

Adult Clinical Ventilator Allocation Protocol (Adapted from New York's protocol):

Key principle: Ventilators go to the patients who are most likely to survive this illness if given ventilator therapy.

All acute care patients who are in need of a ventilator, whether due to COVID-19 or other conditions, are subject to the clinical ventilator allocation protocol. This adult protocol applies to all patients aged 18 and older.

Using clinical criteria, patients who are deemed most likely to survive with ventilator treatment have an opportunity for ventilator therapy to maximize the number of survivors. This guideline's definition of survival is based on the short-term likelihood of survival of the acute medical episode, and is not focused on whether a patient may survive a given illness or disease in the long-term (e.g. years later).

A patient's attending physician/MRP cares for their own patients and performs all clinical evaluations. A triage officer or committee examines a patient's clinical data and determines the patient's level of access to a ventilator (i.e. who is eligible to be placed on, or to continue, ventilator therapy).

The protocol consists of three steps: 1) application of exclusion criteria, 2) assessment of mortality risk, and 3) periodic clinical assessments ("time trials").

Step 1: Exclusion Criteria

A patient's attending physician examines the patient for any exclusion criteria and forwards this clinical data to a triage officer/committee to make the triage decision. Patients with exclusion criteria do not have access to ventilator therapy and instead are provided with alternative forms of medical intervention and/or palliative care².

If medical information is not readily available or accessible, it may be assumed a patient is free of exclusion criteria and may proceed to the next step of the clinical ventilator allocation protocol.

Exclusion Criteria	Potential Exclusion Criteria
Severe cognitive impairment	Moderate cognitive impairment
Pulmonary fibrosis	Severe pulmonary hypertension
Frailty score >6 (see Clinical Frailty Scale below)	Frailty score 5-6 (see below)
Cardiac arrest: - unwitnessed arrest - recurrent arrest with hemodynamic instability	Pre-existing severe end-organ failure, e.g.: - Dialysis (hemodialysis or peritoneal dialysis) - COPD on home O2 - Cardiomyopathy with Grade IV LV function - Liver failure
Diffusely metastatic malignant disease	Irreversible hypotension unresponsive to fluid resuscitation and vasopressors
Traumatic brain injury or CVA/ICH with no motor response to painful stimuli	

Step 2: Mortality Risk Assessment Using SOFA

A clinical scoring system, SOFA (Sequential Organ Failure Assessment), is used to assess a patient's mortality risk. Total score (0 - 24).

Sequential Organ Failure Assessment (SOFA) Score					
System	0	1	2	3	4
Respiration: PaO₂/FiO₂ (mmHg)	>400	<400	<300	<200	<100
Coagulation: Platelets (x10³/uL)	>150	<150	<100	<50	<20
Liver: Bilirubin (umol/L)	<20	20-32	33-101	102-204	>204
Cardiovascular (doses ug/kg/min for at least 1hr)	MAP >70 mmHg	MAP <70 mmHg	Dopamine <5 or Dobutamine (any dose)	Levophed <0.1 or Epinephrine <0.1 or Dopamine 5.1-15	Levophed >0.1 or Epinephrine >0.1 or Dopamine >15
CNS: GCS score	15	13-14	10-12	6-9	<6
Renal: Creatinine (umol/L)	<110	110-170	171-299	300-440	>440

For most patients who are sick only with COVID-19 and have no other comorbidities, the single organ failure is limited to their lungs. However, because the adult clinical ventilator allocation protocol applies to all patients in need of a ventilator, a patient may also have a comorbidity(s) that affects another organ system(s) and his/her mortality risk assessment. Intubation for control of the airway (without lung disease) is not considered lung failure.

A patient's clinical data from Steps 1 and 2 are provided to a triage officer/committee, who assigns the patient a colour code (i.e. blue, red, yellow, or green), which determines a patient's level of access to ventilator therapy (see chart below).

Patients in the red zone have the highest level of access to a ventilator because they are most likely to recover with treatment (and not likely to recover without it) and have a moderate risk of mortality.

If resources are available, patients in the yellow zone also have access to ventilator treatment. Patients in the blue zone have the worst outlook for survival, even with ventilator therapy, and therefore have the lowest access.

Green zone patients are most likely to survive even without a ventilator, or are eligible for ventilator weaning.

