INSPQ INSTITUT NATIONAL DE SANTÉ PUBLIQUE DU QUÉBEC

Aerosol-Generating Procedures on Suspected and Confirmed Cases of COVID-19

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Scope of Recommendations

These recommendations apply to aerosol-generating medical procedures (AGPs) carried out on patients who are suspected or confirmed cases of COVID-19. In contexts of sustained community transmission, risk assessments must be performed to determine whether these recommendations shall also apply during AGPs on individuals who are asymptomatic or have unknown COVID-19 status

See section: AGP management for patients determined to be at no risk of having COVID-19 (“cold patients”).

An overview table of recommendations is provided in the appendix.

Analysis

In the context of the SARS-CoV-2 pandemic, a number of interventions and procedures are now considered AGPs by medical societies while they previously were not. Many of these procedures have not been classified as such by conclusive studies, but are often associated with coughing produced during the procedure and by implication, the presumed production of small aerosols.

For a better understanding of the concept of an AGP as it relates to the risk of COVID-19 transmission, it is important to highlight the following premises:

- SARS-CoV-2 is mainly transmitted through droplets or contact (WHO, 2020). With millions of cases declared worldwide, all public health organizations have clearly established that transmission occurs largely by droplets and contact, usually in contexts of close proximity and extended periods (e.g., family contacts). Airborne transmission is presumed during AGPs which is referred to as opportunistic airborne transmission. This suggests that SARS-CoV-2 is not transmitted by airborne route under usual healthcare circumstances, as opposed to tuberculosis, for example, but rather during procedures that can generate infectious aerosols (Romano-Bertrand S. et al., 2020)
- In contrast with transmission via droplets, aerosols < 5 um can remain suspended in the air, travel long distances, and may cause infection when inhaled.
- The presence of small aerosols, even during breathing, has often been cited as evidence of potential airborne transmission. However, a lack of transmission through the established airborne transmission models (like those of measles and tuberculosis) does not substantiate the mere presence of aerosols as proof of airborne transmission. The role of these aerosols in transmission over short distances remains to be proven.

- Coughing, sneezing and procedures that cause these actions do not by themselves justify a procedure being considered an AGPs. Instead, it is the type of procedures that artificially manipulate the airway and secretions therein that can agitate and dramatically increase the infectious aerosols generated when microorganisms are present.
- In the case of SARS-CoV-2, the role AGPs play in transmission to healthcare workers exposed during these procedures remains to be documented. For the time being, the hypotheses are extrapolated from studies on SARS-CoV-1 and other viruses. Moreover, a widely cited systematic review on SARS-CoV-1 transmission to healthcare workers at hospital centres or in intensive care units has shown consistent airborne transmission for one AGP only: tracheal intubation. The other AGMPs cited in this meta-analysis, non-invasive ventilation (NIV), tracheotomy, and manual ventilation before intubation, are only associated with transmission by aerosols in a few small studies deemed to be of poor quality (Tran et al., 2012). Other procedures cited, being endotracheal aspiration, manual ventilation before intubation, bronchoscopy, administering medication by nebulization, use of high-flow O_2, BiPAP, handling of a Ventimask, defibrillation, chest compressions, insertion of a nasogastric tube, and sputum collection, have not been associated with transmission of infection. At present, there have been no rigorous studies or reviews of cases that demonstrate a clear association between AGPs and transmission of SARS-CoV-2. Case reports sometimes imply transmission while other times calling it into question (Ng et al., 2020; Zhu, 2020) but the quality of these reports is insufficient to draw any conclusion. It has also not been proven that these workers were infected during the AGP, from contamination when removing personal protective equipment (PPE) afterwards, or simply through the community.
- The presence of viral RNA detected by nucleic acid amplification test (NAAT) does not in itself prove that the virus is viable and transmissible. The presence of a viable virus is a prerequisite for transmission. We therefore feel that it is unlikely that the mere presence of viral SARS-CoV-2 RNA in the stool or blood indicate that a procedure carried out at this level (e.g., colonoscopy, thrombectomy via a blood vessel) render the procedure an AGP, especially since no aerosols are generated during these procedures.
- In its review of mask use in the COVID-19 context, WHO (2020) has reaffirmed its position on the use of N95 respirator and only recommends their use in circumstances where COVID-19 patients are undergoing an AGP. These experts specifically name AGPs as being limited to tracheal intubation, non-invasive ventilation (NIV), tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation, bronchoscopy, sputum induction using nebulized hypertonic saline, and autopsies.

