Malvern Sleep Clinic

Malvern Sleep Clinic (MSC)

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August 12, 2020

During the month of May 2020, a document was created to describe the procedure, protocols, and infrastructure to mitigate the chances of the spread of the COVID-19 (Appendix B- Summary of COVID 19 related protocol, and precautions). In this current document, more emphasis has been made on HVAC, Mechanical Ventilation, and Air change per hour on the premises of Malvern Sleep Clinic. For more details, please watch videos on our website **Video 1** (Custom made Aerosol Removal Device), **Video 2** (Air Pura UV 600 Hepa Filter), **Video 3** (Additional ACH improvements in the open area at MSC), **Video 4** (Mechanical Ventilation inpatient setup rooms) and **Video 5** (COVID 19 related signage) to successfully navigate through the extraordinary COVID – 19 times.

CPSO requires that every sleep clinic perform a risk assessment (ORA) to assess the efficacy of control measures that are in place to mitigate the transmission of infections.

Appendix A: This is the document submitted to CPSO to assess the efficacy of control measures that are in place to avoid the transmission of infections.

Appendix B: Contains the detailed document prepared on May 28, 2020, of procedures, protocols, and infrastructure to reduce the chances COVID-19

All of our staff members (Sleep Specialists, Technologists, and the Admin Staff) when interacting with and within 2 meters of patients who screen positive or who might be the carriers of The Coronavirus use Droplet and contact Precautions:

- Surgical/procedure mask (N95 respirator)-When aerosol-generating medical procedures [AGMPs] are performed
- Isolation gowns
- Gloves
- Eye protection (goggles or face shield)
- Perform hand hygiene before and after contact with the patient and the patient environment and after the removal of PPE

In a room where an (AGMP) Aerosol generating medical procedure (CPAP titration) has been performed, and if the room air changes are unknown, there is a waiting period of

more than or equal to 15 minutes for aerosols to settle before the room is accessed by any staff or patients; if re-entry is necessary before settling, Droplet/Contact Precautions are adhered to and N95 respirator is worn to reduce exposure risk.

HVAC units are monitored by the building management HVAC company under the directions of the technical director.

Our ventilation meets the requirements of CAN/CSA –Z317.2 for HVAC and is regularly inspected by an independent HVAC company.

Appendix C shows that there is a documentation to verify that the HVAC systems have been reviewed by an independent HVAC company.

Our sleep clinic ventilation meets the requirements of CAN/CSA-Z317.2 for HVAC requirements.

As per the regulatory requirement, the mechanical ventilation system is inspected every three months to ensure that it is in good condition.

In a room where an AGMP (CPAP titration) has been performed, about 15 minutes of settle time is needed to allow the COVID-19 virus-laden droplets and aerosols to fall and settle down on the ground or the patient's bed. This settling time can be defined as the time needed to remove infectious airborne organisms or infectious aerosols created during the aerosol-generating procedure (CPAP titration) in a room. This settling time begins when the source of infections ends. In our case when we perform the continuous CPAP titrations during the overnight sleep studies, this concept of settle time holds only in the morning when we stop the CPAP titration sleep study.

To determine a specific settle time for a specific room, the number of air changes (ACH) must be evaluated for each room. Air changes per hour are the number of times that the total air volume in a room is completely removed and replaced in an hour. **Appendix D** shows a relationship between the number of air changes per hour and the settling time of the aerosols (e.g if the room has an ACH of 12, the settling time is 35 minutes). More the number of air changes per hour lesser the settling time.

Infection control in the titration rooms:

Rooms 6 7 and 8 are our titration rooms. In every titration rooms two following devices are used:

Aerosol removal device
AirPura UV 600

1. **Aerosol removal device.**

   The Aerosols extractor device is shown in the video**- 1 Custom made aerosol removal device**. This device aims to remove the infectious aerosols coming out of the patient's CPAP mask and then throw these aerosols in the air above the roof of the building. This device consists of a100 CFM exhaust fan to suck the aerosols-jet coming from the exhale holes of the CPAP mask worn by the CPAP titration patient. Most of the aerosols are sucked by this device then thrown out of the roof of the building via a duct pipe going from the patient room to the roof of the building. Air sucking is done in a 4- inch wide duct pipe inlet attached to a 100 CFM exhaust fan installed in the attic above the room ceiling. At the beginning of the sucking pipe there a rectangular shape Plexiglas sheet (17 inches length and 11 inches wide). The purpose of this plexiglass sheet is to obstruct the aerosol jets coming from the CPAP mask to avoid the spread of the aerosols in the air of the patient room. According to Dr. Linsey Marr (https://www.nytimes.com/2020/06/12/well/live/Coronavirus-aerosols-linsey-marr.html) who is one of the few academics in the field of aerosol science; an aerosol released at a height of about six feet would fall after 34 minutes. In our case the aerosols are sucked and obstructed at a height of approximately one foot only, resulting in that majority of aerosols are extracted and get thrown over the roof of the patient room and the remaining aerosols are obstructed by the plexiglass sheet causing the aerosols to fall down and then settle down almost abruptly.

2. **AirPura UV600 Hepa filter** –**Video - 2 AirPura Device**

   AirPura UV600 features the AirPura Germicidal UV bulb along with AirPura UV600 HEPA and Carbon filters which enable AirPura UV 600 to deliver a superior level of airborne pathogen control, effective allergen removal, and chemical absorption. This makes AirPura UV600 an indispensable air purifier for individuals with severe respiratory problems and illnesses pathogen control. AirPura UV600 delivers an impressive airflow of 500 CFM and cleans areas up to 2000 sq. ft.

AirPura UV600 HEPA filter machine is run continuously in the patient rooms where the CPAP titration is being done. AirPura UV600 provides continuous additional air changes in rooms where this unit is run during the night of CPAP titration. AirPura UV600 sucks the potentially infected room air from one side of the unit. When sucked air passes over the UV light bulb, the pathogens present in sucked air are killed, and then the clean air leaves from the other side of the AirPura unit. This way cleaning the air and air changes are happening simultaneously. These air changes happening in the patient room are in addition to the air changes provided by two of our HVAC units to the whole area of the premises of the sleep clinic. The definition of air changes per hour is the number of times that the total air volume in a room is completely removed and replaced in an hour. This is what is being done by the Airpura UV600, when it sucks air from one side and continuously delivered the air from the other side.

Formula to calculate ACH: $\frac{60X\ CFM}{Volume\ of\ Space}$

AirPura UV600 can move the air with a speed of 500 CFM. As an example of Air volume in room # 6 is 834 cubic feet to produce 36 air changes.