If resources become available, patients in the blue zone, or those with exclusion criteria, are reassessed and may become eligible for ventilator therapy.

Triage Chart for Step 2

A triage officer/committee allocates ventilators according to the color code assigned.

Step 2 – Mortality Risk Assessment Using SOFA ¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure
<p>Blue</p> <p>No ventilator provided. Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if ventilators become available.</p>	<p>Exclusion criterion OR SOFA > 11</p>
<p>Red</p> <p>Highest Use ventilators as available</p>	<p>SOFA < 7 OR Single organ failure²</p>
<p>Yellow</p> <p>Intermediate Use ventilators as available</p>	<p>SOFA 8 – 11</p>
<p>Green</p> <p>Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p>No significant organ failure AND/OR No requirement for lifesaving resources</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² Intubation for control of the airway (without lung disease) is not considered lung failure.

At step 2, the triage officer/committee may encounter a situation where there are several patients in the red colour zone³ who are equally eligible for ventilator therapy⁴, and must select which patient gets the ventilator. It is not appropriate for the triage officer to compare patients within the same colour category. If all the eligible patients are adults, a random process (e.g. lottery) should be used to choose who gets the ventilator⁵. Each time another ventilator becomes available, a random selection method is conducted to determine who gets it.

Patients waiting for ventilator therapy wait in an eligible patient pool, and receive alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

Step 3: Periodic Assessments for Continued Ventilator Use (Time Trials)

Periodic clinical assessments at 48 and 120 hours (“time trials”) using SOFA are conducted on patients who have begun ventilator therapy to re-evaluate patients’ risk of mortality. The attending physician/MRP performs the clinical assessments involved in a SOFA score.

The results of the assessment are provided to the triage officer/committee who assigns a colour code (blue, red, yellow, or green) to the patient. The colour code assigned at this time is dependent on the SOFA score itself and the **magnitude of change** between the SOFA score at the current vs previous assessment. The decision whether to continue ventilator therapy for a given patient is dependent on the trend of the SOFA score data.

The guiding principle for the triage decision is that the more severe a patient’s health condition (i.e. the higher the SOFA score) and worsening/no change in mortality risk (i.e. increase or little/no improvement in the SOFA score), the less likely the patient will benefit from continuing ventilator therapy. Conversely, the less severe a patient’s health condition (i.e. low SOFA score) and demonstration of improvement with ventilator therapy (i.e. significant decrease in the SOFA score and in mortality risk), the higher the likelihood the patient continues with this form of treatment.

At 48 hours, a patient must exhibit a pattern of significant improvement to be placed in the red colour zone.

After 120 hours, a patient must demonstrate a pattern of *further* significant improvement in health to be placed in the red colour zone.

The official SOFA assessments only occur after 48 and 120 hours (and subsequent 48 hours) of ventilator therapy. No formal triage decision or action may be taken until a patient’s official assessment. However, at any point during the time trial, even before an official assessment occurs, if a patient develops a condition on the exclusion criteria list and there is an eligible patient waiting, then the ventilator is reallocated. Patients removed from the ventilator are provided with alternative forms of medical intervention and/or palliative care.

Footnotes:

3) *While the yellow category may also have eligible patients waiting for ventilator therapy, all red zone patients must be attended to first. If there are no red zone patients, only yellow zone, then the same decision-making process applies.*

4) *While a SOFA score does provide discrete numbers, it is not appropriate to suggest that a score of 5 is indicative of a lower risk of mortality than a score of 6. Instead, both of these scores suggest that both patients have near equal probabilities of survival. Thus, all patients in the same colour category have the same likelihood of survival.*

5) *However, if the pool of eligible patients includes both adults and children under age 18, young age plays a tie-breaking role. See appendix B, Pediatric Clinical Allocation Protocol.*

6)

7) *If no eligible patients are waiting for ventilator treatment, a patient who does not meet the time trial criteria would continue with the treatment and be evaluated again at the next official assessment.*

