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I, Nathan M Pajor M.D., hereby submit this original work as part of the requirements for the degree of Master of Science in Clinical and Translational Research.

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Improving the Rate of Home Ventilator Alarm Use in a Pediatric Pulmonary Medicine Clinic

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by

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ABSTRACT

Background: Children requiring chronic mechanical ventilation in the home setting are at extremely high risk of morbidity and mortality. Internal ventilator alarms are one mechanism to improve safety for these patients but there are no guidelines or standard practice for how to use these alarms.

Objective: The aim of this quality improvement project was to increase the mean rate of critical ventilator alarms set in our home ventilator population when seen in clinic from 63% to >90%.

Methods: Using the Model for Improvement we developed, tested and implemented a series of interventions using Plan-Do-Study-Act cycles. Our measure was tracked using statistical process control methods. Our primary interventions were: (1) standardization of the clinic workflow, (2) development of an algorithm for ventilator alarms, (3) updating that algorithm based on tracking of recurrent failures and inpatient testing, (4) engagement of staff to change the culture surrounding ventilator alarms.

Results: Baseline data was collected from May 1 – July 13, 2017 on 130 consecutive patients and showed a baseline of 63% of critical alarms set in patient seen in clinic. Observation of the process, standardization of workflow and adaptation of an alarm algorithm led to an increased to 85.7%. Revision of our algorithm to include an apnea alarm in conjunction to increased provider engagement led to rate of 95.1%, exceeding our goal. Continued improvement to a rate of 98.6% was seen and sustained as a result of culture change related to ventilator alarms.

Conclusions: This stepwise approach to ventilator alarms led to a sustained improvement in the rate of critical ventilator alarms used in our chronic ventilator patients. Many of our interventions could be generalizable to other pediatric institutions.

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INTRODUCTION

Available Knowledge

Children requiring chronic mechanical ventilation in the home setting represent a growing population with variable underlying pathologies. Their complexity, reliance on technology, and high degree of medical fragility place them at a high risk of mortality[1]. An assessment of children in the Pennsylvania Ventilator Assisted Children's Program described an overall mortality rate of 27.5% with 18-20% of those deaths attributed to accidental tracheostomy tube decannulation or tracheostomy mucous plugging [2]. The American Thoracic Society (ATS) convened a Pediatric Chronic Home Ventilation Workgroup which produced evidence-based guidelines in 2016 strongly recommending that an awake, attentive and trained caregiver be in the home at all times to address such preventable events [3]. Additionally, they recommended the use of pulse oximetry in addition to internal ventilator alarms or other monitoring devices to help alert caregivers of potential emergencies; however, evidence supporting this recommendation was limited [3]. Home mechanical ventilators contain multiple internal alarms intended to provide safe operation. Some are default alarms intended to sound during a mechanical failure (loss of power, low battery, circuit disconnection, etc.), while others are manually set and intended to sound when a respiratory parameter falls outside of the set range (low minute ventilation, low tidal volume, high respiratory rate, etc.). The ECRI Institute, a non-profit organization which investigates approaches to improved patient safety named inappropriately set ventilator alarms as one of their top ten health technology hazards of 2019 [4]. At present, there is minimal existing evidence regarding the effectiveness of ventilator alarms and how they should best be utilized. The ATS guideline regarding use of pulse oximetry was prompted by two small studies suggesting concerns about these ventilator alarms: Kun, et al, found that low pressure alarms on home ventilators may fail to sound when used with pediatric-sized tracheostomy tubes [5]. Farre, et al, found that many of the ventilator alarms were non-functional when evaluated in the home setting [6]. Documentation from home

ventilator manufacturers recommends using multiple manual alarms to detect serious events without indication as to how those alarms should be set [7]. No existing literature describes how frequently ventilator alarms are set, the methodology used or the processes by which these alarms are implemented in a clinical setting.

Given the high risk of this patient population and the lack of an existing process for managing ventilator alarms in our pulmonary clinic, we developed an interdisciplinary, team-based series of interventions based on the Model for Improvement to address this problem [8].

Problem Description

The present improvement project was carried out in the Cincinnati Children's Hospital Medical Center (CCHMC) Pulmonary Medicine clinic. Our baseline data, obtained from 130 consecutive clinic patients between May and July 2017, requiring chronic invasive ventilation for all or a portion of each day, showed that an average of only 63% of what we deemed the most critical ventilator alarms (circuit disconnect, low minute ventilation, low tidal volume) were ordered by the physician before departure from clinic. Each patient was evaluated by a respiratory therapist and physician at each visit and all ventilator and alarm settings were documented in the electronic health record but there was no standardized approach to evaluating and setting ventilator alarms. Analysis of the process showed that ventilator alarms were a low priority topic at clinic visits with variable consideration of alarms and approach to setting alarms.

