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TractManager

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Non-Invasive Ventilation for the Treatment of COVID-19 Patients

Executive Summary

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Non-Invasive Ventilation for the Treatment of COVID-19 Patients

Situation

As COVID-19 is a novel virus, there is little empirical evidence to guide disease management. However, with new cases being confirmed daily and the rate still increasing, clinicians taking care of patients with COVID-19 need guidance now (Wilson, K. et al., 2020). COVID-19 patients may experience difficulty breathing as the virus enters the lower respiratory tract. This will result in shortness of breath (SOB), rapid respirations, decreased SpO₂, and increased heart rate as the virus migrates to the lungs, damaging lung tissues and blood vessels in the alveoli. This decrease of oxygen in the blood can result in hypoxemic respiratory failure. According to the World Health Organization, approximately 14% develop severe disease that requires hospitalization and oxygen support, and 5% require admission to an intensive care unit (WHO, 2020).

As the volume of COVID-19 patients requiring ventilatory support increases, the number of available ventilators has drastically decreased, causing wide-spread shortages in the United States. With the depletion of ventilators, non-invasive ventilation (NIV) efforts have emerged as potential options for respiratory care. An evaluation has been requested of the current evidence and data available to treat COVID-19 diseased patients with altered pulmonary status during a ventilator shortage. This assessment will address non-invasive ventilation methods.

Problem Statement:

What is the current and evolving state of practice supporting the use of noninvasive ventilation for the treatment of COVID-19 patients experiencing hypoxemic respiratory failure? *What is best practice for utilizing ventilators designed for NIV to provide invasive ventilation?*

Technology Under Evaluation:

Non-invasive ventilation methods:

1. Continuous positive airway pressure (CPAP)
2. Bilateral positive airway pressure (BiPAP)
3. High-flow nasal oxygen (HFNO)

Background

Among patients who developed severe disease, the median time to dyspnea ranged from 5 to 8 days, the median time to acute respiratory distress syndrome (ARDS) ranged from 8 to 12 days, and the median time to ICU admission ranged from 10 to 12 days. Clinicians should be aware of the potential for some patients to rapidly deteriorate one week after illness onset. Among all hospitalized patients, a range of 26% to 32% of patients were admitted to the ICU. Among all patients, a range of 3% to 17% developed ARDS compared to a range of 20% to 42% for hospitalized patients and 67% to 85% for patients admitted to the ICU (CDC, 2020).

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Patients may continue to have increased work of breathing or hypoxemia even when oxygen is delivered via a face mask with reservoir bag (flow rates of 10–15 L/min, which is typically the minimum flow required to maintain bag inflation; FiO₂ 0.60–0.95). Hypoxemic respiratory failure in ARDS commonly results from intrapulmonary ventilation-perfusion mismatch, or shunt, and usually requires mechanical ventilation (WHO, 2020).

With a large influx of high acuity patients requiring intubation and invasive mechanical ventilation, providers have also investigated the use of noninvasive ventilation methods as an alternative for ventilators. However, frequent monitoring is warranted with the use of non-invasive ventilation devices, related to the risk associated with secondary inhalation of emissions released by infected patients. With these non-invasive systems, the exhaled breath from the patient is vented directly to the surrounding air. This plus the high flow delivery amplifies dispersion of virus from contagious patients into the environment (CDC, 2020).

Technology Description:

Noninvasive ventilation refers to the administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube). This practice avoids intubation and sedation of the patient. NIV can be delivered with a mask that is tightly fitted to the face, around the head, or via nasal cannula. The use of noninvasive ventilation has become an integral tool in the management of both acute and chronic respiratory failure, in both the home setting and in the critical care unit. The flexibility of NIV allows it to be a valuable complement in patient management. Its use in acute respiratory failure is well accepted and widespread (Hoo, 2020).

Noninvasive ventilation also delivers high flow rates to create positive end expiratory pressure. This opens the airways providing support for patients with sleep apnea, chronic pulmonary, heart and neuromuscular disease to decrease work of breathing Hoo, 2020).

