Home mechanical ventilation: A retrospective review of safety incidents using the World Health Organization International Patient Safety Event classification

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BACKGROUND: There is a paucity of patient safety information from the community sector related to the medically fragile population requiring home mechanical ventilation (HMV). To improve safety, the risks HMV patients encounter must first be understood.
OBJECTIVES: To describe patient safety incidents within the HMV population and discuss opportunities for preventing harm.
METHODS: A retrospective observational review of on-call logs from the Ontario Ventilator Equipment Pool (VEP) was conducted. Classification of 248 on-call logs from April 1, 2011 to March 21, 2012 was completed using the standardized tool of the World Health Organization's (WHO) *Patient Safety Taxonomy – International Classification System* to quantitatively describe the types of incidents arising. Analysis of data classification was completed using descriptive and nonparametric statistics.
RESULTS: Patient incidents were positive in 188 on-call logs; emerging from these were 227 incident types. Patient incident types included medical device issues (99 device failures, 41 user errors, 12 equipment availability), documentation (20 unavailable labels/prescriptions, four unclear information), clinical processes (16 inadequate treatment or general care) and clinical administration (10 inadequate handover or transfer of care). Patient incidents were associated with mild harm in 87 cases.
CONCLUSIONS: The on-call logs were a good source of quality improvement data to understand harm and patient safety issues emerging in the HMV population. However, establishing a formal incident review and reporting system is required to provide a more comprehensive understanding.

Key Words: *Chronic ventilation; Patient safety; Quality improvement; Respiratory incident*

La ventilation mécanique à domicile : une analyse rétrospective des incidents de sécurité au moyen de la Classification internationale pour la sécurité des patients de l'Organisation mondiale de la Santé

HISTORIQUE : Peu d'information sur la sécurité des patients provenant du secteur communautaire porte sur la population fragilisée sous ventilation mécanique à domicile (VMD). Pour améliorer la sécurité, il faut d'abord comprendre les risques que courent ces patients.
OBJECTIFS : Décrire les incidents de sécurité des patients au sein de la population sous VMD et examiner des possibilités de prévenir les dommages.
MÉTHODOLOGIE : Les chercheurs ont réalisé une étude d'observation rétrospective des registres d'appel de l'*Ontario Ventilator Equipment Pool* (VEP). Ils ont classé 248 registres d'appel prélevés du 1er avril 2011 au 21 mars 2012 au moyen de l'outil standardisé *Taxonomie pour la sécurité des patients –Système de classification internationale* de l'Organisation mondiale de la Santé (OMS) afin d'effectuer une description quantitative du type d'incidents. L'analyse de la classification des données a été effectuée au moyen de statistiques descriptives et non paramétriques.
RÉSULTATS : Les incidents des patients étaient positifs dans 188 des registres d'appel, et 227 types d'incidents en ont émergé. Les types d'incidents des patients incluaient des problèmes avec les dispositifs médicaux (99 défaillances de dispositifs, 41 erreurs des utilisateurs, 12 problèmes de disponibilité de l'équipement), la consignation (20 étiquettes ou prescriptions non disponibles, quatre renseignements nébuleux), les processus cliniques (16 traitements ou soins généraux inadéquats) et l'administration clinique (10 transferts de soins inadéquats). Dans 87 cas, les incidents se sont associés à de légers dommages.
CONCLUSIONS : Les registres d'appel étaient une bonne source de données d'amélioration de la qualité pour comprendre les dommages et les problèmes liés à la sécurité des patients émergeant au sein de la population sous VMD. Cependant, il faut créer un système officiel d'analyse et de signalement des incidents pour mieux les comprendre.

Mechanical ventilation may be defined as a life-support system designed to replace or support normal ventilatory lung function (1). The typical individual requiring home mechanical ventilation (HMV) includes those with amyotrophic lateral sclerosis (ALS), central hypoventilation syndrome, chronic obstructive pulmonary disease, kyphoscoliosis, obesity hypoventilation syndrome, spinal cord injury (SCI), Duchenne muscular dystrophy, myopathies and myotonic dystrophy (2). Technology has evolved significantly and, currently, HMV is a staple of care for these patients.

