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Innovations in Practice

# How can the collaboration between manufacturers of medical devices and bedside clinicians lead to improved applications of the devices?

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## Abstract

### Introduction

In late 2019, the leaders of a respiratory department at an academic medical center (AMC) in the Southeastern United States (U.S.) decided to change the humidity delivered to patients via invasive and noninvasive mechanical ventilation from passive to active in the intensive care units (ICUs). The AMC purchased the humidifiers that were new in the U.S. market. The manufacturer provided education and training. Almost a year after implementation, the leaders found the humidifiers turned off or on standby, with a heat moisture exchanger (HME) placed in-line and a water trap by the expiratory filter.

### Approach

The leaders requested help from the manufacturer. The manufacturer sent its clinical specialist (CS) twice to the AMC to re-educate and re-train in real time at the bedside. Plan-Do-Study-Act (PDSA) cycles were implemented to troubleshoot problems and improve adherence to active humidity.

### Findings

The respiratory therapists (RTs) did not recall the appropriate steps for setting up the heaters. Instead of asking the leaders for help, the RTs took it upon themselves to turn off the humidifiers, use HMEs, and add a water trap by the expiratory filter to collect excess humidity in the circuit and reduce the need for frequent expiratory filter changes. In addition, other issues were discovered during the process. Those issues exacerbated the alarm situations.

### Discussion

A knowledge gap and a breakdown in communication led to inappropriate use of humidifiers and the implementation of active humidity in the ICUs. PDSA cycles and the involvement of the manufacturer's CS in real-time training and troubleshooting at the bedside resulted in the intended outcomes.

### Conclusion

The process was a learning experience for both the bedside clinicians and the manufacturer. The process led to improvements in the heater's design, its placement on the ventilator cart, the circuit design, and the development of educational materials to guide clinicians.

#### Practice Implications

The true test of a product is its release to the market for widespread use. The outcomes of the process improvement demonstrated the importance of collaboration among all

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stakeholders and that breaking silos across research, design, testing, and implementation is crucial for a successful new device launch.

## INTRODUCTION

While rounding on patients receiving invasive mechanical ventilation (INV) in November 2020, the respiratory leaders (RLs) of an academic medical center (AMC) in the Southeastern United States (U.S.) found that the ventilators' humidifiers (HMDs) were either off or on standby (SB). Some circuits had a heat moisture exchanger in line and a water trap near the expiratory filter. When the RLs asked the respiratory therapists (RTs) for reasons, the RTs reported that the HMD was constantly alarming and that troubleshooting was time-consuming. RTs reported that they were unable to identify the causes of the alarms, despite changing the circuits. They noted excessive rain on both limbs of the heated-wire circuit, which contradicts the expected operation of the circuit. The RTs explained that they added water traps to the expiratory limbs near the filters to collect water, thereby reducing the need to replace the expiratory filters.

Turning off the HMDs or placing them on SB eliminated the HMDs' excessive alarms, which caused noise contamination and alarm fatigue in the environment. The RTs and nurses had to respond to alarms, and patients were not getting sufficient rest due to their frequency. Compounding the problem, most patients were in isolation for COVID-19; therefore, entering the patient's room meant an extra five minutes to don personal protective equipment (PPE) and another five minutes to doff it. Given that the number of INV devices used at the AMC during the pandemic was in the 80s per day and excluding non-invasive ventilation devices and heated high-flow oxygen, it became extremely difficult to troubleshoot the HMD. As a result, it was necessary to identify the root causes of the problems with the HMDs.

A key point to note is that the RTs did not notify the leadership team of any problems they encountered with the HMDs, citing insufficient time to report them or to troubleshoot. All they knew was that the HMDs did not work and suggested returning to passive humidity.

### PROBLEM STATEMENT

The AMC leaders aim to continue using active humidity during INV; however, they realized the RTs have gaps in knowledge regarding the proper setup and troubleshooting of the newly purchased HMDs, as well as the ease of reporting equipment malfunctions. The problem was compounded by the COVID-19 pandemic, which caused an inadequate staffing-to-workload ratio. Workload was impacted by higher-than-normal acuity and the number of patients requiring invasive mechanical ventilation.

### PURPOSE

The RLs aim to improve the RTs' knowledge of the newly purchased HMDs and to simplify the reporting process for equipment problems, ensuring that the active humidity is used appropriately for all patients who require INV.

