

Critical Care During a Pandemic

Final report of the Ontario Health Plan for an Influenza Pandemic (OHPIP)

Working Group on Adult Critical Care Admission, Discharge and Triage Criteria



April 2006

Acknowledgements:

This report reflects the work of many skilled and dedicated individuals who worked tirelessly over the past two years while dealing with a subject that can be both intellectually and emotionally challenging. We would like to thank the panel of experts (appendix 1) who participated in the retreat to finalize the draft protocol. The group also thanks the OHPIP steering committee, the Emergency Management Unit and the Critical Care Transformation team for their support and encouragement. Finally, we wish to recognize the leadership and foresight of the Hon. George Smitherman, Minister of Health and Long-Term Care in recognizing the importance of working to prepare Ontario to respond to an influenza pandemic, and for encouraging planners to tackle difficult issues in order to produce a plan that will serve as an example internationally.

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Introduction

At the outset it is essential to state three key principles which underpin the foundations of this report, and triage in particular. First, a triage protocol for critical care is not aimed at deciding who will or will not receive care. All patients will be cared for. Every human life is valued and every human being deserves respect, caring and compassion. However, this does not mean that all patients will or should receive critical care. Those who do not receive critical care will not be abandoned; rather they will continue to be cared for with alternative levels of care. The second important principle is that triage does not challenge or contravene ethical doctrine. In fact, triage is the application of ethics in a very practical manner. Effective triage will ensure that fairness and justice prevail during a time when circumstances would leave people vulnerable to inequitable treatment. A thoughtful and carefully implemented triage protocol is based on clear and transparent criteria and can protect individuals from any inequities. Finally, in a resource-rich country such as Canada, the type of triage described below is only ethically, legally and morally justifiable in an overwhelming crisis, such as an influenza pandemic, when all available resources are in danger of becoming exhausted. This protocol **should not** be viewed as a first step toward any type of resource rationing under ordinary circumstances. It is to be used only in genuinely extraordinary situations.

This report will begin by providing a brief perspective on the need for triage during a pandemic. A discussion pertaining to the general critical care response will follow in order to provide context for the role of triage. Next, background regarding triage will be discussed before outlining the draft protocol proposed by the working group. A detailed explanation of the rationale used to support the protocol will also be provided. Finally, the working group will offer recommendations to the Ontario Health Plan for an Influenza Pandemic [OHPIP] steering committee and Ministry of Health and Long-Term Care [MOHLTC] regarding next steps to finalize and operationalize this protocol.

The Pandemic Perspective

As outlined in the OHPIP¹, the Canadian Pandemic Influenza Plan² [CPIP] and the medical literature^(1;2), health care resources will be overwhelmed during an influenza pandemic. Estimates vary widely as to what the true impact may be. For the purpose of pandemic triage surge capacity planning the 'Flu Surge' model³ was used assuming a 35% attack rate over 6 weeks. This results in a higher peak patient volume than with an 8 week model used when planning for a sustained response. Using the current statistics for the Ontario population, hospital capacity and intensive care unit [ICU] resources, a 6 week model predicts that hospital admissions in Ontario for patients with influenza will peak at 1 823 per day. This translates to 72% of the total hospital capacity being utilized by influenza patients. Similarly, the demand for ICU resources will peak at 171% of current existing ICU bed capacity and 118% of the current ventilator capacity solely for patients with influenza. When considering these statistics, as overwhelming as they are, one does not have a true appreciation of the gravity of the situation without also considering the current day-to-day ICU utilization rates which is over 90%⁴.

It is also important to note that 'Flu Surge' does not take into account reductions in hospital capacity due to illnesses among health care workers. Although there is a limited ability to increase the amount of ICU resources available during a pandemic, they will be insufficient to meet these increase demands on the system. These dramatic but plausible predictions highlight the need to have strategies that will optimize Ontario's Critical Care system to meet the needs of the public during an influenza pandemic.

¹ Ontario Health Pandemic Influenza Plan, May 2004, pg 6 & 10.

² Canadian Pandemic Influenza Plan, February 2004, pg 18.

http://www.health.gov.on.ca/english/providers/program/emu/pan_flu/flusurge.html

⁴ Final Report of The Ontario Critical Care Steering Committee, March 2005.

The CPIP does not provide guidelines for admission to critical care units. The CPIP simply states:

“Management of patients in the ICU will be similar to interpandemic influenza care. The clinical presentation of the disease and the availability of resources will determine which changes may be desirable throughout the pandemic..”⁵

Further, the CPIP does not provide specific guidance with regard to the allocation of scarce resources:

“Prioritization of health resources at times of critical shortages will also need to be considered. Local community-based centers and hospitals need to take a multi-disciplinary approach and include ethical and legal considerations when developing any prioritization processes. If supplies, equipment, and access to intensive care must be rationed, a fair and equitable prioritization process will need to be established.”⁶

Pandemic plans developed for other jurisdictions^{7,8,9} have also identified the need for developing methods of rationing critical care resources during periods of scarce supply. However, even these plans specifically developed for critical care during an influenza pandemic¹⁰ do not provide guidance with respect to triage.

In December 2004, the OHPIP Operations Subcommittee convened a meeting to discuss the allocation of scarce critical care resources,

especially ventilators, during an influenza pandemic. A decision was made to strike a working group of clinicians from the critical care field to explore this issue. Dr Michael Christian was assigned as project lead for the “Adult Critical Care A/D/T Working Group”, comprised of members as listed above. The working group assessed a broad range of issues related to critical care during a pandemic, made recommendations to the OHPIP Steering Committee, and identified future activities for the working group in their interim report (dated April 19, 2005).

⁵ Canadian Pandemic Influenza Plan, February 2004, pg 297.

⁶ Canadian Pandemic Influenza Plan, February 2004, pg 354.