Infection control in sleep diagnostic rooms

Room 1, 2,3,4,5,9 are our sleep diagnostic rooms. Each diagnostic room is equipped with Levoitt Hepa filter CFM 300. For example, room # 4 Levoit Hepa filter with a speed of 300 CFM can provide an additional 21 ACH. When we add this ACH (21 ACH) to the building ACH (14.3), the total ACH 35.4 is achieved. This value of ACH is much higher than recommended ACH in **Appendix D & G**

Infection control for open area

The total air volume of the open area (whole clinic) is 24360. Total CFM from Exhaust fans, 2 washrooms exhaust fans, 3 setup rooms exhaust fans one reception area exhaust fan and 3 AirPura is 3700 CFM. From 24360 volume and 2800 CFM, we get 5 ACH along with an additional building HVAC creating 14.3 ACH. When we add both values of ACH total ACH is 19.3, which is above the recommended ACH in **Appendix D & G.**

Appendix D shows the relationship between the air changes per hour and the settling time for the aerosols in the air**.**

HEPA – HEPA is a type of pleated mechanical air filter. It is an acronym of for “high-efficiency particulate air filter”

Air change per hour is calculated by multiplying the CFM (cubic feet per minute) and dividing by the volume of space/ room. (**Appendix G**)

In simple terms, the air change is the number of times all of the air in a room can be purified or changed.

Although the whole infrastructure described here proves that the air in the Malvern sleep clinic very safe, still N95 masks and other PPE must be worn by the overnight sleep technologists when entering the CPAP titration rooms. Other procedures and protocols have already been described in another document. **Appendix B**

References:

1. IPAC Assessment Checklist for IHF during COVID-19
2. ASHRE – HVAC Design Manual for Hospitals and Clinics
3. CDC – Guidelines for Environmental Infections Control in Health-Care Facilities.
4. CFM and Air change---https://www.youtube.com/watch?v=4201RP8dhVQ
5. CFM and Air change---https://www.youtube.com/watch?v=alwA0-iSZ_s
6. Dr. Marr: https://www.nytimes.com/2020/06/12/well/live/Coronavirus-aerosols-linsey-marr.html

CHECKLIST

July 7, 2020

Infection Prevention and Control Assessment for Independent Health Facilities and Out of Hospital Premises During the COVID-19 Pandemic

Preamble

This checklist has been developed to guide individuals (e.g., assessors) in conducting infection and prevention and control (IPAC) assessments of Independent Health Facilities (IHFs) and Out of Hospital Premises (OHP) during this COVID-19 pandemic. It can also be used by those working in IHFs and OHPs for self-assessment and to guide policies, procedures, preparedness and response planning. Prior to restarting or continuing services, IHFs and OHPs should complete an organizational risk assessment (ORA) that assesses the efficacy of control measures that are in place to mitigate the transmission of infections.

This assessment checklist is to be used in addition to—and does not replace—the advice, guidelines, recommendations, directives, or other direction of provincial Ministries and local public health authorities. The checklist was informed by the documents listed under Sources.

Contents

IHF/OHP name:

IHF/OHP address:

Self-Assessment ☐ **Assessment** ☐

Date: **Time:**

Name(s) and designation of Assessor:

Setting contact name(s) and phone number(s):

1. Reception and Waiting Area(s)

1	Reception/Waiting Area	Yes	No	N/A
1.1	Signage is posted at the entrance to the IHF/OHP and at reception areas requiring all patients and any visitors to wear a face covering/non-medical mask (if available and tolerated), perform hand hygiene, maintain respiratory etiquette and then report to reception to self-identify.			
1.2	Signage is accessible and accommodating to patients and visitors (e.g., plain language, pictures, symbols, languages other than English and French).			
1.3	There is access to alcohol based hand rub (ABHR)/hand sanitizer with 60% – 90% alcohol.			
1.4	All health care providers (HCPs), other staff, patients and visitors perform hand hygiene upon entering the IHF/OHP.			
1.5	Face covering is provided when physical distancing is not possible, and if the patient and visitor are not wearing their own face covering.			
1.6	The need for patients to wait in the waiting room is minimized (e.g. spreading out appointments, spacing out chairs in the waiting room having each patient staying outside the IHF/OHP until the examination/procedure room is ready for them and then calling in, by phone preferably).			
1.7	Tissue boxes and lined waste receptacles are available for appropriate disposal; hands-free waste receptacles are preferred.			

Notes:

2. Screening – Staff, Patients and Visitors

2	Screening – Staff, Patients and Visitors	Yes	No	N/A
2.1	All staff are aware of the symptoms of COVID-19 and self-monitor; they have been instructed to remain at home, or return home from work, if symptoms develop.			
2.2	All staff are screened daily, including temperature checks, at the beginning of the day or shift and recorded in a log.			
2.3	All staff responsible for screening have access to ABHR/hand sanitizer.			
2.4	**Active screening of patients prior to appointment:** Using the latest COVID-19 Patient Screening Guidance Document on the MOH COVID-19 website, patients are screened over the phone for symptoms of COVID-19 **before coming for their appointments**. If a patient screens positive over the phone, the appointment should be deferred if possible and the individual referred for testing.			
2.5	**Active screening of visitors prior to appointment:** If a visitor is to accompany a patient to an appointment, the visitor is also screened prior to the appointment.			
2.6	Staff conducting screening of patients and visitors on site are ideally behind a barrier to protect from contact/droplet spread. • If a Plexiglas barrier is not available, staff maintain a 2-metre distance from the patient. • Screeners who do not have a barrier and cannot maintain a 2-metre distance use Droplet and Contact Precautions; this includes the following personal protective equipment (PPE): gloves, isolation gown, a surgical/procedure mask, and eye protection (goggles or face shield).			
2.7	**Active screening of patients and visitors (who are accompanying a patient) on site:** • Patients and visitors are screened, including temperature check, using the latest COVID-19 Patient Screening Guidance Document on the MOH COVID-19 website.			

	• If a patient screens positive, the appointment should be deferred if possible and the patient should be referred for testing. • In the event a visitor screens positive, they should be referred for further assessment and testing			
2.8	There is a process to record/log who has entered and exited the IHF/OHP that includes all staff, patients, visitors accompanying patients and other essential visitors (e.g., courier, laboratory pick-up personnel, delivery personnel, mail delivery, suppliers).			

Notes:

3. Positive Screening: Providing Care

3	Positive Screening: Providing Care	Yes	No	N/A
3.1	A patient who screens positive for symptoms of COVID-19 over the phone is instructed to self-isolate immediately and referred to a local testing location or emergency department; patients with severe symptoms are directed to the emergency department.			
3.2	Symptomatic patients requiring procedures that cannot be postponed are scheduled at end of day, where possible.			
3.3	A patient who screens positive at the IHF/OHP wears a surgical/procedure mask and is advised to perform hand hygiene.			
3.4	Patients who screen positive are immediately placed in a room with the door closed (not cohorted with other patients), where possible, to avoid contact with other patients in common areas of the IHF/OHP (e.g., waiting rooms).			
3.5	Where it is not possible to move a patient who screens positive from the waiting room to an available examination/procedure room, the patient is instructed to return outside (e.g., vehicle or parking lot, if available and appropriate) and informed that they will be contacted when a room becomes available.			

3.6	HCPs offer clinical assessment and examination to patients who screen positive **only if** HCPs are able to follow Droplet and Contact Precautions and are knowledgeable on how to properly don and doff PPE (i.e., gloves, isolation gown, a surgical/procedure mask, and eye protection (goggles or face shield).			
3.7	HCPs not able to follow Droplet and Contact Precautions and/or not knowledgeable on how to properly don and doff PPE, divert the care of the patient as appropriate.			