The availability of HMV has enabled greater patient freedom and improved quality of life (3). Strategic efforts have come into place in Ontario to support the transition of patients out of the intensive care unit (ICU) into the community while on home mechanical ventilators (4). This, in part, is economically driven (5).

Patients residing in Ontario who require HMV are supported for their equipment needs through the Ontario Ventilator Equipment Pool (VEP) (5). Established in 1994, the VEP is a provincial service operated by Kingston General Hospital (Kingston, Ontario) that provides equipment to thousands of clients across Ontario. It is funded by the Ministry of Health and Long-Term Care and is a central provincial depot for respiratory equipment. The VEP loans equipment to eligible individuals of all ages who require these devices at home and who have been approved under the ministry's Assistive Devices Program. The VEP provides several related services including 24 h telephone technical support seven days per week and educational support. After normal business hours, support is offered through a telephone on-call service staffed by one registered respiratory rherapist per shift. The on-call logs generated were the primary records analyzed in the present study.

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TABLE 1
Incident type

1. Clinical administration
2. Clinical process/procedure
3. Documentation
4. Health associated infection
5. Medication
6. Blood products
7. Nutrition
8. Oxygen/gas/vapour
9. Medical device/equipment
10. Behaviour
11. Patient accidents
12. Infrastructure/building
13. Resource/organization management

Data adapted from reference 9

TABLE 2
Degree of harm

None – patient outcome is not symptomatic, or no symptoms detected and no treatment is required
Mild – patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (eg, extra observation, investigation, review or minor treatment) is required
Moderate – patient outcome is symptomatic, requiring intervention (eg, additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long-term harm or loss of function
Severe – patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function
Death – on balance of probabilities, death was caused or brought forward in the short term by the incident

Data adapted from reference 9

Limited information about the safety of ventilated patients in the community exists. There is a paucity of patient safety information from the community sector related to the medically fragile population requiring HMV. To improve safety, therefore, we must first understand the risks HMV patients encounter. The objective of the present study was to describe patient safety incidents within the HMV population and discuss the opportunities for preventing harm.

A Google search of "patient harm while on home mechanical ventilators" yields anecdotal confirmation that harm can occur. Results included a report in 2010 of a National Health Service agency nurse turning off a patient's ventilator by mistake. The patient with an SCI was left with severe brain damage after the incident (6). Studies show that the relative safety of patients receiving HMV require greater research and investigation due to the number of unknown factors (eg, appropriateness of patient or caregiver training in the community) (2).

The guidelines for transitioning patients from acute care to home established by the Canadian Thoracic Society recognize many of the risks and, in general, these can be grouped as patient medical stability risk, family and other caregiver support risk, equipment and other resource allocation risk (2).

A 1999 study investigated patient safety problems among 3,013,287 general homecare clients (7); the results indicated that 13% had experienced an adverse event. Factors associated with the occurrence of adverse events included (8):

- Complexity of client medical condition
- Client acceptance of care responsibilities
- Failure to identify and control risk
- Delays in implementing services
- Incomplete patient or caregiver education before discharge from acute care
- Equipment management, use or misuse

To understand the generalized risks associated with HMV, it is essential that a common system of measurement be available. A common framework is required to measure the findings arising from the VEP on-call data to compare against findings already found within the literature. One such framework is the World Health Organization's (WHO) International Classification for Patient Safety (9).

The WHO produced a technical report outlining a conceptual framework that defined and harmonized patient safety concepts into an internationally agreed on classification (9). The intent was that information could be compared, measured and analyzed based on a common taxonomy. Within the framework, 13 incident types were defined and included (9):

1. Clinical administration
2. Clinical process/procedure
3. Documentation
4. Health-associated infection
5. Medication
6. Blood products
7. Nutrition
8. Oxygen/gas/vapour
9. Medical device/equipment
10. Behaviour
11. Patient accidents
12. Infrastructure/building
13. Resource/organization management.