⁷ A Model Plan for Influenza Pandemic Preparedness Version 3.1, September 2001, Ireland.

⁸ Australian Action Plan for Pandemic Influenza, October 2003.

⁹ UK Health Departments’ Influenza pandemic contingency plan, March 2005.

¹⁰ Australian and New Zealand Intensive Care Society Influenza Pandemic Planning for ICU, August 2001.

Recommendations of the Working Group:

- The OHPIP steering committee adopt the ethical framework by Sunnybrook & Women's College Health Sciences Centre Clinical Ethics Centre The Joint Centre for Bioethics "Ethics in a Pandemic Influenza Crisis: Framework for Decision-Making" and use this to guide the development of protocols pertaining to triage and resource allocation during a pandemic.
- The operations subcommittee appoint members and alternatives to a triage advisory committee who will form the central triage advisory committee during a pandemic and assist with the development of triage guidelines prior to a pandemic. This committee will have to be appropriately resourced to allow necessary training and preparation.
- The MOHLTC along with the OHPIP steering committee ensure that the infrastructure requirements for effective triage exist or are developed including processes for data collection and analysis of clinical information about the infection, monitoring of resource availability, and communications.
- The MOHLTC embark on an effort to recruit and train physicians in all communities who may serve as triage officers during mass casualty events or a pandemic. These activities may be partnered with other emergency preparedness resources such as the Emergency Medical Assistance Team [EMAT] or the initiative to improve chemical, biological, radiation and nuclear [CBRN] preparedness.
- A review of legislation and the legal issues related to triage in a civilian health care system be completed and reported back to the OHPIP steering committee.
- The communications subcommittee develop a communications strategy to inform the public about issues related to the management of scarce resources during a pandemic.
- Ensure that a working group is struck to develop management guidelines for palliative care.
- Once critical care triage protocols have been finalized, they should be tested in a pandemic exercise following pilot testing with focus groups of critical care physicians from both the community and academic ICUs
- The potential role of Critical in the centralized triage system should be explored.
- A retreat should be sponsored to facilitate the development of the critical care triage tool.

Future Actions of the A/D/T Working Groups:

- Assist with the development of a tool for triaging critical care resources during a pandemic, including the development of inclusion, exclusion, and Minimum Qualifications for Survival [MQS] criteria.
- Assist the OHPIP Operations Subcommittee in further developing a proposed system for centralized triage during a pandemic including identifying the required infrastructure necessary to operationalize the system.
- Assist the operations subcommittee in identifying the requirements for training triage officers and identify potential resources for conducting such training.

Many of the recommendations of the working group were incorporated into the 2005 iteration of the OHPIP. The discussion below describes the working groups activities related to triage.

Critical Care Response During A Pandemic In Context

During a pandemic, as with any large emergency, a series of strategies such as code orange protocols and mass critical care will be employed in an attempt to build surge capacity (figure 1). However unlike virtually any other emergency that has struck North America in the past century, these strategies alone will quickly fall far short of the ability to deal with the numbers of patients who will seek care during a pandemic. Consequently, difficult decisions will have to be made about how best to prioritize scarce resources to maximize the benefit of these resources for the community as a whole. This process is called ‘triage’, and will be explored in detail in the next section of this report. First, however, it is important to understand other strategies that must be employed to maximize system capacity.

The first response to any anticipated demand on a hospital that will exceed its ability to provide care

for patients through routine operations should be to implement an external disaster or “code orange” protocol. Most code orange protocols include a series of strategies (figure 1) that work in concert to provide short-term surge capacity and operate on an incident management system [IMS](3). Some but not all of these strategies will be applicable during a pandemic because dealing with an influenza pandemic is not a matter of short-term surge capacity, but rather long-term sustainability. For example, in other types of emergencies one of the fastest ways to increase human resources is to hold back a shift from going home, thereby immediately doubling staff complement. In a pandemic that will last several months, this type of strategy will not be feasible. However, other human resources strategies will be useful in a pandemic many of which are described in the OHPIP. Examples include calling back retired staff, or identifying and redeploying to the ICU staff who previously worked in critical care, but who have subsequently moved to other departments.

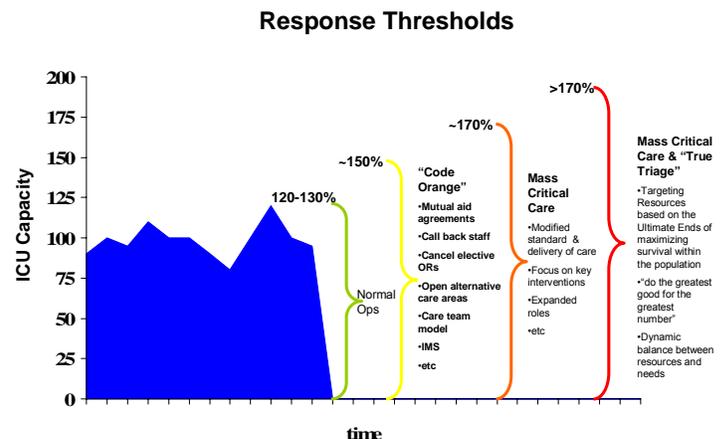


Figure 1

a prolonged emergency impacts on the broader health care system, and beyond. Therefore during a pandemic, elective and non-emergent services will have to be scaled back to increase capacity in a systematic fashion. This will require a coordinated approach between hospitals and community-health sectors, to provide for a full spectrum of services with reduced capacity, but sufficient to address the urgent needs of the population.

