient safety (P5S) to advance

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patient safety. P5S was modeled after the aviation industry's Commercial Aviation Safety Teams.[1] The purpose of P5S was to address national patient safety challenges through voluntary partnerships between public and private entities.

In this study, we used mechanical ventilator adverse events as an example to better understand patient safety challenges. Mechanical ventilation technology has evolved since the advent of the iron lung. Modern day ventilators provide support to patients with different ventilation needs and in various environments. Technological advances of ventilators have resulted in the development of newer modes of ventilation, increased ventilator triggering functions, and increased monitoring capabilities. However, there are a number of potential safety risks associated with the use of mechanical ventilators, including infection, pneumothorax, and lung injury.[2,3] Lack of synchrony between the patient and the ventilator can lead to adverse outcomes, such as increased duration of mechanical ventilation.[4] When untoward ventilator events occur (eg, improper settings, disconnections, dislodgement of the endotracheal tube (ETT), or ventilator malfunction, rapid response by the health-care provider is necessary.[3]

One strategy to help understand the potential safety risks associated with mechanical ventilators is through national analysis of adverse event reports. In 2005, the Patient Safety and Quality Improvement Act authorized the Agency for Healthcare Research and Quality to create a national network of patient safety databases. This database is designed to aggregate data from multiple reporting systems to detect common causes of adverse events across the country and to facilitate early detection of uncommon but significant emerging adverse events. The database aggregates the data based upon use of a common format for summarizing data.[4,5]

This project is a first step in evaluating the value and feasibility of comparing adverse event reports from a variety of adverse event reporting databases for an important national issue, mechanical ventilators. In this study we used retrospective ventilator-related adverse events reported in 2012 from the following incident reporting systems: the Pennsylvania Patient Safety Authority's Patient Safety Reporting System, UHC's Safety Intelligence Patient Safety Organization database, and the FDA's Manufacturer and User Facility Device Experience (MAUDE) database. The event categories and formats varied among the 3 reporting systems, because each was developed by different stakeholders for unique purposes, and the reporter's role varied. Despite variances in databases, commonalities among these databases exist, and differences can expand our learning. This study serves as a test of concept for the feasibility of a public-private partnership. The phrase "public-private partnership," as used in this paper, is meant to indicate a collaboration between public and private entities to work together to improve patient safety.

QUICK LOOK

Current knowledge

Organizations have their own databases characterizing adverse events related to mechanical ventilators, and no common taxonomy is available for comparison. Testing the concept of a public-private partnership to compare adverse events using mechanical ventilators as an example has not been explored.

What this paper contributes to our knowledge

Through the development of a common taxonomy, adverse events from 3 reporting systems were compared for commonalities and differences. A public-private collaboration for investigating ventilator-related adverse events is feasible and adds to the knowledge by providing a complete picture of safety issues. The distribution of event types varied between the 3 reporting systems, due to the objectives of the systems and the individuals providing the reports.

The objective of this study was threefold: to test the concept of a public-private partnership (P5S), to advance our understanding of safety issues related to ventilator events, to develop a common classification system for categorizing adverse events related to mechanical ventilators, and to perform a comparison of adverse events across different adverse event reporting systems.

Methods

We performed a cross-sectional analysis of ventilator-related adverse events reported in 2012 from the following incident reporting systems: the Pennsylvania Patient Safety Authority's Patient Safety Reporting System, UHC's Safety Intelligence Patient Safety Organization database, and the FDA's MAUDE database. The adverse events used in this study were extracted from the databases to include only ventilator-specific adverse events.

After reaching a formal working agreement, staff from Johns Hopkins University, the Pennsylvania Patient Safety

Supplementary material related to this paper is available at http://www.rcjournal.com.

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Authority (PSA), UHC, and the FDA collaborated to perform the analysis. Each organization independently funded the contributions of team members. Team members collaborated through regularly scheduled teleconferences throughout the study period.

Description of the Databases

Pennsylvania Patient Safety Authority's Patient Safety Reporting System. The PSA is a state government agency charged with reducing medical errors through the collection of data about adverse events, identification and analysis of problems, and recommendation of solutions that make health care safer. Adverse event reports are submitted by patient safety officers or infection prevention staff. About half of all reports are transmitted from hospitals' internal commercial reporting systems.