Notes:

4. Personal Protective Equipment (PPE)

4	Personal Protective Equipment (PPE)	Yes	No	N/A
4.1	HCPs conduct a point of care risk assessment (PCRA) before every patient interaction to determine the level of precautions required.			
4.2	PPE, appropriate for the task to be performed, is available and easily accessible; PPE includes gloves, gowns, facial protection (including surgical/procedure masks and N95 respirators), and/or eye protection (including safety glasses, face shields, goggles, or masks with visor attachments).			
4.3	HCPs who are required to wear PPE are trained in the use, care, and limitations of PPE, including the proper sequence of donning and doffing PPE.			
4.4	In IHFs/OHPs where N95 respirators are used, HCPs are fit-tested at least every two years and whenever there is a change in respirator face piece or the user's physical condition, which could affect the respirator fit and seal-check.			
4.5	Surgical/procedure mask is worn for the full duration of the shift for HCPs working in direct patient care areas.			

4.6	Surgical/procedure mask is worn by all staff working outside of direct patient care areas when interacting with other HCPs and staff when physical distancing cannot be maintained. Note: Eye protection (e.g., goggles or a face shield) for the duration of shifts is required			
4.7	HCPs, when interacting with and within 2 metres of patients **who screen negative**: • Wear surgical/procedure mask • Require the use of eye protection (goggles or a face shield) • Perform hand hygiene before and after contact with the patient and the patient environment and after the removal of PPE			
4.8	HCPs, when interacting with and within 2 metres of patients **who screen positive** use Droplet and Contact Precautions: • Surgical/procedure mask **(N95 respirator when aerosol-generating medical procedures [AGMPs] are performed**) • Isolation gown • Gloves • Eye protection (goggles or face shield) • Perform hand hygiene before and after contact with the patient and the patient environment and after the removal of PPE			
4.9	PPE is removed and hand hygiene is performed just at the exit of the examination/procedure room.			

Notes:

5. Hazard Controls

5	Hazard Controls	Yes	No	N/A
5.1	Consultations, assessments and follow-ups are conducted over the phone, video or secure messaging when possible and appropriate.			
5.2	All elective aerosol-generating medical procedures (AGMPs) performed in IHFs and OHPs for patients screening/testing positive for COVID-19 are postponed until the illness is resolved.			

5.3	AGMPs are performed in an airborne infection isolation room with the door closed, where possible. If such a room is not available, an AGMP is performed in a single room with the door closed.			
5.4	The number of people in the room during procedures is kept to a minimum and only highly experienced staff perform AGMPs.			
5.5	In a room where an AGMP has been performed, and room air changes are unknown, there is a waiting period of ≥15 minutes for aerosols to settle before the room is accessed by any staff or patients; if re-entry is necessary prior to settling, Droplet/Contact Precautions are adhered to and an N95 respirator is worn in order to reduce exposure risk.			
5.6	There are written policies and procedures for staff, patient and visitor safety including for infection prevention and control; these are easily accessible to staff.			
5.7	Staff are provided opportunities/resources for education and training (e.g., Routine Practices and AGMPs).			

Notes:

6. Physical Capacity/Environment

6	Physical Capacity/Environment	Yes	No	N/A
6.1	There is sufficient space to follow physical distancing guidelines of maintaining at least 2 meters from other people.			
6.2	Traffic flow for common spaces is minimized (e.g., physical markings in IHF/OHP, signage to limit number of riders is noted in/by elevator).			
6.3	Breaks and lunches are staggered to help ensure physical distancing of staff.			
6.4	ABHR/hand sanitizer is available both outside and inside the examination/procedure rooms.			
6.5	Each examination/procedure room has a tissue box and waste receptacle (hands-free is preferred).			

6.6	ABHR/hand sanitizer is located throughout the IHF/OHP, including at point-of-care.			
6.7	Signage is posted throughout the IHF/OHP reminding staff and patients of the signs and symptoms of COVID-19, and the importance of proper hand hygiene, physical distancing, and respiratory etiquette.			

Notes:

7. Critical Supplies and Equipment

7	Critical Supplies and Equipment	Yes	No	N/A
7.1	A stable supply of PPE and other essential supplies (e.g., ABHR/hand sanitizer, liquid soap, and paper towels) are ensured and the supply in place is reviewed considering local and regional sector inter-dependencies.			
7.2	Employer sources and provides PPE to HCPs in accordance with their responsibilities to ensure workplace safety under the Occupational Health and Safety Act.			

Notes:

8. Human Resources/Occupational Health and Safety

8	Human Resources/Occupational Health and Safety	Yes	No	N/A
8.1	The number of staff working on site in the IHF/OHP is minimized; tasks that can be done from home or outside of regular hours will minimize staff interactions with each other and patients.			
8.2	HCPs who have returned from travel in the last 14 days: • from outside of Canada **OR** • from a COVID-19 affected area within or outside of Ontario **AND/OR** • have had a confirmed, unprotected exposure to a person with COVID-19 self-monitor for symptoms and continue to work with specific precautions **if they are deemed critical to operations.**			
8.3	There is a process/policy in place for follow up of any exposures/infections stemming from the workplace that includes notification to the Ministry of Labour, Training and Skills Development for occupational illnesses.			
8.4	Staff, including HCPs, who test positive for COVID-19 report their illness to their manager/supervisor or to Employee Health/Occupational Health and Safety as per usual practice.			
8.5	Employer provides written notice within four days of being advised that a staff has an occupational illness, including an occupationally-acquired infection, or if a claim has been made to the Workplace Safety and Insurance Board (WSIB) by or on behalf of, the worker with respect to an occupational illness or infection, to the: • Ministry of Labour, Training and Skills Development, • Joint Health and Safety Committee (or health and safety representative), and • Trade union, if any.			
8.6	HCPs report to their Employee Health/Occupational Health and Safety department before returning to work.			

Notes:

9. Environmental Cleaning

9	Environmental Cleaning	Yes	No	N/A
9.1	IHFs/OHPs comply with IPAC best practices for environmental cleaning.			
9.2	Surfaces, furnishings, equipment, and finishes are smooth, non-porous, seamless (where possible), and cleanable (e.g., no unfinished wood or cloth furnishings).			
9.3	Chemical products used for environmental cleaning are: • licensed for use in Canada; • prepared and used according to manufacturer's instructions for use (MIFU) for dilution, temperature, water hardness, use, shelf life and storage conditions; • labelled with expiry date; and • stored in a manner that reduces the risk of contamination.			
9.4	Contact time (surface remains wet for the required amount of time to achieve disinfection), as indicated on the MIFU, is adhered to.			
9.5	There are procedures for cleaning each area of the IHF/OHP; if cleaning is contracted out, the cleaning contractor has procedures in place for cleaning each area of the IHF/OHP.			
9.6	In multi-unit buildings (e.g., mixed use office/medical buildings), tenants engage with landlords to ensure that the building is following best practices of cleaning in common spaces (e.g., elevators).			
9.7	All common areas are regularly cleaned and disinfected (e.g., minimum daily).			
9.8	After every patient visit, shared patient equipment is cleaned and disinfected before use on another patient.			
9.9	Treatment areas (areas within 2 metres of the patient) including all horizontal surfaces and equipment used on the patient (e.g., exam table, thermometer, BP cuff) are cleaned and disinfected before another patient is brought into the treatment area or used on another patient.			
9.10	Barriers/covers on equipment surfaces that can become contaminated are used (e.g., paper on exam table); barriers/covers are removed and discarded between patients and surface is cleaned and disinfected. Clean barrier/barriers are placed prior to the next patient.			
9.11	Plexiglas barriers are included in routine cleaning (e.g. minimum daily) using a cleaning product that will not affect the integrity or function of the barrier.			