Using these definitions, incidents can be classified. This information can subsequently be used to improve patient outcomes by determining contributing factors as well as opportunities for system improvement. The WHO conceptual framework has been adopted by the Canadian Patient Safety Institute (CPSI), the Ontario Hospital Association and the Institute for Safe Medication Practice – Canada, to provide a common nomenclature and method in incident analysis.

METHODS

Study procedures

A retrospective observational review of on-call logs from the Ontario VEP was conducted. Classification of on-call logs from April 1, 2011 to March 21, 2012 was completed using the standardized tool of the WHO's *Patient Safety Taxonomy – International Classification System* (9).

The VEP after hours on-call service documents events related to patient problems arising in the evening, overnight and on the weekends. Only logs pertaining to patients requiring HMV were analyzed.

Analysis

Logs were classified as either positive or negative for the occurrence of a patient safety incident. Positive incidents were assessed using the WHO conceptual framework for *International Classification for Patient Safety* definitions (9). First, the incidents were categorized into the 13 incident types (Table 1) and the degree of harm (Table 2). Second, the incidents were described according to patient safety definitions (Table 3). In addition, patient characteristics, including diagnosis (from existing VEP records), incident characteristics, incident type and other on-call respiratory therapist (RT) actions, were described. The data were analyzed using nonparametric descriptive statistics including the mean, SD and Mann Whitney U tests to determine significance of age in patients experiencing harm.

The first author (LY) reviewed all on-call data and performed the analysis. An element of judgement was needed to perform the analysis. Assessor qualifications include 15 years working with

TABLE 3
WHO conceptual framework for *International Classification for Patient Safety* definitions used

Patient safety incident – an event or circumstance that could have resulted or did result in unnecessary harm to a patient
Contributing factor – a circumstance, action or influence that is thought to have played a part in the origin or development, or to increase the risk of an incident
Patient outcome – is the impact on a patient that is wholly or partially attributable to an incident. Where harm has occurred, the degree of harm is the severity and duration of any harm and any treatment implications that result from the incident
Mitigating factors – actions or circumstances that prevent or moderate the progression of the incident toward harming the patient
Actions taken to reduce risk – steps taken to prevent reoccurrence of the same or similar patient safety incident and on improving system resilience

Data adapted from reference 9

patients needing long-term ventilation, 10 years as a VEP on-call therapist, and 10 years working in the field of patient safety and risk including classification of incident types and harm levels based on the WHO framework at two academic health centres in Toronto (Ontario). The present study was approved by Charles Sturt University, School of Biomedical Sciences Ethics in Human Research Committee (Burlington, Ontario) and Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board (Kingston, Ontario).

RESULTS

On-call logs were reviewed for the period between April 1, 2011 and March 31, 2012. A total of 268 logs were reviewed. Of these, 248 logs pertained to patients requiring long-term ventilation, either invasively or noninvasively. Twenty logs were removed from the data because they related to nonventilated patients. One hundred eighty-eight of 248 (75.8%) experienced a patient safety incident; 87 (46.3%) of these incidents were associated with mild harm.

Patient characteristics

Patients requiring on-call assistance were male (n=138 [55.6%]) and female (n=110 [44.4%]). The mean (± SD) age of those experiencing any patient safety incident was 57.9±22.8 years (range three to 97 years). The mean age for those experiencing a patient safety incident associated with mild harm was 58.7±22.1 years (range three to 94 years). The mean age for those experiencing no harm was 57.3±23.5 years (range five to 90 years). There was no statistical difference in age between the groups who experienced a patient safety event with or without harm (P=0.99).

The majority of patients requiring the on-call service had a neuromuscular diagnosis including patients with muscular dystrophy, myopathy, SCI and ALS (ALS patients: n=35 [10 invasive ventilation, 25 noninvasive ventilation]). All diagnostic groupings based on the review of incidents from the VEP records are summarized in Table 4.

