

Guidelines for Acquisition of Ventilators to Meet Demands for Pandemic Flu and Mass Casualty Incidents

Including

Addendum #1 (June 5, 2006)

Addendum #2 (January 30, 2008)

Introduction

Following the tragedy of September 11, 2001 and the anthrax mailings of the same year, the U.S. medical community has undertaken steps to deal with a potential event that could result in a large number of patients requiring mechanical ventilation. More recently, the threat from nature, in the form of the Avian Flu (H5N1), has accelerated preparations for a pandemic flu, which might result in thousands of patients requiring mechanical ventilation.

At present, the H5N1 flu remains difficult to transmit from person to person, but mutation of the virus could change this quickly. Reports from Southeast Asia suggest that the virulence of H5N1 results in severe acute respiratory failure (ARF).

In the United States, the treatment for ARF is supplemental oxygen and mechanical ventilation. Thus we can expect a surge in demand for ventilators if a pandemic of H5N1 were to occur.

In the wake of a pandemic flu with a virulent flu strain like H5N1, patients with survivable illness will die from lack of resources unless more ventilators that have the capabilities to provide ventilatory support for patients with ARF are readily available.

Mechanical Ventilation in the U.S.

Mechanical ventilation typically is implemented and managed by respiratory therapists, in intensive care units, under the direction of a physician.



Despite the severity of ARF, most patients survive. However most patients with severe ARF, except when caused by conditions immediately correctable by antidotes, (e.g., naloxone for opiate overdose), are likely to die.

Typically U.S. hospitals maintain a sufficient numbers of ventilators, support equipment, and supplies to meet

current health care demands. At times of peak demand (i.e., flu season), hospitals frequently are required to supplement their ventilator inventories, by renting additional ventilators. Thus, U.S. hospitals have virtually no reserve ventilators to respond to a disaster or pandemic.

Mechanical ventilators, used in critical care settings, are complex microprocessor-driven devices designed to support a wide range of medical conditions, acuities, ventilation modes, flow rates, and pressure settings. The high cost of purchasing and maintaining such critical care ventilators makes stockpiling these devices financially impractical.

A simple ventilator setting error can cause patient injury or death. The extensive training and competency requirements necessary to operate these ventilators safely and effectively

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impedes the use of support personnel who may be called upon to assist respiratory therapists if a pandemic or other mass casualty event hits the country.

The following represents the recommendations from the American Association for Respiratory Care to assist with decisions to plan and implement mass casualty response for both pandemics (H5N1) and other mass casualty disasters.

It must be emphasized that ramping up ventilator capacity, for any mass casualty response, will likewise require ramping up of human resources to assist respiratory therapists and physicians with treatment of patients requiring mechanical ventilation. This human resource issue is a key factor in ventilator selection, of no less importance than the ventilator itself.

Recommendations of Additions to the U.S. Strategic National Stockpile (SNS)

We understand that the U.S. Centers for Disease Control and Prevention's Strategic National Stockpile (SNS) program owns and maintains approximately 6,000 mechanical ventilators for distribution to states affected by mass casualty events. However, a serious influenza pandemic is likely to overwhelm even the SNS inventory.

Therefore, we recommend that the current SNS inventory be expanded.

- At least 5,000 to 10,000 ventilators that are similar to ventilators that are currently in the SNS, with the ability to control tidal volume, rate, and PEEP, as well as having an alarm system, should be acquired.
- These additional ventilators should include 1,500 critical care ventilators with the same features and capabilities as those currently in use in ICUs across the country. Of this 1,500, 1,000 should be adult and 500 should be pediatric ventilators. This added resource will help meet the anticipated surge in demand for the most clinically versatile ventilators that will support the clinical needs of the severe H5N1 patients, especially those who have co-morbidities.

A reliable triage system is absolutely necessary to identify the patients who cannot be managed with the more numerous but less complicated ventilators, and to assure that they receive the appropriate ventilator support necessary to sustain them throughout the incidence of H5N1.



As such, local planning will be essential.