Rationale

In June 2017 we established a multidisciplinary team consisting of respiratory therapists, nurses, medical assistants, and physicians involved in the care of our chronic invasive ventilator-dependent population in both the inpatient and outpatient settings to allow for shared knowledge. The team reviewed the

current ventilator alarms utilized in inpatient and outpatient settings and the process for collecting and evaluating information in the pulmonary clinic setting. Gaps in knowledge and process were identified. Using the Model for Improvement, global and SMART (Specific, Measurable, Actionable, Relevant, Time-Bound) Aims were defined and a key driver diagram was developed describing the team's theory for improvement. We tested our hypothesized strategies for improvement using Plan-Do-Study-Act (PDSA) cycles to allow for further testing and refinement.

Specific Aim

Our specific aim in this project was to improve the rate of critical alarms ordered at departure from pulmonary clinic in our chronic invasive ventilator population to >90% and to sustain the improvement over time.

METHODS

Context

Cincinnati Children's Hospital Medical Center (CCHMC) provides care for approximately 280 children requiring chronic invasive home ventilation. Patients are transitioned from ICU to home ventilators during their index admission within our 24-bed Transitional Care Center (TCC). Care within the TCC is provided by a dedicated group of nurses, respiratory therapists, nurse practitioners and physicians. The patients are discharged home after they have achieved medical stability, completed caregiver education and established home nursing care. The majority of patients discharged from our TCC are placed on a Philips Trilogy 100 ventilator (Philips Respironics, Murrysville, PA) with the remainder using the LTV 1200 ventilator (Carefusion, Yorba Linda, CA). Based on bedside testing within the TCC, we determined that for the majority of patients, the circuit disconnect alarm, the low minute ventilation alarm and, on the

Trilogy ventilators, the low tidal volume alarm were most sensitive in detecting decannulation and mucous plugging events without generating an untenable number of nuisance alarms.

Upon hospital discharge, our home ventilator patients are followed regularly in Pulmonary clinic. A pre-visit planning meeting is held on a weekly basis to discuss upcoming clinic patients. The meeting is led by the clinical director of the home ventilator program and attended by nurses, respiratory therapists, social workers and dieticians who will see patients in the coming week. Notes from the meeting are disseminated to all providers. Prior improvement efforts have assured that all ventilator settings, including alarm settings, are documented at each clinic visit. All patients receive a phone call reminder one week prior to their scheduled visit reminding them to bring their home ventilator to clinic, even if they only require overnight support. Our chronic ventilator population is seen primarily by a group of 9 pediatric pulmonologists with dedicated nursing staff. A small group of outpatient respiratory therapists evaluate each ventilator-dependent patient at every clinic visit and obtain vital signs, Philips NM3 (Philips Respironics, Murrysville, PA) respiratory profile monitor data including ventilator volumes and end-tidal carbon dioxide readings and review history with the family. For patients on the Trilogy ventilator, they are also able to obtain ventilator download data from the internal data card if requested.

CCHMC has a robust quality improvement infrastructure within the James M. Anderson Center for Health Systems Excellence. Faculty and staff participate and receiving training in quality improvement methodologies through involvement in ongoing projects and multiple course offerings on improvement science. Assistance in methodology and data analysis is available through outcomes managers within the divisions and within the Anderson Center.

Key Drivers

Prior to any intervention we spent approximately one month observing the clinic workflow process for patients on chronic ventilator support. Several potential failure modes were identified: (1) there was a lack of standardized process for collecting data in the clinic and for discussing that data collection with the primary provider; (2) there was no standardized guideline or algorithm for setting alarms and so individual alarms settings relied on provider preference and priority; (3) certain patient groups had a high propensity for nuisance alarms and so poorly tolerated most alarm settings. This including children who had un-cuffed tracheostomy tubes and subsequent large leaks and also infants and toddlers who had low average tidal volumes. And lastly, (4) there was lack of staff awareness with regard to alarm settings and low priority was placed on addressing and setting ventilator alarms. Based on this assessment our improvement team developed key drivers to address the poor rate of critical alarms being set and proposed a number of possible interventions aimed at addressing those key drivers as described in Figure 1.

