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**Pandemic Part I:
Exclusion Criteria for Critical Care during a Pandemic
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A significant amount of discussion has been generated by the Associated Press' recent story based on a May, 2008 scientific article in *Chest*, a journal for critical care and lung specialist. The AP article was entitled *Pandemic List Suggests Who Lives, Dies*. Even this author was alarmed by the story, imagining recommendations where classes and/or categories of people would be denied healthcare on the basis of a set of rigid, superficial characteristics such as age, mental acuity, gender, race, or others. The article in *Chest* entitled *Definitive Care for the Critically Ill During a disaster: A framework for allocation of scarce resources in Mass Critical Care*, is the work of "a task force for Mass Critical Care Summit Meeting, January 26-27, 2007, Chicago, Illinois."

After reading the entire journal article which prints out to 28-pages, I find there is no reason to be alarmed at the article but only at the potential pandemic it addresses. The authors of the article are obviously extremely well informed about the issues they address and also are equally obviously committed to the value of an individual human life. After reading the article through four times, I find the complexity of the issues addressed to be daunting and also I find this to be an admirable attempt to grapple with very complex issues.

The article considers that if a pandemic similar to the 1917 influenza pandemic occurs – and the authors would suggest that the probability would better be addressed as "when" and not "if" it occurs -- there is a potential for millions to be affected and there is no simple solution for the treatment of that many people. The complexity of the issues involved is further understood when it is observed that the authors are only dealing with one aspect of the entire issue which is critical care for those who will require intensive care unit treatment and/or artificial ventilator support during such a pandemic. The abstract published with the *Chest* article states:

"Anticipated circumstances during the next severe influenza pandemic highlight the insufficiency of staff and equipment to meet the needs of all critically ill victims. It is plausible that an entire country could face simultaneous limitations, resulting in severe shortages of critical care resources to the point where patients could no longer receive all of the care that would usually be required and expected. There may even be such resource shortfalls that some patients would not be able to access even the most basic of life-sustaining interventions. Rationing of critical care in this circumstance would be difficult, yet may be unavoidable. Without planning, the provision of care would assuredly be chaotic, inequitable, and unfair."

This is the heart of the issue for the authors. They are not trying to play God with other peoples' lives; they want to be fully human and compassionate in the delivery of care to those who are affected in a pandemic.

It is in this context that the "exclusion criteria" published in the article must be viewed. These exclusion criteria, which are objective -- which means they are not based upon subjective opinions but upon measurements which were reproducible from one observer to another -- relate only to whether a person should be placed in an intensive care unit or whether they should be placed on a ventilator during a pandemic. Furthermore, these "exclusion criteria" are ONLY proposed for the unique instance where resources have been exhausted and choices must now be made for which patient should be treated in the ICU and which one should not.

The article points out however that these "exclusion criteria" will not be triggered unless one the following occurs:

- Declared state of emergency or incident of national significance
- Initiation of national disaster medical system and national mutual aid and resource management
- Surge capacity fully employed within health-care facility
- Attempts at conservation, reutilization, adaptation, and substitution are performed maximally
- Identification of critically limited resources (ventilators, antibiotics)
- Identification of limited infrastructure (isolation, staff, power)
- Request for resources and infrastructure made to local and regional health officials
- Current attempt at regional, state, and federal level for resource or infrastructure allocation

Even then the "exclusion criteria will not be utilized unless in addition to the above any of the following occurs:

- Lack of critical equipment
- Mechanical ventilators
- Beds
- Medical gases (oxygen)
- Antibiotics
- Vasopressors
- Crystalloid
- Operating room equipment

- Lack of critical infrastructure
- Security
- Isolation ability
- Personal protective equipment
- Decontamination equipment
- Power
- Staff support (food, housing, medication)
- Inability to transfer patients to another facility (alternate care site, hospital) that limits ability to perform clinical care
- Lack of specialty care (eg, burn, surgical, trauma)
- Lack of adequate staff

In the event of the above, the “exclusion criteria” – the criteria on the basis of which choices will be made as to whom receives ICU or ventilator care -- are:

1. SOFA (Sequential Organ Failure Assessment) score criteria: patients excluded from critical care if risk of hospital mortality $\geq 80\%$. (The concept of greater than 80% potential of death in hospital is not a subjective judgment but is objective in that it is based on a SOFA score and/or the presence of the failure of six organ systems at the same time, i.e., cardiovascular, neurological, renal (Kidney), etc.)

