(A) Policy Statement

The Respiratory Care Department will deliver Nitric Oxide (NO) when ordered by a physician. It is a medical gas with selective pulmonary vasodilator properties, approved by the FDA for off-label use in adults. It is delivered via the Inovent device, along with a mechanical ventilator.

(B) Purpose of Policy

To ensure the proper, safe set-up and delivery of inhaled nitric oxide.

(C) Procedure

1. Inovent Delivery and Safety
   - NO administration will be performed in the OR, Cath Lab and ICU’s only.
   - NO therapy must be ordered by either a Pulmonologist or Cardiothoracic Surgeon.
   - NO will be administered via the Inovent device, which precisely regulates NO delivery and monitors concentrations of nitric oxide, nitrogen dioxide and oxygen.
   - Nitrogen dioxide (NO2) is a toxic byproduct of nitric oxide and oxygen. If NO2 levels exceed 5 parts per million (ppm), lower concentrations of nitric oxide should be used.
   - If methemoglobin levels (MetHb) increase above 5%, the NO should be weaned to a lower dose. Assure that the patient is not receiving other medications that can cause methemoglobinemia, such as lidocaine, nitroglycerin, dapsone, metaclopromide and sulfonamides. If MetHb levels remain elevated despite NO reduction, NO should be discontinued and treatment with methylene blue be considered.

2. Indications for Off-Label Use
   - Vasoreactivity in the cardiac cath lab or in the ICU.
   - Refractory hypoxemia in ARDS. Early in the course of ARDS, atelectatic portions of the lungs are often recruitable. Adjunct therapies include optimum PEEP or prone positioning which may allow reduction of the inspired oxygen concentration to a non-toxic level (<.60FiO2). If the patient remains hypoxemic (PaO2/FiO2) < 150 despite optimizing ventilatory parameters, NO administration may be considered.
   - Pulmonary Artery Hypertension (PAH)

3. Procedure for Use: this is only a guideline for its use
   - Set up and calibration will be exactly as described in the Inovent Delivery System Operation and Maintenance Manual
✓ Lo-cal calibration is completed automatically and performed per manufacturer’s specifications. Hi-calibration will be done monthly by a member of the Respiratory Care Department. Mallinckrodt Tech Support will perform safety checks, as per their protocol.
✓ ABG should be obtained prior to the initiation of NO. Baseline calculation of PaO2/FiO2 should be made and/or hemodynamic measurements including Pulmonary Artery Pressure (PAP) and Pulmonary Vascular Resistance (PVR).
✓ NO should be started at 10 ppm
✓ ABG and MetHb analysis should be performed prior to NO initiation, 1 hour after initiation of NO and QAM MetHgb
✓ NO response is considered positive if the PaO2 / FiO2 ratio increases by 20% or if the mean PAP or PVR decreases by 20%
✓ If there is no response at 10 ppm, a trial of 20 ppm may be conducted. Non-responders should not be continued on NO.
✓ Responders will be continued on NO with the goal of reducing the FiO2 to < .60 with a SpO2 > 90%.
✓ Once the FiO2 is lowered to a non-toxic range, the NO should be weaned aggressively as patients responsive to NO become tolerant over a 96 hour period.
✓ All patients managed with NO will be evaluated on a daily basis to determine weaning readiness.

4. Weaning Readiness
✓ NO dose should be reduced by half, every 4 hours, keeping the FiO2 less than .60 and the oxygen saturation > 90% until the dose is 5 ppm.
✓ At 5 ppm, wean by 1 ppm, every 2 hours.
✓ If the SpO2 < 90% during the weaning process, return to the previous NO level, and attempt to wean again in 4 hours.

5. Pulmonary Hypertension: Testing for Pulmonary Vasculature Vasoreactivity
✓ Involves a non-intubated patient inhaling nitric oxide to assess vasoreactivity.
✓ Patients with the appropriate response to the nitric will be started on Flolan to treat the PAH.
✓ Patients will be admitted to the ICU and a Swan-Ganz catheter placed.
✓ When ordered, the nitric oxide will be set-up as usual, through 840 or 980 ventilator or in the NIV mode. A regular BiPap machine cannot be used; there must be an inhalation and an exhalation line in the circuit.
✓ The patient’s NIV full face mask must be snug, if not tight.
✓ Nitric Oxide will be started at 20 ppm for 1 hour, then dropped to 5 ppm for one hour and then DC’d. There may be different concentrations, so make sure there is a written order for this procedure.

6. Documentation
✓ In the EMR, on the Respiratory Care Flow Sheet, and on the Daily Activity Sheet, the therapist must document when the nitric was started, the ppm and the tank number. A small sticker on the side of the tank should be placed on the Respiratory Care Flowsheet. A second tank sticker should be placed on the RT Daily Department Activity report next to the specific ventilator patient information.
✓ Ppm and tank pressure must be documented with each vent check.

7. Hazards and Precautions
Nitric oxide is a colorless, highly diffusible gas with a density about the same as air. In the presence of oxygen, nitric oxide combines with oxygen to form nitrogen dioxide. OSHA has set a nitric oxide exposure limit of 25 ppm when breathing for more than 8 hours.

Nitrogen dioxide is cytotoxic. In concentrations of 5 ppm or greater, it can cause inflammation in the human lung. To safeguard against this, the nitrogen dioxide analyzer is preset to alarm if concentrations reach 5 ppm.

No pregnant healthcare workers, visitors or those anticipating pregnancy should work with, visit, or care for patients on nitric oxide delivery.

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<th>Approved by:</th>
<th>Review/Revision Date:</th>
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<tbody>
<tr>
<td>/s/ Michael J. Taylor</td>
<td>12/01/2015</td>
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<tr>
<td>Director, Respiratory Care</td>
<td>12/01/2019</td>
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| /s/ Monecca Smith                   | Date                  |
| AVP Patient Care Services/Chief Nursing Officer |                       |

Review/Revision Completed By:
Director, Respiratory Care

Next Review Date: December 1, 2022

Policies Superseded by This Policy:

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.