9.12	There is a regular schedule for environmental cleaning in the designated reprocessing area that includes a written policy and procedure and clearly defined responsibilities.			
9.13	Laundry is handled at the point of use in a manner that prevents contamination.			
9.14	Non-essential items are removed from patient care and common areas (e.g., magazines and toys).			
9.15	Waste is disposed of in accordance with provincial regulations and local bylaws, with attention to sharps and biomedical waste.			

Notes:

10. Reprocessing of Reusable Medical Equipment/Devices

The following section contains highlights from the IPAC Checklist for Clinical Office Practice – Reprocessing of Medical Equipment/Devices. Refer to this IPAC Checklist when completing a more comprehensive review of reprocessing of medical equipment/devices.

10	Reprocessing of Reusable Medical Equipment/Devices	Yes	No	N/A
10.1	Non-critical items (e.g., treadmill hand-rail, mammography paddles, oximetry probes and airflow sensors) are cleaned and low-level disinfected between patients and when soiled.			
10.2	Semicritical medical equipment/devices receive, at a minimum, high-level disinfection (HLD); sterilization is preferred, as per equipment/device and disinfectant MIFU for time, temperature and concentration.			
10.3	Critical (and preferably semicritical) medical equipment/devices are either disposed of or sterilized using a recommended (as per MIFU) sterilization process.			
10.4	Semicritical and critical medical equipment/devices labelled as single-use are not reprocessed and/or reused.			

Notes:

11. Heating, Ventilation and Air Conditioning (HVAC)

11	Heating, Ventilation and Air Conditioning (HVAC)	Yes	No	N/A
11.1	Facilities have an HVAC system that is monitored by IHF/OHP staff or building management.			
11.2	There is documentation to verify that the facility has reviewed the HVAC system with the building management and confirms that patient treatment areas meet CSA requirements.			

11.3	Ventilation meets the requirements of CAN/CSA-Z317.2 for HVAC requirements.			
11.4	If the building does not have acceptable HVAC coverage per treatment area, facilities that perform AGMP have an adequate air purification system(s) to ensure safety for all staff and patients per treatment area and room size.			
11.5	As per the regulatory requirement, the mechanical ventilation system is inspected every six months to ensure it is in good condition.			

Notes:

Sources

1. Ontario. Ministry of Health. COVID-19 Guidance for the Health Sector webpage. Available from: http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/2019_guidance.aspx.

2. Ontario. Ministry of Health. COVID-19 Guidance for the Health Sector: Health Sector Resources. COVID-19 Operational Requirements: Health Sector Restart. Available from: http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/operational_requirements_health_sector.pdf.

3. Ontario. Ministry of Health. COVID-19 Guidance for the Health Sector: Health Sector Resources. COVID-19 Guidance: Independent Health Facilities. Available from: http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/2019_ihf_guidance.pdf.

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7. Ontario Agency for Health Protection and Promotion (Public Health Ontario). COVID-19 Public Resources: How to self-monitor. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/factsheet-covid-19-self-monitor.pdf?la=en.

8. Ontario. Ministry of Health. COVID-19 Guidance for the Health Sector: Symptoms, Screening, and Testing Resources. COVID-19 Reference Document for Symptoms. Available from: http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/2019_reference_doc_symptoms.pdf.

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10. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Putting on personal protective equipment/Taking off personal protective equipment. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/ipac/ppe-recommended-steps.

11. *Occupational Health and Safety Act*, R.S.O. 1990, c. O.1. Available from: https://www.ontario.ca/laws/statute/90o01.

12. Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Best practices for environmental cleaning for prevention and control of infections in all health care settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2018. Available from: https://www.publichealthontario.ca/-/media/documents/b/2018/bp-environmental-cleaning.pdf?la=en.

13. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices. 3rd ed. Toronto, ON: Queen's Printer for Ontario; May 2013. Available from: **https://www.publichealthontario.ca/-/media/documents/b/2013/bp-cleaning-disinfection-sterilization-hcs.pdf?la=en.**

14. CSA Group. CAN/CSA-Z317.2-15: Special requirements for heating, ventilation, and air-conditioning (HVAC) systems in health care facilities.

15. CSA Group. CAN/CSA-Z8000-18: Canadian health care facilities.

16. *Health Care and Residential Facilities*, O Regulation 67/93. Available from: **https://www.ontario.ca/laws/regulation/930067.**

Malvern Sleep Clinic

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May 28, 2020

Dear Referring Physician/Patient,

Our team of Sleep Medicine specialists, Sleep technologists and Admin staff members hope you are doing well and staying safe in these challenging times.

This unprecedented situation has put our lives on hold, which has not been easy!

We are now in the process of gradually and incrementally opening the Malvern Sleep Clinic for overnight diagnostic sleep studies starting May 28, 2020.

As always, our priority is the health and safety of our patients and our talented team of sleep specialists, sleep technologists and admin staff. To that end, we are proud to announce our opening as a **"COVID-19 protected sleep clinic"** with numerous protocols, procedures and the changes in the infrastructure for everyone's health and peace of mind.

A special COVID 19 related training session was held in the clinic to explain the new procedures and protocols with emphasis on the fact that the improved clinic environment is safe for patients and our staff members. In this training the main emphasis was that conducting the overnight sleep studies outweighs the risk of any potential COVID 19 or other infection.

The following is a brief summary of protocols and precautions:

- COVID-19 patient screening will be done when we book the patients and it will be repeated when the patients come to the clinic.
- We are limiting the number of patients in our facility in order to maintain appropriate social distancing. Our patients waiting area in front of the reception desk will remain CLOSED. Patients will be escorted directly to the overnight sleep study room.
- To minimize the exposure, all consultations will be done "VIRTUALLY".
- The Malvern Sleep Clinic will remain compliant with provincial and local orders and will adhere to safety guideline provided by the CPSO, IHF and the local public health department.
- Patients will be asked to refrain from bringing family members or friends at the time of appointment for the clinic.