UHC Safety Intelligence Patient Safety Organization. UHC, an alliance of academic medical centers and their affiliated hospitals, offers an array of performance improvement products and services. The UHC Safety Intelligence Patient Safety Organization collects near miss and adverse event data from >40 organizations nationally. Adverse event reports are entered by frontline staff and distributed to managers who provide additional commentary on the equipment defects and factors contributing to the event. UHC shares patient safety concerns identified in aggregate event reports and opportunities for improvement through national presentations and publications.

MAUDE. The FDA is an agency within the United States Department of Health and Human Services that promotes public health through the regulation and safety assurance of medical devices and other products. The MAUDE database houses adverse event reports submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters, such as health-care professionals, patients, and consumers.

Development of a Common Taxonomy

The FDA, UHC, and PSA databases each use a general adverse event reporting system that contains specific categories for equipment-related events and ventilator-related issues (eg, self-extubation and ventilator setting issues). The 3 databases have different types of reports, categorization, and coding of events. In order to compare the findings at each organization, common classification taxonomy specifically for ventilator-associated adverse events was developed (see Appendix 1 at http://www.rcjournal.com). Common taxonomy is defined as commonly occurring categories of adverse events that can used be used to classify or compare and contrast the events from multiple adverse event reporting systems to facilitate classification. The taxonomy was created through collaborative efforts and iterations between UHC, PSA, and FDA. Sample cases were reviewed by all 3 organizations to establish usability of the taxonomy.

Once the taxonomy was finalized, testing was conducted on the inter-rater agreement of reviewers in classifying each event scenario based on the taxonomy using a sample of 30 cases (10 from each database). These 30 cases were reviewed independently within each organization. More than one category could be selected for each case. One scenario was excluded because raters agreed that it was not clear whether a ventilator was involved. Because raters could select more than one taxonomy category or subcategory, we performed a simple percentage agreement calculation. Agreement was defined as all 3 reviewers coming to the same decision.

Database Search Methods

Each organization's database was searched for adverse events associated with ventilators. The search criteria focused on ventilators used in the acute care setting (eg, intensive care, oscillatory, bilevel positive airway pressure, CPAP, and synchronized inspiratory positive airway pressure) within the calendar year 2012. All ages and levels of patient harm (near miss, no harm, harm, or death) were included. Events involving ventilator-associated pneumonia were excluded. The FDA selected a random sample of events, UHC selected a systematic random sample of events, and PSA reviewed all events. The methodology used by each organization is described below.

PSA. For the PSA database, the search methodology consisted of a Structured Query Language (SQL) server query using the following parameters: (1) any event occurring in 2012 or later; (2) not a fall, skin integrity, medication error, or adverse drug event; (3) not a ventilator-associated pneumonia event; (4) narrative description of the event or equipment involved, including vent or ventilator as a standalone term, maquet, or servo (not limited to these ventilator manufacturers); and (5) narrative description of the event or equipment involved, including self-extubation, self-decannulation, hyperventilation, wean, and terms indicating that the patient was just being placed on a ventilator.

FDA. The FDA database (MAUDE) was searched using the following criteria: (1) reports occurring in the year 2012, (2) reports with ventilator-specific adverse events using FDA's taxonomy to classify device types.

Table 1. Inter-Rater Agreement on Taxonomy

Agreement	Agreement on All Choices, % (*n*)*	Agreement on at Least One Choice, % (*n*)*
At all levels of taxonomy	76 (22/29) (95% CI 58–88)	86 (25/29) (95% CI 69–95)
At highest level of taxonomy	90 (26/29) (95% CI 74–96)	100 (29/29) (95% CI 88–100)

* Raters were able to choose more than one category of adverse event in taxonomy. CIs were calculated using the Wilson score method.

Reports that were classified under a ventilator-specific issue but did not involve a ventilator were omitted from further analysis. For example, a face mask may be classified as a non-continuous ventilator in FDA's taxonomy but is an accessory, not a ventilator. Additionally, reports indicating alarms/failures during pre-use checks and routine preventive maintenance were omitted from the analysis, since there was no patient involvement. After this initial review, a total of 274 events were ventilator-specific and were classified using the common taxonomy.