## BACKGROUND: ACTIVE VERSUS PASSIVE HUMIDITY

For almost two decades, the AMC RTs used heat moisture exchangers (HMEs) to provide passive humidity during INV. Thick secretions were widely noted in patients receiving INV. The delivery of inhaled mucolytics and hypertonic sodium chloride solutions (3% and 7%) along with chest physiotherapy, artificial airway obstructions, and frequent bronchoscopies was required for pulmonary hygiene and maintaining airway patency. Ventilator-associated pneumonia (VAP) rates did not change compared to years prior when active humidity was in use. The AMC RLs were switched from passive to active humidity for all patients on INV to reduce mucus plugging caused by HMEs, decrease the work of breathing associated with mucus plugging, and provide gentle, comfortable airflow to the patients' airways. Active humidity aligns with best practice for INV.

Following the implementation of HMDs in 2019, the AMC RLs observed a decrease in ventilator length of stay (LOS) from 5 days to 3.5 days, particularly in the medical and neurointensive care units (ICUs). When it comes to reporting broken or malfunctioning equipment, the AMC RLs had a reporting process that was established for decades. There is a knowledge gap regarding the appropriate method for reporting such issues, and the reporting process needs improvement.

## LITERATURE REVIEW

The use of HMEs became predominant toward the mid-1990s and continued through the 21st century. Studies show that HMEs increase dead space in the circuit, leading to the need to adjust the ventilator settings to compensate for the dead space and maintain arterial carbon dioxide ($CO_2$) levels within appropriate ranges. In 2006, Boots et al.[1] noted that the type of humidification used during invasive mechanical ventilation does not affect the ventilator-associated pneumonia (VAP) rates; however, the air flow resistance in the HME increases the longer the HME is in line. Mo et al.[2] concluded, based on a meta-analysis, that there was no difference in VAP rates between patients placed on HME and those who received active humidity during INV. Mo et al.[2] added that their conclusion requires further investigation due to the inability to have truly blinded randomized controlled research studies. Another study showed that the choice of humidification does not affect the VAP rate or the obstruction of the artificial airway.[3]

On the other hand, Menegueti et al.[4] stated that they were unable to draw a definitive conclusion that HMEs are not associated with VAP and that further research is needed.

Some researchers addressed the use of the HME during low tidal volume ventilation. Gillies et al.,[5] Solomita et al.,[6] and Lellouche[7] concluded that the use of HMEs is not recommended with the low tidal volume approaches during protective lung ventilation or air leaks. The frequency of changing HMEs remains controversial due to the several types of HMEs in the market, differences in patient populations, disease processes, and ventilator settings.[5]

Another factor to consider when using HMEs is the delivery of inhaled medications (IMs). HME must be removed or special types of HME must be used during the delivery of IMs.[8] If the RTs forget to remove the HME or change its setting during the delivery of IMs, the patient will not receive the IMs. The IMs are absorbed by the HME, which will lead to an increase in airway resistance, high pressure and low tidal volumes alarms, and patient ventilator asynchrony. If the RT fails to return the HME inline or adjust its settings after treatment completion, the patient will not receive humidified air.

If continuous IMs are required, the HME must be removed from the circuit, or inhaled medication mode must be activated until the continuous IM delivery is completed. The patient will not receive any humidity during the delivery of continuous IMs, thus increasing the risk of mucus plugging. Montigaud et al.[9] concluded in their research study the need to continue active humidification during the delivery of inhaled medications. They noted that more medication was delivered to the lungs under active humidity than under passive humidity. They also highlighted that the placement of nebulizer proximal to the Y allowed the delivery of more medications to the lungs than when it was placed distal to the Y. On the other hand, Jacquier et al.[10] found in their in vitro research study that more medication was delivered to the patient when the nebulizer was placed at the heater inlet rather than by circuit Y.

In addition, the frequency of HME replacement depends on the manufacturer's recommendations and HME performance. Breaking the circuit is inevitable when the HME needs to be changed. HMEs are changed every 24 hours and as needed in between.[5] Breaking the circuit can increase the risk of VAP, alveolar de-recruitment, and drop in oxygenation. One study showed that the use of HME led to a decrease in patients' body temperature by about 0.5 degrees Celsius (C), leading clinicians to replace the HME with active humidity.[5]

Active humidity during INV has advantages over HME. Al Ashry and Modrikamien[11] cited the differences between the use of passive humidification and active humidification. Active humidification involves the use of HMDs, water chambers, special circuits, and temperature probes that allow monitoring and adjustment of temperature and humidity based on the temperature set on the heater, the flow rates, the patient's minute ventilation, and room temperature. Lellouche[7] advocated the use of heated humidification during INV and noted that it would improve patient tolerance and comfort for both INV and non-invasive ventilation.