Classification

The following classification is largely based on evidence collected by the Unité d'évaluation des technologies et des méthodes d'intervention en santé (UETMIS) at CHU de Québec-Université Laval, whose reports can be consulted on the INSPQ website at https://www.inspq.qc.ca/covid-19.

More recent reviews of the literature on AGPs also propose this hierarchy of measures in a context that lacks more rigorous scientific data (Harding et al., 2020; Jackson et al., 2020). Other experts are more categorical in their definition, which is simply a binary one: "It is either an AGP or not an AGP," and yet others add another category: uncertain AGP.

The following procedures are associated with a known risk of infectious aerosol transmission (known AGP) for suspected and confirmed cases of COVID-19. "Known" refers to procedures that have been listed for years as carrying an increased risk of infection by airborne transmission and recognized as such by the medical community long before the COVID-19 pandemic.

- Tracheal intubation and extubation
- Bronchoscopy
- Cardiopulmonary resuscitation[1]
- Manual ventilation before intubation
- Aspiration of tracheal secretions with open-circuit suctioning on an intubated patient or patient with a tracheotomy
- Sputum induction (saline instillation technique ~~and other similar techniques~~)
- Nasopharyngeal aspirate (NPA) in children
- Autopsy

The following procedures are associated with a possible risk of infectious aerosol transmission (possible AGP) for suspected and confirmed cases of COVID-19.

- Non-invasive positive-pressure ventilation via face mask (e.g., BiPAP, CPAP,[2] and other similar techniques that actively deliver air into the airway using a device that operates with positive pressure or nebulization, such as with breath stacking and cough assist devices).
- Tracheotomy and tracheostomy care. It is important to specify here that the tracheotomy, as in the surgical intervention, is what is considered an AGP. The tracheostomy care that potentially generates aerosols is the deep suctioning of secretions through the tracheostomy, but dressing changes in the area, secretion suctioning from the outlet of the cannula, application of topical care to the site and changes of cannula are not considered AGMPs.
- In the context of the COVID-19 pandemic, it is appropriate to add any surgical intervention via the nasopharynx or oropharynx, as well as thoracic surgery on any patient who is a confirmed or suspected COVID-19 case, since SARS-CoV-2 is prevalent in the nasopharynx, oropharynx, and lungs and a surgical intervention performed at these sites, especially when done using a motorized tool, has a high likelihood of generating infectious aerosols containing COVID-19 (Mick et al., Thamboo A. et al).

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1 According to an analysis by UETMIS, chest compression done as part of CPR has been classified as an AGP with uncertain and little documented risk. Other organizations are in agreement with UETMIS; as quoted in a report from the INESSS (https://www.inesss.qc.ca/fileadmin/doc/INESSS/COVID-19/COVID-19_INESSS_RCR.pdf): "Seven of them (Ontario Health, Heart and Stroke Foundation, Canadian Red Cross, Public Health England, Resuscitation Council, the European Resuscitation Council, and the American Heart Association) distinguish the risk of transmission according to the components of CPR and consider that chest compressions and defibrillation do not constitute AGPs." [translated from the original French]

2 The Association des Pneumologues de la province de Québec recommends ceasing positive-pressure treatment for long-term patients who do not have severe nocturnal hypoxemia, regardless of their COVID-19 status. However, this decision must be made by an individual with the expertise to make such a decision.

The following procedures are associated with an undocumented risk of infectious aerosol transmission (undocumented AGP) for suspected and confirmed cases of COVID-19.

