Emerging Practices to Combat Coronavirus Disease (COVID-19): Managing critical supplies

COVID-19 Clinical Knowledge Transfer from Vizient members and industry resources
Updated: April 20, 2020

Vizient is committed to ongoing research of Vizient members’ emerging practices and other related updates to federal and regulatory guidelines in support of efforts to combat the COVID-19 pandemic. The purpose of this document is to assist our members with critical information to supplement this work. As new information surfaces, updates will be provided.

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Practice trends

There is continued focus on managing the supply of N95 respirators and other PPE. Several members are in the process of sourcing or evaluating KN95 respirators for potential use in clinical areas. In addition, the FDA has given emergency use authorization for decontamination of N95 respirators. Members are establishing policies that focus on extending their use. Several members are providing scrubs to staff who provide care to patients with COVID-19. In addition, the CDC has updated their guidelines on the use of face coverings for outpatient pharmacy staff and customers. There is also new information on producing face shields and isolation gowns.

The FDA has issued guidance to help expand the availability and remote capabilities of infusion pumps and accessories. Medtronic has posted open-source ventilator product specifications.

As the demand for ventilators increases, the ventilator manufacturers are joining to form the Ventilator Training Alliance (VTA) to provide centralized training for health care professionals. With this increase in ventilator demand, there is also concern around the availability of ventilator-related medications. Vizient has released a ventilator medication demand tool.

Vizient has compiled state by state information on the Strategic National Stockpile. FEMA has provided a response to help distinguish between rumors and facts regarding the response to COVID-19.
Supply shortages, alternate source suppliers and Strategic National Stockpile

Monitoring supply list for shortages
GHX has provided an updated cross reference list for managing critical supplies including alternatives. Supplies and equipment to monitor and prepare for shortages:

- Ventilators (critical care and transport), BIPAPs, CPAPs, vent filters, enteral pumps and feeding
- Thermometers
- Portable critical care monitors
- IV Pumps
- IV solutions, IV pump cassette sets, IV standard tubing, IV start kits, IV flushes
- MDI (metered dose inhalers)
- ET tubes
- All respiratory-related consumables (nasal cannulas, tubing, O2 face masks)
- Beds
- Morgue operations and body bags
- Nitrile gloves

Updated 4/9/2020

Alternate Source Suppliers
Vet alternate source suppliers claiming to have N95 masks or other PPE. Request they show the Establishment Registration Number or Firm Registration Number and a copy of the device listing along with the Regulation Number of the specific device.

The FBI issued its White Notice LIR 200323006 “Criminals Exploiting COVID-19 Outbreak for Financial Gain through Procurement and Consumer Fraud.” The notice includes details on markings and where model numbers should be located on the mask.

FEMA has provided a response to help distinguish between rumors and facts regarding the response to COVID-19. Addresses topics such as “Is FEMA seizing PPE or Re-Routing Medical Supplies When it’s delivered to the United States”

Additional information:
- Options for organizations to report fraud or scams
- FBI field office information to report fraud
- FBI fraud submission site

Updated 4/16/2020

Strategic National Stockpile
The AARC has released this Strategic National Stockpile Ventilator Training video. AARC encourages respiratory therapists to be prepared to operate the stockpile ventilators should the need arise.

To obtain products not available through your distributor or contracted supplier, make a request through your state. Be sure to develop a “case for need” for those supplies once they arrive at the state level. Include how
many cases you currently have, how many you anticipate needing, how many are currently under investigation and use rate.

- ASTHO Authorization Toolkit
- HHS Strategic National Stockpile
- Strategic National Stockpile: Vizient State by State Guide

*Updated 4/16/2020*

**Facial protection (N95, face shields, procedure and surgical masks)**

**KN95 respirator utilization**

Following the FDA’s April 3 PPE Letter of Authorization, several members are now sourcing KN95 respirators for potential use in clinical areas. Some members are requesting product samples for evaluation (e.g. fit testing) and approval from formal committees (e.g. Infection Prevention and Control) before placing orders with vendors.