Scaling back elective services and surgeries frees up areas in hospitals such as surgical intensive care units, endoscopic units, step-down units and

post anaesthetic care units [PACU] that are well equipped to provide critical care for critically ill influenza and non-influenza patients. How much critical care capacity can be increased will depend largely on the availability of ventilators, and personnel skilled in managing critically ill patients. Additional personnel can be realized through scale-back of elective and non-urgent services – skills these HCWs poses may not have previously been applied to critical care but may be readily transferable to critical care. This later group has significant potential for increasing critical care capacity when a care team model is applied (figure 2). In this model, health care workers [HCWs] who have useful skills but lack experience in a specific area can work in teams supervised by those with the relevant experience. Instead of individual HCWs caring for one or two patients, a team of HCWs, who amongst them possess a complete skill set and relevant experience, collectively care for a group of patients. As an example, in this model, a team composed of 2 ICU nurses supervising 3 step-down nurses working in conjunction with a respiratory therapist and a physician could care for 8 to 10 patients. This versus the traditional staff compliment of 1:1 or 1:2 ratio of critical care nurses, for example 4 ICU nurses caring for 5 ventilated patients.. The use of care teams has proven to be effective in past emergencies(5;6).

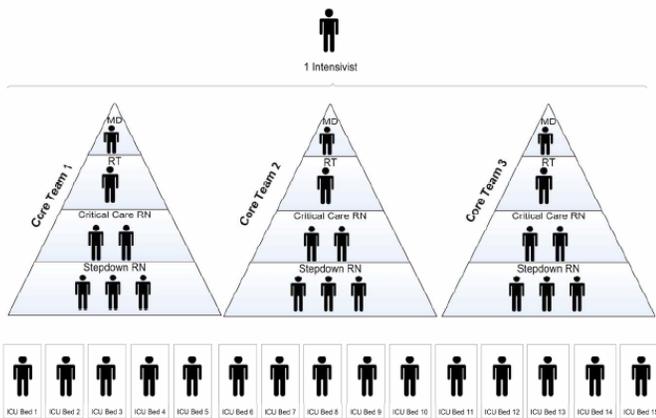


Figure 2

If after all efforts to expand capacity, demands still exceed available capacity, the type of care being provided must be altered to focus on key interventions (table 1). This model of care is referred to as mass critical care(7;8). Mass critical care is aimed at ensuring resources are targeted to optimize both the effectiveness and efficiency of resource utilization including both supplies and

manpower. Only after all of the above strategies have been employed to maximize system capacity is it reasonable to implement the triage strategies outlined in the next section.

Key critical care interventions:	
•	Basic modes of ventilation
•	Hemodynamic support
•	Antibiotics
•	Disease specific countermeasures
–	ie/ thrombolysis
•	Prophylaxis
–	ie/ DVT

Table 1

Triage Overview

During a disaster, including a pandemic, surge capacity may be maximized and despite the implementation of mass critical care, resource scarcities will still occur. In such situations it is necessary, and in fact mandated by international law(9-11), to utilize methods for allocating resources that are both equitable and maximize the benefit to the population at large(6). Such methods are referred to as ‘triage’, not to be confused with the prioritization “triage” systems(12) used in emergency departments on a routine basis(13). To differentiate between the two, the term ‘TRUE Triage’ or ‘Targeting Resources to achieve Ultimate Ends’ has been suggested (work In Press, M. Christian). The original concept of ‘triage’ was developed during wartime(11) where scarce resources were used to provide the maximum benefit to the population at large, even if it meant that individual victims who might have been saved under other circumstances could not be treated optimally(13;14). Triage must be based upon established medical criteria, not factors such as socioeconomic status or political affiliation, and represents a dynamic balance between resource availability versus demand(13).

Further, human rights, humanitarian laws(10) and strict adherence to ethical practices, such as transparency and accountability must be observed when triage protocols are being developed(8). Health care providers practicing in an emergency have to balance the needs of individuals with the responsibility they also have to all others in the community as guardians of important resources.

In short, the primary goal of triage is to be able to “do the greatest good, for the greatest number”(13). A full exploration of the ethical issues related to triage can be found in the literature(9;11) as well as the framework included in the Ontario Health Pandemic Influenza Plan [OHPIP](15) and the report produced by the Joint Centre for Bioethics¹¹. Further discussion of the ethical implications of a triage protocol for use during a pandemic will be discussed below.

Unfortunately, no triage systems have been developed for use in critical care or medical illnesses. Illness severity scoring systems(16-18) currently used in critical care research have reasonable abilities to predict ICU outcome, but they are cumbersome to use and therefore particularly impractical for use during a disaster when human resources are scarce. Further, although validated for predicting outcome, they have not been validated for guiding, or more specifically restricting, treatment. Military triage systems(19-21) are good only as a model for critical care triage since they were devised specifically for trauma and not medical conditions or biological events. The ‘SEIRV’ triage system was developed for use in bioterrorism attacks and is used to categorize patients as susceptible, exposed, infectious, removed and vaccinated [SEIRV] (22). Although a very robust system which provides many lessons that can and should be applied to the overall response to bioevents, it does not address issues dealing with resource allocation and has limited applicability during a pandemic where the virus is ubiquitous in the community. The SERVI system uses inclusion, exclusion and minimum qualifications for survival [MQS] to guide triage decisions. These should also be used in all critical care triage systems.

Accurate triage is critical to maximize survival. Triageing patients inappropriately to critical care is called “over-triage”(13). Over-triage results in inappropriate resource expenditures. Frykberg showed that over-triage of patients involved in

¹¹ Stand On Guard For Thee: Ethical considerations in preparedness planning for pandemic influenza. University of Toronto Joint Centre for Bioethics Pandemic Influenza Working Group. November 2005. <http://www.utoronto.ca/jcb/home/documents/pandemic.pdf>

terrorist bombings is directly related to overall increased mortality rates. Real-time data about patient outcomes during a disaster is required to allow modification of the triage criteria in order to prevent under or over triage. Another possible mechanism to fine tune triage criteria is to use computer modeling based on databases of patients with similar illnesses (ie/ influenza) from non-bioevent occurrences. The utility of such modeling was demonstrated by Dr Garner and his colleagues during their work on trauma triage guidelines(23).

