

IMPLIMENTING PANDEMIC INFLUENZA VENTILATOR ALLOCATION

Implementing a Pandemic Influenza Ventilator Allocation Plan:

A proposal for St Peter's Health Partners based on The New York State Task Force on Life and The Law's

2015 Ventilator Allocation Guidelines

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Introduction

It has been estimated that on average in the United States more than 200,000 hospital admissions are associated with influenza annually (Thompson 2004, p 1339; NYS Taskforce, p 24) On average, based on data collected over nearly 30 influenza seasons, approximately 24,000 respiratory and circulatory deaths in the US are believed to be influenza-related. (CDC 2010). Although unpredictable, influenza pandemics can impose a much greater burden on the health care system. In 1918, one quarter of the US population was infected in that pandemic and over 650,000 of those people died, and it is believed that worldwide influenza is estimated to have killed as many as one third of the worlds entire population in the 1918-1919 flu pandemic. (Calleigh, p 694; WHO 2009, p 13) A similar influenza pandemic in the US now could mean 80 million people ill with influenza. (Calleigh, p 694). However, unlike in 1918 we now have health care services and technology that can save many lives. Antiviral medications may decrease the severity and length of illness, vaccination will hopefully minimize the number of people infected, and antibiotics and better supportive measures such as mechanical ventilation will help minimize deaths related to secondary infections and respiratory compromise.

Unfortunately, in the event of an influenza pandemic similar in scale to the 1918 outbreak, there is no way we will be able to meet the needs of every single patient requiring intensive medical therapy, particularly mechanical ventilation. The New York State Task Force on Life and The Law estimates that in the instance of an influenza pandemic on the scale of what was experienced in 1918-1919, statewide there would be a shortfall of nearly 16,000 ventilators at the peak of a 6-week pandemic. Even if the outbreak were more modest, like the Asian flu in 1957 and Swine flu in 1968, there might only be a surplus of 575 ventilators statewide. These numbers are forecast based on current population estimates and the 2015 New York State Critical Assets Survey including the number of ventilators available and currently in use in New York State as well as the state ventilator stockpile.

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In their 2013 Guidelines for Crisis Standards of Care during Disasters, the American College of Emergency Physicians remind us:

Rather than doing everything possible to try to save every life; in a disaster, it will be necessary to allocate scarce resources to save as many lives as possible. This “crisis care” is simply what a prudent person would do with the scarce resources at hand. Crisis care, by no means, however, implies “substandard” care; crisis care is what a reasonable practitioner would do (and want for himself and his loved ones), given the limited resources at hand. (p. 1)

While predicting when the next influenza pandemic will occur and how many people may be infected is an extremely difficult task, it seems certain that we will face another severe influenza pandemic that will surpass our resources. This paper will examine how St Peter’s Health Partners can begin to prepare for the overwhelming demands a severe influenza outbreak will impose on our acute care hospitals. It will review the process of ventilator allocation in adults and will introduce other aspects of pandemic preparedness that will impact the organizations ability to meet the needs of critically ill patients.

Ethics of Pandemic Planning and Resource Allocation

In a 2007 paper for The Hastings Center, Nancy Berlinger and Jacob Moses discuss the ethical importance of planning for a pandemic. “When planners know there will not be enough of what people will need, they have a duty to create and test the rules and tools that will help first responders make fair decisions during a crisis. (p. 2) The duty to plan for disasters to the best of our ability and our duty to steward scarce resources and distribute them justly are important parts of our professional duty to care as health care providers and health care systems. Clinicians and health care organizations need thoughtful plans in place and rehearsed before a pandemic occurs to ensure principles such as fairness and equal protection for all groups of people while at the same time permitting the bedside clinicians to focus on providing the best possible care of each individual patient.

2015 Ventilator Allocation Guidelines

In 2015, The New York State Task Force on Life and the Law, a group of clinicians, legal experts, ethicists and religious scholars, released new guidelines for the allocation of mechanical ventilators in the setting of pandemic influenza. Building on guidelines first issued in 2007, the document addresses ventilator allocation for adult, pediatric and neonatal patients. It provides ethical, clinical and legal guidance for institutions in New York State developing pandemic influenza response plans.

The primary goal of the Guidelines is to save the most lives in an influenza pandemic where there are a limited number of available ventilators. To accomplish this goal, patients for whom ventilator therapy would most likely be lifesaving are prioritized. The Guidelines define survival by examining a patient's short-term likelihood of surviving the acute medical episode and not by focusing on whether the patient may survive a given illness or disease in the long term (e.g., years after the pandemic). Patients with the highest likelihood of survival without medical intervention, along with patients with the smallest likelihood of survival with medical intervention, have the lowest level of access to ventilator therapy. Thus, patients who are most likely to survive without the ventilator, together with patients who will most likely survive with ventilator therapy, increase the overall number of survivors. (NYS Task Force, p 12)

While many of the topics discussed here do apply to pediatric and adult populations, the process of ventilator allocation discussed in this paper will focus on adult patients.