Interventions

Standardized Clinic Workflow: The primary intervention to the clinic workflow aimed at standardizing patient data collection by the respiratory therapist (RT) and obtaining the necessary information required to appropriately address alarms. For those patients on Trilogy ventilators, the majority of our clinic population, we conducted several tests comparing the estimated exhaled tidal volumes obtained from the NM3 monitor compared to the data downloaded from the ventilator SD card. While providers considered the NM3 data more useful in determining appropriate ventilator settings, this information was less helpful in establishing alarm parameters as the ventilator alarms are only based on the ventilator data. There was significant difference between the NM3 and download data such that, after multiple PDSA cycles, our team elected to adopt the practice of routinely obtaining ventilator download data at the start of each clinic visit to have it available when the RT and physician discussed the patient.

During testing for this intervention, we collected sample data on the number of families who failed to bring their home ventilator to clinic despite the pre-visit phone call reminder. We found that 5 of the 16 (31%) families we sampled did not bring the appropriate ventilator to clinic either because they child was on nocturnal support only or because they brought only the backup/travel ventilator. In an attempt to mitigate this, we conducted several tests aimed at obtaining downloads through home health companies in advance of clinic. The amount of time invested in reaching the various home health companies, delays in obtaining the downloaded data and data that needed to be sent repeatedly if unreadable led us to abandon this intervention.

As part of the RT patient assessment, questions about alarm frequency and type would be asked at the time that alarm settings were documented from the home ventilator. These questions were asked consistently during our observed visits though RTs were not blinded to the reasons for observation and many were members of our improvement team so we are unable to determine the degree to which this influenced our observation.

Alarm Algorithm: To address the need for RT and physician provider guidelines in setting ventilator alarms, we developed a proposed algorithm which was tested and modified both in the outpatient clinic setting and in our inpatient TCC unit. The algorithm offered general guidelines for how to set each critical alarm based on data obtained from the clinic ventilator download or data observed during the clinic visit. As there was no evidence to guide the creation of this document, it was based off consensus recommendations from the chronic ventilator physician providers and respiratory therapists within our improvement team. The algorithm was tested in our TCC patients who were stable on their home ventilators and awaiting discharge. The LTV ventilator, used for the minority of our patients, with the activation of the low minute ventilation alarm, was found in this testing to be sensitive to accidental disconnect events, obstructive mucous plugs or accidental decannulation events. The Trilogy ventilator,

used in the majority of our patients, was found to be reasonably sensitive to similar events with a combination of the circuit disconnect alarm, the low minute ventilation alarm and the low tidal volume alarm. Exceptions are discussed further below. Once our algorithm was implemented in clinic we performed follow-up phone calls for the first patients with new alarms set to assure no substantial increase in nuisance alarms.

In addition to providing guidance to all providers on setting ventilator alarms, the algorithm also served as a tool to empower the clinic RT staff to suggest alarm changes to the physician provider. The workflow describe above would allow all necessary data to be collected and then, based on the algorithm, the RT could propose new alarm settings which the physician could sign prior to seeing the patient or adjust based on additional history after their visit. In the event that a recommended alarm was not set following team discussion, the RT was asked to document the reason along with the final set ventilator alarms in the electronic health record. The final algorithm can be seen in Figure 2.

Apnea Alarm: A Pareto analysis of each failure to set a critical alarm was conducted on an ongoing basis throughout our improvement effort. The reasons for alarm failure were obtained through manual chart review and based on RT or physician documentation. The most common reason for failure was a high rate of nuisance alarms when setting the low exhaled tidal volume (Vte) alarm in children with low average tidal volumes. The Trilogy ventilator allows the low Vte alarm to be set at a minimum level of 40mL. For infants and small children, this leads to frequent alarms when their average tidal volume falls within the 50-100mL range.

The second most common failure was due to large leak in children with un-cuffed tracheostomy tubes and consequently low average tidal volumes that led to frequent nuisance alarms. These two reasons accounted for 72.9% of all failures during the intervention period. As most children who can tolerate a large leak or use an un-cuffed tube are weaning from ventilator support, clinically stable and vocalize

suggesting patent upper airway, we elected to focus on addressing that most common failure mode: low average tidal volumes and inability to tolerate the low tidal volume alarm on the Trilogy ventilator without excessive nuisance alarms.