A. SOFA > 15

B. SOFA > 5 for ≥ 5 d, and with flat or rising trend

C. ≥ 6 organ failures

Because this concept is so new to those reading this column and at the risk of becoming too technical, the following is how the SOFA score is calculated:

Components of System	SOFA Points			
	1	2	3	4
Pao ₂ /fraction of inspired oxygen, mm Hg	< 400	< 300	< 200 with respiratory support	< 100 with respiratory support
Platelet count, x 10 ³ /μL	< 150	< 100	< 50	< 20

Total bilirubin, mg/dL (μmol/L)	1.2–1.9 (20–32)	2.0–5.9 (33–101)	6.0–11.9 (102–204)	> 12.0 (> 204)
Level of hypotension or need for vasopressor	Mean arterial pressure < 70 mm Hg	Dopamine level ≤5 μg/kg/min, or dobutamine (any dose)	Dopamine < 5 μg/kg/min, or epinephrine ≤0.1 μg/kg/min, or norepinephrine ≤ 0.1 μg/kg/min	Dopamine > 15 μg/kg/min, or epinephrine > 0.1 μg/kg/min, or norepinephrine > 0.1 μg/kg/min
Glasgow coma scale	13–14	10–12	6–9	< 6
Creatinine, mg/dL (μmol/L) or urine output	1.2–1.9 (110–170)	2.0–3.4 (171–299)	3.5–4.9 (300–440) or < 500 mL/d	> 5.0 (> 440) or < 200 mL/d

How to calculate SOFA score: Each of the six components above is assigned a score based on a patient’s clinical or laboratory data; the total SOFA score is calculated by adding the score for each of the six components together. MAP = mean arterial pressure.

If a patient had the following values for the above, the SOFA Score would be as is calculated below:

- Lung Function as measured by the ratio of the blood oxygen level divided by the percentage of oxygen the patient is receiving. For instance, if the patient’s blood oxygen level is 70 and the patient is on 80% oxygen, the value for this measure would be 88 or <than 100, which means that this element of the calculation of the SOFA score would contribute “4” to the total.
- Total platelet count – the platelets are the small elements in the blood which help the blood to form a clot. The platelets are affected by severe illness and when they start dropping the patient’s condition has worsened. If this patient’s platelet count, which is a simple blood test is less than 20,000, this contributes “4” to this patient’s SOFA score.
- Total bilirubin is one measure of the function of the liver. This is determined by a simple blood tests. If the patient’s bilirubin is 7, this would contribute “3” to the SOFA score.
- “Hypotension” refers to low blood pressure and the “vasopressor” agents are those medications which are used in intensive care to support and/or to sustain the blood pressure. If this patient’s is on three “vasopressor” agents at a low dose, the SOFA score would be increased by 3.

- The Glasgow Coma Score is an object measure of the patient's state of consciousness. It is a standard score used in the hospital routinely. If this patient's Glasgow Score is less than six, it adds "4" to the SOFA Score.
- If the Creatine, which is a simple blood test, is greater than 5, it adds "4" to the SOFA Score.

In the case of this patient, the SOFA score would be 23 which would mean that this patient has greater than an 80% change of not surviving this hospitalization. Notice this score does not involve the patient's age, financial ability, insurance status, gender, ethnicity, citizenship or any other characteristic other than physical and medical condition. And, each of these criteria is based on objective data, not on subjective opinion.

The exclusion criteria continues as follows:

2. Severe, chronic disease with a short life expectancy

- A. A. Severe trauma
- B. B. Severe burns on patient with any two of the following:
 - i. Age > 60 yr
 - ii. > 40% of total body surface area affected
 - iii. Inhalational injury
- C. Cardiac arrest
 - i. Unwitnessed cardiac arrest
 - ii. Witnessed cardiac arrest, not responsive to electrical therapy (defibrillation or pacing)
 - iii. Recurrent cardiac arrest
- D. Severe baseline cognitive impairment
- E. Advanced untreatable neuromuscular disease
- F. Metastatic malignant disease
- G. Advanced and irreversible neurologic event or condition
- H. End-stage organ failure meeting the following criteria:
 - i. Heart
 - a. New York Heart Association class III or IV heart failure
 - ii. Lungs
 - a. COPD with FEV₁ < 25% predicted, baseline PaO₂ < 55 mm Hg, or secondary

pulmonary hypertension

- b. Cystic fibrosis with postbronchodilator FEV₁ < 30% or baseline PaO₂ < 55 mm Hg
 - c. Pulmonary fibrosis with vital capacity or total lung capacity < 60% of predicted, baseline PaO₂ < 55 mm Hg, or secondary pulmonary hypertension
 - d. Primary pulmonary hypertension with New York Heart Association class III or IV heart failure, right atrial pressure > 10 mm Hg, or mean pulmonary arterial pressure > 50 mm Hg
- iii. Liver
 - a. Child-Pugh score ≥ 7
 - I. Age > 85 yr
 - J. Elective palliative surgery

As can be seen, these criteria relate only to decision making about ICU or ventilator care in the extremely ill. They do not cross ethical boundaries and provide a rational, compassionate, objective criteria for determining whether or not a person should receive critical care in the face of an overwhelming number of people needing such care and there being inadequate resources to provide that care for everyone.

Next week, we will discuss the suggestions made by this work group and the overall framework in which medical ethicists are working in order to make certain that while there could be great loss of human life in a pandemic, we would not lose our humanity. The following week, we will discuss what you can do to protect yourself and your loved ones in the event of a pandemic.