UHC. The database was searched for all events entered under a ventilator-specific event category, and a text search was conducted to find other pertinent events entered under other categories of the UHC's proprietary taxonomy, such as equipment events. Ventilator-specific events from UHC's proprietary taxonomy include self- or unplanned extubation and ventilator setting issues, including alarm not audible, alarm not set properly, settings wrong or changed without authorization, and other ventilator setting issues. Other events were retrieved with a text search using the key words ventilator, vent, and pap (eg, CPAP, bilevel positive airway pressure, synchronized inspiratory positive airway pressure). Unrelated event types, such as medication-related, laboratory, and transfusion events, were excluded. Events related to surgery were excluded.

Analysis of the Data

Once each organization had its dataset of ventilator-related adverse events, reviewers read the narrative descriptions of each event and classified it according to the developed common taxonomy. One event may have been classified under more than one event type category. Therefore, the counts in each category do not equal the total number of events reviewed.

The analyses were performed independently by the respective organizations to maintain confidentiality of data. This also allowed events to be analyzed and classified by individuals most familiar with the data. Since the data represent random (or exhaustive, in the case of PSA) samples of events within each institution, simple comparisons of multinomial proportions across institutions are possible. However, since the data are subject to a variety of potential reporting biases, we restricted our formal statistical analyses to basic comparisons at the highest level of the taxonomy.

Each of the databases measured the level of harm using different scales. UHC used the Agency for Healthcare Research and Quality Common Format version 1.1; PSA used the National Coordinating Council for Medication Error Reporting and Prevention scale; and the FDA used a 3-level scale consisting of death, injury, and malfunction. In the common taxonomy, the data were collapsed into 3 categories: near miss event, reached the patient but no harm, and patient harmed (including death) in order to compare the databases.

Results

Inter-Rater Agreement on Common Taxonomy

Exact agreement (all similar categories at all levels of taxonomy) occurred for 76% of cases (22 of 29) (95% CI 58–88%) (Table 1). Agreement at the highest level of the taxonomy (all similar categories) occurred for 90% of cases (26 of 29). Agreement on at least one choice (all levels of taxonomy) occurred for 86% of cases (25 of 29). Agreement on at least one choice at level 1 of the taxonomy occurred for 100% of cases (29 of 29).

Database Search

The PSA search yielded 252 relevant reports; all were included in this analysis (Table 2). The FDA search yielded 5,780 reports, of which a random sample of 800 reports were evaluated by the FDA reviewer; of these, 274 were identified as ventilator-specific events and thus included in this analysis. Of the 2,059 events yielded in the UHC search, a systematic random sample of 700 events was included in their analysis.

Distribution of Ventilator Events

The 3 event types most commonly reported to the UHC and PSA databases were airway/breathing circuit issues (62 and 26%, respectively), human factor issues (32 and 49%), and ventilator malfunction events (13

Table 2. Classification of Ventilator Events (Highest Level of Taxonomy) by Reporting System

Category*	UHC (no. = 700), % (no.)	PSA (no. = 252), % (no.)	FDA (no. = 274), % (no.)
Airway/breathing circuit issue	62.4 (437)	25.8 (65)	2.9 (8)
Human factor issue	32.0 (221)	49.0 (123)	2.9 (8)
Ventilator malfunction	13.0 (91)	21.0 (53)	58.0 (159)
Power source issue	2.5 (18)	4.4 (11)	39.0 (107)
Alarm issue	1.7 (12)	2.4 (6)	10.9 (30)
Occlusion issue	3.0 (21)	4.0 (10)	0.7 (2)
Gas supply issue	2.0 (14)	3.2 (8)	1.1 (3)
Stand-by mode adverse events	0.4 (3)	1.2 (3)	0.7 (2)
MRI/CT scan issue	0.4 (3)	1.6 (4)	0.4 (1)
Foreign material issues	0.7 (5)	1.2 (3)	0 (0)
Unknown or ventilator issue could not be determined	0 (0)	1.2 (3)	0 (0)

* More than one category could be selected for each case.
UHC = University HealthSystem Consortium
PSA = Pennsylvania Patient Safety Authority
MRI = magnetic resonance imaging
CT = computed tomography