Developing A Triage Protocol For a Pandemic

The Critical Care A/D/T working group reviewed the medical literature to identify potential triage systems that could be modified for use during an influenza pandemic. Unfortunately, no triage systems have been developed for use in critical care or medical illnesses. However, the Sequential Organ Failure Assessment score [SOFA](24) was identified by the working group as potentially having utility for inclusion as a component of a triage tool. The SOFA score has not been used for the rationing of critical care resources but it was designed with this in mind(24). Additional benefits of the SOFA score is that it is not disease specific but rather uses general physiologic parameters applicable to a wide variety of conditions. Further, the scale has been validated on a wide range of patients with various reasons for being in critical care. Thus it has better applicability during a pandemic when it will be applied to all critical care patients as opposed to disease specific scoring systems. Preliminary drafts of this proposed tool were developed and included in 2nd iteration of the OHPIP.

In addition to reviewing the scoring systems currently employed in critical care units, the working group also reviewed triage systems used by the Canadian Military, US Military and in the pre-hospital field(19-21). For the reasons discussed above, these were felt to be good models upon which to design a critical care triage system. The working group developed an early prototype triage protocol which was discussed in the 2005 OHPIP. In January of 2006 a retreat was held with experts from across the province to provide comment on the prototype which was incorporated by the working group to yield the draft presented below.

Draft Triage Protocol and Rationale

The draft protocol being recommended to the OHPIP steering committee for broader consultation is detailed in Appendix I. It is not possible to develop a perfect triage protocol in advance of the pandemic as many factors are unknown and unpredictable at this point. The current protocol is not able to take into account the natural history of a yet unknown pandemic strain of influenza, nor can it predict which groups are more or less likely to have poor outcomes. Further, given that triage is a dynamic process dependant on both the demands and availability of resources, the protocol will have to evolve over time. The primary goal of the current protocol is to provide a starting point. This protocol is intended to provide guidance for making triage decisions during the first days to weeks of a pandemic, following which a cycle of evaluating the supply/demand balance and triage outcomes – then modifying the protocols – will be required.

Although this is referred to as a triage protocol for use during a pandemic, it must be noted that the triage protocols apply to all patients who are being considered for admission to critical care, since there is only a single pool of critical care resources that must be shared by both those with and without influenza. Patients should be triaged when the physician or HCW attending to them believes that they meet the inclusion criteria for ICU. If the patient is not at a centre with critical care services, they should be triaged remotely prior to transfer to a critical care centre to minimize unnecessary transfers if the patient does not meet the criteria for admission to the ICU, or meets the exclusion criteria.

The triage protocol has three main components. The first component is the inclusion criteria. Broadly speaking these criteria identify patients who may potentially benefit from admission to critical care. The inclusion criteria primarily focus on respiratory failure given that the ability to provide ventilatory support is fundamentally what differentiates the ICU from other acute care areas such as step-down units, etc. With expanded care models developed as part of the surge capacity response it is anticipated that hemodynamic support and other advanced care modalities will be provided in areas that have appropriate monitoring but don't typically provide that level of

care. However, should hemodynamic support not be available elsewhere, it will qualify as an inclusion criteria.

The second component is the exclusion criteria which can be broken down into 3 categories: 1) people who currently have a very poor prognosis/chance of survival even when treated aggressively in an ICU, 2) people who will need a level of resource that simply cannot be met during a Pandemic situation and 3) those with underlying significant and advanced medical illnesses whose underlying illness has a poor prognosis with high short-term mortality even without their current concomitant critical illness. The first category identifies patients who have a low probability of recovery or overall poor prognosis irrespective of the amount of resources dedicated to their care. Essentially these are the 'hard' boundaries that many intensivists recognize from their day-to-day care of patients. For example, severe burns with two or more high risk factors have a significant mortality risk(25). Cardiac arrest patients who have unwitnessed or recurrent arrests and those who do not respond to prompt electrical interventions such as defibrillation or cardiac pacing, require significant resources but rarely survive to discharge(26). Finally, those patients with a SOFA score of > 11 have a mortality rate in excess of 90% even with full critical care during a normal period. It must be remembered that during a pandemic mass critical care will be performed focusing only on key interventions likely resulting in at least equivalent if not higher mortality rates then seen in studies validating the SOFA score.

Some people *may* benefit from ICU care during a normal period, yet these benefits are achieved with an intense use of resources and often prolonged care. During a pandemic, with a triage goal of doing the most for the most, such intense consumption of resources will need to be limited. Patients requiring large volume blood transfusions have, at this time, been listed as an exclusion criteria, as many conditions requiring large transfusion are often associated with high mortality rates. Further, the availability of blood products may be limited if we cannot identify "clean" or uninfected potential donors and therefore turn donors away out of fears of infecting others through blood transfusions. Hence, the availability of blood during a pandemic remains uncertain at this point.

The third cluster of exclusion criteria include patients such as those with advanced cancer or immunosuppression who have very high resource requirements and are likely to suffer significant complications from influenza among other infections. Others in this cluster of exclusion criteria are those patients who have end stage organ failure involving their heart, liver or lungs. The cut offs selected here are adopted from the transplant literature(27;28)¹². These cut offs typically represent a mortality of >50% within the next one to two years as the baseline natural history of their organ failure. Given that transplantation is unlikely during a pandemic, combined with the cumulative mortality risk from their acute illness requiring critical care, these patients again fall into a category when considerable resources would have to be expended with an overall low probability of survival.

