Standard Operating Procedure / Protocol:

Critical Care Management of Novel 2009 S-OIV H1N1in a Pandemic Situation

I. Introduction:

In the spring of 2009, a novel swine origin influenza virus (S-OIV) of the H1N1 subtype emerged and resulted in a pandemic situation. With this pandemic, hospitals experienced an influx of critically ill patients. Few, if any, institutional standard operating procedures were in place to deal with a virus of this nature. This document is an example of protocol which may have been useful at the onset of this pandemic and may be used as a model for future pandemics of similar characteristics.

II. Purpose

To describe a clinical management strategy for pandemic 2009 H1N1 that includes the identification of critical illness risk factors, and optimization of resources for timely treatment resulting in favorable outcomes while maintaining the safety of healthcare workers and the hospitalized population. .

III. Scope

a. Provide guidance to all institutional clinicians regarding suspected and probable cases of 2009 H1N1, with specific attention to the diagnosis and treatment of such cases.
b. Establish methodology to enhance infection control within the institution, especially with respect to all equipment, staff, patients, and visitors as well as in the community. Identify strategies for optimizing institutional capacity, and communication between staff members and other institutions.

c. Prepare an approach for identifying cases with increased risk factors for critical illness to be carefully monitored.
d. Provide evidence-based guidelines for the critical care of 2009 H1N1 patients including ventilatory, non-ventilatory, and medical management strategies.
e. Recognize cases with likelihood of requiring extracorporeal support which need to be followed by appropriate service or referred to appropriate tertiary centers identify the potential hazards and/or consequences of an H1N1 or similar pandemic.
f. Review the progression of critical care to ECLS including patient selection, contraindications, and optimal procedures for initiating, maintaining, and terminating extracorporeal support specifically for 2009 H1N1 or other similar pandemics causing acute respiratory distress, and/or failure.
g. Identify the potential hazards and/or consequences of the 2009 H1N1 or similar pandemic to patients, healthcare personnel, and the community at large and evaluate the toll pandemic 2009 H1N1 will take on institutional, regional, state/provincial, national, and international resources.
h. Suggest methods to recognize and confirm possible Tamiflu-resistant 2009 H1N1 cases for opportune timing of treatment alternatives.
i. Provide a forum to report findings and data periodically at an institutional level as well as regionally, nationally, and globally.

IV. Definitions

a. ACT – Activated Clotting Time
b. CV - Cardiovascular
c. ECLS – Extracorporeal life support
d. ECMO – Extracorporeal membrane oxygenation

V. Safety

a. Establish a re-education of surgeons, intensivists, nurses and all cardiac team members as to the initiation, maintenance, and termination of ECLS.
b. Ensure adequate resources are available and in-house to carryout extracorporeal lung support for an institutionally acceptable number of patients.
c. Discuss product requirements, volumes, costs, and dates of delivery with ordering and stocking staff, to ensure proper resource access.
d. Provisions to establish a communication pathway that allows for quick and expedient resolution of ECLS conduct discrepancies or concerns.
e. Increased and improved communication amongst all disciplines within the critical care team, including intensivists, ICU team members, perfusionists, nurses, respiratory therapists, residents, physicians etc.

VI. Responsibilities

a. Perfusionists
    i. Encourage and drive open communication among all staff members involved in ECMO management.
    ii. Support changes in staff coverage for ECLS cases; this may require taking additional shifts, and staying past regular shift hours.
    iii. Ensure proper sizing of all cannulae.
    iv. Ensure proper sizing and priming of ECLS circuit.
    v. Ensure proper management of ECLS included; blood gasses, patient hemodynamics, and blood product administration according to departmental and institutional standardized protocols and procedures.

VII. Selection Process:

These criteria have been adapted from the recently published guidelines put forth by the Extracorporeal Life Support Organization (ELSO) in April 2009. The selection process will be carried out in a graded fashion, taking into consideration the patient status, and changes in resource availability. The goal is to use limited ECMO/ECLS resources on patients with the greatest likelihood of survival. The same criterion should be used for all patients referred for the same resource.

Mechanical ventilation should remain the primary therapy for patients with H1N1 pneumonia. ECLS will only be considered if the patient fails optimized mechanical ventilatory support. Optimized mechanical ventilatory support should include at a minimum, where available, all of the following:

1. Advanced ventilator modes including inverse ratio pressure control ventilation and airway pressure release ventilation
2. Aggressive titration to high levels of positive end expiratory pressures (PEEP)
3. Adequate sedation and pharmacologic paralysis;
4. Control of fluid status (limitation of intake; aggressive diuresis);
5. Prone positioning;
6. Inhaled nitric oxide (NO) and/or inhaled epoprostenol;
7. High frequency oscillatory ventilation (HFOV)
8. Adequate time to determine effects of above.