*Added 4/16/2020*

**Facial protection protocols**

Multiple members have either recently implemented or are implementing universal masking for staff. This is typically combined with an extended use policy, controlled release of masks and patient cohorting strategy. N95 and masking extended use policies are frequently for a “one shift” duration after which staff turn in equipment for reprocessing at designated recycling centers. The “one shift” duration may vary based on role of the health care worker – for instance, an environmental staff member with intermittent interaction with confirmed or suspected patients may reuse the same mask for a longer period of time.

*University of Washington Medicine Extended-Use Masking Policy*

*Added 4/9/2020*

**Sterilization and reprocessing strategies**

The FDA has issued guidance to expand the availability and capability of sterilizers, disinfectant devices and air purifiers. Members should immediately collaborate with infection prevention and clinical teams to establish policies and resources to support reuse and sterilization of items to minimally include: respirators, masks, face shields and isolation gowns. Members should plan ahead for senior leadership support and a physical presence in patient care areas to ensure the collection of equipment from staff for reprocessing.

PPE sterilization resources:

- FDA EAU for STERRAD Sterilization Systems
- FDA EAU for STERIS Sterilization Systems
- FDA Emergency Use Authorization for Battelle Decontamination System
- UMass researchers find medical-grade masks can be sterilized, reused
- University of Nebraska provider resources
- Guidelines from Journal of Patient Safety
- ClordiSys decontamination
- 3M statement
Self-manufacturing of face shields

Many hospitals are 3D printing or using laser cutting techniques to produce face shields. FDA has issued guidance and a FAQ related to these practices. In addition, the NIH has released a supply chain response which represents an effort with the FDA, VA and America Makes to connect health care providers and 3D printing organizations. The University of Wisconsin-Madison has posted resources related to face shield production on its website as has Washington University in St. Louis. Members are deploying aggressive strategies to disinfect and reuse face shields as well as eye protection.

Non-NIOSH approved equipment

The FDA issued a PPE Letter of Authorization on April 3, which “authorizes disposable respirators manufactured in China, which are not NIOSH-approved, pursuant to certain criteria, including additional validation and review by FDA to confirm the respirator’s authenticity…” Manufacturers of such equipment will be required to confirm the respirator’s authenticity through one of the following criteria:

- It is manufactured by an entity that holds one or more NIOSH approvals for other models of filtering-facepiece respirators (FFRs) produced in accordance with the applicable standards of authorization in other countries that can be verified by FDA.
- It has a regulatory authorization under a jurisdiction other than China that can be authenticated and verified by FDA.
- It demonstrates acceptable performance to applicable testing standards as documented by test reports from a recognized independent test laboratory that can be verified by FDA.

Once a manufacturer of such equipment is authorized by the FDA for distribution, the respirators will be included in Appendix A under the Emergency Use Authorization, which provides authorization for the respirators to be distributed and used in health care settings when used in accordance with CDC’s recommendations under this EUA.

Based on available scientific evidence, the FDA has concluded that certain imported disposable FFRs that are not NIOSH-approved are appropriate to protect the public health or safety.

Homemade masks, partnering with local manufacturers and product donations

A number of provider organizations are accepting homemade masks, while others are still restricting sourcing through their standard manufacturing channels. Some organizations are making their own, working with local manufacturers or accepting donated homemade masks.

- CDC: Updated Guidelines for Crisis Alternate Strategies for N95 Respirators
- Kaiser NCAL Covid-19 Playbook
- The Joint Commission Statement on Shortage of PPE
The Joint Commission Statement on the use of Face Masks from Home

Updated 4/9/2020

PPE for Sterile Compounding

The USP Statement discourages the reuse of disposal PPE outside of their best practice standards (i.e. the reuse of a disposable gown for one shift/day) due to the contamination risk; however, USP is not an enforcement agency.