Incident characteristics

Patient calls emerged from all Ontario Local Health Integration Networks (LHINS) (Table 5), the most frequent being from the South West LHIN (n=26 [13.8%]) and Champlain LHIN (n=26 [13.8%]). Calls originated from three distinct settings including home (n=175 [93.1%]), acute care (n=8 [4.2%]), other (eg, vacation location or unknown [n=3 (1.6%)]) and long-term care (n=2 [1.1%]). Callers were primarily relatives (n=82 [43.6%]) (spouses, parents, children) or the patients (n=75 [39.9%]) themselves. The balance of the calls were from regulated health care professionals (n=16 [8.5%]) (registered nurses, registered practical nurses and registered RTs), unregulated health care workers (primarily personal support workers [n=14 (7.4%)]) or friends (n=1 [0.5%]).

TABLE 4
Patient diagnostic groupings – all incidents (Ontario Ventilator Equipment Pool, 2011/2012) (n=188)

Diagnosis	Patients
Neuromuscular disorder	83 (44.1)
Obstructive sleep apnea	28 (14.9)
Obesity hypoventilation syndrome	24 (12.8)
Chronic obstructive pulmonary disease	19 (10.1)
Central respiratory drive depression	17 (9.0)
Unknown other (information unavailable)	10 (5.3)
Chest wall deformity	7 (3.7)

Data presented as n (%)

Incident type

Of the 188 on-call logs that were positive for a patient safety incident, where each call could yield more than one incident type (9), 227 different incident types were identified (Table 6). The majority of patient incidents were medical equipment issues (n=164 [72.2%]) including noninvasive and invasive devices (BiPAP™, VPAP™, Trilogy™, LTV™), adjunctive equipment (masks, circuits) or humidifiers. Documentation incidents (n=25 [11.0%]) included unavailable labels/prescriptions (showing patient ventilator settings) and unclear information (potentially outdated information). Clinical process (n=17 [7.5%]) incidents included inadequate treatment or general care (eg, setting up patients on inappropriate settings. Clinical administration (n=10 [4.4%]) type incidents included inadequate handover or transfer of care issues (eg, patients leaving hospital settings without knowledge of how to use life-support equipment. Behaviour incident types (n=7 [3.1%]) arose from risky patient behaviour (eg, patient choosing to ignore alarms for weeks). Resource incidents (n=3 [1.3%]) were related to organization of community teams and availability or adequacy of policies/guidelines/protocols (eg, health care workers assigned to care for HMV patients without adequate training). One patient accident incident type (n=1 [0.4%]) was recorded as a specific mechanical threat to breathing (eg, malfunction of portable suction device coinciding with blockage of tracheostomy tube).

Patient outcomes

For the 87 incidents found to have mild harm, 115 incident types (Table 7) were associated with these events. Harm occurred because of one or a combination of:

- Delays in therapeutic interventions (n=72 [38%]);
- Inadequate therapeutic intervention (n=45 [24%]);
- No therapeutic intervention (patient refusal to continue using device for prolonged period >48 h) (n=25 [13%]); or
- Potential respiratory failure (n=1 [0.5%]).

Contributing factors/hazards

Patient safety incidents can have contributing factors that influence the development of the incident or increase the risk (9). These include patient, caregiver, environmental organizational and external factors (9). In the present study, patient (n=61 [34%]) and caregiver (n=58 [32%]) factors were related to cognitive (base knowledge, understanding) and performance (technical error) deficits, as well as behavioural factors (engaging in risky behaviour). Other patient factors were pathophysiological (eg, visual impairments/arthritis/muscle weakness and communication difficulties (eg, language barriers). Environmental factors (remote location) (n=7 [3.9%]), organizational factors (inadequate protocols and policy, organization of teams, organizational culture) (n=30 [16.7%]) and external factors (product, technology, infrastructure and system issues) (n=23 [12.8%]) were also found.