Vargas et al.[12] stated that, based on their meta-analysis, patients' clinical conditions must be considered when determining the type of humidification to use. Restrepo and Walsh[13] advocated for the use of active humidity during INV with temperatures at the patient's circuit wye (Y) between 34 °C and 41 °C. They also noted that the use of active humidity improves patient tolerance and facilitates secretion clearance when the patient has pneumonia. They added that HMEs are contraindicated when the patient has hemoptysis and when the patient's body temperature is below 32 °C.

Furthermore, active humidity provides the appropriate humidity needed inside the lungs during INV because the patient's upper airways are bypassed. Upper airways, under normal conditions, heat and humidify the air that is going into the lungs. To provide humidity level during INV like the normal airway humidity level at 100% relative humidity (RL), the humidity level delivered to the patient's airway should be between 33 and 44 mg/L. This means the HMD temperature should be maintained between 34 °C and 41 °C.[13] This amount of humidity helps to maintain healthy mucosa and epithelium.[14] It preserves the mucociliary clearance by allowing thinning of the secretions and reducing mucus plugging of the tracheal bronchial tree and the artificial airway.[15] Heated humidity has the potential to improve patient tolerance to INV.[16]

Mucus plugging of the tracheal bronchial tree or the artificial airway can cause an increase in vent days. It contributes to patient ventilator asynchrony, high peak inspiratory pressures, low tidal volume, decrease in $SpO_2$, intolerance to suctioning and repositioning, atelectasis, and worsening of respiratory status.[15] For the patients with tracheostomy tubes, it is best to use active humidity instead of HME.[17]

Kelly et al.[18] noted that active humidity is safer than passive humidity when smaller tidal volumes are in use during INV, whether the patient is an adult or pediatric. They added that active humidity is preferred to prevent artificial airway blockage. They concluded that further studies are needed to compare the effectiveness of hygroscopic HMEs, as hydrophobic HMEs can lead to artificial airway obstruction.

## HMD TYPES

Different HMDs exist in the market. Some of them incorporate single lumen heated wire circuit, double lumen heated wire circuit, and single lumen heated wire circuit and porous expiratory limb, or double lumen heated wire circuit with porous expiratory limb. Solomita et al.[6] noted that maintaining the heater temperature at one specific level does not necessarily provide the appropriate humidity to the patient; thus, finding HMDs that allow the adjustment of the temperature at the patient's circuit Y is crucial.

Based on the information above and given the extremely high acuity of the patients the AMC treats, the AMC RLs decided to purchase HMDs in 2019. The AMC was the second site in the U.S. to purchase this FDA-approved innovative heater technology.

The HMD's technology was innovative at the time the RLs decided to purchase them because it included a temperature probe embedded within the breathing circuit wall, which eliminated the need to store and sterilize the tem-

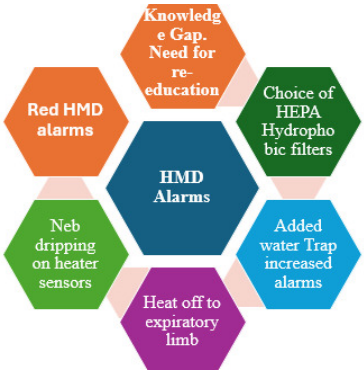


**Figure 1. Identifying other issues needing to be addressed**

perature probe cables. This feature aligned with infection prevention. The HMD's design was also innovative because it guided the RTs to the proper adjustments of the settings to meet the temperature at the circuit Y, providing individualized temperature and humidity settings to meet the patient's needs. The heated expiratory limb eliminates the rainout that can cause the ventilator to self-cycle, which can be misinterpreted as patient ventilator asynchrony. At the time the AMC RLs purchased the HMDs, no other FDA-approved HMDs with similar technology were available. The HMD technology was appealing to the AMC RLs due to cost-effectiveness, infection prevention, and tailored humidification and temperature delivery to the patient's airways.