The final aspect of the triage protocol deals with the “minimum qualifications for survival” [MQS]. This term is also borrowed from military triage protocols and represents a ceiling on the amount of resources that can be expended on any one individual. Again this is a concept very foreign to western medical systems but has been required in war zones and refugee camps. An illustrative example can be drawn from these fields to better explain the concept. In a drought situation in a refugee camp, physicians are often faced with many patients who have dehydration, but at the same time have a very limited supply of saline solution to treat patients. When faced with a severely dehydrated patient on the verge of cardiovascular collapse and volume resuscitation is being provided, such a patient often require liters and liters (possibly 10 or more liters) of fluid to attempt to reverse the hypovolemic shock, which often in the end is not possible to do. Continuing to treat such a patient means that 5 or 10 other patients with early hypovolemia who could have been saved with 1 – 2 liters of iv fluid will in turn also succumb to dehydration because the iv fluids were all used in a failed attempt to save a single individual. The alternative is to place a ceiling on the amount of resources that

¹² National Protocol For Assessment Of Cardiothoracic Transplant Patients. March 2002. Prepared by the UKT Cardiothoracic Advisory Group. A special health authority of the national health service. UK Transplant, Fox Den Road, Stoke Gifford, BRISTOL, BS34 8RR

will be allocated to anyone individual to ensure that the maximum potential benefit of the available resources can be realized and a larger number of people overall can be saved.

This situation, unfortunately, is not all that different from what we would likely face in critical care units during a pandemic. Thus, the suggested triage protocol includes MQS that dictate reassessment at 48 and 120 hours as well as an ongoing ceiling if a patient ever develops a SOFA score of ≥ 11 or any other exclusion criteria. The key component of the MQS is its attempt to identify early those patients who are not improving and are likely to have a poor outcome. Often in day-to-day practice, this poor outcome isn't realized until several days or weeks of intensive care have been invested in the patient. Clearly in a pandemic, when resources are scarce, this is a less-than-ideal situation, thus necessitating the MQS.

The final component of the triage protocol is the prioritization of patients for potential admission to the ICU and ventilation. For ease of use, the common blue/red/yellow/green colour scheme was used.

- ✚ **Blue** patients are those who fall in to the expectant category and should not receive critical care. Depending on their condition and medical issues the patient may either continue to have curative medical care on a ward or palliative care.
- ✚ **Red** patients are highest priority for ICU admission and a ventilator if required. In selecting the patients who will fit into this category the aim was to find the balance between those who are sick enough to require the resource and will do poorly if they don't receive it, but are not so sick that they are unlikely to recover even if they do receive the care. Patients with a single organ failure, particularly those with respiratory failure due to influenza and who otherwise have a very low SOFA score are also included in the red category assuming they have no exclusion criteria. The goal is to optimize the effectiveness of the triage protocol so that every patient who receives resources will survive. Clearly this an idealistic endpoint that is not likely to be achieved with 100%

success, but it will be used as a target to guide how the triage protocol will be modified by monitoring patient outcomes during the pandemic.

Yellow patients are those who at baseline are very sick and may or may not benefit from critical care. They should receive care if the resources are available but not at the expense of denying care to someone in the red category who is more likely to recover. At the re-assessment points, patients who are improving are given high priority (red) for continued care, while those who are not showing signs of improvement or worsening are prioritized as yellow.

Green patients are essentially those who should be considered for transfer out of the ICU.

Ethics Considerations

The work of this group to produce this draft triage protocol was guided by the ethics framework included in the 2005 iteration of the OHPIP as well as the more recent report “Stand On Guard For Thee: Ethical considerations in preparedness planning for pandemic influenza”¹³ from the Joint Centre for Bioethics [JCB] in addition to the members of the JCB who sat on the working group. In their report “Stand on guard for thee” the JCB outline 10 substantive and 5 procedural values that should guide decision making regarding for an influenza pandemic (see table 2). This section of the report will discuss each of the applicable values and detail how the protocol embodies them. In each case the description from the JCB report will be provided in italics followed by commentary pertaining to the protocol.

¹³ Stand On Guard For Thee: Ethical considerations in preparedness planning for pandemic influenza. University of Toronto Joint Centre for Bioethics Pandemic Influenza Working Group. November 2005. <http://www.utoronto.ca/jcb/home/documents/pandemic.pdf>

Values To Guide Ethical Decision-Making For A Pandemic Influenza Outbreak	
Substantive	Procedural
<ul style="list-style-type: none"> • Individual Liberty • Protection of the public from harm • Proportionality • Privacy • Duty to provide care • Reciprocity • Equity • Trust • Solidarity • Stewardship 	<ul style="list-style-type: none"> • Reasonable • Open and transparent • Inclusive • Responsive • Accountable

Table 2

Individual Liberty:

“In a public health crisis, restrictions to individual liberty may be necessary to protect the public from serious harm. Restrictions to individual liberty should: be proportional, necessary, and relevant; employ the least restrictive means; and be applied equitably.”

Clearly the triage protocol is a restriction of the liberty currently enjoyed by individuals in our society to access care. However, this restriction is felt by the working group to be necessary in order to serve the public as a whole and protect the greater public from the potential harm of unnecessary deaths due to inappropriate utilization of resources. The protocol is proportional in that it is flexible based on the available resources (ie/ ‘yellow’ patients will have access if the resources are available) and mandating reassessments of triage status. Similarly, it is to be used only when necessary, and is equitable in that it applies to all patients being considered for admission to ICU.

Equity:

“All patients have an equal claim to receive the health care they need under normal conditions. During a pandemic, difficult decisions will need to be made about which health services to maintain and which to defer. Depending on the severity of the health crisis, this could curtail not only elective surgeries, but could also limit the provision of emergency or necessary services.”