- High-flow nasal cannula (e.g., Optiflow). The classification of this AGMP is under review.
- Digestive endoscopy procedures
- Transesophageal echocardiogram (TEE)
- Insertion and removal of a chest tube
- Ophthalmology procedures not involving the tear ducts, sinuses, or canaliculi
- Laryngoscopy
- Nebulization therapy

The following procedures are not considered AGPs:

- Conventional oxygen therapy with face mask (e.g., Ventimask)
- Nasopharyngeal swab for adults and children
- Insertion of a nasogastric tube
- Jejunostomy, gastrostomy
- It appears unlikely that surgical procedures or interventions for which the site of entry does not contain the virus (for example, thrombectomy via the groin, laparoscopy without intestinal entry) generate infectious aerosols containing COVID-19, in contrast to sites recognized as containing high concentrations of the virus (for example, the nasopharynx and oropharynx). However, for laparoscopies, there are specific recommendations for the insufflation and CO_2 exsufflation pressure, smoke evacuation, etc., which can be consulted on the INPSQ website.

Recommendations

In light of the aforementioned premises and in consideration of the work done by UETMIS and the review of the most recent literature on the subject, CINQ suggests a risk grading for AGPs:

- We recommend that for AGMPs with known or possible risk of infectious aerosol transmission, airborne/contact precautions with eye protection be applied throughout the duration of the AGP until the end of the post-AGP wait time (depending on the number of air changes in the room). This recommendation is based on a high degree of scientific evidence and a favourable analysis of the benefits and risks (level of certainty: high).
- For undocumented AGPs, we suggest droplet/contact precautions with eye protection be put in place instead of airborne/contact precautions with eye protection. This recommendation is based on limited scientific evidence (for example, lack of specific studies on the issue, or the studies being methodologically weak) and a balanced analysis of the benefits and risks (expert opinions, level of certainty: low).

Comments and Context for Recommendations: These recommendations are intended to optimize healthcare quality. Their aim is to assist healthcare settings in implementing measures to prevent AGP-related infections. They are supported by a review of the evidence conducted by UETMIS as well as a review of the most recent literature.[3]

It is important to emphasize that there is a high level of agreement between these recommendations and those of other international learned societies, although they are not identical. This reflects the uncertainty that results from the lack of scientific evidence around certain procedures with "undocumented" risk. Due to this lack of evidence, learned societies have issued recommendations based on expert opinions, which can result in some variation in their recommendations. If airborne transmission remains possible, it is certainly not predominant and is possibly even exceptional. Transmission during the majority of the above-mentioned procedures is itself not scientifically well documented. However, a certain risk cannot be completely ruled out and this risk perception may lead to differing recommendations. Due to the lack of data, some advocate for a more cautious attitude and the application of airborne precautions to minimize risk.

In cases of unknown or relatively low risk, the choice whether or not to apply certain preventive measures is, to a certain extent, related to risk perception. Other factors to consider include equipment availability, allocation of resources to the detriment of other needs, ethical decisions, the implications associated with preventing airborne transmission (e.g., negative pressure room, air exchange), and the implications of individual transmission. All of these variables are largely outside the scientific framework on which our recommendations are based.

Given the low level of certainty regarding the recommendation for undocumented procedures at risk of producing aerosols, it is possible that various environments will adjust and apply this recommendation differently (for example, between different facilities in the province or even different departments in the same facility) according to local epidemiology and impact. However, the limit for modulation remains to be determined. This adjustment could reflect variation in different stakeholders' values and risk perception. It may be necessary to involve a number of stakeholders to arrive at a local consensus.

Considering the possible increase in transmission during these procedures:

- Limit these procedures to those that are absolutely necessary.
- Try to postpone an AGP until the patient will no longer be contagious with COVID-19, or replace the procedure with an alternative in the interim (e.g., transthoracic echocardiogram [TTE] in place of a transesophageal echocardiogram [TEE]).
- Insofar as possible, try to schedule AGPs in advance to avoid having to perform them in emergency.
- Limit the number of people in the room to the experienced healthcare workers who are needed to carry out the procedure.
- For AGPs with splash risk, wear a waterproof long-sleeved gown (either disposable or washable, depending on local regulations) in addition to the recommended personal protective equipment.
- A visor is recommended as the first choice over safety goggles for AGPs with a known or possible risk (except for children's NPA). Ensure that the chosen eye protection does not interfere with the adjustment and seal of the N95 respirator and that the N95 respirator does not interfere with the eye protection. Prescription eyeglasses are not considered adequate protection.