These three non-invasive ventilation methods discussed are not considered “closed systems” versus the traditional ventilator that can trap pathogens with a breathing tube and filter. CPAP (continuous positive airway pressure) and BiPAP (bi-level positive airway pressure) systems are non-invasive devices. While they successfully offer respiratory support, these machines are associated with decreased delivered airway pressures and flows due to leaks around the facemask, along with skin breakdown across the nose and cheeks, and lower patient tolerance, which may result in limited therapeutic effect.

The BiPAP machine has filters located at the back of the machine where the device draws circulating air from the room. With a non-closed system, a virus as COVID-19 can spread by way of aerosolization.

According to a study by Heinzerling et al., on February 26, 2020, the first U.S. case of community-acquired coronavirus disease 2019 (COVID-19) was confirmed in a patient hospitalized in Solano County, California:

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During a 4-day hospitalization, the patient was managed with standard precautions and underwent multiple aerosol-generating procedures (AGPs), including nebulizer treatments, bilevel positive airway pressure (BiPAP) ventilation, endotracheal intubation, and bronchoscopy. ***Performing physical examinations and exposure to the patient during nebulizer treatments were more common among HCP with laboratory-confirmed COVID-19 than among those without COVID-19. Patient source control (e.g., patient wearing a mask or connected to a closed-system ventilator during HCP exposures) might also reduce risk of SARS-CoV-2 transmission.*** Although the index patient was not masked or ventilated for the majority of hospital A admission, at hospital B, where the patient remained on a closed system ventilator from arrival to receiving a positive test result, none of the 146 HCP identified as exposed developed known COVID-19 infection (CDC, 2020).

Continuous Positive Airway Pressure (CPAP)

CPAP systems offer basic support for a spontaneously breathing patient by providing continuous positive airway pressure through the nasal cavity by means of a face mask. They are designed to use air pressure as a “stent” to keep the patient’s airways open.

A CPAP system has very few settings as opposed to an invasive ventilator. They can only be set on one pressure and it does not cycle. The patient also must initiate all of their breaths on their own. These systems are typically prescribed for patients with sleep apnea.

Bilevel Positive Airway Pressure (BiPAP)

BiPAP ventilators are similar to a CPAP machine with advanced modes, monitoring and alarms. In addition to providing continuous airway pressure, BiPAP machines have added features. They can be set to include a breath timing. This tracks the amount of breaths per minute a person should take. If the patient breaths fall below the setting the device will temporarily increase the air pressure which can force the person to breathe.

BiPAP machines have two pressure settings: the prescribed pressure for inhalation (ipap), and a lower pressure for exhalation (epap). The dual settings allow the patient to get more air in and out of their lungs. BiPAP machines are prescribed for: Chronic obstructive pulmonary disorder (COPD), obstructive sleep apnea, obesity hypoventilation syndrome, pneumonia, asthma flare-up, poor breathing after an operation and neurological disease that disturbs breathing.

High-flow nasal cannula oxygen (HFNO)

High flow devices are designed to provide a continuous flow of gas to exceed the patient’s inspiratory demands and to help to reduce work of breathing in spontaneously breathing patients. These devices provide heated humidified air at high flow rates with adjustable oxygen concentrations from 21% to 100% FiO₂. The added humidity eliminates the drying effect of flow rates reaching up to 60 l/m. The delivered high flow decreases dead space, opens and maintain the patient’s airway, increases volumes within the lungs, and assists in the removal of CO₂. The

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high flow oxygen can be delivered via specialized nasal cannulas connected to a specific device that can deliver FiO₂ at flow rates up to 60 Liters/min.

The high flow rates have other advantages in that high flow rates minimize room air entrainment, thereby increasing the FIO₂ that can be provided to patients; are able to wash out dead space carbon dioxide, improving the efficiency of oxygen delivery; and the increased flow rate translates into positive end-expiratory pressure (PEEP). The small amount of positive pressure provided does help reduce the work of breathing and improve breathing patterns similarly to that achieved with CPAP (Hoo, 2020).

Heated, humidified, high-flow nasal cannula oxygen has been available for over a decade, but refinements and increasing clinical experience have made it a solid alternative for management that exists in the spectrum of options before noninvasive and invasive mechanical ventilation. This modality was initially developed for neonatal patients, and refinements have permitted its use in adults (Hoo, 2020).

A new entrant into the high flow therapy market is a high flow therapy system that includes a flow generator, humidifier, breathing circuit, and patient interface. The device operates on room air or a mixture of room air and oxygen and is leveraged for those suffering from pulmonary diseases, including COVID-19 diseased patients (Masimo 2020).