The manufacturer's clinical specialist (CS) trained the RTs on the use of HMDs upon purchase, with bi-weekly visits after the first two weeks of on-site education. A few months later, COVID-19 took the world by surprise and impeded CS's ability to continue on-site education.

## METHODOLOGY

The goal of this research was to identify knowledge gaps regarding appropriate heater setup and the causes of alarms, to help RTs troubleshoot effectively. When contacted in November of 2020, the manufacturer's CS was allowed to return on-site to help with re-education.

An application was submitted to the AMC IRB. Given the observational, descriptive nature of the research study, the IRB determined that the standard IRB process was not required. The IRB provided a letter to support the determination.

Once the knowledge gap was identified, a series of interventions to reeducate and retrain the RTs was initiated. Taking into account human factors, resistance to change, and the pandemic, several cycles of re-education, retraining, and reassessment were implemented. Plan-Do-Study-Act (PDSA) cycles were used to evaluate the effectiveness of the interventions. As the bedside education and rounding continued, the RLs and CS were able to identify other contributing factors that caused the HMD's alarms. Those factors included the type of filters and nebulizer used.

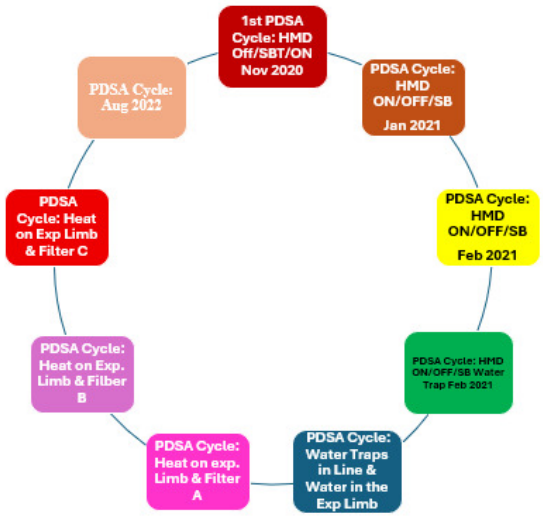


**Figure 2. PDSA Cycles**

The type of filters and lack of turning the heat on the expiratory limb caused high rainout and led the RTs to place a water trap on the expiratory limb. The pneumatic nebulizer (PN) was placed above the HMD and was dripping on the heater sensors. The dripping was caused by high pressures and delivery of medication during the inspiratory phase. As a result, the RLs decided to implement a mesh nebulizer (MN) and trialed different types of filters to identify the most efficient one, while ensuring that heat was activated on the expiratory limb.

The method used to identify the RTs' base knowledge included asking the RTs to demonstrate setting up the HMD, the mode to use, and adjusting the temperature based on the temperature measured at the Y. Also, the RTs were asked to demonstrate how to troubleshoot the different alarms, one by one (see **Table 1**).

Planning and implementing education approaches included mandatory in-person with hands-on at bedside, PowerPoint (PP) presentations in person and via email, synopsis in the morning and evening huddles, and printing hard copies of the PP and posting them in binders in the ICUs and the RT department. Education was initiated in November 2020 with the heater CS on site for hands-on training for one week. The CS returned in January 2021, for one week and in February 2021, for another week. The CS, in collaboration with the AMC respiratory educator and supervisors, provided hands-on training and education at the bedside in real time.

To ensure all RTs were reeducated and retrained, RTs were required to sign an attendance roster that included the date of the in-service, the clinician who provided it, and their signature. If they attended the in-service more than once, they had to sign the roster each time. The roster allowed the RLs to track the attendance and identify the RTs who still needed re-education. The RLs ensured all RTs were educated. New hires were trained with hands-on experience in the classroom and at the bedside. They were provided with the PowerPoint presentation, too. The RT educa-

**Table 1. RTs' knowledge over 21 months of education and training**

| | # Of RTs Interviewed | # Of the RTs who knew all correct settings | # Of RTs who knew some settings | # Of RTs with Zero Knowledge |
|---|---|---|---|---|
| Cycle 1 | 46 | 0 | 15 | 31 |
| Cycle 2 | 48 | 8 | 13 | 27 |
| Cycle 3 | 57 | 24 | 14 | 19 |
| Cycle 4 | 62 | 47 | 9 | 6 |
| Cycle 5 | 44 | 32 | 8 | 4 |
| Cycle 6 | 30 | 24 | 6 | 0 |
| Cycle 7 | 34 | 27 | 7 | 0 |
| Cycle 8 | 32 | 26 | 6 | 0 |
| Cycle 9 | 75 | 75 | 0 | 0 |