If the patient remains in life-threatening respiratory failure despite these maneuvers then ECLS can be considered. (ECLS H1N1 Expert Working Group Recommendations, 2009)

The following are stages set forth by the ECLS H1N1 Expert Working Group Recommendations from the Alberta Critical Care Network, 2009;

Stage I: There are no limitations to currently available ECLS resources.

Stage II: There are some limitations to currently available ECLS resources.

Stage III: There are no ECMO resources available.

Stage I: Veno-Venous ECMO will be the primary treatment for patients with oxygenation failure in this stage.

Indications:

1. Hypoxemic respiratory failure: $PaO_2/FiO_2 < 80$ on 100% O_2 or a Murray Score 3-4.

2. Hypercapneic respiratory failure: $PaCO_2 > 80$ despite aggressive measures to control hypercarbia.

3. The above despite aggressive attempts at optimal mechanical ventilatory support as described above.

Contraindications:

1. Mechanical ventilations at high settings ($FiO_2 > 90\%$, Pplat > 30 cm H_2O) for 7 days or more.

2. Contraindication to systemic anticoagulation

3. Age > 60 years

4. Morbid obesity (BMI>40)

5. Cachexia/severe malnutrition

6. Co-morbidities which will have significant impact on short or medium term outcomes or present technical difficulties to the delivery of ECLS. Examples include but are not limited to:

i) Severe lung disease with home oxygen requirement, chronic hypercapnea, or pulmonary hypertension

ii) Class IV cardiac disease

iii) Liver disease with portal hypertension, previous variceal bleeds, or hepatic encephalopathy

iv) Chronic renal failure requiring dialysis

v) Severe peripheral vascular disease

vi) Long standing diabetes mellitus with end organ damage

7. Metastatic or otherwise advanced malignancy

8. Immunosuppresion

i) Pharmacologic suppression with absolute neutrophil count <400/ml3

ii) Acquired immune deficiency syndrome.

9. Low pre-morbid functional status/high dependant state. Examples include but are not limited to:

i) Chronic dementing illness

ii) Patients from chronic care facilities/nursing homes

iii) Patients unable to independently perform ADLs

10. Necrotizing pneumonia

11. Refractory septic shock

12. Multisystem Organ Failure

i) This does not preclude the presence of some degree of organ dysfunction particularly if the organ dysfunction is minor and related to the therapy for the H1N1 pneumonia. For example, mild renal dysfunction felt to be pre-renal associated with diuresis to assist lung function on MV.

13. Moribund/not expected to survive >7 days from non-pulmonary disease states

Exit Strategy:

Per existing practices of weaning from ECMO

Stage II: Veno-Venous ECMO will continue to be the primary treatment for patients with oxygenation failure at this stage, with increasing restrictive pass criteria.

Indications

1. All of the indications from Stage I
2. ECLS resources will be reserved for patients with viral pneumonia or conditions with a similar or better outcome. No other use will be allowed.

Contraindications

1. All of the contraindications in Stage I in addition to:
    i) Age > 40 years
    ii) Evidence of any organ dysfunction other than pulmonary

Exit Strategy:

Must be able to free up ECMO for use with other patients whose survival may be determined as more likely, or be able to terminate ECMO if patient is deteriorating despite therapy. Termination of ECMO should be considered in the following situations:

1. Improvement in pulmonary function that patient can be sustained on optimized mechanical ventilation.
2. Development of ventilator associated pneumonia, non-pulmonary sepsis, or multisystem organ failure
3. Development of pulmonary emboli
4. Bleeding complications
5. No significant improvement in pulmonary function after 14 days of ECMO.

Stage III: No ECMO resources are available.

Optimized mechanical ventilation will be the only option until patients currently undergoing ECMO return to mechanical ventilation or they fail to survive.

Indications

1. Identical to that in stage II.

Contraindications

1. Identical to that in stage II.

Exit Strategy:

1. Identical to that in stage II.

VIII. Procedure

a. ECLS for patients with H1N1.
    i. See standard operating procedures for ECMO, all H1N1 specific expectations will be outlined in the management section (section VIII) of this policy.

IX. Associated Materials

Ordering manager should plan for total respiratory and cardiac support in determining necessary products and equipment.