[3] For each recommendation, an assessment was also carried out on the magnitude of the alternative options' risks and benefits. A "favourable" analysis of the benefits and risks suggests that the benefits are clearly greater than the risks associated with the recommendation. A "balanced" analysis of the benefits and risks suggest that the risks and benefits are of a similar magnitude.

- Respect the required waiting time according to the ventilation characteristics of the room used (number of air exchanges per hour for a 99.9% elimination rate) before entering the room without personal protective equipment.
- In emergency situations where the patient's COVID status is unknown and waiting for the NAAT results would be detrimental to the patient, airborne/contact precautions with eye protection should be applied, according to the regional epidemiology.

AGP management for patients determined to be not at risk of having COVID-19 ("cold patients")

An asymptomatic patient's risk of contagiousness complicates how the protection of healthcare workers is managed during an AGP. This is why it is important to assess each patient before carrying out an AGP to determine their COVID-19 exposure criteria or whether they are asymptomatic but contagious. A patient is considered "cold" if:

- The four following points apply:

They are asymptomatic for COVID-19 after a thorough clinical assessment, which must be repeated for admitted patients.

They have no documented exposure to a known case or to an environment where there has been an outbreak (e.g., CHSLD, senior's residence) in the last 14 days.

They have not travelled outside of Canada in the last 14 days.

They have been admitted to a unit where there have been no diagnosed cases of COVID-19 in the last 14 days (patients or healthcare workers).

OR

They have recovered from COVID-19 in the last 3 months (according to the recognized recovery criteria).

In May 2020, the Ministère de la Santé et des Services sociaux (MSSS) published the first version of NAAT testing indicators (priorities M1 to M22) and recommended carrying out this test in the 48 hours prior to certain AGPs (e.g., pre-intubation, pre-bronchoscopy if N95 respirators are not universally worn for this procedure). Numerous facilities have accordingly implemented this guideline for both hospitalized and external patients.

With the arrival of the second wave and the accumulation of confirmed cases in certain regions of Québec, some centres may want to consider the alert levels developed by the MSSS (green [vigilance], yellow [early warning], orange [alert], and red [high alert] zones) as exposure risk criteria. For example, a patient living in a red zone would be considered at risk. It is important to highlight that for asymptomatic patients considered "cold," their probability of being a SARS-CoV-2 carrier depends on the current prevalence within the population. If prevalence is very low, use of a pre-AGP NAAT may not be cost-effective and screening via a questionnaire to determine symptoms and exposure criteria would be sufficient (e.g., in a green zone). Conversely, in a high-prevalence context, use of additional airborne/contact precautions with eye protection at all times for AGPs could be an option.

On the other hand, and for equally justifiable reasons (reduced use of PPE, increased daily workload when most patients are in isolation, constraints caused by the isolation itself and related to the patient's access to therapeutic and diagnostic procedures), use of a NAAT 48 hours before the AGP may be justified if the result would lead to the use of different precautions. In this respect, a patient who meets exposure criteria may be

considered “cold” when the NAAT is negative 48 hours before the AGP and application of standard precautions would be sufficient (see appended table). In this case, prioritizing pre-AGP COVID-19 NAATs may help minimize exposure risk for healthcare workers.

A **negative** NAAT for COVID-19 carried out 48 hours before the AGP on an asymptomatic patient who does not meet exposure criteria would conclude that the patient does not have a sufficient viral load for COVID-19 detection and that the AGP could therefore be carried out using standard precautions, unless another infectious and contagious disease is suspected (tuberculosis, for example). An appearance of new symptoms compatible with COVID-19 on the day of the AGP requires re-assessment before the procedure can be carried out.

In circumstances where the wait time for the NAAT result may be detrimental to the patient, any known risk or possible risk AGP that is considered urgent (for example, emergency intubation of a patient in the emergency department who cannot be questioned), could be carried out using airborne/contact precautions with eye protection without waiting for the NAAT result, still according to regional epidemiology.