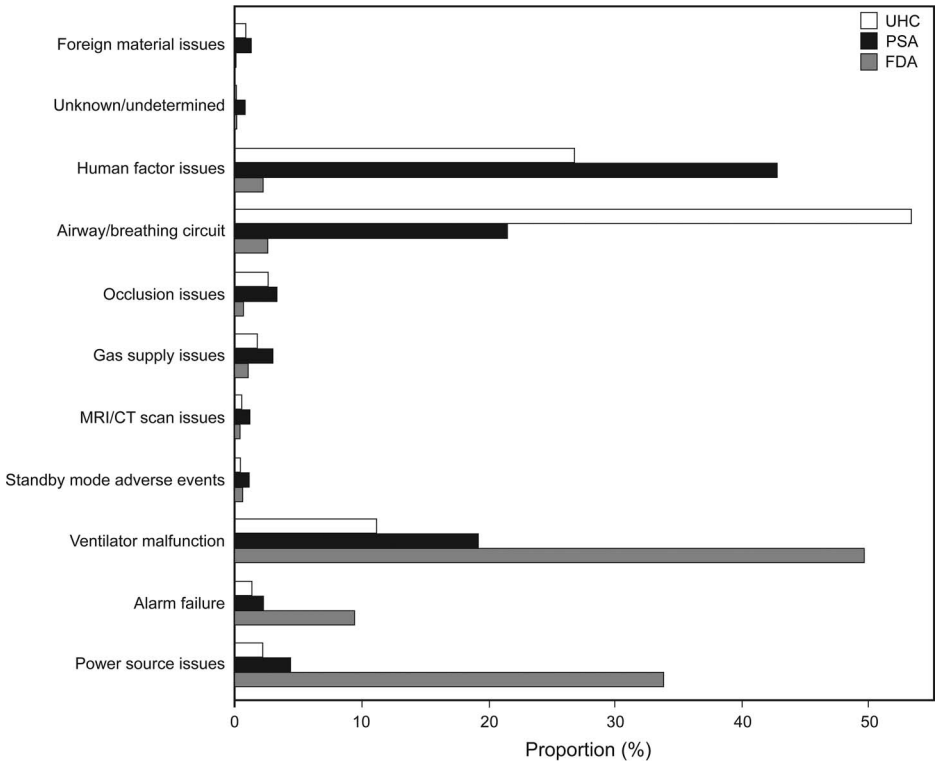

Fig. 1. Distribution of events within each reporting system (normalized by institutions). UHC = University HealthSystem Consortium; PSA = Patient Safety Authority; MRI = magnetic resonance imaging; CT = computed tomography.

and 21%). The top 3 event types reported to the FDA were ventilator malfunction (58%), power source issue (39%), and alarm failure (11%). Figure 1 shows the distribution of events within each reporting system. A test comparing multinomial proportions across institutions was highly significant (chi-square test, $P < .001$).

Airway/Breathing Circuit Issues

Airway/breathing circuit issues were the most common event category in the UHC database (62%) and second most common event category in the PSA database (26%) (Table 3). Within this category, unplanned extubations, consisting of self- and accidental extubation, were the most

Table 3. Airway/Breathing Circuit Issues by Adverse Event Reporting System

Airway/Breathing Circuit Issues	UHC (62.4%, no. = 437), % (no.)	PSA (25.8%, no. = 65), % (no.)	FDA (2.9%, no. = 8), % (no.)
Unplanned Extubation	92.4 (404)	78.5 (51)	12.5 (1)
Self-extubation	86.6 (350)	72.6 (37)	0 (0)
Accidental extubation	13.4 (54)	27.4 (14)	100 (1)
Disconnection/detachment/loose connection	5.5 (24)	12.3 (8)	87.5 (7)
Leak (not associated with disconnection)	2.1 (9)	9.2 (6)	0 (0)

UHC = University HealthSystem Consortium
PSA = Pennsylvania Patient Safety Authority

Table 4. Human Factor-Related Ventilator Issues by Adverse Event Reporting System