- Due to COVID-19 pandemic shortages, sterile compounding personnel are faced with the option of reused PPE for product protection or none at all.
- Some state boards of Pharmacy (one of the enforcers of USP standard/related state laws) have provided guidance regarding sterile compounding compliance under conditions related to COVID-19 and resultant shortages that allow for USP non-compliant PPE conservation strategies during this pandemic.

Prior to the USP statement, Vizient’s USP compliance expert, Katrina Harper provided recommendations for member pharmacy teams (member log-in required).

Added 3/30/2020

Critical capital and ventilators

Infusion Pumps

COVID-19 patients may require continuous infusion of medications, nutrition or other fluids. To ensure adequate supply of infusion pumps and accessories, the FDA has issued guidance to help expand the availability and remote capabilities of these supplies during the COVID-19 pandemic. This document notes the FDA will not object to limited modifications to the indications, functionality, hardware, software, design or materials of devices used to support patients requiring continuous infusion therapy.

Added 4/9/2020

Ventilators

As demand for ventilators increases, Vizient is closely monitoring the demand of ventilator-related medications required to support patients on ventilators and investigating ways to help members anticipate and manage the increase. Vizient’s Pharmacy Solutions team has developed a tool to accurately project demand for ventilator medications over a four-week period by drug and drug class.

In addition to the ventilator medication demand tool used to accurately project demand for ventilator medications, Medtronic and other leading ventilator manufacturers joined to form the Ventilator Training Alliance (VTA). The alliance is an industry-wide effort to provide health care professionals one central location for training across many ventilator models.

The VTA has launched an app with ventilator training resources including:

- How-to videos
- User guides
- Equipment manuals
- Troubleshooting guides
- Other ventilator-operation expertise
The training material was provided by alliance members Dräger, GE Healthcare, Getinge, Hamilton Medical, Nihon Kohden and Philips, Medtronic and Vyaire. Additional companies are expected to join the alliance in the coming weeks. COVID-19 has increased the demand for respiratory therapists and where there are shortages, nurses and other medical professionals can find on-demand training.

Many organizations are discussing and/or already sharing ventilators to mitigate shortages and improve access to this necessary equipment. Statements from the American Association for Respiratory Care (AARC), Society of Critical Care Medicine (SCCM), American Society of Anesthesiologists (ASA), Anesthesia Patient Safety Foundation (APSF), American Association of Critical-Care Nurses (AACN) and American College of Chest Physicians (CHEST) were released March 27, against the use of ventilator sharing.

They argue that this should only be done in a “last-ditch effort” after careful consideration and in consultation with the Ethics committee/Institutional Review Board, and recommend other options in the AARC statement and guidance document.

The FDA recommendations for mitigation strategies were released on March 22, while HHS issued guidance for optimizing ventilator supply and usage on March 31.

Many members are repurposing anesthesia machines, CPAP and BiPAP devices as ventilators; however, these efforts require direct collaboration with anesthesiologists and respiratory therapists for extensive advanced planning and ongoing execution. Medtronic has posted open-source ventilator product specifications.

**ECMO**

ECMO may be offered for patients with refractory hypoxemic respiratory failure/acute respiratory distress syndrome (ARDS) due to COVID-19. The WHO has established guidelines for utilizing ECMO when COVID-19 is suspected. Organizations should consider:

- **How** to prioritize and allocate ECMO resources.
- **When** the organization’s response strategy should include use of ECMO.
- **What** personnel and equipment will be needed.
- **How** to mitigate shortages of ECMO since alternatives are more limited.

See newly published literature from The Lancet on Planning and provision of ECMO services for severe ARDS during the COVID-19 pandemic and other outbreaks of emerging infectious diseases and from JAMA Network on Preparing for the Most Critically Ill Patients With COVID-19: The Potential Role of Extracorporeal Membrane Oxygenation.

**Added 3/31/2020**

**Blood products**

Prepare for possible reduction in blood supply due to reduced blood drives.

