


Novel Technology Deployed for Remote Ventilator Management by Respiratory Therapists During the COVID-19 Pandemic: Lessons Learned

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Abstract

A novel remote ventilator management (control) technology (Omnitool) was implemented for use with ICU patients during the COVID-19 pandemic to mitigate in-person respiratory therapist interactions and preserve personal protective equipment. In the latter half of 2020, eight mechanical ventilators were purchased and enabled for Omnitool deployment through the application of a vendor software option. Subsequently, these ventilators were outfitted with commercially available informatics hardware that permitted remote communication and management via the existing hospital network. In total, 17 patients with COVID-19 respiratory failure were placed on Omnitool enabled ventilators between January 1, 2021-April 30, 2021. The median Omnitool use days was 10. Deployment of a novel remote ventilator management technology is feasible; however, further study is needed to simplify the set up and utilization of the system. Future demands for remote ventilator management are predictable, whether in rural areas, military scenarios without adequate RT staffing, or in circumstances with new and easily transmissible toxic infections, and will continue to encourage the development of relatively easy to apply informatics-based solutions. Herein we share five lessons learned from our Omnitool deployment.

Keywords

COVID-19, intensive care, critical care, respiratory failure, remote control, remote management, ventilator

Introduction

Early in the COVID-19 pandemic, Intensive Care Unit (ICU) teams struggled with competing priorities. ICUs faced a paradigm shift from predominantly in-person, patient-centered care, to remote patient care and remote monitoring; these approaches minimized staff exposure to the patient and preserved the limited supply of personal protective equipment (PPE).^{1,2} The dichotomy of in-person versus remote care was epitomized by the numerous in-person respiratory therapist (RT) interactions required to monitor and adjust ventilator settings for mechanically ventilated patients with COVID-19 respiratory failure coupled with the minimal use of remote monitoring for ventilators and the absence of remote management solutions.

The remote management or control of medical devices, such as ventilators, has historically been met with Food and Drug Administration (FDA) regulatory challenges related to data security and patient safety concerns. The distinction between remote monitoring and remote management is vast. Remote monitoring allows for view only of device settings and data; in contrast remote management permits the changing of settings through bidirectional communication with the device.

Prior to the COVID-19 pandemic, the FDA approved the NKV-550 Series ventilator (Nihon Kohden, Tokyo, Japan)

with a first of its kind remote ventilator management technology, entitled Protective Control®. Protective Control® is a fully operational “secondary” display that is wired to the NKV-550 and mounted outside the patient room within direct sight of the patient.^{3,4} Due to the pandemic’s global effect on manufacturing and supply chain, these devices were not readily available for purchase at the onset of the pandemic and neither the ICU nor RT communities were very knowledgeable about them due to limited marketing.

Therefore, ICUs responded with their own creative solutions for remote ventilator management utilizing existing ventilators.⁵ When possible, the ventilator control panel was

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disconnected from the ventilator body and extended outside the patient room on an umbilical electrical cable.⁶ Other ICUs placed the entire ventilator outside of patient rooms by orienting the head of the bed near a bidirectional wall conduit for the ventilator circuit to pass through.⁵

Biomedical engineering and RT groups also explored, but, to our knowledge, never deployed, novel solutions for remote ventilator management that were designed to be used with existing ventilators. For example, Johns Hopkins University (Baltimore, MD) and Stanford University (Stanford, CA) built robotic systems to remotely control ventilators via a laptop outside of the patient's room.^{7,8} A group at the University of California at San Diego (La Jolla, CA) developed a universal remote control system for makeshift ventilators to interface with telemedicine software.⁹

Garzotto et al proposed the idea of a generic remote management platform capable of supporting a variety of medical devices.¹⁰ Their system would be located in a control room and would monitor and control the core life-support systems utilized in an ICU (ie ventilators, infusion pumps and continuous renal replacement devices) using an interoperable language and a minimum set of parameters for each device type. To our knowledge, as well, this remote platform has not been deployed for clinical care.