Human Factor Issues	UHC (32%, no. = 221), % (no.)	PSA (49%, no. = 123), % (no.)	FDA (2.9%, no. = 8), % (no.)
Protocols (manufacturer/organization) not appropriately and/or adequately followed	23.5 (52)	65 (80)	12.5 (1)
Incorrect clinical settings	35.7 (79)	21.1 (26)	12.5 (1)
Incorrect circuit setup	16.3 (36)	7.3 (9)	0 (0)
Inadequate training	14.5 (32)	1.6 (2)	12.5 (1)
Incorrect alarm settings	4.1 (9)	4.1 (5)	0 (0)
User unable to interpret and/or adequately respond to alarm(s)/error code(s)	2.3 (5)	0 (0)	50 (4)
Backup system unavailable or inadequate	3.2 (7)	0.0 (0)	0 (0)
User interface concerns	0.5 (1)	0.8 (1)	12.5 (1)
Inadequate instructions for use	0 (0)	0 (0)	0 (0)

UHC = University HealthSystem Consortium
PSA = Pennsylvania Patient Safety Authority

common subcategory (92% in UHC, 79% in PSA). Disconnection issues comprised the main breathing circuit issue subcategory found in the FDA database (88%).

Common descriptions of self-extubations involved the patient grabbing and pulling out or coughing out the ETT. Often, prevention measures, such as restraints, were in place, but the patient was still able to reach and pull out the tube. The staff frequently described that the patient was able to shift his/her body down toward the foot of the bed while in restraints, enabling the patient to reach and remove the tube. Patients were often receiving sedation, but this was insufficient in preventing self-extubation. In most cases, staff were alerted by the alarm or were present at the bedside, and the patient was manually ventilated and reintubated.

Disconnections in the breathing circuit and leaks were reported less frequently in the UHC and PSA databases (2–12%). Disconnections were the main airway/breathing circuit issue found in the FDA data (88%).

Human Factor Issues

Human factor issues were the most common event category in the PSA database (49%) and second most common event category in the UHC database (32%) (Table 4). In both the UHC and PSA databases, the majority involved non-compliance with organizational or manufacturer protocols (23.5 and 65%, respectively), incorrect clinical settings (35.7 and 21.1%, respectively), and incorrect circuit setup (16.3 and 7.3%, respectively). A common example of non-compliance with organizational protocols involved clinicians changing the settings without informing the respiratory therapist. Only a few human factor issues were found in the FDA data. It is difficult to ascertain whether this was due to the nature of the adverse events reported, the nature of the information in the reports, or the nature of the random sample.

Ventilator Malfunction

Ventilator malfunction was the most common event type reported in the FDA database (58%) and the third most commonly reported in the UHC (13%) and PSA (21%) databases (Table 5). In about half of the cases in the UHC and PSA databases, the ventilator stopped ventilating the patient. In the FDA database, almost 70% of the ventilators ceased delivering ventilation. Situations in which the ventilator continued to ventilate the patient, the reading

Table 5. Ventilator Malfunction Issues by Adverse Event Reporting System

Ventilator Malfunction	UHC (13%, no. = 91), % (no.)	PSA (21%, no. = 53), % (no.)	FDA (58%, no. = 159), % (no.)
Malfunction and not ventilating the patient	48.3 (44)	47.2 (25)	69.2 (110)
Malfunction but continuing to ventilate patient	51.6 (47)	49.1 (26)	30.8 (49)
Monitor settings not displaying/holding	23.4 (11)	30.8 (8)	0 (0)
Setting readings incongruent with value set	29.8 (14)	7.7 (2)	24.5 (12)
Ventilator alarm persisted after intervention	19.1 (9)	34.6 (9)	12.2 (6)
Other/unknown	27.7 (13)	26.9 (7)	63.3 (31)
Software issue	0 (0)	7.7 (2)	0 (0)
Upgrade version, corruption, error	0 (0)	50.0 (1)	0 (0)
Other/unknown	0 (0)	50.0 (1)	0 (0)

UHC = University HealthSystem Consortium
PSA = Pennsylvania Patient Safety Authority