Mitigating factors, and actions to reduce risk and RT actions

The key mitigating factors contributing to reducing the harm potentially resulting from 248 patient safety incidents included patient

TABLE 5
Ontario Local Health Integration Netowork (LHIN) distribution of Ventilator Equipment Pool on-call logs, 2011/2012 (n=188)

LHIN	Population estimate*, n	On-call logs, n	% of calls
Central East	1,356,500	10	5.3
Central	1,353,000	11	5.8
Hamilton Niagara Haldimand Brant	1,262,000	22	11.7
Champlain	1,100,500	26	13.8
Toronto Central	1,093,000	19	10.1
Mississauga Halton	899,000	8	4.3
South West	871,000	26	13.8
Waterloo Wellington	633,500	11	5.8
Central West	627,000	7	3.7
Erie St Clair	610,000	15	8.0
North East	553,000	6	3.2
South East	443,000	13	6.9
North Simcoe Muskoka	376,500	10	5.3
North West	234,000	4	2.1
Total	11,412,000	188	

**Population estimates obtained from reference 11*

TABLE 6
Incident type* (with and without harm)

Incident type	Process, equipment types or document	Problem	n (%)
Medical device	Invasive and noninvasive ventilators, humidifiers, adjunctive equipment	Device failure	99 (43.6)
		User error	41 (18.1)
		Equipment availability	12 (5.3)
		Inappropriate	9 (4.0)
		Dislodgement	3 (1.3)
Documentation	Labels or prescriptions	Unavailable	20 (8.8)
		Unclear	4 (1.8)
		Delay in access	1 (0.4)
Clinical process	Treatment, general care, assessment	Inadequate	17 (7.5)
Clinical administration	Handover or transfer of care discharge	Inadequate	10 (4.4)
Behaviour	Patient	Noncompliant or risky	7 (3.1)
Resource	Resource management	Service, staff, policy adequacy	3 (1.3)
Patient accident	Threat to breathing	Mechanical	1 (0.4)

**n=227 incident types originating from 188 on-call logs; one call log can yield more than one incident type (9)*

(n=29 [12%]) or caregiver (n=69 [28%]) education and availability of replacement equipment (n=84 [33.9%]). Based on the available logs for review, the most frequent action taken to mitigate harm was calling for help through the on-call service (n=248 [100%]). Actions to reduce risk were related to patient and caregiver education/training (n=98 [21.3%]) provided by the RT, replacement of equipment (n=82 [17.8%]) and coordination to support further access to needed services (connections to homecare companies, prescribing physicians) (n=81 [17.6%]).

The most common on-call actions by the RT included reassurance, coordination of care with various agencies (homecare companies, after-hours equipment storage centres, VEP, original prescribing hospitals), dispatch of replacement equipment, temporary alarm and setting adjustments and clinical advice (eg, interface/mask issues) (Table 8). Other clinical advice included advising of potential patient decline and recognizing sources of interface leak.

Description of calls – further context

While on-call logs can be classified using the WHO framework, qualitative description aids in providing more context. Four calls are described to capture some of the challenges faced by patients on HMV.

Call 1

A 90-year-old woman was set up on noninvasive ventilation due to central respiratory drive depression. She stated that she was discharged without education or training. She was reluctant to continue using the device due to continuous alarms and discomfort on the machine. On troubleshooting, the on-call therapist adjusted the ramp settings to make the device more comfortable and discovered that the patient and her husband had filled the circuit rather than the humidifier with water. The patient described an inability to disconnect the circuit from the humidifier due to the strength required to do so. She instead attempted to disconnect the circuit closer to the mask which lead to water blockage in the tubing and an inability to use the device. Three more calls were made within two weeks to the VEP on-call service, suggesting a continued inability to operate the device.