- For pediatric patients, only one of parent or guardian is permitted.
- For appointment cancellations we need to be notified at least 24 hr. in advance, so we can offer that spot to another patient.
- Our technologists and admin staff have been trained how to wear the proper personal protection equipment. All staff will be wearing mask when not at their workstation, and those coming in contact with patients will be wearing mask, eye protection, and protective gown/coat.
- We have installed Plexiglass barriers/shields guards in our reception and technical areas.

RESPIRATORY ETIQUETTE AND ENVIRONMENTAL CLEANING PRACTISES

1. We always follow the IHF and CPSO recommended infection control and disinfection procedures to clean our electrodes and sensors.
2. We are in the process of installing super HEPA air purifier with UV light in the filter chamber. This air purifier will be left on continuously in the clinic.
3. This air purifier has been tested and validated by McGill University and now being used in the Intensive Care Units (ICU) of several well reputed hospitals in Canada.
4. After disinfecting every patient room with the HEPA air purifier in the morning and evening, cleaning and disinfecting high touch, non-patient care items and surfaces will take place at least twice a day, or more frequently as use and circumstances warrant. It will include, but not limited to:
    - Door: Knobs, Panel
    - Office desks
    - Chairs, especially arm rests and levers for adjusting chair height and recline
    - Desktop computers, Clipboards, pens, keyboards, computer monitors, etc.
    - Telephones
    - Wall switches
    - Handles of the desk drawer
    - Handles
    - Filing cabinets
    - Floor
    - We will ask the patients to wear a mask, and sanitize his/her hands when they visit the clinic

    <u>Restrooms:</u>

    - Sink and faucets
    - Mirror, soap and towel dispenser
    - Toilet bowl, seat, and tank
    - All washrooms have been equipped with toilet seat cover dispenser
    - Handrails
    - Doorknobs and door panels (including stalls)
    - For the time being the shower facility will be closed.

- During this days, patient will not be allowed to take shower in the Sleep clinic (We do not need to say this again)

Break rooms:

- Seats
- Fridge/Freezer - door, handle, panels, touch controls
- Microwave – touch panel, door, handle
- Sinks and faucets
- Countertop
- The patients will bring their own water bottle.

Disinfection of Patients setup rooms

All the disinfection and procedures for setup rooms mention in MSC Policy and Procedure manual are still valid. At the time of hooking and unhooking of patients rooms exhaust fans must be turned on. HEPA filter machines will be used for at least 10 minutes in the patients set up rooms after every patient hook and unhook patients procedure is complete to get rid of any potential presence of virus aerosols in the air of setup rooms.

If you have any question, please call in the clinic (416-282-9119).

Iqbal Singh Dhanju MSc. Ph. D., RPSGT
Technical Director/Manager
Malvern Sleep Clinic
PH: 416-728-7076

Dr. David J. Ross, MD, FRCP (C)
Medical Director/Sleep Specialist
Malvern Sleep Clinic
Phone: 416-282-9119

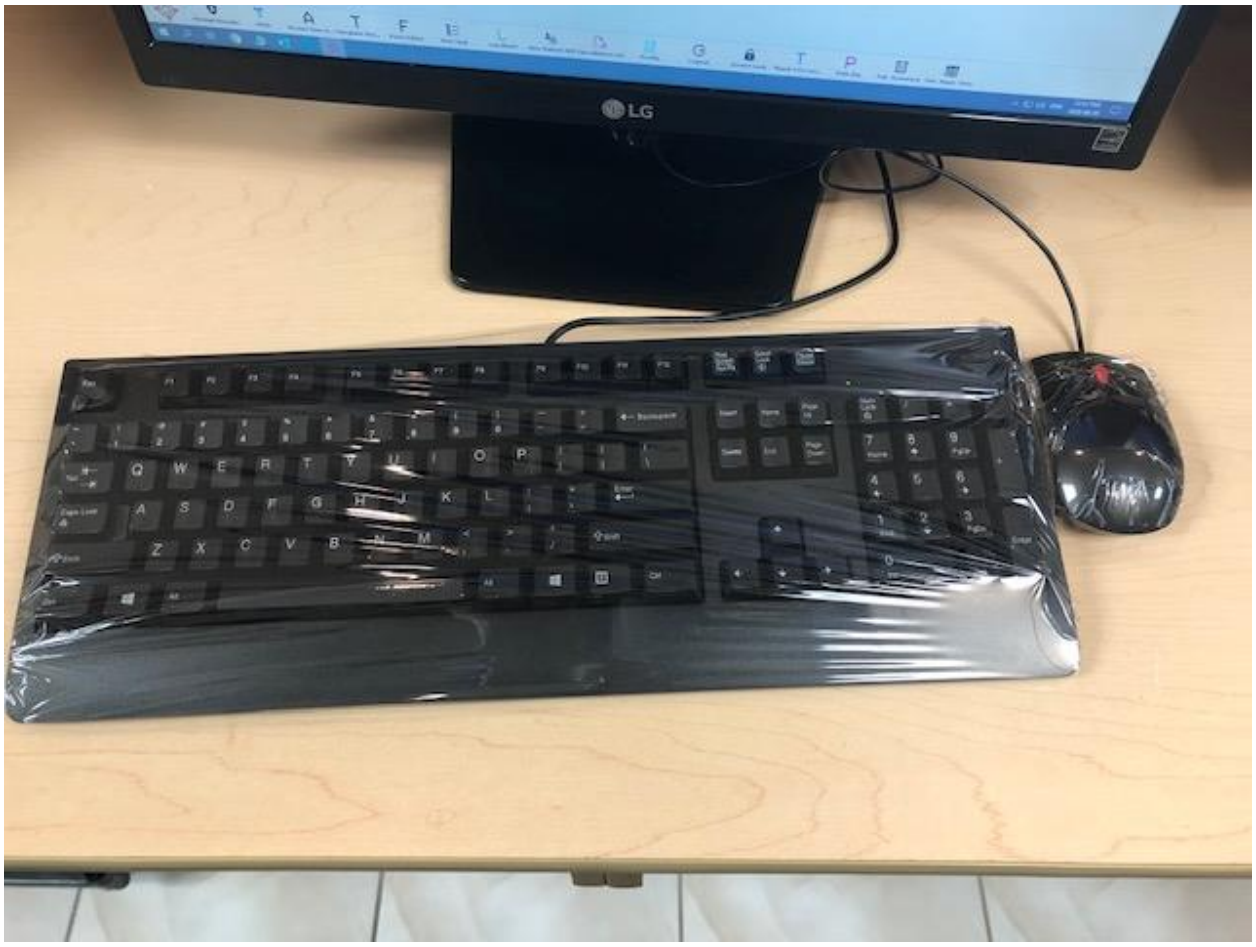

Attention Patients


EXIT

Changes have been made for the fabric items used for the patient's beds so that cleaning, hot sterilization of blankets, cleaning of bed sheets or towels is done every day or more often as needed.

In pediatric patients rooms vinyl beds disinfecting is being done by spraying and cleaning with Saniblend Disinfectant spray. The side railing polyester material is being replaced by vinyl material. This vinyl material is clean and disinfected every day.

Hot steamer is used every day to sterilize the curtains in patient’s rooms.