Implementation

The recommendation of the Task Force is that ventilator allocation plans not be initiated until hospitals are operating at surge capacity including taking steps to reduce the need for ventilators such as cancelling elective procedures that require ventilators, realigning staffing as needed to accommodate the increase in ventilator patients. The Task Force feels that policies for ventilation allocation that follow the guidelines should be instituted state wide and the direction to institute ventilator allocation plans would come from the Department of Health. (NYS Task Force, p 13)

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Recommendation: St Peter's Health Partners should institute a ventilator allocation policy when the State Department of Health has declared a statewide shortage of ventilators and the hospitals are operating at surge capacity to maximize the number of ventilators available for acute care. Once the policy is initiated, it will apply not only to new admissions but to patients on mechanical ventilation at the time the policy is instituted. St Peter's Health Partners should also work with other regional facilities to find ways to share resources and reduce unequal access to care in the region.

Triage committee

One of the central issues that needs to be established in a ventilator allocation policy is a clear statement of who will be making these decisions. While the Task Force states that either a triage officer or triage committee may be appropriate depending on the physician staffing at a given institution, they do clearly state that the physician responsible for the bedside, day to day care of a patient in should not be responsible for determining if a patient is eligible for mechanical ventilation.

First, this framework permits attending physicians to fulfill their obligation to care for their individual patients without facing a conflict of interest; they can advocate for their patients and not also be responsible for deciding to withhold or withdraw ventilator treatment. Second, separating the attending physicians from the triage decision-makers also ensure that the person(s) in this role is a senior/supervisory clinician (i.e., has the most clinical experience and/or relevant training). ... Further, this person(s) will make allocation decisions consistently across a group of patients. Finally applying role sequestration enhances the capacity for maintaining professionalism by helping to decrease burnout and stress for health care providers providing direct critical care during the epidemic and for the decision-makers, and for all clinicians to sustain their integrity as healers. (NYS Task Force, p 38)

This sequestering of roles is also the recommendation of the Centers for Disease control in their 2011 guidance document, *Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic or Other Public Health Emergency*, stressing that the separation of the roles of patient care and triage allow for impartial decision making while allowing the

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patient's physician to focus on the best interests of each patient. (p. 16) The CDC recommendations go on to further outline the composition of the triage team.

The triage expert should be a senior-level provider within the institution with the experience, respect, and authority to carry out the function. When possible, it is desirable to establish a triage team composed of at least three members rather than relying upon a single triage expert. The team approach allows for consultation, multiple professional perspectives, and a broader base of support from clinical/community stakeholders. The suggested professional makeup of a triage team would include at least a critical care nurse, a respiratory care professional, and a physician. It is also desirable to have an ethicist on the triage team if available. (CDC 2011, p 17)

While separating the role of bedside clinician and triage can help decrease stress for physicians, psychological support for triage committee members is still highly recommended during and after their participation since the decisions they will be making may cause great emotional distress. (Christian, p 13.11)

Recommendation: Because St Peter's Hospital incorporates three acute care hospitals, it might be appropriate to have one triage committee, composed of a critical care attending, a critical care nurse manager, and a respiratory therapy manager or supervisor, to oversee all three hospitals since the committee does not have to function at the bedside. This committee will need to have access to information on ventilator availability as well as the clinical data provided in the mortality risk assessments outlined below.

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Exclusion criteria

Patients facing near-immediate mortality even with aggressive therapy are excluded from receiving mechanical ventilation under the Task Force's guidelines. This includes:

- Cardiac arrest: unwitnessed arrest, recurrent arrest without hemodynamic stability, arrest unresponsive to standard interventions and measures.
- Trauma-related arrest: Irreversible age-specific hypotension unresponsive to fluid resuscitation and vasopressor therapy, Traumatic brain injury with no motor response to painful stimulus (i.e., best motor response = 1 on Glasgow Coma Scale).
- Severe burns: where predicted survival $\leq 10\%$ even with unlimited aggressive therapy.
- Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy. (NYS Task Force, p 57)