Call 2

A 59-year-old man with ALS was on noninvasive ventilation. The caller was the patient's daughter. She described a high dependency on the device and, as such, was provided with a back-up power supply (ie, battery). At the time of the call, the patient's home was experiencing a power failure and, at this time, the daughter called to indicate a lack of knowledge on how to attach the noninvasive support device to the battery. Additionally, it was discovered the battery was not charged and, as such, could not be used.

Call 3

A 48-year-old woman with a neuromuscular disorder was on invasive ventilation. Her husband was the primary caregiver along with support from an RT from the local homecare company. The RT was on vacation and the gauge on the ventilator was not moving. The husband, who stated that he could neither read nor write, had difficulty with troubleshooting. He discovered a crack in the swivel with the help of the on-call therapist. He did not have any back-up equipment and stated that the circuit had not been replaced or cleaned since 2007. Duct tape was used to seal the leak in the swivel. The VEP sent replacement tubing the next business day.

Call 4

A 56-year-old woman with advancing ALS was sent home on a new ventilator (Trilogy™) after being set up through a day study at an acute care centre. She was invasively ventilated on the device. The day staff member escorting the patient was provided with training. By the evening, the ventilator began to alarm with a low-pressure alarm. The night care providers (registered practical nurses) were not given training. Written documentation regarding prescription settings, including tracheal cuff volume, were also not provided. The patient and her husband stated that they did not know how to use the device, and the husband was reluctant to offer any help because he was on dialysis and had medical concerns of his own. Attempts to coordinate training for the caregivers were unsuccessful. Subsequent low pressure and low tidal volume alarms continued. Two additional calls to the VEP on-call service were noted over the next few days. By day 7, the caregivers still had not received education. The patient was short of breath. The on-call RT advised the patient to be manually resuscitated and transferred to an emergency room.

DISCUSSION

In the present study, a retrospective review of Ontario VEP on-call logs was systematically analyzed. We found 188 positive patient safety

TABLE 7
Incident type* (with harm)

Incident type	Process, equipment types or document	Problem (n [%])
Medical device	Invasive and noninvasive ventilators, humidifiers, adjunctive equipment	Device failure (44 [38.3])
		User error (17 [14.8])
		Equipment availability (5 [4.3])
		Inappropriate equipment (7 [6.1])
Documentation	Labels or prescriptions	Unavailable (14 [12.2])
		Unclear (2 [1.7])
Clinical process	Treatment, general care, assessment	Inadequate (12 [10.4])
Clinical administration	Handover or transfer of care discharge	Inadequate (4 [3.5])
Behaviour	Patient	Noncompliant or risky (6 [5.2])
Resource	Resource management	Service, staff, policy adequacy (3 [2.6])

**n=115 incident types originating from 87 on-call logs; one call log can yield more than one incident type (9)*

incidents from 248 on-call records reviewed. Patient incidents were associated with mild harm in 87 cases. Quality improvement opportunity can be obtained through this data source.

Patient characteristics

We did not find significant differences in age between the groups that did (n=87) and did not (n=99) have mild harm associated with patient safety events (P=0.99). Limited conclusions can be drawn from this but may be reflective of underutilization of the on-call service due to lack of awareness and unrecognized barriers to access for the elderly (11). More research may be warranted with consideration of outreach (11) for this particularly fragile population among an already at-risk group of HMV users.

In the present study, the majority (n=83 [44.1%]) of callers had a neuromuscular diagnostic grouping . Comorbidities could not be determined based on the documentation available. One group of particular concern within the neuromuscular grouping were the ALS patients (n=35 [10 ventilator use, 25 noninvasive ventilation]). In this group, death usually occurs as a result of progressive respiratory muscle involvement, with 50% of patients dying within three years of symptom onset (2). In advancing ALS, the patient becomes more dependent on ventilatory support.

The use of noninvasive ventilation can pose a critical risk for this ALS population. Based on our results, the majority of ALS patients used noninvasive ventilation. It is recognized that choosing noninvasive ventilation for more dependent patients has resulted in sentinel events nationally and internationally (12). Noninvasive bi-level devices are not designed for continuous life-support and should not be used in patients with insufficient respiratory capacity to tolerate brief interruptions in therapy (12).