This value speaks to the core necessity for developing a triage protocol in the first place. A triage protocol assists in fairly distributing resources by preventing a few sick patients early

in the pandemic from consuming all of the resources, thus denying other equally needy patients who follow. While it may be unfortunate that some patients do not receive all that they need, this does not by default make it unfair.

Trust:

“Trust is an essential component of the relationships among clinicians and patients, staff and their organizations, the public and health care providers or organizations, and among organizations within a health system. Decision makers will be confronted with the challenge of maintaining stakeholder trust while simultaneously implementing various control measures during an evolving health crisis. Trust is enhanced by upholding such process values as transparency.”

The triage protocol helps to engender the trust of the public in several ways. Firstly it is being established by experts in the field well in advance of a pandemic with time for thoughtful contemplation and participation. The process is based on relevant criteria derived from the currently known best evidence available in the medical literature. It has been developed in a transparent manner openly acknowledging its limitations and with plans for revision as information becomes available regarding prognostic factors/survival and resource availability in an pandemic. An appeals/review of decision-making process is also incorporated into the triage plan as described below. The triage plan’s details will in the end be informed by broad consultation and will be made public.

Solidarity:

“As the world learned from SARS, a pandemic influenza outbreak, will require a new vision of global solidarity and a vision of solidarity among nations. A pandemic can challenge conventional ideas of national sovereignty, security or territoriality. It also requires solidarity within and among health care institutions. It calls for collaborative approaches that set aside traditional values of self-interest or territoriality among health care professionals, services, or institutions.”

The triage protocol will be implemented across all hospitals and monitored via a central triage agency. This will help to ensure a consistent application of the protocol. The development of the protocol has been collaborative with clinicians

from a variety of fields beyond critical care, as well as various levels of care providers.

Stewardship:

“Those entrusted with governance roles should be guided by the notion of stewardship. Inherent in stewardship are the notions of trust, ethical behaviour, and good decision-making. This implies that decisions regarding resources are intended to achieve the best patient health and public health outcomes given the unique circumstances of the influenza crisis.”

The committee has striven to uphold this fundamental notion as it has developed the triage plan. A comprehensive triage plan is essential to achieve ethical stewardship in the midst of the chaos of a pandemic. The motivation for developing this triage protocol and the objectives of it align very well with those described above.

Reasonable:

“Decisions should be based on reasons (i.e., evidence, principles, and values) that stakeholders can agree are relevant to meeting health needs in a pandemic influenza crisis. The decisions should be made by people who are credible and accountable.”

Every effort has been made to base the triage protocol on sound science wherever any relevant data exists. The criteria developed for inclusion and exclusion have been reviewed by a wide range of clinicians and have been found to have face validity. That is, they are consistent with current medical literature and the clinical experience of those who have reviewed the protocol. Finally, in terms of credible and accountable decision making, it is recommended that there be a central triage committee with significant knowledge and experience in triage as well as having trained triage officers applying the protocol in the field. The triage officers would be accountable back to the central triage committee.

Open and transparent:

“The process by which decisions are made must be open to scrutiny, and the basis upon which decisions are made should be publicly accessible”.

The triage protocol will be opened to public comment and publicized both in the OHPIP as well as in the peer reviewed medical literature. It is recommended by the working group that the Ministry not only include discussion of the protocol during media interviews about the OHPIP, but that they actively work to educate and inform the public both about the need for triage and the types of changes patients can expect in the delivery of health care during a pandemic.

Inclusive:

“Decisions should be made explicitly with stakeholder views in mind, and there should be opportunities to engage stakeholders in the decision-making process.”

As discussed above, the recommendation of the working group is to take this draft protocol forward to further consultation with the public and other stakeholder consultations. As part of the current process, broader critical care input is currently being sought.

Responsive:

“There should be opportunities to revisit and revise decisions as new information emerges throughout the crisis. There should be mechanisms to address disputes and complaints.”

The triage protocol incorporates a process to review and revise based on new knowledge that will arise during the pandemic and on resources supply/demand. In addition, it importantly incorporates an appeal process. The working group recommends that the central triage committee be formed to monitor the triage process, revise the protocol throughout the pandemic and address appeals for exceptions from the field. Arrangements should also be made prior to a pandemic to address disputes of triage officers, clinicians or family members with the triage protocol. One possible dispute resolution process is to create an appeals panel consisting of recently retired clinicians with critical care experience and retired judges who can convene using telecommuting technologies to arbitrate and resolve conflicts in a timely manner. All efforts should be made to minimize the need for such appeals through public and health care education regarding the triage protocols and thorough training of the triage officers.

Accountable:

“There should be mechanisms in place to ensure that decision makers are answerable for their actions and inactions. Defense of actions and inactions should be grounded in the 14 other ethical values proposed above.”

The first step in ensuring accountability is to ensure that the triage protocols are defensible in ethics and law. Thus, the working group recommends that a legal opinion be obtained from the Attorney General's office regarding the legal standing of these triage protocols prior to a pandemic. Subsequently, once the triage protocols themselves have been found to meet the standard of law, physicians who apply them will be accountable to their College in the same manner as any other circumstance. The standard against which clinicians should be judged is that of what any other reasonable physician would do in the same circumstance. The difficulty in this, however, is that since a pandemic is a very unique circumstance, it may be difficult to determine the standard of care.

Recommendations for Operationalization and Next Steps

Effective triage depends on an established, skilled and practiced infrastructure. Implementing a new infrastructure in the middle of a major disaster is a recipe for failure. Therefore, the working group recommends that the infrastructure required for critical care triage during a pandemic be integrated with and be built upon the foundation for surge capacity that is going to be developed by the critical care transformation team lead by Dr Tom Stewart. The working group feels that this will create the optimum conditions for success and strengthen both initiatives. This approach is also the most cost effective approach. In the remainder of this section, the specific infrastructure that is required for critical care triage during a pandemic will outlined as well as the next steps in the development process recommended by the working group.