Before the start of every shift (Day and Evening shift) items like keyboard, mouse etc. are disinfected and wrapped in plastic wrap as seen in the picture.
After each shift these plastic wraps must be disposed off and new plastic wrapping is done again after disinfecting keyboard, mouse etc.

Infrared thermometers are being used to record the temperature of everyone entering in the clinic.

Everyone must fill the following Self Assessment Form.

Malvern Sleep Clinic
Self Assessment Form

Staff Name: _____ Date: _____

Today's Temperature: _____

Screening Questions

1. Do you have any of the following unexplained minor symptoms:

Fever		Yes		No
Chills		Yes		No
Cough that's new or worsening		Yes		No
Shortness of Breath		Yes		No
Headache		Yes		No
Sore Throat		Yes		No
Muscle ache		Yes		No
Lost of taste or smell?		Yes		No
Pink eye /Conjunctivitis eye		Yes		No

2. Are your in any of these at risk group?
    - 65 years old or older
    - Getting treatment that compromise your immune system
    - Having a chronic health condition
    - Regularly going to hospital or health care setting or treatment
3. In last 14 days, have you been in close physical contact with someone who tested positive for COVID 19?
   _____Yes _____NO
4. In the past 14 days, have you returned from or travel to any other locations outside of Canada?
   _____Yes _____NO
5. Are you wearing Mask and Gloves?

_____

Signature

APPENDIX C

HVAC System Maintenance Schedule

Sample Preventive Maintenance Schedule for HVAC Systems

For each item, place a "X" in the appropriate box. "Y" indicates "Yes. Fan is in compliance." "N" indicates "No. Fan does not comply."

FAN ID/LOCATION: _____

INSPECTION DATE: _____

TASK	YES	NO	FOLLOW UP	COMMENTS
Inspect and clean exhaust grilles to prevent blockage & airflow retardation	Y	N	DATE DATE	
Visually inspect filter housing for holes and proper filter seal	Y	N	DATE DATE	
Clear outside air intake of debris	Y	N	DATE DATE	
Check return/exhaust dampers move freely	Y	N	DATE DATE	
Check filters for proper installation/spacers	Y	N	DATE DATE	
Check pressure set points	Y	N	DATE DATE	
Check steam/CW lines have no leaks	Y	N	DATE DATE	
Check return/exhaust belts are tight	Y	N	DATE DATE	
Check fan bearings/sheaves are lubricated	Y	N	DATE DATE	
Check humidifier controls are in working order	Y	N	DATE DATE	
Check fan lights are in working order/PSI	Y	N	DATE DATE	
Check fan cleanliness	Y	N	DATE DATE	

Document #2

Table 2: Time Required for Removal or Settling of Aerosols by Air Changes per Hour (ACH)

AIR CHANGES PER HOUR (ACH)	TIME REQUIRED FOR REMOVAL OR SETTLING OF AEROSOLS IN MINUTES (99.9% EFFICIENCY)
2	207
4	104
6	69
8	52
10	41
12	35
15	28
20	21
50	8

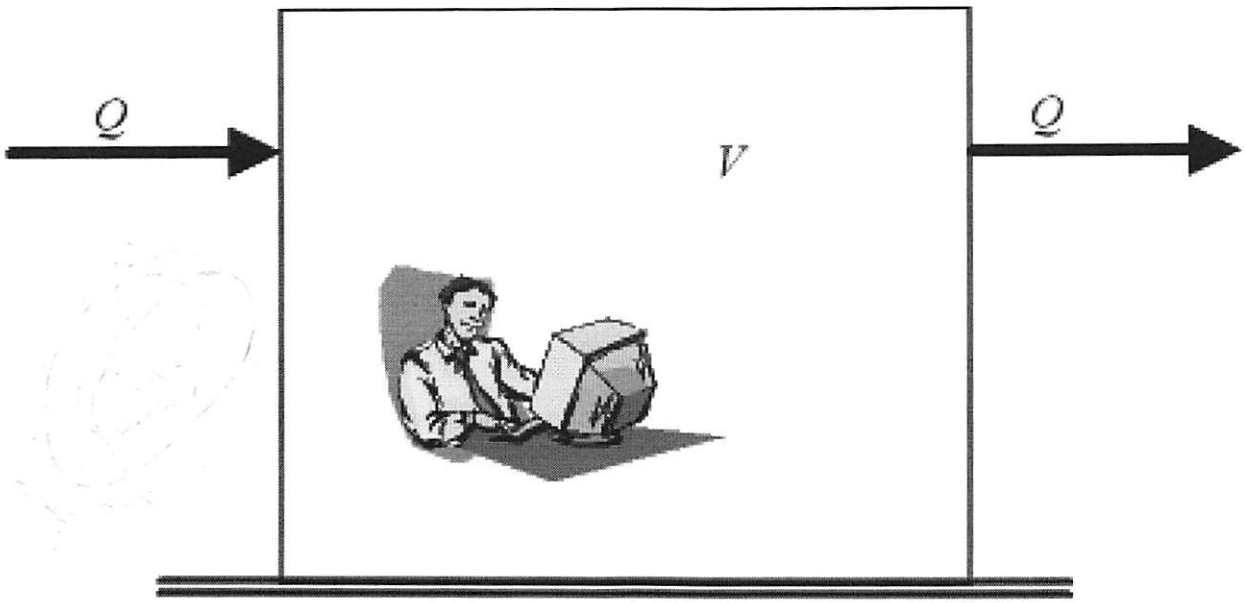
Adapted from: Centers for Disease Control and Prevent, Guidelines for Environmental Infection Control in Health-Care Facilities (2003): Table B.1. Air changes/hour (ACH) and time required for airborne-contaminant removal by efficiency. Available at: https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html#tableb1

44 Dentists should consult an HVAC professional to assess the existing HVAC system and calculate the actual ACH for the dental practice. Dentists may use the actual ACH to calculate a fallow time using Table 2.

a. Dentists should retain copies of any documentation supporting the HVAC assessment and any need for engineering controls.

Options to improve ACH (and further reduce the fallow time) may be explored, including:

b. Consulting an HVAC professional to determine whether changes to the existing HVAC system are possible to improve ACH for the dental practice.
c. If changes to the existing HVAC system are not possible or adequate, dentists may consider the use of an in-operatory air cleaner (e.g. HEPA filtration) to increase the effective air changes per hour (eACH) for a specific operatory.
d. If an in-operatory air cleaner (e.g. HEPA filtration) will be used to increase the effective air changes per hour (eACH) for a specific operatory, the HVAC professional must also take into account several additional factors, including:
    i. any structural changes that may be necessary to contain the spread of aerosols (e.g., the addition of floor to ceiling walls or barriers),
    ii. the type of unit being considered (e.g. fixed versus portable),
    iii. the cubic feet of the operatory and airflow rate of the unit, and
    iv. the optimal placement and operation of the unit.



engineeringtoolbox.com

The table below indicates air change rates (air changes per hour) commonly used in different types of rooms and buildings.

- Note! - be aware that it may be necessary to calculate required supply air based on no. of persons in the room or building. More information about required supply air per person can be found here.