In early 2020, Medtronic (Minneapolis, MN) partnered with Northwestern Memorial Hospital (Chicago, IL) to pilot an informatics-based remote monitoring and control software system for ventilators in response to the pandemic.^{11,12} This software allowed clinicians to both remotely view and adjust ventilator settings from outside of a patient's room, but they were restricted from remotely powering off the device. In March 2020, Medtronic re-branded this technology as the Omnitool ventilator remote control platform, which was granted Emergency Use Authorization (EUA) by the FDA, limited to COVID-19 patients, to last for the duration of the pandemic. The Omnitool was then offered by Medtronic to customers using the Medtronic Puritan Bennett 980 ventilators (PB 980s).¹³ Our facility incorporated the Omnitool into 8 newly purchased PB 980s with the hope that use of this remote ventilator control platform would mitigate in-person RT interactions.

The goals of this study are to describe and retrospectively assess the deployment process of the Omnitool and its live application on patients with COVID-19 associated respiratory failure in the first quarter of 2021 and share lessons learned.

Material and Methods

During the height of the COVID-19 pandemic (March 2020 – May 2020) we began exploring methods to enable the remote management of our ventilators. In June 2020, 8 PB 980s with Omnitool were ordered for our 20-bed oncological adult ICU as part of a routine replacement purchase for end-of-life ventilators. We opted to incorporate the Omnitool platform in these new ventilators at the time of purchase. Global supply chain issues during the pandemic delayed delivery of these PB 980s by several months. While waiting for delivery, we began

sourcing the requisite informatics hardware and created a workflow for use of the Omnitool. In December 2020, the PB 980s were delivered and our informatics and RT departments began configuration and testing. The system was enabled for patient use in January 2021.

Hardware Setup

At the highest level, we needed to attach a computer to the PB 980 that would permit bidirectional communication with the device (Fig. 1, left panel). We selected wired connectivity for the Omnitool to avoid known radio frequency interference issues with the hospital's WIFI. We also restricted remote operation of the Omnitool to a PC permanently located in a nursing station directly outside of each patient's ICU room. This ensured direct line of sight to the patient and ventilator during remote management. Only Omnitool trained RTs were privileged and given sign-on access for the Omnitool. User rules, including ongoing audits of use, were developed in accordance with a consensus report on "Emergency Use Guidance for Remote Control of Medical Devices" published by the Association for the Advancement of Medical Instrumentation (AAMI) and guided our workflow for this novel technology.¹⁴

Respiratory Therapy Workflow

RT management team in conjunction with the Critical Care Medicine (CCM) Service leadership developed a standardized workflow for initiation of the Omnitool enabled PB 980s. For any COVID-19 positive patients already admitted to our ICU and on mechanical ventilation as of January 1, 2021, we sought safe opportunities to switch these patients to Omnitool enabled PB 980s. For any new COVID-19 positive patients admitted to the ICU, we prioritized use of the Omnitool enabled PB 980, as available, in case of intubation.

As the remote management concept and technology was novel, we left the decision to perform in-person or remote patient-ventilator assessment to the discretion of the RT. We found that the most significant decisional factor was a perceived need to directly interact with the patient during the assessment, commonly based on patient stability. The less stable the patient, the more likely the RT would choose an in-person assessment.

A notable aspect of our ICU informatics platform that made us comfortable in safely deploying the Omnitool technology for remote ventilator management was our multilayered approach to patient monitoring. Physiological data and alarms are continuously transmitted from bedside monitors to central nursing stations, with select alarms being further routed to pagers and Wi-Fi enabled phones. The bedside monitoring data can also be viewed remotely on a web application. Ventilators and other respiratory devices are incorporated into secondary surveillance hardware and software that transmits device data and specified alarms to both a web based user interface and dedicated pagers carried by RTs. Additionally, every ICU patient room has high definition web cameras that are frequently