Critical Points to Consider In Local Planning

Human Resources Issues

- Under normal conditions critical care professionals are in short supply. Using a triage system to reduce services to essential non-elective levels will free some personnel and equipment.
- If the need for mechanical ventilation overwhelms the staffing capacity, noncritical care professionals will be enlisted to assist in patient care, but only after undergoing some degree of training by respiratory therapists and other critical care specialists.
- Therefore:
 - √ Ventilators must be easy to use.
 - √ Ventilators must have adequate alarms to include loss of power source (gas and/or electricity), low pressure, high pressure, and disconnect.
 - √ Standardized training programs must be undertaken to first train the trainers, and then facilitate the training and use of additional caregivers.
 - √ The complexity of mechanical ventilation requires that respiratory therapists play the lead role in this educational effort.
 - √ The purchasing decision for these devices should

include local disaster management teams, critical care physicians, and respiratory therapists.

- √ Ventilators used by EMS professionals for emergency care and transport typically do not offer the parameters and operational limits needed for prolonged ventilation of the patient with ARF.

Logistical Support

- Adequate supplies of ventilator circuits, heat and moisture exchangers, suction equipment, and pulse oximeters must also be readily available in order to maintain airway clearance, and monitor oxygenation.
- Ventilator circuits (tubing/valves) used to connect the patient with the ventilator must be sterilized, if reusable, or replaced when ventilators are switched to different patients over the course of the pandemic.
- Natural disasters may eliminate electricity, or a pandemic may require continuing ventilator use in facilities not designed or configured for the wide array of medical technology devices. Since all mechanical ventilators are powered by compressed gas (air), and/or electricity, plans must include pre-identified additional sources for high capacity air compressors that can power several ventilators simultaneously. These compressors must be able to produce clean and dehumidified air at within a pressure range specified by the ventilator manufacturer. Gasoline- or dieselpowered generators should also be identified in the plan.
- Oxygen supply may be limited by events that destroy commercial infrastructure (hurricane) or hospital supplies (flood, earthquake.)
 - √ Oxygen consumption of ventilators must be limited
 - √ Ventilators capable of operating from compressed gas and a variety of electrical sources are preferred.
- Infants and children will also be victims, so ventilators should be capable of ventilating pediatric patients.
- In case of contagious respiratory disease caregivers should use appropriate protections.
 - √ Non-invasive (mask) ventilation should be avoided due to risk of contamination.
 - √ Caregivers must wear currently recommended personal protective equipment and receive appropriate training for its use and all procedures related to the decontamination process.
 - √ Caregivers should minimize exposure time.

Ventilator Capabilities and Capacity

- The following ventilator capabilities are necessary to treat patients with H5N1 and the resultant ARF.
 - √ Operate across a wide range of patient populations (infants to adults)
 - √ Easy, safe operation.
 - √ Minimal maintenance.
 - √ Operate for 4-6 hours when electric and gas supplies are unavailable. This battery operation might include internal and external batteries.
 - √ Ventilation of acute respiratory failure will require, at a minimum, the ability to control tidal volume,

respiratory rate, inspired oxygen concentration, and positive end-expiratory pressure (PEEP).

- √ Note that devices used in EMS are designed for short-term use (transporting patients) and therefore may not have any value in a pandemic flu or mass casualty event.
- Increasing ventilator capacity
 - √ Stockpiling of ventilators with the characteristics necessary to meet the challenges of ARF is recommended.
 - √ Stockpiling ventilator power sources and the previously mentioned supplies and equipment is recommended.
 - √ If not currently in place, a system to periodically inventory and test stockpile equipment must be instituted virtually at the time of acquisition.
 - √ Efficient utilization of current, non-stockpiled ventilators must occur.
 - o Cancel elective surgery and utilize anesthesia ventilators.
 - o Allocate ventilators appropriately between hospitals, municipalities, and cities.
 - o Request all hospitals to determine the existence and condition of obsolete, yet functional, ventilators that could be used in the event of a pandemic or other disaster.
 - o Establish a procedure for appropriate distribution of local ventilator stockpiles, if they exist.
 - o Make advance arrangements with equipment rental companies to ascertain their ability to supply ventilators.
 - o Assess access to SNS reserves.

Summary

- Ventilator reserves must be versatile enough to meet the ventilator demands of a mass casualty and/or pandemic event.
- Planners should consider standardization of ventilators when practical, in order to simplify: a) training support staff, b) inventory of support resources (circuits, etc), and c) anticipated site of use.
- Ease of usage and ease in training must be considered at time of ventilator purchase.