Assessment

Recommendations and Guidelines:

According to the World Health Organization (WHO) and [Surviving Sepsis Campaign COVID-19 Subcommittee](#), the following recommendations pertain to adult and pediatric patients with ARDS who are treated with non-invasive or high-flow oxygen systems:

- High-flow nasal oxygen (HFNO) should be used **only in selected patients with hypoxemic respiratory failure**.
- Non-invasive ventilation (NIV) should be used **only in selected patients with hypoxemic respiratory failure**.
 - *Bubble nasal CPAP may be used for newborns and children with severe hypoxemia.*
- Patients treated with either HFNO or NIV **should be closely monitored for clinical deterioration**.

The FDA issued guidance outlining a policy for respiratory devices during the COVID-19 pandemic, *Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*:

If the number of ventilators in your facility is running low, consider alternative devices capable of delivering breaths or pressure support to satisfy medically necessary treatment practices for patients requiring such ventilatory support. Health

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care providers should use their judgment based on the condition of the patient and the circumstances in the facility to choose the best option.

Examples of alternative uses of respiratory devices to address shortages included the following:

- Noninvasive ventilation (NIV) patient interfaces capable of prescribed breath may be used for patients requiring such ventilatory support, including NIV Patient Interfaces labeled for sleep apnea.
- Continuous Positive Airway Pressure (CPAP), auto-CPAP, and bilevel positive airway pressure (BiPAP or BPAP) machines typically used for treatment of sleep apnea (either in the home or facility setting) may be used to support patients with respiratory insufficiency provided appropriate monitoring (as available) and patient condition. BiPAP may be used for invasive ventilation.

Take appropriate precautions with environmental control (for example, negative pressure) or additional filtration where feasible: Ventilating patients with communicable diseases using devices that are single limb or noninvasive without a filtered seal from atmosphere may contaminate the room air and increase risk of transmission. This risk may be exacerbated by high-flow nasal cannula systems or CPAP machines (FDA, 2020).

The **American Association for Respiratory Care (AARC)** provides guidance on how to use a ventilator designed for NIV to provide invasive ventilation. The AARC states that CPAP machines do not provide ventilatory support, but bilevel devices are considered ventilators, as they provide positive pressure ventilation and therefore can be used as an invasive ventilator (AARC, 2020). The **American Society of Anesthesiologists** has recommended for patients with known or suspected COVID-19 infection: *In patients with acute respiratory failure, it may be prudent to proceed directly to endotracheal intubation, because non-invasive ventilation (e.g. CPAP or BiPAP) may increase the risk of infectious transmission (ASA, 2020).*

On April 21, the NIH released treatment guidelines for COVID-19. Per the NIH, these guidelines, intended for healthcare providers, are based on published and preliminary data and the clinical expertise of the panelists, many of whom are frontline clinicians caring for patients during the rapidly evolving pandemic.

For Ventilatory Support, the following guidelines have been issued in regard to NIV methods:

- For adults with COVID-19 and acute hypoxemic respiratory failure despite conventional oxygen therapy, the Panel recommends high-flow nasal cannula (HFNC) oxygen over noninvasive positive pressure ventilation (NIPPV).
- In the absence of an indication for endotracheal intubation, the Panel recommends a closely monitored trial of NIPPV for adults with COVID-19 and acute hypoxemic respiratory failure for whom HFNC is not available.

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- For adults with COVID-19 who are receiving supplemental oxygen, the Panel recommends close monitoring for worsening of respiratory status and recommends early intubation by an experienced practitioner in a controlled setting.

These guidelines are posted online: <http://covid19treatmentguidelines.nih.gov/> and will be updated often as new data are published in peer-reviewed scientific literature and other authoritative information emerges.

Financial Considerations

When and if possible, utilization of regional population analytics including transmission, hospitalization and death rates secondary to COVID-19 should be integrated into decision making to monitor and anticipate the potential need for ventilatory support. An up-to-date inventory of all types of ventilatory support and corresponding service records will provide an accurate depiction of supply, and guide surge planning if needed. Pre-planning and monitoring will insure a closer match for equipment demand with patient needs. Existing contractual agreements should be leveraged for best pricing of NIV equipment. Monitoring supply behavior is suggested and encouraged for future business relationships.