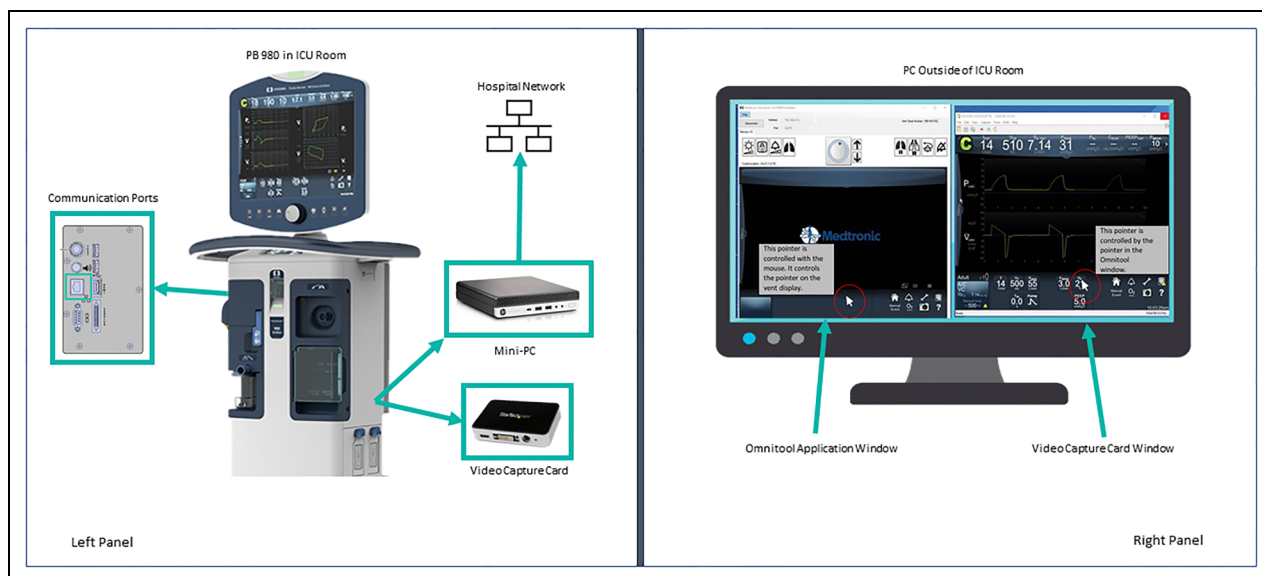


Figure 1. An Omnitool enabled mini-PC and video capture card were mounted on the side of the ventilator and connected via the ventilator’s communication ports (left panel). This mini-PC was wired to the hospital’s network to allow remote access of the Omnitool and video capture of the ventilator display via a dedicated nursing PC outside of the ICU room (right panel). Accessing the nursing PC (right panel), the RT performed a series of four steps unique to the remote Omnitool application: First, the RT logs into the “ICU Remote Desktop” application which establishes remote connection to the mini-PC on the ventilator (left panel). Second, once remote connection is established, two windows (Omnitool application and video capture card) automatically open side by side on the PC display (right panel). Third, the RT then verifies the ventilator serial number within the Omnitool application window, confirming connection to the correct device. Finally, the RT then points and clicks within the Omnitool application window to control the ventilator. The video capture card window displays the ventilator monitor interface so that the RT can visualize ventilator settings, measurements, and waveforms.

observed by bedside nursing and can be accessed by ICU clinicians when logged into the secure hospital network.

Comprehensive Omnitool use data was not available due to limitations of the video capture card; consequently, the ICU Census dataset maintained by the CCM Service was analyzed to determine Omnitool engagement during the first four months of 2021. We received IRB approval for this retrospective review and were granted a waiver of informed consent.

Results

From January 2021 through April 2021, 17 COVID-19 patients admitted to ICU for respiratory failure and intubated were placed on Omnitool enabled ventilators. The day we began our study there were 2 COVID-19 patients in the ICU on mechanical ventilation. Both patients were transferred to Omnitool enabled PB 980s. During the study, another 29 COVID-19 patients were admitted to the ICU in respiratory failure. Of those, 24 patients were intubated, and 15 were placed on an Omnitool enabled PB 980; thus totaling 17 patients using an Omnitool enabled PB 980. Due to lack of availability of Omnitool enabled PB 980s at time of intubation, 9 patients were placed on non-Omnitool ventilators.