Table 6. Power Source Issues by Adverse Event Reporting System

Power Source Issues	UHC (2.5%, no. = 18), % (no.)	PSA (4.4%, no. = 11), % (no.)	FDA (39.0%, no.= 107), % (no.)
Electrical power failure/surges (external to device)	0 (0)	9.1 (1)	0.9 (1)
Device electrical failures	5.5 (1)	18.2 (2)	4.7 (5)
Failure to power up	16.7 (3)	9.1 (1)	56.1 (60)
Disconnection of power cord	44.4 (8)	9.1 (1)	0.9 (1)
Device battery power issue	33.3 (6)	54.5 (6)	37.4 (40)
Failure to run on battery power	66.7 (4)	50.0 (3)	77.5 (31)
Premature discharge of battery	16.7 (1)	16.7 (1)	20.0 (8)
Battery issue could not be determined	16.7 (1)	33.3 (2)	2.5 (1)

UHC = University HealthSystem Consortium
PSA = Pennsylvania Patient Safety Authority

display was incongruent with the set value, the ventilator alarm persisted despite troubleshooting the issue, or monitor settings stopped displaying or holding the settings. In the majority of events when the ventilator malfunctioned, staff either responded to an alarm or visualized a malfunction such as the screen going blank and then manually ventilated the patient until the patient could be placed on a different ventilator. Since rapid intervention was necessary for these critically ill patients, time did not permit troubleshooting the ventilator malfunction, and ventilators were changed out even in cases where the ventilator appeared to be ventilating the patient. Software issues were difficult to determine based on the lack of information available.

In ventilator malfunction reports, follow-up was not documented in almost 60% of the cases in the UHC dataset. Of the 91 malfunction events, 39 events (43%) contained information regarding the defective component or reason the ventilator malfunctioned. Twenty-four events were reported to have a defective component, and 15 events were due to a maintenance/user error. Defective components included flow sensors, expiratory filters or cassettes, and other miscellaneous accessory components. In some cases, failure to complete necessary maintenance (eg, change expiratory filters or calibrate) or user errors (eg, the wrong type of circuit or calibration or setting errors) led to the malfunction. Some of these events were also categorized under human factor issues.

One hundred fifty-nine malfunction events were identified in the FDA dataset. Of these, 46 events included information on the cause of the malfunction (Table 2). Among these, 43 were associated with a device component, mostly the breath delivery unit, central processing unit, and graphical user interface cable. Other reported device component issues involved the backlight inverter and flow sensor. Root causes of these component issues were difficult to determine due to the limited information contained in the report. The vast majority of these reports were submitted by the manufacturer.

Power Source Issues

Power source issues were the second most common ventilator-related event in the FDA data (Table 6). In the FDA data, the majority of these power source issues involved the failure of the ventilator to power up or battery power issues. Of the battery power issues, most involved a failure to run on battery power or premature discharge of

Table 7. Severity of Harm

Severity of Harm	UHC (no. = 700), % (no.)	PSA (no. = 252), % (no.)	FDA (no. = 274), % (no.)
Event did not reach the patient (near miss)	8.9 (62)	11.1 (28)	NA
Event reached the patient but did not cause harm*	84.0 (588)	83.7 (211)	85.8 (235)
Event resulted in patient injury, including death	7.1 (50)	5.2 (13)	14.2 (39)

* Identified as a malfunction in the FDA's Manufacturer and User Facility Device Experience database.
UHC = University HealthSystem Consortium
PSA = Pennsylvania Patient Safety Authority
NA = not applicable because data were not collected in that database

the battery. Overall, power source issues were limited in the UHC and PSA data. Disconnections of the power cord were the most common type of power source issue in the UHC data, and battery power issues were the most common in the PSA data.

Other Ventilator Issues

Across databases, the ventilator-related categories with fewer reports included occlusions in the tubing (1–4%) and gas supply issues (1–3%). Failures in audible and visual alarms were less common in UHC and PSA data (2%) but were the third most common issue in the FDA data (11%). Occlusions were caused by moisture/condensation or an obstruction in the tubing. Additionally, gas supply issues were caused by disconnections or inadequate supply from the wall or tank. Alarm problems involved failure in audible and/or visible alarms or enunciation of the alarm to areas external to the patient rooms.