Triage Officers:

The type of triage proposed in this report is challenging both clinically and psychologically. Therefore it is essential that proper training be

provided prior to a pandemic with ongoing support provided throughout the pandemic. Prior experience shows that the best triage decisions are made by senior physicians who have training in triage and significant clinical experience to draw upon. During a pandemic when resources are scarce it may not be possible to meet this ideal. Although in most circumstances it will be necessary to have a triage officer assess patients in person, mechanisms should also be developed to assist less senior or experienced physicians by making available access to more senior/experienced triage officers to provide advice. Building upon existing infrastructure such as the 'NorthNetwork' and 'Telestroke' should be considered to facilitate this. Further, very clear and well funded processes need to be in place to support triage officers to deal with the significant psychological stress we anticipate will be associated with performing this function.

Central Triage Committee:

While the triage protocol has been designed for ease of use in the field during a pandemic, ongoing modifications will need to be made to the protocol as the pandemic evolves. Such modifications however are complex and require the analysis of a large amount of data and therefore are not amenable to individual triage officers doing this in the field. Further, if individual triage officers began modifying their protocols independently, equity, trust, solidarity and reasonableness are all at risk of being compromised. Thus it is necessary to have a central committee who are very familiar with triage protocol development to oversee triage during the pandemic. Through their triage officers in the field, the triage committee must have absolute command and control over the critical care resources in order to ensure accountability.

Intelligence:

Good triage must be based on good information. A wide variety of information including the demands on the system, resource availability, natural history of influenza and patient outcomes in critical care are all important to enable appropriate triage decisions to be made. Thus it will be necessary to ensure that the central triage

committee has real time access to the necessary system and epidemiologic data.

Communications Network:

In order to efficiently implement the triage protocols there must be an efficient communications network that allows two-way communications between the "field" and the command centre. This should allow for the flow of data up to the central triage committee as well as new directives and advice down to the field. Given that such infrastructure does not currently exist, the province needs to invest in technology that would allow reliable communication with and between triage officials given that delays in communication may lead to under- or over-triage.

Protocol Activation:

Knowing when to 'pull the trigger' or activate a system is a challenge in any emergency. This task becomes even more challenging when an event is dynamic (evolving over time) rather than static (a single point in time). A pandemic is the extreme of a dynamic event as it may evolve over months. Therefore knowing when to implement the triage protocol will be a particular challenge. However, the same is true of knowing when to implement surge capacity strategies, mass critical care or any of the other pandemic response programmes. If the triage protocol is implemented too late, many resources will be utilized by a few patients early in the pandemic. In addition, the ICUs may quickly become 'gridlocked' with patients. However, given the implications of being declined for ICU admission, implementing the protocol too early also carries with it significant consequences for individual patients. The quality of the decision will depend on the availability of accurate information regarding resource availability and the epidemiology of the pandemic.

Answering the question when to activate the triage protocol, however, is only half the question. The second consideration is how to implement the protocol. Given that a pandemic is a dynamic event that evolves over time, one approach would be to implement the protocol in a gradual fashion, particularly if only a gradual influx of cases initially. This could be accomplished in two ways. First,

the breadth of the exclusion criteria could be expanded in a graded manner. Secondly, the protocol could be applied to new patients who are being considered for admission as opposed to applying the protocol to those already admitted to the ICU at the time the pandemic begins. However, should there be a rapid influx of patients requiring critical care, it may be necessary to apply the protocol 'retroactively' to patients already admitted to the ICU. In either case, this is one area of triage that still requires further discussion prior to a pandemic.

Next steps:

The immediate next steps recommended by the working group are:

1. Obtain a legal opinion regarding the triage protocol from the Attorney General of Ontario
2. Broader consultation within the health community
3. Educate the public regarding the need for triage during a pandemic, and seek public input regarding the draft triage protocol
4. Design and document a concrete plan with the Critical Care Transformation Team as to how the required infrastructure will be developed.

Conclusions

A tremendous amount of time, energy and consideration has been invested in developing a triage protocol to assist in critical care resource allocation during the first days to weeks of a pandemic. This is a starting point for the ongoing work that will have to be done during a pandemic. Every effort was made to ensure that this protocol not only conforms with but embodies the ethical framework endorsed by the OHPIP.

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- - Appendix I - -

Triage Retreat Participants
January 6, 2006

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- - Appendix II - -

Critical Care Pandemic Triage Protocol

Any patient requested to be assessed for possible admission/transfer to critical care will undergo the following steps in assessment:

- Step 1: Assess to see if patient meets inclusion criteria
 - If patient meets inclusion criteria proceed to Step 2
 - If patient does NOT meet inclusion criteria reassess patient in future if there is a deterioration in clinical status
- Step 2: Assess for exclusion criteria
 - If no exclusion criteria proceed to Step 3
 - If exclusion criteria PRESENT 'Blue tag' patient, do not transfer to critical care. Continue current level of care or palliate as indicated (see palliative care guidelines)
- Step 3: Proceed to triage tool, 'Initial Assessment'

*Note: This triage protocol applies to **ALL** patients undergoing assessment for possible admission/transfer to critical care.*

Inclusion Criteria

The patient must have 1 of criteria A or B

- A) Requirement for invasive ventilatory support:
- Refractory Hypoxemia (SpO₂ < 90% on non-rebreather mask/ FiO₂ > 0.85)
 - Respiratory Acidosis with pH < 7.2
 - Clinical evidence of impending respiratory failure
 - Inability to protect or maintain airway
- B) Hypotension:
- Hypotension (SBP < 90 or relative hypotension) with clinical evidence of shock (altered level of consciousness, decreased urine output, or other end organ failure) refractory to volume resuscitation requiring vasopressor/inotrope support that cannot be managed on the ward.