For our cohort of 17 patients (F = 9, M = 8), the average age was 62 years, median hospital length of stay (LOS) was 25 days and median ICU LOS was 14 days. All 17 patients

were intubated emergently, 6 subsequently received tracheostomies and 10 were treated with proning. The median Omnitool use days was 10. Nine patients died in the ICU including 1 planned extubation, 2 terminal extubations, 1 tracheostomy, and 5 while intubated. Eight patients survived to hospital discharge: 3 extubated, 3 decannulated, and 2 with tracheostomy tubes still in place.

A retrospective search of our hospital’s Quality and Safety Event Reporting system found no ventilator or airway related reports for the 17 patients while the Omnitool application was used. A query of our ICU Census dataset found that there were no unplanned extubations. Finally, we found no comments directly relating to use of the Omnitool system in a search of the free text comments from the RT flowsheets.

Discussion

We would like to share five lessons learned during this Omnitool deployment. First, as our hardware configuration of the Omnitool platform was designed first and foremost with clinical deployment in mind, we did not think about monitoring its use. The video capture card that was installed was limited in its capabilities and could not directly track Omnitool clicks or more detailed interactions. In retrospect, incorporation of an enhanced video capture card would have recorded all Omnitool interactions and permitted a robust analysis of its use. Thus, we suggest the inclusion of sophisticated tracking

software to monitor the activities of remote management systems be included in future Omnitool iterations.

Second, we found that the informatics workflow for activation and utilization of the Omnitool was far more challenging than in-person ventilator engagement where neither logging into the ventilator nor validating the ventilator serial number are needed. Perhaps the next generation Omnitool will have a simpler RT access process. Third, in our configuration, Omnitool login was restricted to the nursing PC directly outside of the patient's room for safety reasons. This meant that the RT would have to coordinate with nursing for PC availability even as the nurses were similarly trying to remotely manage patient care with external physiological monitoring and infusion pumps at the same location. In the future, the Omnitool application would need to be more readily accessible likely via secure wireless transmission with mobile workstations.

Fourth, extensive simulation training for remote ventilator management would have been optimal in developing the Omnitool workflow, training and comfort level for the RTs. However, a simulation model was not available at the beginning of 2021. Thus, when staffing was low and patient levels were surging, we saw no alternative to implementing broad use guidelines as we were deploying novel technology. Surely, adoption of brand-new technology was not ideal under these conditions and perhaps hospitals should create standardized approaches to deploying and educating staff on the use of new technologies even if the conditions are less than ideal.

Lastly, the patient-ventilator engagement inclusive of the ventilator and its accessories, patient reactions to ventilator adjustments, as well as changes in the patient's clinical condition (ie, low level ventilator circuit leaks, total saturation of a bacterial filter in the ventilator circuit ventilator, decreased cuff pressure, or dyssynchrony), may be associated with adverse interactions that are visible primarily at the patient's bedside. Therefore, we believe that three elements are prerequisites for safely deploying ICU based remote ventilator management, a) direct line of sight into the patient's room, b) robust local and remote patient monitoring and c) thoughtful and well delineated user rules for RT remote ventilator management that mandate periodic in-room patient-ventilator assessments.

Circumstances like COVID-19 are rare, but future demands for remote ventilator management, whether in military scenarios or rural areas without adequate RT staffing, or in situations with new and easily transmissible infections, are predictable and will continue to encourage the development of FDA approved, economical informatics-based solutions. As an example of forward movement, Thornhill Medical (Ontario, Canada), manufacturer of the FDA-approved MOVES-SLC ventilator, a device primarily used in military settings, recently received a grant from the U.S. Department of Defense to help accelerate medical device interoperability and remote control in disaster environments.¹⁵ Hopefully this grant leads to the further development and comparison of remote management ventilator platforms using various strategies and configurations.

Conclusions

Our actual implementation of the Omnitool suggests that the deployment of a novel informatics-based remote ventilator management technology is feasible; however, further study is needed to simplify the configuration and utilization of the system. We are confident that remote ventilator management technology will be refined and gain approval for use beyond the current pandemic so that we and others, may continue to explore its utility.

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