Level of Harm

Across all 3 databases, the vast majority (range was 93–95%) of ventilator-related events, including those that did not reach the patient, and those that reached the patient but did not cause harm (Table 7). In the UHC and PSA databases, 9 and 11% of these events, respectively, did not reach the patient (the FDA does not collect near miss events). Across all databases, about 85% of the events reached the patient but did not cause harm. These events are defined as malfunctions in the FDA database. The FDA database had a greater percentage of events that reached the patient and resulted in some level of injury or death (14%) than UHC and PSA (7% and 5%, respectively). The categories with the greatest number of harmful events across all databases were patient breathing/airway circuit issues (n = 38, 3.1%), ventilator malfunctions (n = 31, 2.6%), and human factor issues (n = 25, 2.1%).

Discussion

Overall, we found that (1) through the development of a common taxonomy, adverse events from 3 reporting systems can be evaluated, (2) the types of events reported in each database were related to the purpose of the database and the source of the reports, and (3) a public-private collaboration for investigating ventilator-related adverse events under the P5S model is feasible. Common types of ventilator problems were human factor issues, unplanned extubations, and ventilator malfunction.

Distribution of Events

The distribution of event types varied significantly between the 3 reporting systems, probably because of the objectives of the systems and the individuals providing the reports. Since frontline caregivers populate UHC and PSA data, it is not surprising that the most commonly reported events were care-related issues (human factor issues and unplanned extubations). This is consistent with previous reports of events in the ICU, where wrong settings and unplanned extubation were the 2 most common events.[5] On the other hand, since manufacturers, importers, device user facilities, healthcare professionals, patients and consumers populate most events in the FDA data, the majority of events involve device malfunctions. For example, power source issues were the second most common event in the FDA database. These are the types of events the database was designed to receive. In the clinical environment, if the ventilator does not power up, it is unlikely that it was connected to the patient, and this might not get reported by the frontline caregiver.

Ventilator Malfunction

Ventilator malfunction was the most common event type reported in the FDA system. In many of the events, it was difficult to determine whether the ventilator performed appropriately given the situation or whether the ventilator itself failed. One challenge in understanding ventilator malfunctions is that their use on critical care patients may prevent users from troubleshooting ventilator failures during the actual event. At the time of the incident, reporters often did not know why the ventilator alarmed, erred, or

shut down. Engineering departments might have further assessed ventilator failures, but important supplemental information was not always provided. The root cause of ventilator malfunctions may be stored within the ventilator software event log, which is available for biomedical engineering departments to use for diagnostic purposes; this may be an avenue to consider for more detailed categorization in the future.

Unplanned Extubations

Unplanned extubations were the most common event type in the UHC database and the most prevalent event seen across all ventilator events. Although unplanned extubations were collected as ventilator events, the collection of these events under this category does not imply relatedness of unplanned extubations to the device per se. Nevertheless, because of the important clinical safety concern related to mechanical ventilation, unplanned extubations are the most commonly occurring adverse events and were included in this analysis. The literature suggests that the rate of unplanned extubations in adult patients ranges from about 2 to 22%.[6-13] Similar to our findings, most unplanned extubations are self-extubations.[7,9,10] These events can result in inadequate respiratory function, hypoxemia, cardiopulmonary arrest, and death.[12-14] Accidental removal or self-removal of the ETT can result in upper airway injuries, bronchospasm, arrhythmias, aspiration, and pneumonia.[7,11,13] Approximately 50% of these patients will require re-intubation (range of 10–78%).[6-8,11,13,15,16]

Based upon the literature, successful strategies for the prevention of unplanned extubations include standardized protocols for securing the tracheal tube,[15,17-20] titration of sedation,[15-17,21] weaning patients off mechanical ventilation,[16,20] tube suctioning, patient hygiene, and transport.[15] Although it may seem intuitive that restraining patients might prevent self-extubations, the rate of patients in restraints at the time of unplanned extubation is roughly 60%.[10,15,16,20] This suggests that restraints do not prevent self-extubation. Moreover, they can contribute to agitation,[10] and are discouraged unless necessary due to other safety concerns.[22,23]

However, unplanned extubations generally are not related to the functioning of the ventilator itself. The key contribution of the ventilator is to alert caregivers to the airway disconnection. Here, ventilators play a crucial safety role in ensuring that caregivers are alerted to this specific issue, so that prompt intervention can be implemented.