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Non-Invasive Ventilation Devices

| Manufacturer | Model Name | List Price | Average Price | Notes |
|---|---------------|------------|---------------|--|
| Philips Healthcare (Traditional/Basic BiPAP) | V60 | \$19,325 | \$12,964 | Ventilatory support system for spontaneously breathing ped-adults. These models offer advanced modes designed to support synchrony and comfort for the patient and provide leak compensation. This is offered via the Auto-trak option and the AVAPS option (Average Volume Assured Pressure Support-Auto Adaptive Mode) |
| | V30 | \$5,613.50 | \$4,039.12 | Low acuity NIV support with auto-titration, Auto-Trak, AVAPS option |
| | Dream Station | \$2,353 | \$1,296 | Traditional CPAP/BiPAP machine designed for sleep lab and home care applications |

Service Cost 3 -6% of list price

| Manufacturer | Model Name | Price Range | Notes |
|---|------------------------------------|-------------------|--|
| ResMed (CPAP/BiPAP Systems) <i>supportive systems designed for homecare and low acuity patients in the healthcare setting</i> | Astral 100 | \$6,200 - \$7,200 | Supportive systems designed for homecare and low acuity patients in the healthcare setting |
| | Astral 150 | \$8,500 | Invasive and NIV option, basic ventilation support |
| | Stellar 100 | \$4,400 - \$5,000 | Invasive and NIV, includes FiO2 monitor option, double-limb circuit |
| | S9 VPAP, S9 Lumis Series - VPAP ST | \$1,000 - \$2,000 | Stellar Series: NIV option, VAPS (volume assured pressure support) Lumis Series: invasive and NIV option, VAPS |

| Manufacturer | Model Name | Price Range | Notes |
|----------------------------|-----------------------|-------------------|--|
| Teleflex | Hudson RCI Neptune | \$707 - \$800 | Heated Humidifier (with ConchaSmart Technology) |
| Vapotherm | Precision Flow Plus | \$4500 - \$6,460 | High Flow Device |
| | | \$240 - \$640 | Stand |
| | | \$4,740 | Complete System |
| Fisher & Paykel | Optiflow/AIRVO 2 | \$2,036 - \$2,250 | High Flow Device |
| | | \$380 - \$433 | Stand |
| | | \$3,250 | Complete System (device, stand, mounting tray, basket, flowmeter, oxygen hose. |
| | MR850 | \$825 - \$930 | Heater/Humidifier |
| | Bubble CPAP Generator | \$2,036 - \$2,250 | Generator plus overflow container |

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| Non-Invasive Ventilation Consumables | | |
|--------------------------------------|---|--------------|
| Manufacturer | Model Name | List Price |
| Teleflex | Neptune ConchaSmart Circuit | \$22 |
| | ISO-GARD Circuit | \$23 |
| | Comfort Flo Plus Cannula | \$24 |
| | Comfort Flo High Flow Nasal Cannula Therapy | \$25 |
| Manufacturer | Description | Price Range |
| Multiple | Nasal Mask | \$42 - \$80 |
| | Full Face Mask | \$60 - \$130 |
| | Nasal Pillow Mask | \$70 - \$105 |
| | Oral Mask | \$135 |
| | Pediatric Mask | \$59 - \$120 |
| | Machine Filters | \$2 - \$10 |
| | Tubing | \$5 - \$15 |

| Non-invasive Ventilation Dealers | | |
|----------------------------------|------------------------|--------------|
| Dealer Name | Rental Type/Model | Monthly Rate |
| Freedom Medical & Martab Medical | Advanced NIV (V60) | \$600-\$700 |
| | BiPAP | \$200-\$300 |
| | Basic CPAP | \$40 |
| Dealer Name | Equipment for Purchase | |
| Tri-anim | BiPAP/CPAP | |
| Mercury Medical | BiPAP/CPAP | |
| Quality Medical | BiPAP/CPAP | |
| BEMES | BiPAP/CPAP | |

****TractManager Capital and Consumables Benchmarking Database**

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Operational Considerations

CPAP machines, BiPAP machines, and high-flow nasal cannula oxygen can be viable solutions for low acuity patients but require modifications due to COVID-19 concerns. With these non-closed systems, COVID-19 can spread by way of aerosolization infecting other patients and healthcare workers, so precautions must be addressed:

