HOBIT Technical Memo No. 5

SUBJECT: COVID-19 Infection Prevention and Control Considerations for the HOBIT Trial

Issue Date: February 1, 2021

MEMO:

This MEMO provides discussion of infection prevention and control recommendations regarding COVID-19 (SARS-CoV-2 virus) and the treatment of HOBIT Trial subjects who are either COVID-19 positive, are experiencing COVID-19 like symptoms (persons under investigation), or have a high risk of infection from a recent exposure to a COVID-19 positive individual within the last 14 days.

SCOPE:

This MEMO will address the management of HOBIT subjects who are: 1) COVID-19 positive, 2) persons under investigation (PUI), or 3) at high-risk during conduct of clinical trial procedures.

PURPOSE:

Because of the unique challenges for treating COVID-19 positive, PUI's, or high risk HOBIT subjects, this MEMO is provided as a supplemental guide for transmission-based precautions. It is not meant to replace or supersede your hospital's internal infection prevention and control policies, departmental policies and procedures, or public health authority guidance.

CONCERNS:

COVID-19 patients enrolled in the HOBIT trial may pose increased risk of SARS-CoV-2 virus transmission to others during trial procedures.

SPECIAL NOTE REGARDING <u>MONOPLACE CHAMBERS</u>:

Information and recommended guidelines that are unique to monoplace chambers will be highlighted in light grey.

TRANSMISSION-BASED PRECAUTIONS AND RECOMMENDED GUIDELINES:

1. Staff: Staff involved with direct care of HOBIT subjects who are COVID-19 positive, PUI's, or at high risk for COVID-19 should follow your hospital's policy for handwashing and use of PPE.

2. Ventilator care:

    a. Filtration: Ventilators should be equipped with dual-limb breathing circuits. The expiratory limb of the ventilator circuit should have a mechanical type HEPA filter placed after the exhalation valve. Select a HEPA filter that is effective for filtering the SARS-CoV-2 virus. (Ref. 1- 3, page 4). An electrostatic bacterial/viral filter is also recommended between the ventilator and the supply limb of the ventilator circuit.

    CAUTION: Monoplace applications: An artificial nose/HME (heat moisture exchanger) should never be placed at the circuit wye "Y". *Rationale: Because the subject cannot be accessed during a monoplace treatment, an HME placed on the wye "Y" creates an increased risk of airflow restriction or blockage from mucus or increased moisture within the HME device.*

    CAUTION: HEPA filters should be changed daily (after two treatments). HEPA filters should be closely monitored during the hyperbaric treatment for increased airflow resistance that may lead to auto-PEEP or breath-stacking on the ventilator. This can noted by observing the PIP and PEEP readings on the airway manometer. Changing the HEPA filter daily will minimize this risk.

    CAUTION: In general, it is recommended that when a filter of any type is used on the **expiratory limb side** of the subject's breathing circuit, the filter should be exchanged every 24 hours. The subject's airway pressures and expiratory volumes should always be closely monitored for unsafe deviations from normal.

b. Disconnecting the ventilator circuit: When it is necessary to disconnect the subject from the ventilator circuit, such as for BVM ventilation or changing circuits for transport, the circuit should only be disconnected at the end of exhalation. Avoid disconnecting the ventilator circuit when the subject is coughing or during periods of asynchrony (bucking the ventilator). Careful planning should be used to minimize the number of ventilator disconnects required. *Rationale: Reduces the risk of virus aerosolization.*

c. Suctioning: All subjects should have an in-line or closed suction "Ballard" type suction system connected to the subject's ET tube so that the circuit is not opened or disconnected for ET tube suctioning.

d. Portable suctioning machine: The portable suction machine should have a HEPA filter on the exhaust side.

e. Changing ventilator circuits: If a separate ventilator circuit is used only for the HBO treatment and this circuit is left unused between HBO treatments, we recommend replacing the circuit and filters every 24 hours.