Currently, there are mitigating strategies and actions to reduce risk for this ALS group. However, there are opportunities to further support this segment of the HMV population. Some of the existing mitigating strategies described in the present study include providing back-up equipment in the home routinely and actions to reduce risk relate to sending replacement equipment (n=82 [17.8%]) immediately when failure occurs. The literature suggests that highly dependent patients could benefit from other strategies such as home surveillance using videophone monitoring and transmission of oximetry to leverage available technology in support of home safety (13).

TABLE 8
On-call respiratory therapist actions (Ventilator Equipment Pool, 2011/2012)

Action	n (%)
Recommend alternative interface	14 (3.0)
Adjust alarms or change settings	17 (3.7)
Reassurance	28 (6.1)
Coordination of care	81 (17.6)
Equipment dispatch	82 (17.8)
Education	98 (21.3)
Other clinical advice	140 (30.4)
Total actions for 248 on-call logs, n	460

Incident characteristics

Most calls were from patients and their families. This reinforces the importance of patient and family caregiver support. In a risk review of the HMV population, a key part of any home care program is the education of patients, families and caregivers (13). More specifically, this would include competency training on how to operate the ventilator, improving the ability to remedy simple problems and providing the knowledge of when to seek advice (13). Additionally, safety considerations need to evolve with the course of the underlying disease (13).

In this retrospective review, patient (n=61 [34%]) and caregiver (n=58 [32%]) base knowledge and understanding were the largest contributing factors to patient safety incidents. This finding suggests opportunity for improved education in HMV for both patients and caregivers. There is a general lack of resource support for home-ventilated patients and their caregivers (4). Many caregivers are not satisfied with the current education system for HMV (4). They express the need for more information on HMV (ie, related emergency care management and medical techniques) (5). In 2002, a sentinel event alert was released by The Joint Commission in the United States on the prevention of ventilator-related deaths and injuries (14). The Alert reported 23 deaths or injuries related to long-term ventilation (14). Root cause analysis revealed inadequate orientation/training processes to be a contributing factor 87% of the time (14). Our findings support the need for more educational support for patients and caregivers in the home.

With respect to the distribution of on-call service use according to LHIN region, opportunity to make local improvements potentially exist. Due to study time limitations and information availability at the VEP, we were unable to compare on-call service user regional profile to the overall population of VEP patient distribution according to LHIN. Where disproportionate or underutilized service use arise, opportunity for improvement with local prescribing centres could be targeted.

Incident types

The majority of incidents were equipment related (n=164 [72.2%]). In the present study, incidents were the result of equipment malfunction, user error, lack of equipment availability, inappropriate equipment choice and dislodgement of equipment parts. A review of the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database revealed more than 150 alleged home mechanical ventilator malfunctions or failures in 2010 (15). In our findings, 99 alleged equipment failure or malfunction incidents were isolated. While our findings may appear high, MAUDE is a passive surveillance system and values may be under-reported (15). The FDA MAUDE database noted at least 11 patient deaths related to HMV (15). Of note, in five of the 11 deaths, the ventilator did not alarm (15). While alarm adjustments were required in 3.7% of RT actions in our study, no deaths occurred.

With user errors (n=41 [8.1%]), human factors considerations in the design of home equipment should be encouraged especially with respect to patient and family end users. As noted in the qualitative description

of calls, limitations in functional ability (arthritis, poor vision, muscular weakness) and cognitive ability (literacy) were barriers.