To address this, we began trialing the Trilogy apnea alarm in our inpatient TCC unit. The apnea alarm is designed to sound in the event that a patient's spontaneous respiratory rate drops below a set threshold. For children that require high set rates and have impaired respiratory drive or inadequate respiratory muscle strength to trigger the ventilator, this results in excessive nuisance alarms; however, for infants with chronic lung disease of prematurity for whom this alarm failure is most common but who have normal respiratory drive and are often placed on sub-physiologic set rates as they wean from ventilator support, the apnea alarm, based on our testing, serves as a reasonable substitute to the low Vte alarm with similar sensitivity to potentially life-threatening events. The use of apnea alarm was added to our previously described alarm algorithm.

Staff Engagement & Sustainability: The group of respiratory therapists, nurses, and physicians caring for our chronic ventilator populations is relatively small and so significant awareness of this project was established through repeated interventions as well as ongoing discussion and brief huddles with key members of the improvement team. Once the key interventions above were implemented, we utilized our weekly pre-visit planning meeting to discuss alarm settings for each patient scheduled in clinic for the upcoming week. Initially, the upcoming patients were pre-reviewed by a pulmonary fellow to suggest possible changes at the meeting. To increase the level of reliability, alarm settings were incorporated into an automated electronic template showing patient information which includes growth parameters, recent visits and admissions and additional information which is tracked and discussed at each pre-visit planning meeting. Alarm notes were sent as part of the emailed weekly pre-visit meeting

notes but this intervention was stopped after several months when discussion became routine and we had achieved and were able to sustain our improvement goal.

With full adoption of these interventions into our daily clinic practice there was a noticeable change in the frequency of alarm discussion across both outpatient and inpatient providers. This led to sustained and further improvement without additional intervention which we attributed to a fully adopted culture change related to ventilator alarms.

Study of the Interventions

We measured the number of critical alarms ordered following each clinic visit as a percentage of the total possible number of critical alarms. If a patient was on a Trilogy ventilator there were three possible critical alarms that should be set: circuit disconnect, low minute ventilation and low Vte. If the patient was on an LTV ventilator, there was one critical alarm that should be set: low minute ventilation. We calculated the set number of critical alarms (numerator) and total number of critical alarms (denominator) for groups of 10 consecutive patient seen in clinic because of our variability in number of clinic visits from week to week. The variation in denominator between groups was due to number of patients seen on either Trilogy or LTV ventilator. These data were recorded on an annotated p-chart. Of note, with incorporation of the apnea alarm, we counted apnea alarm as a substitute for low Vte alarm only in the scenario where the patient's low Vte alarm could not reasonably be set due to frequent nuisance alarms. Use of the apnea alarm in our algorithm did not affect the denominator of our measure.

These alarm settings were charted in the EHR as part of our standard clinic workflow which existed prior to the onset of this project. The data were extracted from the EHR and manually reviewed in order to perform a Pareto analysis on individual causes of failure.

Analysis

A quantitative, time series study design was used for analysis with statistical process control methods and accepted industry criteria used to designate change as random variation (common cause variation) or attributable to a specific cause (special cause variation) [9]. Annotated p-charts were updated monthly during the period of frequent intervention and then approximately quarterly once goal was sustained. The mean and upper and lower control limits were calculated and displayed on the p-chart.

Human Subjects Protection

The present study fell within the CCHMC Institutional Review Board's guidance for quality improvement projects that did not constitute human subjects research.

RESULTS

The study period began on May 1, 2017 with interventions trialed through April 1, 2018 when we achieved our SMART Aim goal. Data collection was continued through January 24, 2019 to demonstrate sustainability. There were 690 clinic visits during the entire time period. Baseline data was collected from May 1, 2017 to July 13, 2017 on 130 consecutive visits and demonstrated that critical alarms were set, on average, 63% of the time. In assembling our improvement team and beginning observation of the clinic workflow on July 19, 2017, we saw an increase in the mean percentage of critical alarms set to 80.8% based on p-chart rules for special cause. We attribute this primarily to the effect of observation on staff awareness and attention to alarms however there remained significant common cause variability between groups of patients. Changes to clinic workflow through August and September of 2017, in addition to the adoption of our alarm algorithm on August 17, 2017, led to further improvement to 85.7% which was expected based on our theory that empowered RTs would drive improvement. We also observed decreased variation in the measure compared to the baseline study

period that was likely due to standardization. The consistent failure to set alarms on children with small tidal volumes and large leaks became more evident as the processes became better standardized. This led to full adoption of the apnea alarm on November 30, 2017. This, in conjunction with continued efforts to engage care providers through discussions at weekly pre-visit planning meetings led to an increase in mean percentage of alarms set to 95.1%, exceeding our initial goal of 90%. High reliability interventions including the alarm algorithm and incorporation of alarm discussion into weekly meetings allowed for sustainability of this mean rate until October 2018. At that time, we noted sustained further improvement which met p-chart criteria for special cause. Discussion with team members led this shift in our centerline to be attributed to a noticeable change in culture as alarm discussion became more frequent and engrained into clinic workflow and decision-making. Our current rate of critical alarms being set has been sustained at 98.6% since October 2018.