The exclusion of these patients promotes judicious use of scarce resources and promotes utility by ensuring that scarce resources are allocated to the patients who are most likely to benefit from them. The list is flexible, with its catch all "any other conditions" category. For instance, the Task Force chose not to exclude specific disease states such as end stage renal disease requiring dialysis, but if it becomes evident as the pandemic progresses that this population does have a very high mortality even with aggressive care, it may be appropriate to exclude those patients as well. It was decided that advanced age should not be used as an exclusion criteria because it would be discriminatory. "Age already factors indirectly into any criteria that assess the overall health of an individual." (NYS Task Force, 5) Another group the Task Force specifically mentions are those chronically ventilator dependent. The guidelines advise that these patients become "subject to the clinical ventilator allocation protocol only if they arrive at an acute care facility for treatment." (NYS Task Force, 13)

Mortality Risk Assessment

For patients who aren't excluded based on the above criteria, a mortality risk assessment will be made using the Sequential Organ Failure Score (SOFA). (Ferreira 2001, p1754) This assessment is performed when the patient is initially triaged and again at 48 hours and 120 hours after the initial assessment. After reviewing exclusion criteria and completing the mortality risk assessment, patients will be triaged to

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palliative care, high priority, intermediate priority, or low priority based on their SOFA score. (See Appendix) High priority patients are to be allocated ventilator patients first. Once all high priority patients have received ventilators, then remaining ventilators may be allocated to intermediate priority patients. If any ventilators remain, any patients that may have otherwise received only palliative care or alternative therapy may be considered for mechanical ventilation.

There remains the question of what to do if there are not enough ventilators for high priority patients. The Task Force recommends a randomization process should be used to allocate the ventilators. Some have recommended that a “first-come, first-served” policy be used as alternative to a randomization scheme when two or more patients have equal claim to available ventilators. Since it would be uncommon that two patients are truly identical in their claim on scarce resources, Hick et al argue for a third option in their 2007 article, *Clinical review: Allocating ventilators during large-scale disasters – problems, planning, and process*:

When, according to guidelines or the triage team’s clinical experience, the claim to the resource is clearly not equal, the patient with a more favorable prognosis/prediction shall receive the resource. The triage team should ask for and receive whatever patient information is necessary to make a decision but should NOT consider subjective assessments of the quality of the patients’ life or value to society and, in fact, should ideally be blinded to such information when possible. (Table 4)

The most important thing in allocating ventilators within the same group is to establish the method in advance and use the same method every time. This continuity will promote fairness of opportunity.

Recommendation: In the instance where there are insufficient ventilators for the number of patients within a group, a lottery should be used to randomly allocate the ventilators. This limits the number of subjective assessments that might weight other decisions such as who was “first” and who has the most favorable prognosis in a group of patients with similar prognoses.

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Time Trials

Once a mechanical ventilation trial is initiated, a mortality risk assessment is repeated at 48 hours and 120 hours and the patient is again triaged to palliative, high, intermediate, or low priority.

Appropriately, a patient's access to a ventilator depends on the patient's own clinical status, as objectively measured, rather than on a direct competition with other patients presenting for care. Further, a patient receives a set amount of time to benefit from ventilator treatment before s/he is evaluated on whether s/he is eligible for continued ventilator use. A patient who does not benefit over time (i.e., demonstrate improvement in overall health after receiving ventilator treatment) will lose access to the ventilator. Thus, this system honors the ethical principles of caring for patients while also stewarding resources wisely. (NYS Task Force, 50)

If between the scheduled assessments, a patient is identified as meeting the exclusion criteria, palliative care should be considered and mechanical ventilation should be discontinued if an eligible patient of high or intermediate priority is waiting for a ventilator.

Any patient who is continued on mechanical ventilation at the 120 hour mortality risk assessment will be reevaluated every 48 hours by the triage committee. The decision to continue mechanical ventilation at each assessment should be based on SOFA criteria with consideration of clinical improvement or deterioration, the underlying diagnosis and its known progression, current status of the pandemic and available resources, and alternatives for care (treatment options, transfer to another facility).

Appeals and Review

In any allocation of scarce resources, there will be disagreement. Patients, family members, physicians and other care team members may question the clinical assessment and decision of the triage committee. There should be mechanisms in place to try to minimize the frequency with which conflict occurs by ensuring the triage system is accurate, effective, fair and transparent. To this end, a retrospective review can be helpful to monitor the utility of the triage plan and amend it as necessary.