3. Resuscitation bags:

a. Resuscitation bags should be protected with HEPA Type filters (see fig. 1, page 4). Use of resuscitation bags should be minimized since this requires the subject to be disconnected from the circuit creating a potential for airborne or droplet contaminates. **NOTE:** A HEPA type filter connected to the ET tube will increase dead space (see fig. 1, page 4).

4. Cuff exchange from air to NS:

a. Staff performing this procedure should have full PPE protection, including: respirators (e.g., N95), eye protection (e.g., face shield or goggles), gloves and

isolation gowns. This procedure is considered an aerosol-generating procedure (AGP), and your hospital's AGP policies should be followed.

b. Recommend following the HYCEP maneuver. This procedure can be found in the HOBIT website Toolbox along with an instructional video.

c. We recommend using a "minimal seal" technique versus the "minimal leak" technique because of the added risk of droplet and aerosol generation with a "minimal leak".

d. Since this procedure would be considered an AGP, it is recommended (following your hospital's AGP policies) that the cuff exchange be performed in the ICU prior to transport to the hyperbaric department.

5. Maintaining proper distancing: Per CDC guidelines; a distance of at least six (6) feet shall be maintained from the subject and caregivers unless wearing recommended PPE.

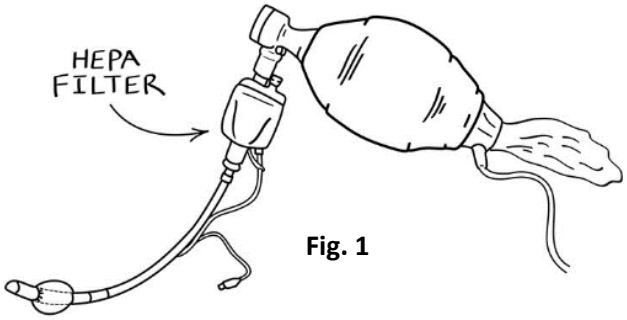

Fig. 1

Ref. 1: EFFICIENCY OF HEPA FILTERS
https://www.hamilton-medical.com/en_US/E-Learning-and-Education/Knowledge-Base/Knowledge-Base-Detail~2020-03-18~Efficiency-of-HEPA-filters~d5358f88-753e-4644-91c6-5c7b862e941f~.html

Ref. 2: FILTRATION OF BREATHING GASES
http://clinicalfoundations.org/assets/cf_12.pdf

Ref. 3: PROCEDURES TO MINIMIZE VIRAL DIFFUSION IN THE INTENSIVE CARE UNIT DURING THE COVID-19 PANDEMIC
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7247976/

HYPERBARIC FACILITY ROOM:

Low Risk Level: Due to the subject's source control and the recommended guidelines outlined in this memo, the HOBIT subject would be considered a low-risk for SARS-CoV-2 virus transmission to other hyperbaric patients or staff in the hyperbaric facility.

1. Room Ventilation: The room or area being used to prep the subject should be well ventilated.
2. Partitions: Portable partitions or privacy curtains should be placed to maintain privacy and to create a soft barrier for maintaining proper distancing.
3. Personnel: Minimize the number of staff members directly involved with preparing the subject for the HBO treatment. All personnel should continue to wear full PPE.
4. Disinfection: Follow your hospital's policies and procedures for proper disinfection of the area after use.

HYPERBARIC CHAMBER:

1. Surface Preparation Time inside the Chamber: If a subject is placed inside the chamber for pre-dive preparations, the chamber doors should remain closed and sealed with the chamber's exhaust completely open to prevent pressurization while the chamber is ventilated on the surface. This will help eliminate potential aerosol contaminates by forcing them out through the chamber's exhaust. However, if the chamber doors do not seal completely on the surface and there is air leak from unsealed doors into the staff and patient areas, consider the use of portable HEPA filtration to aid in cleaning the chamber atmosphere without ventilating the chamber on the surface.
2. During Treatment: The chamber should be well ventilated throughout the treatment.
3. Ventilator exhaust: For both monoplace and multiplace applications. If possible, exhaust from the ventilator should be contained through wide-board tubing with the

end of the wide-bore tubing placed in close proximity to a chamber exhaust source (e.g., Evac system, or chamber exhaust). This will prevent or minimize the circulation of airborne contaminates in the chamber's atmosphere that may also escape when the chamber door is opened at the end of treatment. **Caution:** The wide-bore tubing should be added/connected after the exhalation valve. **(See page 11; Further Cautions and Comments on Ventilator Exhaust)**