The majority of AGPs are one-time procedures. For this reason, it is possible to know the time frame to carry out a NAAT before an anticipated AGP (e.g., bronchoscopy). However, for certain AGPs that are regular and continuous (e.g., BiPAP, CPAP), repeated NAAT testing may be considered appropriate by some clinicians. The arrival of saliva tests may also help in this area.

These are interim recommendations that are evolving as scientific knowledge and regional transmission of the virus develops.

Appendix: AGMP Summary Table

Risk level of infectious aerosol transmission	Medical procedures	Required measures (Additional precautions and Routine practices)	
		▶ Suspected or confirmed COVID-19 patient OR ▶ Patient with exposure criteria OR In an emergency situation where waiting for the NAAT result will be detrimental to the patient (in a situation considered to be at risk of COVID-19 and according to local epidemiology)	**For a patient considered not at risk of having COVID-19 ("cold patient"), meaning:** 1. Asymptomatic for COVID 2. Not meeting documented exposure criteria 3. Has not travelled outside of Canada 4. Admitted to a unit where there have been no COVID cases for 14+ days OR If criteria 2, 3, or 4 are not met: negative NAAT 48 hours before AGP OR Infection resolved within the last 3 months
Known risk	**Known AGP** ▶ Endotracheal intubation and extubation ▶ Bronchoscopy ▶ Cardiopulmonary resuscitation (excluding chest compressions) ▶ Manual ventilation before intubation ▶ Aspiration of tracheal secretions with open-circuit suctioning on an intubated patient or patient with a tracheotomy ▶ Sputum induction (saline instillation technique)	▶ Airborne/contact with eye protection	▶ At a minimum: Wear a medical mask[1] and eye protection ▶ Wear gloves and gown according to routine practices
Possible risk	**Possible AGP** ▶ Non-invasive positive-pressure ventilation via face mask (e.g., BiPAP, CPAP, and other similar techniques that actively deliver air into the airway using a device that operates with positive pressure or nebulization such as with breath stacking and cough assist devices). ▶ Tracheotomy and tracheostomy care ▶ Surgical intervention via the nasopharynx or oropharynx ▶ Thoracic surgeries	▶ Airborne/contact with eye protection	▶ At a minimum: Wear a medical mask[1] and eye protection ▶ Wear gloves and gown according to routine practices

Risk level of infectious aerosol transmission	Medical procedures	Required measures (Additional precautions and Routine practices)	
		▶ Suspected or confirmed COVID-19 patient OR ▶ Patient with exposure criteria OR In an emergency situation where waiting for the NAAT result will be detrimental to the patient (in a situation considered to be at risk of COVID-19 and according to local epidemiology)	**For a patient considered not at risk of having COVID-19 ("cold patient"), meaning:** 1. Asymptomatic for COVID 2. Not meeting documented exposure criteria 3. Has not travelled outside of Canada 4. Admitted to a unit where there have been no COVID cases for 14+ days OR If criteria 2, 3, or 4 are not met: negative NAAT 48 hours before AGP OR Infection resolved within the last 3 months
Undocumented risk	**Undocumented AGP** ▶ High-flow nasal cannula (e.g., Optiflow[2]) ▶ Digestive endoscopy procedures ▶ Transesophageal echocardiogram (TEE) ▶ Insertion and removal of a chest tube ▶ Ophthalmology procedures not involving the tear ducts, sinuses, or canaliculi ▶ Laryngoscopy ▶ Nebulization therapy	▶ Droplet/contact with eye protection	At a minimum: Wear a medical mask[1] and eye protection Wear gloves and gown according to routine practices ▶ A pre-AMP RT-PCR test is not recommended for AMPs without documented risk

[1] Medical masks include procedural masks and surgical masks. Refer to: Masques chirurgicaux ou de procédures : choix de l'équipement [in French only].

[2] The classification of high-flow oxygen therapy is under review.

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Aerosol-Generating Medical Interventions on Suspected and Confirmed Cases of COVID-19

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