- Monitor current CDC and professional guidelines on the use of non-invasive ventilation devices related to the risk associated with secondary inhalation of emissions released by infected patients.
- **Take appropriate precautions with environmental control (for example, negative pressure) or additional filtration where feasible:** Ventilating patients with communicable diseases using devices that are single limb or noninvasive without a filtered seal from atmosphere may contaminate the room air and increase risk of transmission. This risk may be exacerbated by high-flow nasal cannula systems or CPAP machines (FDA, 2020).
- **Conserve the use of accessories used with NIV devices and ventilators:** consider extending the shelf life and duration of use of these products for treating individual patients, depending on the availability of resources.
- Utilize non-vented masks with viral filters to reduce the spread of COVID-19.
- N95 masks should be worn during high-risk, aerosol-generating procedures or high potential exposure of patients with known or suspected aerosol transmittable diseases such as Covid-19 (OSHA, 2009).
- Leverage Airborne Infection Isolation Rooms (AIIR)
 - AIIRs are single patient rooms that have been equipped with negative pressure ventilation capacity (Ather, 2020). Negative air pressure is achieved by ventilation systems that create an inward directional airflow from the corners of the patient room. The air is then transmitted from the hospital room to the outside of the building. It is vital that the door and windows to AIIRs are kept closed at all times to prevent a reversal of airflow.
 - AIIRs should be entered into through an anteroom. This is a clean, not sterile, area used for transition healthcare personnel in and out of the airborne room. The anteroom should contain a full supply of all personal protective equipment (PPE) such as procedure or surgical masks, N95 respirators, eye protection, gloves and gowns all of which should be disposable. A dedicated hamper should be provided for the disposal of any PPE after exiting the room into the anteroom. A sink for handwashing and medical grade hand sanitizer should also be readily accessible in the anteroom.
- Maintain proper communication and establish processes within facility's respiratory program:

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- Enforce education and training for respiratory staff for NIV ventilators modified to provide invasive ventilation.
- The **American Association for Respiratory Care (AARC)** provides guidance on how to use a ventilator designed for NIV to provide invasive ventilation: <https://www.aarc.org/>.
- Follow the FDA's recommendations for Ventilator Supply Strategies:
 - See the [Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease-2019 \(COVID-19\) Public Health Emergency](#). The policy fosters the continued availability of certain safe and effective medical devices while being flexible regarding manufacturer modifications made to ventilators, anesthesia gas machines and other respiratory devices, and their accessories, in response to the COVID-19 public health emergency.
- Align with Senior Clinical staff to discuss developments and innovation for NIV ventilator modified equipment.
 - Currently there are multiple projects underway to develop viable modifications to BiPAP / CPAP systems.
 - Healthcare systems, medical schools, and engineering specialists have collaborated by developing modified circuits and offer information related to converting BiPAP systems to ventilators. Some of the modifications and innovation witnessed in the clinical setting to convert NIPPV to ventilators witnessed are:
 - Utilizing an endotracheal tube to deliver oxygenated air through a two-filter system with a CPAP machine.
 - Converting a BiPAP machine to a ventilator by creating a 3D printed T-piece adapter and including two high-efficiency HEPA filters at both ends (Libassi, M, 2020).
 - Creating negative pressure hood from a portable salon hair dryer, reversing the direction of the blower, and installing a disposable HEPA filter pulling air away from the patient and surroundings (NYU, 2020).
 - University of Texas issued a study on the delivery of CPAP respiratory support for COVID-19 using repurposed technologies. The team used a novel 3D-printed Venturi system with a standard PEEP-valve breathing circuit. (Culmer et. al, 2020).
- Terminal cleaning of rooms after patient discharge should be performed by EVS workers, and they should wear a gown and gloves when performing terminal cleaning. A facemask and eye protection should be added if splashes or sprays during cleaning and disinfection activities are anticipated or otherwise required based on the selected cleaning products. Shoe covers are not recommended at this time for personnel caring for patients with COVID-19 (CDC, 2020).

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- Follow manufacturer instructions and/or obtain an IFU for cleaning NIPPV equipment upon patient discharge.