Disposables:

a. Membrane Lung: The Quadrox D® (Maquet) is most commonly used membrane lung. (ELSO Registry, 2009) There should be plenty available to deal with the number of patients anticipated to be affected by the pandemic.
    i. Can be used in all patients > 10 kg.
    ii. Can be used for up to one month according to manufacturer's recommendations.

b. Pump: A centrifugal pump would be used most often; however a servo regulated roller pump has been noted in other centers. Depending on access and availability there may be a requirement for a secondary plan.

i. Examples centrifugal pumps currently used for such purposes include; The Rotaflow®, Revolution®, Centrimag®, and Biomedicus® pumps. The primary advantages of a centrifugal pump are that of smaller priming volume (approximately 32mL), smaller blood-surface contact area, will not pump air bubbles > 5mm forward (pump will stop). (Values from Maquet Rotaflow® pump)

c. Heat Exchanger: There is a heat exchanger built into the Quadrox D®.

d. ECMO Circuit Pack: Institution ECMO packs need to be available or to be quickly constructed as needed.

e. Monitors: Management of patient and ECMO are mainly driven by patient monitors. Inlet/outlet pressures, blood gasses, and saturation levels can be measured continuously, but can be measured intermittently if the data is needed for management.

<u>Hardware:</u>

f. Centrifugal Pump Console
g. External Drive Unit
h. Emergency Drive Unit
i. Oxygenator Holder: i.e. Maquet Quadrox D® holder
j. Oxygen tank holder
k. Pole Mounted Oxygen Flow Meter
l. Full Oxygen tank with regular and key
m. Multiple tubing clamps
n. Ultrasonic grease/paste.
o. Transonic flowmeter and 3/8” probe.

Additional Requirements:

p. Syringes
q. Sterile Blades
r. Alcohol pads
s. Stopcocks
t. Needles
u. Connectors: 3/8" straight, and 3/8"-¼" straights as well.
v. Priming Fluid: Plasmalyte, Plasmalyte A, or Lactated Ringers adjusted with 50 mEq of Sodium Bicarbonate have been used.

X. Management:

a. Anticoagulation Management:
    i. There is a wide range of coagulation tendencies in patients with H1N1 due to the varying degrees of down regulation of protein C (which has anticoagulant properties) during infection and inflammation (Schouten, 2010). Thus, some H1N1 patients are coagulopathic with low heparin requirements and some are hypercoagulable. (ELSO Registry, 2009)

    ii. The use of a hemostasis management system, like the Medtronic® HMS® system, may be advantageous as it would create a heparin dose response curve for each individual patient, taking into account platelet function, hematocrit, effects of drugs already in the system, and individual reaction to heparin.

    iii. Use of an ACT and PTT management protocol, is also indicated at standard intervals as per standard ECMO protocol.

b. Patient Management:

i. Infection control measures should be observed when working with patients to prevent person-to-person transmission of influenza and to control influenza outbreaks further. Some ways which this can be observed are as follows:

1. Practice proper respiratory hygiene and cough etiquette. Beginning at the first point of contact with a potentially infected person to prevent the transmission of all respiratory tract infections in the acute care setting.

2. Respiratory hygiene/cough etiquette includes the following, according to CDC standards (2009):

a. Posting visual alerts instructing patients, and persons who accompany them to inform healthcare personnel if they have symptoms of respiratory infection.
b. As well as to notify nurses, respiratory therapists and other health care workers on rounds this is an infected patient.
c. Providing tissues or masks to patients and visitors who are coughing or sneezing so that they can cover their nose and mouth.
d. Ensuring that supplies for hand washing are available where sinks are located; providing dispensers of alcohol-based hand rubs in other locations.
e. Providing space for coughing persons to sit at least 3 to about 6 feet away from others, if feasible

3. Practice standard contact precautions diligently as outlined according to CDC standards (2009):

    a. Wear gloves if hand contact with respiratory secretions or potentially contaminated surfaces is anticipated.
    b. Wear a gown if soiling of clothes with a patient's respiratory secretions is anticipated
    c. Change gloves and gowns after each patient encounter and perform hand hygiene.
    d. Decontaminate hands before and after touching the patient and after touching the patient's environment or the patient's respiratory secretions, whether or not gloves are worn.
    e. When hands are visibly soiled or contaminated with respiratory secretions, wash hands with soap (either plain or antimicrobial) and water.
    f. If hands are not visibly soiled, use an alcohol-based hand rub.