DISCUSSION

Summary & Interpretation

We describe a stepwise approach to designing and implementing interventions to improve the rate of critical alarms set in our chronic ventilator dependent population. This improvement has been sustained over time. Staff awareness and engagement were crucial to our success in establishing a culture change related to outpatient ventilator alarms. Having a relatively limited number of providers at all levels who are very dedicated to the safety of this patient population allowed for early adoption of interventions and rapid spread to all providers for those that were successful. Respiratory therapists in clinic who are able to obtain necessary data through ventilator downloads and history helped greatly by making all the information available before a patient was evaluated by the physician.

We are not aware of any existing literature to guide the use of home ventilator alarms and so our approach to designing an algorithm through pragmatic bedside testing on our large inpatient service

allowed for standardization of the process and opportunities to better learn. One example of this was the introduction of the apnea alarm which developed from an improved understanding of our prior alarm deficiencies and continued refinement of the algorithm. We anticipate that this algorithm will be generalizable to other centers, especially those who utilize the Trilogy ventilator, and adoption may speed our ability to recognize additional deficiencies and address them.

Limitations

There are several limitations to this work. First, we are measuring a process and our algorithm represents what we think is best practice with regard to ventilator alarms in the home setting but we have no easy way of measuring outcomes with regard to how well these alarms capture events that require intervention in the home or to measure the subsequent frequency of nuisance alarms. We have on-call staff available 24 hours a day to take calls from parents and did not notice a substantial increase in phone calls related to ventilator alarms but this does not exclude the possibility that there was an increase in nuisance alarms concordant with our change in practice. Outcomes such as significant morbidity or mortality related to a failure in ventilator alarms are thankfully very rare in this patient population and so we do not anticipate seeing a change in those measures as a result of this intervention. However, we do feel that activated critical ventilator alarms will improve safety for this very high-risk patient population.

Additionally, many of our interventions are specific to our clinic set up and practice and may not be generalizable to all practices. This includes centers that use alternate ventilators. Our hope is that this work will raise awareness of ventilator alarm practices for all centers who care for children with chronic ventilator dependence.

Conclusions & Future Directions

We have identified multiple areas of spread for these interventions. Our chronic ventilator patients discharged from our inpatient unit are one population with immediate opportunity for spread. Additionally, data are currently being collected on our PICU patients both with chronic and acute ventilator needs to try to standardize our approach to all ventilated patients cared for in our hospital. Finally, we have started ventilator bench testing to better identify deficiencies in ventilator alarms and test combinations of alarms through simulation.

We describe a stepwise approach to implementation and improvement in use of home ventilator alarms in a pulmonary clinic setting. We believe that standardization of clinic workflow, use of algorithm to guide alarm parameters that is adjusted as knowledge is gained, and active engagement of staff can improve the rate of critical ventilator alarms use and improve safety for the chronic ventilator-dependent population. Many of the key drivers described can be applied to other pediatric hospital caring for these children.

This report uses the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) guidelines for reporting quality improvement research in healthcare [10].

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FIGURES

Figure 1: Key driver diagram showing global and SMART Aim, key drivers and interventions. LOR = Level of Reliability; Vte = Tidal Volume

VENT ALARMS – PDSA TESTING

Figure 2: Alarm algorithm showing general guidelines for alarm parameters organized by type of ventilator. Text describes general principles to approach.

Figure 3: Annotated p-chart showing rate of critical alarms set as patients depart from pulmonary clinic visit. Dates span from 5/1/2017 to 1/24/2019. The baseline data ran through July 13, 2017. Centerline was shifted from 63.8% to 80.8% after beginning observation of the process, revision of clinic workflow and implementation of the alarm algorithm. Centerline further increased to 85.7% with addition of apnea alarm. Surpassed goal with shift to 95.1% following multiple interventions to improve team engagement. Sustained at goal with further increase in October 2018 based on full clinical practice change.