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Even with this retrospective review, instances will arise where a prospective assessment and judgement will need to be made to address immediate concerns. The Task Force recognizes that real-time appeals do provide the greatest degree of protection of individual rights. However, during a pandemic this may not be possible due to insufficient staff. In fact, the Task Force found “preliminary feedback indicates that the public understands the challenges inherent in real-time review of decisions in a pandemic, and that such review is somewhat unfeasible.” (p 233)

The Task Force recommends a hybrid approach, incorporating both review of the triage process and a mechanism of real-time appeal if needed. All cases would be reviewed periodically to ensure that triage decisions are being made in accordance with the guidelines and evaluate the need for revisions to improve allocation when needed. In addition,

Real-time individual case appeals would be limited to procedural/technical injustices only (e.g., when a withdrawal decision was made without considering all relevant clinical triage criteria) that could remedy a potential injustice prior to the implementation of a triage decision. (Task Force, 233)

Recommendation: A review committee, consisting of a critical care physician, adult critical care nursing or respiratory therapy manager, and ethics committee member should meet daily to review any decisions to withhold or withdraw ventilator support and verify compliance with this policy. This process will enable rapid identification of needed adaptations of the policy as the pandemic evolves and new information becomes available. None of these committee members should be on the triage committee currently responsible for determining the patient’s course of therapy nor should the physician on the committee be the physician providing bedside care. If there is a perceived procedural or technical injustice (such as if a decision is made without considering all relevant data), a real-time appeal may be requested of this same committee.

Palliative Care

In a pandemic influenza outbreak when the need for medical services exceeds their availability, palliative care will be an essential service. All patients who are awaiting triage or placement on a mechanical ventilator, who have been triaged to receive no mechanical ventilation, or who have not met the criteria to continue with mechanical ventilation should receive support including nutrition, pain management, other methods of respiratory support as needed, as well as psychosocial and spiritual support for the patient and their family.

Recommendation: St Peter's Health Partners, as part of pandemic preparedness training should offer education on palliative care to clinicians and all members of the patient care team appropriate to their positions. When palliative care is initiated, since mechanical ventilation is not available, a DNR order should be written.

Beyond Adult Ventilator Allocation

While this paper has focused on adult patients, clearly policies will be needed for pediatric and neonatal patients as well, in large part since these groups will be competing for some of the same equipment and staff. Realistically, a comprehensive ventilator allocation policy must encompass all three groups. Plans to increase capacity need to be in place as well. Surge capacity plans that cancel elective surgery procedures and expand the physical number of beds for ventilator dependent patients are necessary as well. There are many other considerations when contemplating pandemic influenza preparedness at the institutional level as well. This section will touch on just a few areas that impact the ability to maximize critical care services and ventilator support that will need consideration as part of a larger pandemic influenza plan.

Other care-limiting resources

Ventilators are only one resource that will be in short supply during an influenza pandemic. Many patient care related items such as personal protective equipment, disposable ventilator circuits, oxygen delivery

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devices and possibly oxygen itself, and many of the supplies we use every day. Processing of reusable equipment during staffing shortages and high demand for equipment should also be planned for. Protocols for the just allocation of antiviral medications and vaccinations will also be needed. Not only will antiviral medications and vaccinations be important to patient care, but prevention of illness in staff will be a crucial concern as well.

Staff shortages

Some experts estimate a 20% or more reduction in available staff due to absenteeism as staff stay home due to illness, to care for family, or because of fears of illness. (Ajao, p 637; Qureshi, p 383) The staff to patient ratios we work with most days will not be feasible when there is 1/5 less staff and many more patients. For nursing and respiratory care shortages it may be necessary to look at scope of practice and provide cross training for certain skills as well as training to work at the different hospitals (as respiratory currently does) to allow more flexibility with staffing. In fact, patient care providers at all levels from CNAs through physicians will be need to be flexible. Students and volunteers might also be enlisted to support regular staff. Non-clinical staff might also be trained to assist with tasks like distributing meal trays, helping in the kitchens and transporting patients.

To meet the need for physicians in the setting of an overwhelming demand for critical care, Ajao et al (2015) recommended a two-tier model consistent with recommendations from the Task Force for Mass Critical Care. In this model, a patient-to-critical care physician ratio of 24:1 could be managed with each critical care physician working with up to 4 non-critical care physicians, each in turn responsible for up to 6 patients. (Ajao 2015, 637) St Peter's Health Partner's use of physician assistants and nurse practitioners with critical care experience can serve as an example of how this system might function.