Documentation (n=25 [11%]) was another area for improvement. Patients were frequently unaware of their prescribed ventilator parameters, in part, due to a lack of documentation. In situations of complete equipment malfunction, documentation availability and or patient/family knowledge of required settings is essential in preventing delay of replacement equipment and ensuring effectiveness of replaced devices. Communication is a central theme in patient safety across the health care continuum (14). Findings from this review support the need for more consistent documentation and communication practices. This includes establishing consistent elements for documents across all sites and developing a uniform process for communication of specialized information with referring agencies (16). Documentation access can range from simple labels on a device to more sophisticated electronic linkage of health information to all stakeholders including the patient.

Based on the nature of the on-call logs, equipment type incidents were easily identified and, in fact, occurred most frequently. The more difficult to recognize clinical administration (n=10 [4.4%]) and resource (n=3 [1.3%]) incident types were less likely to be found based on limitations in the context provided by the call logs. However, these events were identified in our study and their existence is supported by the literature. Lang et al (17) described gaps in home safety related to coordination of care, and Van Ineveld et al (16) noted that patient safety is often concerned with failures associated with patient transition. Further interviews with patients and their caregivers could yield a higher incidence of both clinical administration and resource type incidents.

Patient outcome

Medical causes of death or acute hospitalization (ie, moderate and severe harm) in patients on HMV include hypocapnia, hypercapnia, hypoxemia, barotrauma, hemodynamic instability, airway complications, respiratory infection, bronchospasm, exacerbation of underlying disease or deterioration through the natural course of the disease (1). In our findings, only mild adverse events could be identified.

It is unlikely that HMV patients only experience mild harm. One recent publication followed 17 invasively ventilated patients living in a nursing home (18). In this study, one-half of the patients experienced severe incidents. While the on-call logs are a valuable source of quality-improvement data, they were unable to be used to describe situations involving HMV patients experiencing moderate or severe harm. Both moderate and severe harm outcomes were not captured, and likely grossly underestimated because patients presumably went directly to local emergency rooms through paramedic services rather than using the on-call service. Patient outcomes overall were difficult to estimate due to limited patient follow-up. A more formal incident reporting system is required to accomplish this.

Based on the present study and, in concert with the literature, the following recommendations can be made:

1. Develop a standard process, including documentation and education across all prescribing organizations to support the handover and discharge of home-ventilated patients.
2. Enable electronic documentation with shared access among the patient, community caregivers (professional and family), VEP staff, family physicians and prescribing centres (acute/rehab) to support communication across all team members.
3. Improve usability of HMV devices, recognizing limitations of the home setting and the physical limitations of many patients who do not have other caregivers.
4. Investigate the need for interventions, potentially outreach respiratory therapy services linked to expert prescribing Physicians, the VEP, Community Care Access Centre nursing care and home care companies, to support high-risk patients (24 h dependent, elderly, deteriorating conditions).
5. Increase development and application of technology to remotely monitor and support high-risk or fragile patients.
6. Review all VEP patient deaths using the WHO framework and the CPSI incident analysis framework to identify critical incidents and opportunity for improvement.
7. Develop an incident reporting system in the community for patients and caregivers. Analysis of reviews should occur through collective analysis by key stakeholders in partnership with patients and families.

Limitations and next steps

In addition to those already mentioned, there were a number of other limitations to the present study. The on-call logs were used as a proxy to determine the actual number of patient safety incidents. The logs were neither complete patient health records, nor did they constitute an incident recording and management system. The logs were manually recorded and stored, which also led to difficulty in obtaining all call logs in a timely manner. The on-call logs were valuable in furthering the work of understanding the nature of harm for those on HMV in the community. However, as stated, moderate and severe harm was not identified.

Further validation of the findings would include a second reviewer to reanalyze the data. Triangulation of the findings could occur through interviews with on-call staff, patients and their caregivers.

CONCLUSIONS

Patient safety incidents in the HMV population exist but are currently not systematically captured. Strategies to decrease the risks for this population are required if continued efforts to support successful management in the community are to occur. The use of on-call data is valuable to identify some safety improvement opportunity. These opportunities include improved support of patients and caregivers through education, better coordination and documentation, closer examination of subpopulations potentially at higher risk and a formal incident review and reporting system.

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