4. All healthcare professionals should adhere to the droplet precautions outlined below during the care of a patient with H1N1, as outlined according to CDC standards (2009):

    a. Assist patient placement in an isolated room for H1N1 ECMO treatment. If a private room is not available, place (cohort) suspected influenza patients with other patients suspected of having influenza; cohort confirmed influenza patients with other patients confirmed to have influenza. If

additional ECMO patients are in the same room, it will allow for collaboration with colleagues if necessary for coverage, trouble-shooting etc.

b. The perfusionist should always wear a surgical or procedure mask when entering the patient's room. Remove the mask when leaving the patient's room and dispose of the mask in a waste container. While patients on ECMO are traditionally sedated, paralyzed and intubated, their coughing is not so much an issue. However, patient secretions are still being suctioned and contaminated equipment being moved about the room, so all precautions should be taken.
c. If patient movement or transport is necessary, have the patient wear a surgical or procedure mask, if possible.

ii. Vent and lung management: (Taken from ELSO H1N1 Specific Guidelines, 2009)

1. Keep the vent at low settings.
2. Adjust blood gases with the ECLS circuit. Ensure good communication between nursing, respiratory therapist and perfusionist regarding ventilation/ECLS management.
3. Uses of adjunctive maneuvers such as nitric oxide (Napolitano, 2010), surfactant, prone position, fluorocarbon lavage, and percussive ventilation have been shown to be helpful in other centers according to ELSO (ELSO Registry, 2009).

4. Conservative fluid management: To avoid fluid accumulation on the lungs, and in other tissues. (Napolitano, 2010)`

c. Resource management:

i. Staff Scheduling/Management Issues: The perfusion department must first determine their capacity. How many patients requiring ECMO or ECLS may be treated without affecting the operation of the cardiovascular (CV) surgery program, with only minor changes to the perfusion program's staffing schedule? Determine the number of patients to which they can provide ECMO or ECLS, and standard perfusion services to only emergency CV cases.

1. Staff Meetings:
    a. Most departments hold regular staff meetings in order to; evaluate current concerns, discuss research, individual case challenges and solutions, staff scheduling etc. It is important to maintain the agenda of these meetings, and it addition to include a pandemic management and discussion portion. A time for staff to share concerns, discuss H1N1 ECMO/ECLS management specifics, failures, successes, and ideas for improvement with mandatory participation.
    b. Staff Scheduling: One must consider staff rights when scheduling. The utmost attention must be paid to fairness, and time while scheduling. For although everyone's responsibility and duty lies in providing the best care possible for our patients, one must balance that with one's personal duties. As a good department manager you need to be aware of these

issues, and with open communication and objectivity meet these challenges as a whole department. Some of these issues were outlined in Taylor et al., 2010:

i. Limited fuel and transportation due to staff shortages in other industries may result in staff shortages in the hospital department.
ii. School closures could also result in staff shortages as parents may have to stay home to take care of their children.
iii. Insufficient drugs or disposables due to staff shortages would result in additional shortages.
iv. Staff fatigue from excessive workload.

c. This type of effective communication plan according the WHO "Effective Communication Strategy for Avian/Pandemic Influenza" fosters:
    i. Information sharing and education
    ii. Enhanced knowledge and understanding
    iii. The growth of trust and credibility between colleagues.
    iv. Collaboration and cooperation.
    v. Constructive dialogue.
    vi. Support for policies and plans.
    vii. Informed decision making.
    viii. Appropriate professional and supportive behavior of one another.

2. Non-Clinical Risks to Staff: As a department manager it is important to be aware of some of the non-clinical risks to staff members. These risks are well documented (Taylor, 2010) and should be taken into account as they may have clinical implications.
    a. Risks of work-acquired infection or contamination as a result of caring for patients. There is a personal risk of becoming ill which comes at a cost that is not quantifiable.
    b. Inability to deliver normal standard of care due to shortages in resources.
    c. Fatigue due to prolonged working hours and excessive workload.
    d. Potential disagreements with colleagues over treatment restriction decisions.
    e. Pressure to work or provide interventions outside the employee's normal working domain.
    f. Stress related to patient treatment decisions and treatment limitation decisions. Staff will feel frustrated as these restrictions will conflict with their natural desire to be responsible for the care of sick patients and to help these patients recover from serious illnesses.
    g. There may be additional stresses for staff including death of a family member, friend or colleague. Staff may need time off for this, and compassion from their colleagues at work.
    h. There may be a lack of confidence in the management infrastructures and their support
    i. Standards for patient outcomes and increased complication rates as a consequence of care being

provided by staff outside of their normal expertise may provide additional stressors. While at the institutional level full moral and physical support for staff willing to undertake responsibilities outside of their standard scope of practice is necessary. It is also important that the professional organizations produce consensus guidelines for their members and be prepared to provide them full support when working outside of their normal area of expertise.