**Table 2. HMD observations during the first four rounds of education and training**

| # of HMDs observed | # of HMDs in SB | # of HMDs turned OFF | # of HMDs turned ON | # of observations with water trap in line |
|---|---|---|---|---|
| 571 | 207 | 264 | 0 | 471 |
| 468 | 207 | 250 | 11 | 468 |
| 478 | 175 | 248 | 55 | 478 |
| 469 | 174 | 106 | 189 | 469 |

tor and the supervisors were responsible for the continuing education and training of the current and new hire RTs.

Evaluating the effectiveness of the education and training continued for nine cycles based on direct observation, bedside rounding with the RTs, and filling out a document that was created for evaluating the outcome of the education and training. Based on the data collected, education, training, and changing to MN and new filters were established. The data collection forms were updated several times to reflect different phases of the education and interventions taken to correct the alarms.

To ensure timely reporting of the equipment issues and malfunctions, RLs placed the reporting forms in each ICU in locations easily accessible to the RTs and educated the RTs on the proper steps for reporting. The equipment technicians became responsible for replenishing the forms to prevent delays in reporting. Each piece of equipment with the malfunction/broken tag was sent to the biomedical engineering department. This process helped improve the timely reporting of broken HMDs.

## DATA COLLECTION

Using the forms created, dayshift RLs collected data from six ICUs, and nightshift RLs collected data from the other six, across a total of 150 ICU beds. Summaries of the findings of each stage and interventions are provided in **Table 2**. Each instance of data was collected over seven consecutive days. The data was then evaluated, and an action plan for education and training was continued or established based on the data findings.

Based on the data collected, the AMC RLs added to the data collection the presence of water in the expiratory limb because they wanted to evaluate the effectiveness of using the HMD's feature that heats the expiratory limb and reduces the rainout (see **Table 3**). After one round of data collection with the presence of water in the expiratory limb, they implemented turning on the feature that heats the expiratory limb and made it mandatory for appropriate heater setup. To address the water condensation in the filter, they decided to trial three different hydrophobic HEPA filters (see **Table 4**). For the purpose of this paper, the filters are going to be referred to as Filter A, Filter B, and Filter C.

Hydrophobic filters mean the filters allow the gases to pass through but do not allow the water to pass through. This property helps with INV because it reduces the risk of water passing through the filter and reaching the exhalation block. It also reduces the risk of increased respiratory resistance that leads to increased alarms and patient ventilator asynchrony.

When the filter trial was initiated, the RLs decided to limit the number of ventilators they monitored due to the limited availability of filters during the pandemic. They assessed three different filters. They documented if the patient was receiving inline nebulizer, intermittent with PN, or continuous using MNs. Filters were changed in accordance with the manufacturer's recommendations and as needed when water droplets were visible on the filter. Summaries of the findings are provided in **Figures 3-5 and Table 5**.

The data collected helped the RLs identify the best filter to use. The "C filter" came first, followed by "B filter," then "A filter." They continued to monitor the heater settings

**Table 3. Water condensation noticed in the expiratory limb during HMDs observations**

| # of HMDs observations | SB # of instances | Off # of instances | On # of instances | Water traps # of instances | Water in expiratory limb |
|---|---|---|---|---|---|
| 430 | 55 | 48 | 327 | 430 | 430 |

**Table 4. Observations post-implementation of turning on the HMD's expiratory limb heating feature and different brands of expiratory filters**

| | # of HMDs observations | SB # of instances | Off # of instances | On # of instances | Water traps # of instances | Water in expiratory limb |
|---|---|---|---|---|---|---|
| With Filter A | 40 | 2 | 4 | 34 | 2 | 2 |
| With Filter B | 60 | 3 | 4 | 53 | 3 | 3 |
| With Filter C | 60 | 3 | 4 | 53 | 3 | 3 |