48 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (48 Hour Assessment) ¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure
<p>Blue</p> <p>No ventilator provided.² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.</p>	<p>Exclusion criterion</p> <p>OR</p> <p>SOFA > 11</p> <p>OR</p> <p>SOFA 8 – 11 <u>and</u> No Change in SOFA Score Compared to the Initial Assessment³</p>
<p>Red</p> <p>Highest</p> <p>Use lifesaving resources as available.</p>	<p>SOFA < 7 <u>and</u> Decrease in SOFA Score Compared to the Initial Assessment⁴</p> <p>OR</p> <p>SOFA < 11 <u>and</u> Decrease in SOFA Score Compared to the Initial Assessment⁵</p>
<p>Yellow</p> <p>Intermediate</p> <p>Use lifesaving resources as available.</p>	<p>SOFA < 7 <u>and</u> No Change in SOFA Score Compared to the Initial Assessment</p>
<p>Green</p> <p>Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p>No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

³ The patient remains significantly ill.

⁴ These criteria apply to a patient who was placed into the red category at the initial assessment.

⁵ These criteria apply to a patient who was placed into the yellow category at the initial assessment but because a ventilator was available the patient began ventilator therapy.

120 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (120 Hour Assessment) ¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure
<p style="text-align: center;">Blue</p> <p style="text-align: center;">No ventilator provided.²</p> <p style="text-align: center;">Use alternative forms of medical intervention and/or palliative care or discharge.</p> <p style="text-align: center;">Reassess if resources become available.</p>	<p style="text-align: center;">Exclusion criterion</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">SOFA > 11</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">SOFA < 7 <u>and</u> No Change in SOFA Score Compared to the Previous Assessment</p>
<p style="text-align: center;">Red</p> <p style="text-align: center;">Highest</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">SOFA < 7 <u>and</u> Progressive Decrease in SOFA Score Compared to the Previous Assessment</p>
<p style="text-align: center;">Yellow</p> <p style="text-align: center;">Intermediate</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">SOFA < 7 <u>and</u> Minimal Decrease in SOFA Score (< 3 Point Decrease in Previous 72 Hours) Compared to the Previous Assessment</p>
<p style="text-align: center;">Green</p> <p style="text-align: center;">Use alternative forms of medical intervention or defer or discharge.</p> <p style="text-align: center;">Reassess as needed.</p>	<p style="text-align: center;">No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the 48 hour assessment to the 120 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

Decision-making Process for Removing a Patient from a Ventilator

There may be a scenario where there is an incoming red zone patient(s)⁸ eligible for ventilator treatment, and a triage officer/committee must remove a ventilator from a patient whose health is not improving at the 48, 120, or subsequent 48 hour time trial assessments. The triage officer/committee follows these steps to determine which patient should be removed from the ventilator:

First, a blue zone patient(s) is the first patient(s) eligible for ventilator discontinuation.

If there are no blue zone patients on ventilators, then the triage officer/committee proceeds to the yellow zone patients.

If there are several patients in the blue (or yellow) category, the triage officer/committee is not permitted to compare the health of patients within the same colour category. Instead, a randomization process such as a lottery is used to select which patient is removed. A patient may only be removed from a ventilator after an official clinical assessment has occurred, or where the patient develops a medical condition on the exclusion criteria list.

If all ventilated patients at the 48, 120, and subsequent 48 hour time trial assessments receive a red zone colour code, then none of these patients discontinue ventilator therapy. The incoming red zone patient(s) remain in an eligible patient pool and receive alternate forms of medical intervention and/or palliative care until a ventilator becomes available.

Alternate forms of Medical Intervention and Palliative Care

Palliative care and/or alternative forms of medical intervention are provided to those who are waiting for, or are not eligible for, a ventilator.

Palliative care is provided to all patients throughout the triage process, regardless of prognosis.

Conclusion

The triage process requires regular reassessments of the status of the pandemic, available resources, and of all patients. As new data and information about the pandemic viral strain becomes available during the pandemic, the adult clinical ventilator allocation protocol may be revised accordingly to ensure that triage decisions are made commensurate with updated clinical criteria.

Footnotes:

8) While there may be yellow zone patients waiting for ventilator therapy, all red zone patients must be attended to first. In limited circumstances, where incoming patients are only yellow zone, these patients may only receive ventilator therapy if there are any blue zone patients currently receiving ventilator treatment. Already-ventilated yellow zone patients would NOT be removed from the ventilator with the arrival of incoming yellow zone patients, since both of these patients have equivalent likelihoods of survival (i.e. both are in the same colour category).