Exclusion Criteria

The patient is excluded from admission/transfer to Critical Care if **ANY** of the following are present:

- Severe trauma (*needs to define further*)
- Severe burns
 - A patient with any two of the following:
 - i. Age > 60 years old
 - ii. TBSA > 40%
 - iii. Inhalation injury
- Cardiac Arrest
 - Unwitnessed cardiac arrest
 - Witness cardiac arrest not responsive to electrical therapy (defibrillation, cardioversion, or pacing)
 - Recurrent cardiac arrest
- Severe cognitive impairment
- Advanced untreatable neuromuscular disease
- Metastatic Malignancy
- Advanced & irreversible immunocompromise
- Severe and irreversible neurologic event/condition
- Endstage organ failure meeting following criteria
 - Cardiac
 - i. NYHA class III or IV heart failure
 - Lung
 - i. COPD with FEV1 < 25% predicted, baseline PaO2 < 55 mmHg, or secondary pulmonary hypertension
 - ii. CF with postbronchodilator FEV1 < 30% or baseline PaO2 < 55 mmHg
 - iii. Pulmonary fibrosis with VC or TLC < 60% predicted, baseline PaO2 < 55, or secondary pulmonary hypertension
 - iv. Primary pulmonary hypertension with NYHA class III – IV heart failure, or right atrial pressure > 10 mmHg, or mean pulmonary arterial pressure of > 50 mmHg
 - Liver
 - i. Child Pugh Score ≥ 7
- Age > 85 years old
- Requirement for transfusion of > 6 units PRBC within 24 hour period
- Elective palliative surgery

SOFA Scale

Variable	0	1	2	3	4
PaO ₂ /FiO ₂ mmHg	>400	≤ 400	≤ 300	≤ 200	≤ 100
Platelets, x 10 ³ /μL (x 10 ⁶ /L)	> 150 (> 150)	≤ 150 (≤ 150)	≤ 100 (≤ 100)	≤ 50 (≤ 50)	≤ 20 (≤ 20)
Bilirubin, mg/dL (μmol/L)	<1.2 (< 20)	1.2-1.9 (20 – 32)	2.0-5.9 (33 – 100)	6.0-11.9 (101 – 203)	>12 (> 203)
Hypotension	None	MABP < 70 mmHg	Dop ≤ 5	Dop > 5, Epi ≤ 0.1, Norepi ≤ 0.1	Dop > 15, Epi > 0.1 Norepi > 0.1
Glasgow Coma Score	15	13 – 14	10 – 12	6 – 9	< 6
Creatinine, mg/dL (μmol/L)	<1.2 (< 106)	1.2-1.9 (106 – 168)	2.0-3.4 (169 – 300)	3.5-4.9 (301 – 433)	>5 (> 434)

*Dopamine [Dop], epinephrine [Epi], norepinephrine [Norepi] doses in ug/kg/min
SI units in brackets*

Adapted from:

Ferreira FL, Bota DP, Bross A, Melot C, Vincent JL. Serial evaluation of the SOFA score to predict outcome in critically ill patients. JAMA 2001; 286(14):1754-1758.

Critical Care Triage Tool (Initial Assessment)		
Colour Code	Criteria	Priority/Action
Blue	<ul style="list-style-type: none"> • Exclusion Criteria* <li style="text-align: center;"><u>or</u> • SOFA > 11* 	Medical Mgmt +/- Palliate & d/c from CC
Red	<ul style="list-style-type: none"> • SOFA ≤ 7 <li style="text-align: center;"><u>or</u> • Single Organ Failure 	Highest
Yellow	<ul style="list-style-type: none"> • SOFA 8 – 11 	Intermediate
Green	<ul style="list-style-type: none"> • No significant organ failure 	Defer or d/c, reassess as needed

* If exclusion criteria or SOFA > 11 occurs at anytime from initial assessment to 48 hours change triage code to Blue and palliate.

CC = critical care

d/c = discharge

Critical Care Triage Tool (48 Hour Assessment)		
Colour Code	Criteria	Priority/Action
Blue	<ul style="list-style-type: none"> • Exclusion Criteria or • SOFA > 11 or • SOFA 8 – 11 no Δ 	Palliate & d/c from CC
Red	<ul style="list-style-type: none"> • SOFA score < 11 and decreasing 	Highest
Yellow	<ul style="list-style-type: none"> • SOFA < 8 no Δ 	Intermediate
Green	<ul style="list-style-type: none"> • No longer ventilator dependant 	d/c from CC

Δ = change
 CC = critical care
 d/c = discharge

Critical Care Triage Tool (120 Hour Assessment)		
Colour Code	Criteria	Priority/Action
Blue	<ul style="list-style-type: none"> • Exclusion Criteria* or • SOFA > 11* or • SOFA < 8 no Δ 	Palliate & d/c from CC
Red	<ul style="list-style-type: none"> • SOFA score < 11 and decreasing progressively 	Highest
Yellow	<ul style="list-style-type: none"> • SOFA < 8 minimal decrease (< 3 point decrease in past 72h) 	Intermediate
Green	<ul style="list-style-type: none"> • No longer ventilator dependant 	d/c from CC

* If exclusion criteria or SOFA > 11 occurs at anytime from 48 – 120 hours change triage code to Blue and palliate.

CC = critical care

d/c = discharge

Appeals/Exemptions

In rare and extenuating circumstances at the point of initial assessment where the triage officer and/or the attending intensivist feels that a patient may be triaged as 'Blue' due to an anomaly of the protocol and all likelihood has a significantly lower mortality the central triage committee should be consulted. In some circumstances a 48 hour trial of care may be authorized at the end of which the patient will be re-triaged according to protocol.