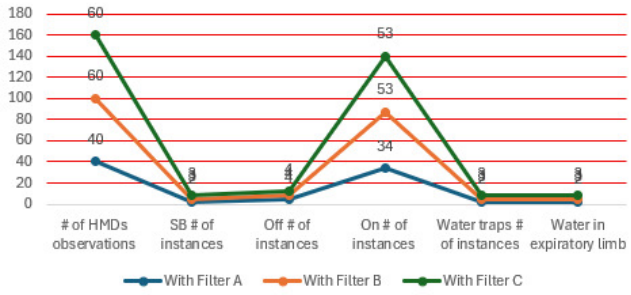


**Figure 3. Data with Each Filter and Heat ON in the Expiratory Limb**

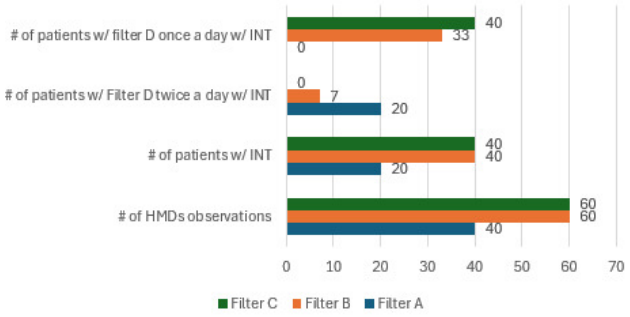


**Figure 4. Frequency of filter changes with INT**

INT, Intermittent Nebulizer Treatments

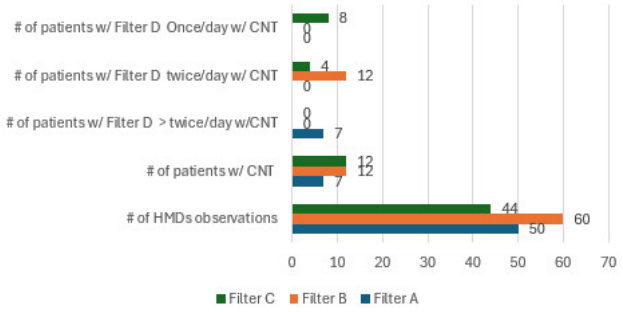


**Figure 5. Frequency of filter changes with CNT**

Note: Some patients were receiving both INT and CNT.

and compliance on a weekly basis with just-in-time observations and interviews.

## PRACTICE IMPLICATIONS AND DISCUSSION

A knowledge gap, breakdown in communication, and the launch of a new device without continuous education support during the post-launch phase (due to an unforeseen, abnormal pandemic environment), along with human resistance to change, provided the perfect recipe for a challenging HMD implementation process. Collaboration among the manufacturer's CS, the AMC RLs, and bedside clinicians led to the identification and resolution of the problems. As a result, the CS and the AMC leaders developed education material to guide the clinicians on the appropriate setup and troubleshooting. To ensure the RTs were competent with the setup and troubleshooting of the HMD, the RLs required each RT to return demonstration of the setup and troubleshooting of each alarm. In addition, the RLs incorporated the HMD setup and troubleshooting in the yearly competencies. The manufacturer initiated a series of HMD upgrades to better serve the patients and bedside clinicians, including a new circuit design for the nebulizer, relocation of the heater bracket, and a more user-friendly HMD design.

In addition, RLs and the manufacturer collaborated to change the corroded sensors, which led to solving some alarms and improved RTs perceptions of the HMDs. The changes improved the RTs willingness to troubleshoot the alarms.

Leaders' rounding purposefully and continuously ensures the checks and balances are followed. Rounding at bedside is crucial for the success of the implementation of any project and to maintain patient safety and quality of

**Table 5. Continuous study and data collection results***

| | |
|---|---|
| # of RTs who were interviewed from both shifts over the last 12 months | 75 |
| # of the RTs who knew how to set the appropriate heater settings | 75 |
| # of RTs who knew how to set some of the appropriate heater settings | 0 |
| # of RTs who did not know how to set the heater settings | 0 |
| Total instances HMDs checked daily | 1800 |
| # of instances HMDs found on SB | 325 |
| # of instances HMDs found turned off | 75 |
| # of instances HMDs found turned on & running | 1400 |
| # of instances ventilators with water traps on the expiratory limb. | 3 |
| # of instances the RTs stated there is water in the exp limb | 3 |

*Spot checks Weekly. One Spot-check per ICU. Min 3 Ventilators per ICU. August 1st, 2021, through August 1st, 2022

care. In addition, rounding with the front-line clinicians at the bedside helps the leaders identify opportunities for improvement and increases retention.