NOTE for Monoplace Applications: Although there is no inside attendant with monoplace treatments, there is potential, even with HEPA filtration on the ventilator exhaust, for aerosol contaminates to be in the atmosphere and escape from the monoplace atmosphere when the chamber door is opened at the end of treatment.

a. ***WARNING****: The wide-board tubing should never be* ***directly connected*** *to any exhaust source inside the chamber, but only in close proximity for a "passive" exhaust of the subject's exhaled tidal volume*. **(See page 11, Further Cautions)**
b. ***CAUTION:*** *As the length of the wide-bore tubing is increased, the resistance to airflow from the subject's exhaled gas will also increase. This can lead to inadvertent PEEP or "breath-stacking" with the ventilator. Recommend testing prior to subject or patient use.* **(See page 11, Further Cautions)**

4. Ventilator Filters: As noted above in Ventilator Care: HEPA filtration should be used on the exhaust limb and an electrostatic type viral filter on the ventilator supply limb.
5. Suctioning: If possible, the exhaust port of the chamber's medical vacuum system (for ET tube suctioning) should be protected with HEPA filtration if it terminates inside the hyperbaric room or inside the hospital. If the vacuum system exhausts to the building exterior, see following item # 6 "Chamber Exhaust".
6. Chamber Exhaust: If the chamber exhaust is not protected with HEPA filtration, the chamber's exterior (outside) exhaust piping should be clearly marked as "Hyperbaric Chamber Exhaust" with signage warning of Oxygen and Biological Hazards and no

smoking or open flame signs. Yellow caution tape or similar could be used to create a soft barrier with signage around the perimeter of the chamber exhaust with at least a 25-foot radius.

7. Inside attendants (IA's): Multiplace IA's should continue to wear the proper PPE and additional PPE supplies should be available inside the chamber as needed during the HBO treatment.

8. Oxygen for Multiplace IA Decompression**:** The respirator (e.g., N95) should be exchanged for the Built-in Breathing System (BIBS) mask or another oxygen breathing device as quickly as possible. The IA should prepare the BIBS mask for donning so this can be done quickly and avoid inhaling during the switch. Avoid multiple unmasked IA's at the same time. Consider positioning the patient and/or BIBS masks in proximity so that IA's are within range of the patient. An alternative option includes the use of a head harness to provide a proper fit and the ability to be hands-free.

9. Hand washing: Sinks with soap and water or hyperbaric compatible hand sanitizers should be available for the IA.

10. Emergency Operating Procedures (EOP's): Your department's EOP's should be reviewed for potential gaps in providing proper care for the subject. It is also important to ensure that staff are supplied with and are using appropriate PPE during any emergencies that may take place during the subject's hyperbaric treatment. All hyperbaric facilities should review each treatment EOP and conduct informal simulations of EOP's to identify latent risks and consider how to mitigate or remove those risks through procedural or mechanical mitigations.

11. Disinfection: Follow your hyperbaric department's specific policy and procedures for proper disinfection inside your chamber after use.

12. Ventilation of Room Post-AGP: Follow your hospital's infection prevention and facility engineering guidance to ensure that the proper air clearance time (ACT) is observed for rooms where an AGP has occurred.