ii. Resource Shortage Issues:

1. Resource Communication:
    a. The ordering manager must communicate as soon as possible, any delays, or problems associated with obtaining the necessary material resources. They should also be in contact with their product managers and be up-to-date with product supply, and availability through the pandemic.
    b. The perfusion department manager must communicate to all involved in the care of these patients of anticipated shortages in resources. These shortages will affect the graded approach to the supply of ECMO/ECLS to these patients.
    c. The perfusion department manager must also ask for daily or weekly feedback from the perfusion department to keep survey of the staff health, general wellbeing and ability to perform duties outlined in their job description. If problems arise, and staffing numbers change due to personal illness (H1N1 or other), family illness, etc., the department

manager must be able to hold department meetings to help brainstorm and solve problems of fatigue, unequal shifts, general findings with patients, learning sharing etc., so that the department can fix the problem, and move forward into being better, and more aware of the full pandemic picture.

iii. Ethical Issues: Critically ill patients admitted with H1N1 influenza suffering with severe respiratory failure, and failing all other support modalities will be candidates for ECMO therapy. There may however be a situation where resource restrictions need to be implied due to mass numbers of patients requiring ECMO. It may not be ethically sound to support all such patients, and therefore a department must have prepared a selection process for patients most likely to benefit from such treatments, in order to provide responsible care to a society suffering from such a pandemic.

1. If the situation arises that ECMO shall not be offered to patients with severe respiratory failure with influenza pneumonia, other patients within the hospital with same or worse expected outcomes will also not receive ECMO.
2. If a patient is referred to receive ECMO, while other patients who are currently receiving therapy are felt to have a better prognosis, and resources are limited, that patient may not be able to receive ECMO therapy. See next point #3.
3. A graded approach to the use of ECMO/ECLS is warranted given the length and duration of anticipated support requirements. Patients generally require ECLS for a number of days (average of 12 days per ELSO database). Restrictive inclusion criteria should be applied in the early stages of a pandemic focusing on patients with the best perceived prognosis. As the demand for ECLS increases

and/or the amount of available ECLS resources decreases, more restrictive entry and exit criteria will need to be applied eventually culminating in a stage where ECLS would not be offered at all. (Alberta CCN, 2009)

4. In addition, the availability of resources may change during a given patient's duration of ECLS therapy. This may affect each patient's grading and thus their likelihood of receiving ECMO therapy.
5. This modality of treatment will only be withdrawn if a severe restriction on perfusion services is imposed due to a lack of material resources, or a redirection of resources to other areas is requested and/or enforced by management.

d. Communication Management during Pandemic Crisis: An organization can compound its problems during an emergency if it has neglected sound crisis and emergency risk communication planning. During a serious crisis, it has been shown, that people; take in information differently, process this information differently, and consequently act differently, then if otherwise in the same circumstance (CDC, 2010) Therefore communication planning must be in place as a platform for strengthening basic infrastructure, not just for a pandemic but for future health crises of international importance.

   i. Create an Action Plan: Delegate tasks to staff members that will assist in making time during the pandemic more efficient. Choose an ordering manager, spokesperson with the nurses, educator etc. Make sure there are specified dates, and clear expectations and goals.
   ii. Stage Simulations and Discuss Scenarios: The more one is able to practice placing a patient on ECMO, maintaining the patients, and terminating from ECMO the more comfortable perfusion, CV

surgeons, intensivists, and nurses are with the treatment, and associated protocols.

iii. Dialogue with Perfusion Community: Seek ways to communicate both formally and informally with your internal perfusion community, as well as at a national and global level. Use this dialogue to determine total resources available, others' experiences with patients and H1N1, their recommendations, and any suggestions they may have.

iv. Create Informal Materials: It is beneficial to those healthcare workers who will be in contact, and assisting patients either pre or post-ECMO for ARDS and H1N1, that they understand the physiology of the process, future implications for care, expectations for treatment and so on. The more people on board that are able to participate and aid perfusion in the proper selection, management, monitoring of these patients, the better the patient outcome.

v. Collaboration: Work with all healthcare professionals (i.e. physicians, nurses, etc.) to provide them with information on staffing capacity, and updates there on, to create informational materials, to aid in treatment and decision making processes. Optimal and best patient care only results when people work together.

e. Institutional protocols are to be referenced for standard ECMO and ECLS.

f. Perfusion departmental protocols and guidelines. Also to be referenced for standard professional behavior expectations, and responsibilities, as well as use of standard perfusion equipment.

References:

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