Building / Room	Air Change Rate *- n - (1/h)*
All spaces in general	min 4
Assembly halls	4 - 6
Attic spaces for cooling	12 - 15
Auditoriums	8 - 15
Bakeries	20 - 30
Banks	4 - 10
Barber Shops	6 - 10
Bars	20 - 30
Beauty Shops	6 - 10
Boiler rooms	15 - 20
Bowling Alleys	10 - 15
Cafeterias	12 - 15
Churches	8 - 15
Classrooms	6 - 20
Club rooms	12
Clubhouses	20 - 30
Cocktail Lounges	20 - 30
Computer Rooms	15 - 20
Court Houses	4 - 10
Dance halls	6 - 9
Dental Centers	8 - 12
Department Stores	6 - 10
Dining Halls	12 -15
Dining rooms (restaurants)	12
Dress Shops	6 - 10
Drug Shops	6 - 10
Engine rooms	4 - 6
Factory buildings, ordinary	2 - 4
Factory buildings, with fumes or moisture	10 - 15
Fire Stations	4 - 10

Building / Room	Air Change Rate - n - (1/h)
Foundries	15 - 20
Galvanizing plants	20 - 30
Garages repair	20 - 30
Garages storage	4 - 6
Homes, night cooling	10 - 18
Hospital rooms	4 - 6
Jewelry shops	6 - 10
Kitchens	15 - 60
Laundries	10 - 15
Libraries, public	4
Lunch Rooms	12 -15
Luncheonettes	12 -15
Nightclubs	20 - 30
Machine shops	6 - 12
Malls	6 - 10
Medical Centers	8 - 12
Medical Clinics	8 - 12
Medical Offices	8 - 12
Mills, paper	15 - 20
Mills, textile general buildings	4
Mills, textile dye houses	15 - 20
Municipal Buildings	4 - 10
Museums	12 -15
Offices, public	3
Offices, private	4
Paint shops	10 - 15
Paper mills	15 - 20
Photo dark rooms	10 - 15
Pig houses	6 - 10
Police Stations	4 - 10
Post Offices	4 - 10
Poultry houses	6 - 10
Precision Manufacturing	10 - 50
Pump rooms	5
Railroad shops	4
Residences	1 - 2
Restaurants	8 - 12
Retail	6 - 10
School Classrooms	4 - 12
Shoe Shops	6 - 10
Shopping Centers	6 - 10
Shops, machine	5
Shops, paint	15 - 20
Shops, woodworking	5
Substation, electric	5 - 10
Supermarkets	4 - 10
Swimming pools	20 - 30
Textile mills	4
Textile mills dye houses	15 - 20
Town Halls	4 - 10
Taverns	20 - 30
Theaters	8 - 15
Transformer rooms	10 - 30
Turbine rooms, electric	5 - 10
Waiting rooms, public	4
Warehouses	6 - 30

Building / Room	Air Change Rate - n - (1/h)
Wood-working shops	8

Be aware of local regulations and codes.

Fresh air supply - make up air - to a room based on the table above can be calculated as

$q = n\ V$ (1)

where

q = fresh air supply (ft^3/h, m^3/h)

n = air change rate (h^{-1})

V = volume of room (ft^3, m^3)

Example - Fresh Air Supply to a Public Library

The fresh air supply to a public library with volume *1000 m^3* can be calculated as

$Q = (4\ h^{-1})\ (1000\ m^3)$

$= 4000\ m^3/h$

- make up air per person

Air Volume Calculator

4 *No. of Changes per Hour (h^{-1})*

1000 *Room Volume (m^3, ft^3)*

calculate!

Air Change Out Frequency in minutes

The "Air Change Out Frequency" in minutes can be calculated as

$n_m = 60 / n$ (2)

where

n_m = Air Change Out Frequency (minutes)

New Ventilation Guidelines For Health-Care Facilities

By Paul Ninomura, P.E., and **Judene Bartley**
Member ASHRAE

The 2001 edition of the *Guidelines for Design and Construction of Hospital and Health Care Facilities*[1] provides recommendations for ventilation for health-care facilities. It is revised periodically and published by the American Institute of Architects Academy of Architecture for Health with assistance from the U.S. Department of Health and Human Services. The new edition has notable changes to the ventilation recommendations.

Table 1 is an excerpt from Table 7.2, Ventilation Requirements for Areas Affecting Patient Care in Hospitals and Outpatient Facilities (of the Guidelines). It summarizes options and changes to the ventilation requirements for selected rooms. The rationale supporting the revisions is described here.

Ventilation Rate Changes

Patient Rooms

One significant change relates to the ventilation recommendations for patient rooms. The "total" air changes per hour (ACH) for the room has increased from 2 ACH to 6 ACH. (This rate may be reduced to 4 ACH when supplemental heating and/or cooling is incorporated in the HVAC design for the room.)

This change reflects recent research[2] that concluded that 6 ACH and 4 ACH (if baseboard heating is provided) are the minimum ventilation rates required to provide satisfactory patient comfort based on computational fluid dynamic (CFD) modeling analysis. Analysis showed that the previous recommended ventilation rate of 2 ACH resulted in high values of Local Mean Age of Air (LMAA) that would manifest as a "stuffy" room. Furthermore, the previous ventilation rate of 2 ACH was acknowledged to be unrealistic with respect to the capacity to address the thermal load in the room.

Labor/Delivery area

The ventilation rates for labor/delivery rooms and labor/delivery/recovery/postpartum (LDRP) rooms have increased from 2 total ACH to 6 total ACH. (This rate may be reduced to 4 ACH when supplemental heating and/or cooling are incorporated in the HVAC design for the room.) This is based on the same research[2] that formed the basis for the change to the ventilation recommendations for patient rooms.

Airborne Infection Isolation Rooms

Airborne infection isolation (AII) rooms remain at 12 ACH. Recent research[3] using CFD analysis concluded that 10 total ACH was the recommended ventilation rate. Higher rates of ventilation did not decrease the exposure of persons in the room to airborne infectious agents. Because 10 ACH was considered to be "close" to the now well-accepted 12 ACH recommended by the Centers for Disease Control (CDC),[4] the Guidelines remain at 12 ACH. The CFD modeling provided a substantiating basis for the CDC Guidelines' recommendation of 12 ACH. It also dispels an inference of the CDC Guidelines that suggests that increasing air exchange rates above 12 ACH will provide additional benefit.

Emergency Rooms and Radiology–Waiting and Triage Rooms

New ventilation recommendations have been established for the first time in ER and radiology waiting and triage rooms. This historic change reflects concerns that these waiting areas are more likely than others to be occupied by persons with undiagnosed communicable respiratory diseases such as tuberculosis.[5] Waiting areas are typically "open areas" rather than enclosed spaces. The basis for the ventilation rate is to supply sufficient ventilation to provide relatively rapid general dilution or filtration of airborne contaminants. The recommended "total" ventilation rate is 12 ACH. The recirculation of the air within this zone with HEPA filters is permissible.[4,6]

Procedure Rooms

Positive pressure rooms. Another major change to the Guidelines was establishing a ventilation rate for "procedure rooms." This rate is similar to that required for operating rooms. The rooms are designed with airflow out of the room, 3 ACH of outside air (OSA) and 15 total ACH. The design intent is to supply a high rate of clean (filtered) air for clean invasive or interventional procedures, thus reducing infectious risks. Typical procedures include

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cardiac catheterization, interventional radiology, insertion of pacemakers and electrophysiology procedures. Operating rooms and procedure rooms in outpatient or freestanding surgicenters require the same ventilation specifications.