Ventilator reserves must be versatile enough to meet the ventilator demands of a mass casualty and/or pandemic event.

- Numbers and types of ventilators should reflect the differences in need between disaster response with mass casualties and a pandemic such as H5N1.
- Ultimately, there will be just one reserve of ventilators to use in both disaster scenarios. As such the need to add ventilators that have ventilation mode capabilities to

support pandemics is paramount.

- The current ventilator stockpile should be expanded by 5,000 to 10,000 ventilators. This should include approximately 1,500 ventilators (1,000 adult and 500 pediatric) with the features and capabilities that can support patients with Acute Respiratory Failure.
- Respiratory therapists can and are assisting agencies at all levels to assure that ventilator stockpiles are not measured by quantity alone, but also clinical capabilities.
- The American Association for Respiratory Care stands willing to assist all emergency preparedness agencies as they provide further consideration to the purchase of ventilators. It will also assist in identifying the support and logistical issues that manifest as part of this process.

Addendum #1

June 5, 2006

We have been notified by the CDC that there are actually about 4,000 ventilators in the CDC's Strategic National Stockpile. These include 2,000 IMPACT 754 and 2,100 LP10 ventilators. An additional 486 ventilators are on order but have not yet been received.

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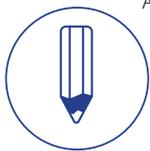
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Addendum #2 January 30, 2008

Non-invasive ventilation

Non-invasive ventilation (NIV), ventilation via a nasal or face mask, is a standard of care for respiratory failure in the patient with chronic obstructive pulmonary disease (COPD).¹⁻⁴ However, the AARC guideline on ventilator acquisition for pandemic flu recommends that NIV not be used and that non-invasive ventilators are not recommended for stockpiling.⁵ This addendum is intended to provide further clarification on these issues. The use of NIV in pandemic flu is not recommended for the following reasons

- Patients with respiratory failure from avian flu progress quickly to acute respiratory distress syndrome (ARDS).^{6,7}
- The use of NIV for ARDS has been reported [8,9] but recent evidence cautions against this practice due to lack of efficacy and potential for complications.^{10,11}
- A recent survey of US hospitals suggest NIV is not commonly used for ARDS.²

- The success of NIV is related to a significant time (1-2 hours) spent by the respiratory therapist at the bedside at initiation of NIV¹³, an impracticality in a pandemic event
- Recognition of NIV failure and the requirement for emergency intubation is also more difficult in a scenario of too many patients and too few caregivers

The AARC guideline on ventilator acquisition for pandemic flu recommends that NIV not be used and that non-invasive ventilators are not recommended for stockpiling

- Some concern over NIV qualifying as an “aerosol producing procedure” possibly increasing the risk of caregiver exposure has been raised^{14,15} although the evidence is weak and the experience from Southeast Asia does not support this theory^{16,17}
- A leading physician from Hong Kong with significant experience in care of patients with severe acute respiratory syndrome (SARS) has also suggested the NIV not be used in febrile respiratory illness.¹⁸

Why not stockpile non-invasive ventilators?

Non-invasive ventilators tend to be cheaper and smaller than many conventional devices, but have limitations which preclude recommendation for stockpiling which include:

- No battery back-up
- Limited monitoring
- Limited alarms
- Inability to provide volume control (most devices provide pressure targeted ventilation)¹⁹

The main advantage of non-invasive ventilators is ability to function in the face of a leak (leak compensation).²⁰

Current hospital inventory

Despite the limitations of non-invasive ventilators, many hospitals have these devices available. In a pandemic situation, we suggest the re-purposing of non-invasive ventilators for use as invasive ventilators. Some of the newer, more sophisticated NIV devices have built in alarms (e.g., Respironics Vision) and are more suitable than those without alarms. When simpler devices are used, the addition of pressure monitoring and low pressure/disconnect alarms is recommended. These devices should also only be used under the supervision of respiratory therapists.

Note: Re-purposing of non-invasive ventilators should only be done under the supervision of respiratory therapists. The traditional single limb circuits with a fixed leak used with a face mask can lead to carbon dioxide re-breathing during ventilation via an endotracheal tube. Use of

circuits with an exhalation valve at the airway would be preferred in this instance

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