- Recommend that elective surgeries be cancelled.
- Adhere and enforce transfusion guidelines by communicating short supply.
- Remind clinicians to test pre and post transfusion to ensure the transfusion is clinically indicated.
- Cell salvage is recommended except where there are contraindications.
PPE conservation and utilization strategies

Allocating scrubs to clinical staff
Some members are providing scrubs to staff directly caring for COVID-19 patients, following protocols to ensure the scrubs are properly doffed at the facility and laundered. They noted this has placed a strain on laundry services. Conversely, other members have not enacted universal distribution of scrubs to all staff members, citing policies identifying facial protection, gloves and gowns as appropriate PPE for COVID-19 patients.

PPE recommendations for pharmacists
The CDC updated Considerations for Pharmacies during the COVID-19 to include new information regarding face coverings for outpatient pharmacies staff and customers.

Remote monitoring to preserve PPE
Use remote interaction with patients in isolation as appropriate to conserve PPE:
- Remote telemonitoring equipment if available.
- Utilize phone or two-way intercom.
- Video conferencing or baby monitors.
- Some organizations are moving IV pumps and vent screens outside the door into the hallway and running IV tube extension sets to the patients to reduce the amount of PPE used.

PPE burn rate
Know your PPE burn rate. COVID-19 patients will significantly increase the normal rate; however, be aware these analyses are highly-contingent on clinical protocols and conservation strategies which vary widely across provider organizations.
- CDC Template for Calculating PPE Burn Rate
- HHS Template for Calculating PPE Burn Rate
Consider patient categories and cohorts to project total daily use per patient, for instance, by supply category:
- Category 1: ICU patient or aerosolizing procedure/case: X caregivers per patient * Y PPE exchanges per day
- Category 2: Non-ICU patients: X caregivers per patient * (Y-Z) PPE exchanges per day

PPE conservation and utilization strategies
- Create firm guidelines for N95 use and assess for appropriate use. Some members are limiting the use of N95s to caregivers for COVID+ ICU patients and aerosolizing procedures. Other alternative strategies may include having Pharmacy convert to PAPRS for USP 800 and 1/2 masks to reduce use of N95 masks.
• Extend the useful life by allowing the provider and clinician to reuse the same mask or respirator as long as it is not visibly soiled or damaged. CDC: Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings. At some organizations, clinical staff retain their N95 masks in paper bags identified with the staff member’s name for reuse.

• Reprocess N95s and other items through sterilization techniques:
  o FDA has issued guidance to provide a policy to help expand the availability and capability of sterilizers, disinfectant devices and air purifiers.
  o N95 Decontamination from N95DECON

• Adapt practice based on CMS guidance of March 10, “Guidance for Use of Certain Industrial Respirators by Health Care Personnel.” This document addresses acceptable temporary alternatives and practices when the supply chain of respirators cannot meet the demand.

• Cohort patients in a way that allows for longer use of a single N95 mask. For instance, some organizations are repurposing operating rooms as multi-bed ICUs for “COVID-19 core” wards where staff remain garbed in PPE.

• Many hospitals are adapting protocols for conserving PPE through “tent” spaces outside the ED. Some of the common protocol components include:
  o Patients who are directed to tents receive a mask at triage.
  o General staff wear surgical masks consistent with droplet precautions and face shields.

• Some members are covering N95 respirators with surgical masks or face shields for droplet protection.

• Reuse googles, face shields and visors for the same patient when possible by disinfecting with an EPA-approved disinfectant.

Added 4/9/2020

Additional resources
• Vizient Masks and Respirators Clinical Resource Guide
• JAMA: N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel
• WHO: Rational Use of Personal Protective Equipment for Coronavirus
• CDC: Checklist for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during the COVID-19 Response

Additional emerging practices
Access resource documents on other topics.
• Emerging clinical practices and evidence
• Surge capacity
• Staff impact
• Testing
• Visitation