Negative pressure rooms. Diagnostic or therapeutic endoscopic procedures involving the airway (i.e., bronchoscopies) increase the risk for air contamination with *M. tuberculosis* in patients with known or undiagnosed tuberculosis, a disease spread by the airborne route. No change was made in the new AIA Guidelines. Bronchoscopy rooms must be maintained at negative air pressure to protect the worker and the environment. Special ventilation is not needed for simple procedures carried out in examination or treatment rooms, e.g., minor surgical suture removal (see sidebar).

Location	Air Movement Relationship to Adjacent Area	Minimum Air Changes of Outdoor Air per Hour	Minimum Total Air Changes per Hour
Patient Room	—	2	6 (4)
Labor/Delivery/Recovery	—	2	6 (4)
Labor/Delivery/Recovery/ Postpartum	—	2	6 (4)
Airborne Infection Isolation Room	In	2	12
Emergency – Triage/Waiting	In	2	12
Radiology – Waiting	In	2	12
Procedure Room	Out	3	15

Table 1: Ventilation rate changes for selected rooms.

Room Pressurization Changes

The room pressurization ("air movement relationship to adjacent area") has changed for several area designations. Revisions are summarized, and the rationale for each is described briefly in the following section.

Surgery and Critical Care

- **Endoscopy (In)**

Negative pressure is required to provide odor control. This is based on clinical experience and changes to negative pressure that are already required by some state codes, e.g., Michigan Minimum Design Standards.[7]

- **Anesthesia Gas Storage (In)**

Airflow into the area assists in containment of leakage of anesthetic gases. This makes the pressure requirement consistent with the recommendation that all air is to be exhausted out of the room and not recirculated.

Ancillary

- **Pharmacy (Out)**

The change to outward airflow is based on pressure requirements recommended by the American Society of Health System Pharmacists (ASHP). A clean environment is essential for drug admixture processes.

This is based on recommendations from ASHP's national coordinating committee on large volume parenterals; ASHP's quality assurance technical assistance bulletin; and the CDC Guideline for the prevention of intravascular device-related infections.[8–10]

Diagnostic and Treatment

- **Medication Room (Out)**

The rationale for *positive* airflow is based on pressure requirements recommended by the American Society of Health System Pharmacists.[8,9]

- **Clean Workroom or Clean Holding (Out)**

The pressure requirements should be *positive,* whether used

Procedure Rooms: Usage

Several types of procedure rooms listed in Table 7.2 are designed with different ventilation recommendations based on variable clinical risk assessments for patients, staff and environmental control. These recommendations apply to outpatient or freestanding surgicenters as well.

• Positive pressure rooms are comparable to operating rooms and require a total of 15 ACH airflow out of the room. The design intent is to optimize the conditions for clean, invasive procedures, thus reducing infectious risks to the patient. Examples of positive pressure procedure rooms are:

a. cardiac catheterization or interventional radiology in a radiology suite,

b. trauma or emergency surgical procedure rooms, and

c. Other invasive procedures such as the insertion of pacemakers or electrophysiology procedures carried out in other locations of inpatient and outpatient facilities

These rooms are not needed for simple physical assessment procedures carried out in examination or treatment rooms such as minor surgical suture removal.

• Negative procedure rooms are comparable to airborne isolation rooms, with different requirements based on their specific usage. For example:

Bronchoscopy rooms, comparable to airborne isolation rooms, require a total of 12 ACH and airflow into the room. The purpose of this design is to eliminate the spread of infectious agents into the surrounding environment from patients with an airborne infectious disease like tuberculosis. The design provides dilution and exhaust of contaminated air from patients with tuberculosis but who must undergo an invasive procedure and reduces risk of exposure to staff performing the procedure.

Endoscopy rooms are designed with 6 ACH and airflow into the procedure room. The number of air changes per hour is less critical than that needed for the control of droplet nuclei (*M. tuberculosis*, *V. zoster*) but a negative pressure improves odor control. This type of clean procedure does not require a positive pressure procedure room since the risk of infectious complication is not from airborne infectious agents.●

to prepare or store clean equipment and/or instruments. Principles of asepsis related to environmental control support the direction of air to flow from clean to soiled areas.[11]

Sterilizing and Supply

- **Sterile Storage (Out)**

The pressure requirements should be *positive* to prevent airborne contamination of sterile and clean materials. Principles of asepsis related to environmental control support the direction of airflow from clean to soiled areas.[11]

Service

- **Clean Linen Storage (Out)**

The pressure requirements should be *positive* to prevent airborne contamination of clean, stored linen. Principles of asepsis related to environmental control support the direction of airflow from clean to soiled areas.[11]

Room Pressurization Measurement and Monitors

Another change is the addition of recommendations for the differential pressure for selected special rooms. Note 11 to the AIA Guidelines Table 7.2 specifies that the differential pressure should be a minimum of 0.01 in. w.g. (2.5 Pa) for operating rooms, bronchoscopy rooms, protective environment rooms, and airborne infection isolation rooms. This provides a quantitative factor to evaluate the adequacy of the "air movement relationship to adjacent areas."

Research and experience[12] on this issue indicates that a pressure differential higher than 0.001 in. w.g. (0.25 Pa) is recommended to 1) reduce adverse effects from normal building pressure fluctuations (due to seasonal variation, winds, etc.); and 2) to provide increased containment/control of airflow for the room. It was acknowledged that the requirement for a differential pressure of 0.01 in. w.g. (2.5 Pa) will require increased attention to the construction of the room to reduce airflow leakage (infiltration/exfiltration) via walls, ceilings, etc.

Additionally, there is a new requirement for continuous, visual monitoring of airflow direction in pressurized rooms. A recent report documented frequent failures in maintaining negative pressure in airborne infection isolation rooms. The actual direction of airflow detected by smoke trail tests contradicted the measurements of built-in air pressure differential gauges in more than half of 82 tested rooms.[13]

Summary

The changes in the ventilation recommendations of the Guidelines reflects:

1. The application of new research, e.g., patient rooms.
2. New concerns for reducing exposure in high-risk areas of

FPO

the health-care facility, e.g., waiting areas.

3. Consistency with the medical program requirements, e.g., pharmacy, anesthesia gas storage, etc., established on evidence-based clinical research and principles of asepsis.

These changes are the result of a multidisciplinary review of the ventilation requirements and the ventilation recommendations are based on definitive scientific basis.

Note

This article focuses on the changes related to the ventilation requirements. Many other changes in the 2001 edition are not addressed here.

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