Some measures may also be useful to encourage attendance such as offering support for staff like facilitating shared child-care and elder-care responsibilities, providing emotional and psychological support, assisting staff with chronic disease access medication when they may need to be at work for

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extended shifts, and providing clear, frequent communication with staff throughout the pandemic. The Employee Assistance Program may be a valuable asset to help meet these needs. (Qureshi, p 387)

Infection Control

Infection control precautions to minimize the spread of infection will be very important. In planning bed allocation, non-infected patients should be housed separately as much as is feasible. Adequate supplies of personal protective equipment will be needed as well as ongoing training in appropriate, judicious use of PPE to offer the best protection while conserving supplies. Other suggestions have included the establishment of a fever clinic at facility entrances to screen staff and visitors for influenza-like illnesses (Health First, Appendix E) Social distancing practices for staff may also help limit spread among staff and protect patients. (Azziz, p 193)

Training

Staff should receive training as part of pandemic influenza preparedness relevant to their work responsibilities and typical expected patient care responsibilities. The NYS Department of Health 2006 Pandemic Influenza Plan suggests two hours of training a year dedicated to such training. (Section 3, p. 6) In addition to infection control issues, such training should include review of appropriate policies for pandemic response to familiarize staff with anticipated changes to standard practice. The DOH has also recommended psychological-support training for appropriate personnel to support not only patients and family but staff as well.

Training may take the form of traditional presentations or on-line learning modules but tabletop drills and, when possible, physical drills will not only help prepare staff but may help identify weaknesses in policies and allow revision before they need to be utilized. “Just-in-Time” training might be utilized to help train volunteers and non-clinical staff to function in positons supporting patient care areas such as dietary, housekeeping, and nutrition or to cross-train licensed staff to a new clinical area, but a plan for these programs should be part of the overall pandemic response plan.

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Any potential triage committee members should receive training on clinical ethics in triage and the allocation of resources. Understanding the rationale behind allocation policy will help committee members overcome personal bias and minimize unjust and inconsistent decision-making. (Berlinger, p 10) This training may also help identify weaknesses in the policy before it needs to be implemented.

Beyond St Peter's Health Partners

Regional Coordination

St Peter's Health Partners should establish relationships with regional hospitals (Albany Medical Center, Ellis, Columbia Memorial at a minimum), local EMS services and county Departments of Health to identify available resources and discuss contingency plans, sharing of resources, and coordination of care issues like interfacility transfer. This planning should also be accompanied by drills to ensure familiarity with plans and identify areas of weakness.

Legal Protection

Clinicians and facilities are rightly concerned about legal liability in the setting of pandemic influenza response, especially when it comes to allocating scarce resources which can result in some patients being denied treatment they might have received in normal circumstances. Currently, no federal or state law offer explicit protection for health care providers in this situation and many state statutes (for example, provisions in Public Health Law regarding withdrawing and withholding treatment and proxy decision making as well as professional misconduct provisions) appear to undermine the ability of physicians to follow the Task Force's guidance. (NYS Task Force, p 217) There is also little case law examining these issues directly although courts have supported isolation, quarantine and compulsory vaccination measures that similarly limit individual rights to promote protection of the larger population during a declared emergency. (NYS Task Force, p 207). The recommendation of the Task Force is new legislation that would provide criminal and civil liability protections for health care providers during a pandemic. They also recommend the State Health Commissioner be given the "authority to adopt a modified medical

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standard of care specific to the emergency” combined with protections against professional discipline.

(NYS Task Force, p 224)

Currently there is no pending legislation in New York State that speaks to these concerns directly although Senator LaValle has sponsored a bill (NY S1803A, 2015-2016) to establish a state pandemic preparedness task force which could incorporate review of legal protection and recommend legislation.

Conclusion

It is expected that we will experience a pandemic influenza outbreak that will exceed our current health care resources. In particular, our ability to provide mechanical ventilation may not meet the demand of a large patient population with respiratory failure from influenza on top of the normal demands of routine care. As part of our professional duty to care for our patients, we have a duty to plan for disasters to optimize our ability to continue to provide care and a duty to use scarce medical resources wisely.

Advanced planning and development of tools such as triage polices can ensure that if there is a need to ration the allocation of mechanical ventilators, it will be done in a just, transparent manner promoting the interests of the community and not unfairly limiting access to care.

The New York State Task Force on Life and The Law has issued guidelines for the allocation of mechanical ventilators in this scenario. The allocation guidelines are based exclusively on objective clinical criteria with a limited set of exclusion criteria. The guidelines are designed to promote equality of access and fairness of opportunity while remaining flexible enough to adapt to new information that may emerge during the pandemic. While compliance with these guidelines is voluntary, they do provide a solid framework for institutions to develop their own policies.

While ventilator allocation will be a critical issue in an influenza pandemic, many other factors will also play an important role in providing for critical care patients and ensuring that those who do require ventilator support can receive it. Hospitals must ensure adequate staffing, not only of clinical staff but support staff as well and all staff should receive annual pandemic response training to promote readiness.

The availability of other supplies such as disposable equipment and personal protective equipment or even physical space to house ventilator patients also need to be included in pandemic planning.

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