When it comes to reporting broken or malfunctioning equipment, the AMC RLs established the reporting process two decades ago and did not change it. The RLs found two gaps in the process: a gap in knowledge for some of the RTs, and time restraints imposed by the unexpected acuity and volume of the patients during the pandemic, and the unavailability of the forms in the ICUs.

From a human factors perspective, the RTs sought to care for patients to the best of their ability. They did not have time to find the broken equipment form because it was not readily available in every ICU. They reverted to the old ways they were comfortable practicing by using the HMEs rather than spending time they could not afford to troubleshoot the HMDs and find the form. They had to make a choice given the short staffing situations imposed by the pandemic due to the much higher volume and acuity of patients than at any other time. They also did not report to the RLs directly the issues because they wanted to return to using HMEs - resistance to change. Educating on the rationale for a change in practice is crucial to obtaining the buy-in from the front-line clinicians. In addition, the RTs were re-educated about the importance of escalating any concerns or issues following the chain of command when they are unable to solve a problem on their own, whether due to knowledge gaps or time constraints. The RLs shared and posted the chain of command and communication pathways in the department to encourage the RTs to escalate problems and concerns at any time. The chain of command and communication pathways are reviewed during every department meeting.

Another gap the RLs found was an opportunity to evaluate the use the MN on all the INV, for INT and CNT, not only to reduce the leakage and corrosion of the HMDs electronic sensors, but also to improve the delivery of the IMs to the patients. The data collection and differentiation of cause and effect gave the RLs the foundation to make a case and purchase the number of the MNs controllers needed to implement the change.[19]

## LIMITATIONS

The AMC RLs initiated the process improvement (PI) during the pandemic, under unusual circumstances. They approached the PI in phases due to limitations imposed by high acuity and volume, as well as the patient-to-RT ratio. The re-education and training took 21 months to reach acceptable levels. If the circumstances were normal, the RLs could have corrected the process in a shorter time with a multipronged approach.

Due to the paucity of medical supplies during the pandemic, the RLs had to compromise when it came to testing the HEPA hydrophobic filters. The number of filters available limited the number of ventilators and patients using each type of filter during the trial. If the RLs repeated the filter trials on a larger scale once the supplies became available, each type of filter would have been trialed for one week.

## CONCLUSION

The process was a learning experience for both the AMC RLs and the manufacturer. Problem-solving requires the leaders to implement the Gemba (the actual place or area where the action is taking place) walk, to actively listen to the front line, effectively apply the PDSA cycles, and collaborate with the manufacturer when the issues are related to a device. Regardless of how big or small the problem is, dissecting it into smaller sections and solving it one section at a time results in impactful solutions. In this case, the problem with the HMDs included a gap in knowledge from the RTs and had contributing factors that exacerbated the HMDs' alarms. Those factors included the PN dripping on the HMDs sensors and causing corrosion, and the RTs using water traps instead of activating the heat on the expiratory limb, which led to an increase in rainout in the expiratory limb and in the filter. The RTs added the water trap to solve the rainout problem because the rainout caused self-cycling, which was interpreted as the patient's high respiratory rate and intolerance to the INV mode. Addressing one issue often reveals additional factors that the leaders must resolve for a meaningful and comprehensive solution.

The best way to learn accurately the reasons for a problem and find the appropriate solutions is direct observation on the ground with interactions with the clinicians, on all shifts. Collaboration between clinicians and manufacturers is essential to continually improve equipment and devices to better serve patients and enhance patient safety. Breaking silos, building bridges, active listening, and taking action to improve processes and devices are essential to the highest quality of care and patient safety.

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CONTRIBUTIONS

All authors contributed to the conception or design of the work, the acquisition, analysis, or interpretation of the data. All authors were involved in drafting and commenting on the paper and have approved the final version.

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COMPETING INTERESTS

All authors have completed the ICMJE uniform disclosure form and declare no conflict of interest.

ETHICS

Ethics approval was waived by the Emory University IRB, which does not require IRB review of studies that do not meet the definitions of “human subjects research” (DHHS) or “clinical investigation” (FDA).

AI STATEMENT

The authors confirm that no generative AI or AI-assisted technology was used to generate content.

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