Disconnections in the Breathing Circuit

Disconnections in the breathing circuit were the most common breathing circuit issue in the FDA database. In the course of clinical care, accidental disconnections and/or extubations may predictably occur as patient/ventilators are moved around. Strengthening some connections may inadvertently lead to more frequent unintended patient extubations. If a break in the patient-ventilator circuit occurs, it is often better that it occur at a ventilator tubing connection rather than from an extubation. However, it is often difficult for clinicians to ascertain the exact location of the misconnection when this error is detected. There is often a frantic search for the location of the disconnection as the patient is unventilated and the ventilator is alarming. In these instances, ventilators can provide diagnostic tools accompanying the alarms, such as location and type of disconnection. Moreover, ventilators can provide specific real-time directions/suggestions to the user on how to mitigate the problem.

Human Factors

Human factor issues were the most common event type in the PSA database. Current ventilators offer a variety of user-selectable options, requiring the user to be knowledgeable. Although manufacturers and user facilities are generally conscientious about providing training, staff shortages and frequent employee turnover in some hospitals can make it difficult to provide adequate formal training in the use of clinical equipment. This could account for the high percentage of human factors events related to following protocols, clinical settings, and circuitry setup. There were also human factor events related to interpreting alarm/error codes (50% of FDA human factor events). During an event, clinicians might benefit from ventilators providing clear displays of the issue, diagnostic tools, or troubleshooting suggestions.

Level of Harm

The distribution of harm scores for these ventilator-related events was similar to that of self-reported adverse events in general. In both the PSA and UHC databases, $>$90% of adverse events did not lead to harm.

Taxonomy and Inter-Rater Agreement

The common taxonomy for aggregation of ventilator-related adverse events showed acceptable inter-rater agreement. Most events fit easily into the taxonomy, but additional description was necessary to understand the specific issues in malfunction events. This taxonomy can be used to understand the specific challenges surrounding ventilator-associated adverse events and to make direct comparisons across reporting systems. When used to aggregate large numbers of adverse events, even across different databases, it can provide a more complete pattern of the issues within the health system. Further development of

this taxonomy and testing with more cases and from other reporting systems will be necessary.

Public-Private Partnership

Technical experts from the FDA, PSA, and UHC voluntarily participated in this project. To facilitate full understanding and allow comparison of information in the respective databases, a public-private partnership was essential for sharing non-public data. The leadership of each organization committed to making this type of collaboration feasible and assisted in the planning, development, integration, and interpretation of study results. This type of collaboration is highly valuable, allows public exchange and dialogue of critical issues, and serves as a model for advancing public health.

Access to national data relating to adverse events is difficult to obtain because interactions between organizations are typically restricted to publicly available information. The public-private partnership opened access to non-public data, and this sharing improved the quality and quantity of adverse events for review. The collaboration allowed for a rapid transfer of knowledge and expertise, contributing to an increased understanding of safety risks associated with mechanical ventilators.

Potential Limitations

This analysis was limited by the voluntary nature of incident reporting, the accuracy of the categorization of events in each database, and the lack of complete documentation in event reports. Because cases were extracted from voluntary reporting systems, the data may not be representative of all ventilator-related events, but our analysis provides a large sample of reported events across different databases and has good generalizability.

The development of a taxonomy specific to ventilator-related adverse events assisted us in identifying the types and frequency of reported safety issues but had limitations. A significant percentage of events were categorized as ventilator malfunction and failure to cycle. These seemed to be catch-all categories for a number of events where further information for the cause of the malfunction was either unknown or not reported. With better understanding of these events through more complete reporting, the taxonomy might be further refined to identify specific ventilator components that malfunctioned.

There was a potential for duplication of the same event across the multiple systems. All hospitals potentially share events with the FDA. Although we do not expect this overlap to be large, it could have inflated the frequency of some adverse events across the different systems. We were unable to account for this, since all cases were analyzed by their respective organizations.

Conclusions

Our work suggests that the public-private collaboration for investigating adverse events under the P5S model is feasible and that leadership commitment is key to ensuring its success. We found that use of a ventilator-specific taxonomy could be useful in analyzing adverse events across multiple reporting systems. Using this taxonomy, we found that ventilator-associated adverse events are frequently associated with human factor issues, airway/breathing circuit issues such as unplanned extubations and ventilator malfunctions.

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