Recommendation

With a large influx of high acuity patients requiring intubation and invasive mechanical ventilation, providers have investigated the use of noninvasive ventilation methods as an alternative for ventilators.

Guidelines addressed are two-fold:

- 1) For *selected* COVID-19 patients with acute hypoxemic respiratory failure, NIV in the form of HFNC and NIPPV are recommended; *but patients should be closely monitored for clinical deterioration*
- 2) Some forms of NIPPV are considered ventilators as they provide positive pressure ventilation and therefore can be used as an invasive ventilator. Innovation and advancements with technology are developing rapidly with the pandemic; however, high efficiency filters must be implemented with the NIPPV equipment and setup to ensure a closed system to prevent aerosolization of the virus. Proper infection prevention protocols must be enforced as well as education and frequent monitoring of governing guidelines and recommendations.

Abstract

Transmission of COVID-19 to Health Care Personnel During Exposures to a Hospitalized Patient

Heinzerling, A. et. al, (2020, April 17). Transmission of COVID-19 to Health Care Personnel During Exposures to a Hospitalized Patient — Solano County, California, February 2020. Retrieved from <https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e5.htm#suggestedcitation>

Background

On February 26, 2020, the first U.S. case of community-acquired coronavirus disease 2019 (COVID-19) was confirmed in a patient hospitalized in Solano County, California (1). The patient was initially evaluated at hospital A on February 15; at that time, COVID-19 was not suspected, as the patient denied travel or contact with symptomatic persons. During a 4-day hospitalization, the patient was managed with standard precautions and underwent multiple aerosol-generating procedures (AGPs), including nebulizer treatments, bilevel positive airway pressure (BiPAP) ventilation, endotracheal intubation, and bronchoscopy. Several days after the patient's transfer to hospital B, a real-time reverse transcription–polymerase chain reaction (real-time RT-PCR) test for SARS-CoV-2 returned positive. Among 121 hospital A health care personnel (HCP) who were exposed to the patient, 43 (35.5%) developed symptoms during the 14 days after exposure and were tested for SARS-CoV-2; three had positive test results and were among the first known cases of probable occupational transmission of SARS-CoV-2 to HCP in the United States. Little is known about specific risk factors for SARS-CoV-2 transmission in health care

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settings. To better characterize and compare exposures among HCP who did and did not develop COVID-19, standardized interviews were conducted with 37 hospital A HCP who were tested for SARS-CoV-2, including the three who had positive test results. Performing physical examinations and exposure to the patient during nebulizer treatments were more common among HCP with laboratory-confirmed COVID-19 than among those without COVID-19; HCP with COVID-19 also had exposures of longer duration to the patient. Because transmission-based precautions were not in use, no HCP wore personal protective equipment (PPE) recommended for COVID-19 patient care during contact with the index patient. Health care facilities should emphasize early recognition and isolation of patients with possible COVID-19 and use of recommended PPE to minimize unprotected, high-risk HCP exposures and protect the health care workforce.

Methods

HCP with potential exposures to the index patient at hospital A were identified through medical record review. Hospital and health department staff members contacted HCP for initial risk stratification and classified HCP into categories of high, medium, low, and no identifiable risk, according to CDC guidance.* HCP at high or medium risk were furloughed and actively monitored; those at low risk were asked to self-monitor for symptoms for 14 days from their last exposure.† Nasopharyngeal and oropharyngeal specimens were collected once from HCP who developed symptoms consistent with COVID-19§ during their 14-day monitoring period, and specimens were tested for SARS-CoV-2 using real-time RT-PCR at the California Department of Public Health. Serologic testing and testing for other respiratory viruses was not performed.

The investigation team, including hospital, local and state health departments, and CDC staff members, attempted to contact all 43 tested HCP by phone to conduct interviews regarding index patient exposures using a standardized exposure assessment tool. Two-sided p-values were calculated using Fisher's exact test for categorical variables and Wilcoxon rank-sum test for continuous variables; p-values <0.05 were considered statistically significant. Analyses were conducted using SAS (version 9.4; SAS Institute). The California Health and Human Services Agency's Committee for the Protection of Human Subjects and CDC determined this investigation to be public health practice.