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ABBREVIATIONS

ACT	Air clearance time (in reference to room ventilation)
AGP	Aerosol generating procedure
BIBS	Built-in Breathing System
CDC	Center for Disease Control
EOP	Emergency operating procedure
ET	Endotracheal
EVAC	Hyperbaric evacuation system (often called “overboard dump” system)
HEPA	High-efficiency particulate air filter
HME	Heat moisture exchange filter (often called an “artificial nose”)
HYCEP	Hyperbaric cuff exchange procedure (replace cuff air with fluid)
IA	Inside attendant (for multiplace chambers)
N95	Respirator (that blocks at least 95% of 0.3 micron test particles)
PEEP	Positive end expiratory pressure
PIP	Peak inspiratory pressure (max pressure during inspiratory phase)
PPE	Personal protective equipment
PUI	Persons under investigation
Wye “Y”	Bifurcation section of ventilator circuit that connects to the ET tube

RESOURCE LINKS

1. **HOBIT Trial:** **HOBIT**
2. **CDC COVID Resources:** Information for Healthcare Professionals about Coronavirus (COVID-19)
3. **NIH COVID Resources:** Home
4. **ANA COVID Resources:** Coronavirus Resources | COVID-19 | ANA Enterprise
5. **AARC COVID Resources:** https://www.aarc.org/nn20-covid-19-news-resources/
6. **UHMS COVID Guidelines:** UHMS Guidelines for infection control, patient treatment, and staff safety considerations related to Hyperbaric Oxygen Therapy (HBO2) in monoplace and multiplace hyperbaric chambers during the novel coronavirus disease (COVID-19) outbreak
7. **American Hospital Association:** Novel Coronavirus (COVID-19) Resources and Special Communications
8. **ECRI COVID Resources:** COVID-19 (Coronavirus) Resource Center
9. **ASHE COVID Resources:** COVID-19 Resources for Health Care Facilities
10. **CMS COVID Toolkit:** Coronavirus (COVID-19) Partner Toolkit

Further Cautions and Comments on Ventilator Exhaust (see page 5):

1. Never place any material over the chamber's exhaust port that will restrict air flow into the chamber's exhaust system.

2. Never connect the ventilator's exhaust directly to the chamber's exhaust or to any exhaust/vacuum source, e.g., BIBS exhaust.

3. Use caution when placing the end of the wide-bore tubing in a location proximal to the chamber's exhaust. Reason: During an emergency abort procedure there may be a tremendous area of vacuum in the area immediately surrounding the chamber's exhaust port. If there is not sufficient area to relieve this vacuum near the end of the wide-bore tubing, it may create negative pressure inside the wide-bore tubing leading to the ventilator and to the subject's ventilator circuit. Please see items No. 6 & 7 below for testing.

4. When adding extended wide-bore exhaust tubing, this should always be added after the ventilator's exhalation valve, **not before**. For some types of ventilators, if the wide-bore tubing is added before the exhalation valve it can lead to a loss of volume due to increased tubing compliance.

5. Minimize the length of the wide-bore tubing as much as possible. Reason: as the length of the wide-bore tubing increases there will be a corresponding increase of airflow resistance.

6. **TESTING:** After adding the wide-bore tubing to the ventilator's exhaust; your ventilator should be tested for normal function and carefully checked for any signs of increased airway resistance. **NOTE:** An increase of airflow resistance can lead to an inadvertent increase of PEEP and increased PIP secondary to breath-stacking. With normal ventilator function, the airway manometer should quickly fall back to zero cmH2O or to the baseline PEEP setting, at the end of inspiration.

7. **TESTING:** Test your ventilator's wide-bore exhaust for negative pressure during an emergency abort procedure to ensure there is no negative pressure to the wide-bore tubing (see item No. 3 above). This can be checked by observing if there is a negative needle deflection on the ventilator's manometer during the chamber's emergency abort procedure. If unable to use the ventilator's manometer, "Tee-in" a separate airway manometer to the wide-bore tubing in order to monitor the ventilator's exhaust for any negative needle deflections on the manometer during an emergency abort procedure.