Conclusion

Patient source control (e.g., patient wearing a mask or connected to a closed-system ventilator during HCP exposures) might also reduce risk of SARS-CoV-2 transmission. Although the index patient was not masked or ventilated for the majority of hospital A admission, at hospital B, where the patient remained on a closed system ventilator from arrival to receiving a positive test result, none of the 146 HCP identified as exposed developed known COVID-19 infection (8). Source control strategies, such as masking of patients, visitors, and HCP, should be considered by health care facilities to reduce risk of SARS-CoV-2 transmission.

This findings in this report are subject to at least three limitations. First, exposures among HCP were self-reported and are subject to recall bias. Second, the low number of cases limits the ability to detect statistically significant differences in exposures and does not allow for

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multivariable analyses to adjust for potential confounding. Finally, additional infections might have occurred among asymptomatic exposed HCP who were not tested, or among HCP who were tested as a result of timing and limitations of nasopharyngeal and oropharyngeal specimen testing; serologic testing was not performed.

To protect HCP caring for patients with suspected or confirmed COVID-19, health care facilities should continue to follow CDC, state, and local infection control and PPE guidance. Early recognition and prompt isolation, including source control, for patients with possible infection can help minimize unprotected and high-risk HCP exposures. These measures are crucial to protect HCP and preserve the health care workforce in the face of an outbreak already straining the U.S. health care system.

References

Wilson, K. C., Chotirmall, S. H., Bai, C., & Rello, J. (2020, April 3). ATS - American Thoracic Society. Retrieved from <https://www.thoracic.org/covid/covid-19-guidance.pdf>

Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19). (2020, April 3). Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html#Asymptomatic>

Soo Hoo, G. W. (2020, April 7). Noninvasive Ventilation. Retrieved from <https://emedicine.medscape.com/article/304235-overview>

Commissioner, O. of the. (2020, March 22). Ventilator Supply Mitigation Strategies: Letter to Health Care Providers. Retrieved from <https://www.fda.gov/medical-devices/letters-health-care-providers/ventilator-supply-mitigation-strategies-letter-health-care-providers>

COVID-19 Information for Health Care Professionals. (n.d.). Retrieved April 15, 2020, from <https://www.asahq.org/about-asa/governance-and-committees/asa-committees/committee-on-occupational-health/coronavirus>

Heinzerling, A. et. al, (2020, April 17). Transmission of COVID-19 to Health Care Personnel During Exposures to a Hospitalized Patient — Solano County, California, February 2020. Retrieved from <https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e5.htm#suggestedcitation>

Culmer, P. (2020, April 19). Delivery of CPAP respiratory support for COVID-19 using repurposed technologies. Retrieved from <https://www.medrxiv.org/content/10.1101/2020.04.06.20055665v2>

Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. (2020, April 21). Retrieved from <https://covid19treatmentguidelines.nih.gov/critical-care/oxygenation-and-ventilation/>

TractManager, Inc. (2020). Financial benchmarks for Noninvasive Ventilation Technology. Retrieved April 23, 2020 from TractManager Capital and Consumables databases.

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Ather, B. (2020, February 17). Airborne Precautions. Reviewed March 2020. Available from <https://www.ncbi.nlm.nih.gov/books/NBK531468/>

COVID-19 Information for Health Care Professionals. (2020, March 20). Retrieved from <https://www.asahq.org/about-asa/governance-and-committees/asa-committees/committee-on-occupational-health/coronavirus>

<https://www.ventilatorsos.com/our-solution.html>. (n.d.). Retrieved April 21, 2020, from <https://www.ventilatorsos.com/>

Nyu. (n.d.). NYU Tandon AirMOD and AirVENT The race to save lives and reduce infection amid COVID-19. Retrieved April 22, 2020, from <https://engineering.nyu.edu/nyu-tandon-air>

Libassi, M. (2020, March 31). Northwell converts BiPAP machines into ventilators for hospitalized COVID-19 patients, uses 3D printed adapter. Retrieved from <https://feinstein.northwell.edu/news/the-latest/northwell-converts-bipap-machines-into-ventilators-for-hospitalized-covid-19-patients-uses-3d-printed-adapter>

Masimo Announces Agreement to Acquire TNI medical AG. (2020, March 19). Retrieved from <https://www.businesswire.com/news/home/20200319005773/en/Masimo-Announces-Agreement-Acquire-TNI-medical-AG>

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