

Revised guidelines for potential aerosol-generating procedures (AGPs) within the ENT clinic

Working Group: Andrew C. Swift, Will Hellier, Gareth Huw Jones, Ram Moorthy

ENT UK at The Royal College of Surgeons of England 35-43 Lincoln's Inn Fields London WC2A 3PE Tel: 020 7404 8373 | Email: <u>entuk@entuk.org</u> | Web: www.entuk.org

Introduction

To create an advisory document that provides clear definitive advice for ENT surgeons carrying out upper airway endoscopy is extremely challenging. We are all dealing with a highly dynamic situation, in which it is difficult to be prescriptive. However, we can aim to offer some sensible advice that can be applied to local circumstances and personal choice.

Objectives of these guidelines

The current revised recommendations are written with the aim of maintaining safe standards to minimise risk to patients and healthcare staff while recognising the diagnostic importance of upper airway endoscopy in ENT patients.

It is recognised that the risk of an aerosol being generated during endoscopy is present but low, and combined with the current reduction in numbers of Covid cases within the community, the combined true risk of being exposed to a significant viral load of SARS-Cov-2 is probably also low.

Upper airway endoscopy is crucial for ENT surgeons to examine the nose, nasopharynx and throat with diligence and precision, but we must all ensure that potential risk to both staff and patients is minimised, and the ability to perform endoscopy is not compromised.

The main limitation at present is not the supply of PPE, but the variable circumstances in which we all work. There is a huge deficiency in the standardisation of the clinical setting, airflow and ventilation, with only certain Trusts starting to address these important issues.

The acceptance by WHO that Covid can be transmitted by airborne and aerosolised virus particles, means that the ventilation characteristics of the rooms used for ENT endoscopy are very important. It is likely that Covid will now be an endemic infection, and therefore there is ongoing need to ensure that staff and patients are protected against airborne disease spread.



All ENT departments need to ensure suitable ventilation or air filtration is in place to allow for safe endoscopy.

The key points are:

- 1 A low but ever-present risk to a potentially lethal virus
- 2 Viral infection spread primarily by aerosol (airborne)
- 3 Whilst stringent protective measures are no longer required, we still should remain vigilant and ensure a reasonable degree of safety.
- 4 Room ventilation and PPE are the most important factors to prevent infection.
- 5 Whilst an FFP3 face mask offers the best protection, we appreciate that in some situations, de-escalated PPE will be preferred.

1 The current state of Covid-19 in the UK

Covid-19 has now been prominent in the UK for over a year, during which time we have acquired a much greater understanding of the virus and the disease.

The UK is now in the privileged position within both Europe and the world of having over half of the population vaccinated. The numbers with Covid in the community are also much reduced, and at the time of writing, relatively low.

We all appreciate how unpredictable and how lethal the infection can be and know that severe disease can manifest in any age group, but that older age groups are more vulnerable if infected.

Even with a reduction of Covid in the community, there is still a potential but low risk of contracting Covid-19 infection in the ENT clinic. There is also continued development and mutational change in the virus, and some viral mutations are more contagious and more dangerous than others. This may lead to new waves of Covid variants, so it is important that precautions and the need for ventilation are considered and maintained.

However, with low numbers of infection, relaxation of rules, and the change in peoples' perception of the virus, there is a real risk of complacency.

Symptoms of SARS-Cov-2 infection may be minimal or not apparent in patients attending clinic, and whilst the risk is low, it is still present. Diagnostic endoscopy will therefore still carry a potential risk.

Whilst rates of SARS-Cov-2 within most UK communities are currently low, we must be cognizant of the fact that should another surge or wave occur, there will be a lag phase before this is recognised. This could lead to a period of increased risk for clinicians choosing not to wear high-level PPE. We all therefore have a duty to remain vigilant and to adapt quickly to change, to prevent serious viral contagion during our normal clinical activities.

2 Spread of SARS-Cov-2 infection

There is now a much better understanding of viral spread via a predominant aerosol (airborne) transmission route. The concepts of viral load and room ventilation are also much more appreciated.

ENT Clinics are now functioning, with Covid restrictions in place, with face masks for all and social distancing.

Clinic appointments are now classed as face-to-face or telephone consultation. The latter are firmly established and seem to be very effective for some patients. However, the face-to-face patients are often those selected out because of the significance and importance of their condition. This is also a group where both rigid and flexible upper airway endoscopy is important in their clinical assessment.

3 Upper airway endoscopy and risk of Covid-19

Upper airway endoscopy was initially considered as a significant risk to clinicians if they happened to perform this on a patient in the early days of infection with Covid-19. Endoscopy was considered as a potential aerosol-generating procedure AGP.

The studies to date suggest the risk of aerosol generation is probably much less than initially perceived. However, there is still a potential of an aerosol production should the patient start coughing or sneezing. Whilst this can occur with some patients, it is unusual, but still unpredictable.

However, if we consider the current risk to ENT surgeons, the overall risk of exposure to Covid-19 virus is probably low. This is based on the low numbers of Covid-19 in the community, and the low risk of actual aerosol generation during endoscopy in the clinic. It must be accepted however, that the numbers with Covid-19 in any community can change, quite rapidly, as was seen with the dramatic increase in cases during the second Covid wave, due in part to a new variant with increase transmission potential. Care must be taken to maintain safe working practices even as Covid numbers reduce.

4 How to maintain safe endoscopy

As explained above, endoscopy is unlikely to generate an aerosol, and even if this did occur, the chance of exposure from an infective patient is also low. However, there is still the potential for risk and this is unpredictable.

There are things with which we can easily continue in order to protect ourselves from potential viral exposure.

4.1 The endoscopy procedure

Asking patients to keep their face masks on during endoscopy so that the mouth and nose is covered, should be helpful in containing an aerosol should coughing and sneezing occur. A cut in the mask can be made to allow passage of the endoscope. Alternatively, the mask can be worn over the mouth but just below the nose, but this method would not offer as much protection as the former technique.

Maintaining a distance from the patient by always using a camera and monitor is a very sensible option.

Explaining to patients to try and avoid sneezing and coughing if at all possible, and if they feel unable to do this, to give some degree of warning so that we can step away and avoid the main blast.

4.2 PPE

Up until now, FFP3 facemask, visor, gown, and gloves have been recommended.

There is a delicate balance in weighing the risk of infection with the wearing of full PPE. This is an area where it is difficult to be prescriptive. There needs to be a consideration in each department, with advice from the local Microbiology/Infection Control Teams, as to what is the most suitable form of PPE.

Many clinicians will prefer a FFP3 mask, visor, gown and gloves, but others may feel a surgical mask, visor and apron may afford enough protection depending on the Covid infection rates in their own region.

This must also be a dynamic choice, as if further waves of Covid occur, and infection rates rise, the previous ENT UK advice at the start of the pandemic will be more applicable.

4.3 The room setting

With aerosol spread being the most important vector for viral transmission, room ventilation is of utmost importance. However, this is a highly contentious point as many NHS clinic rooms have inadequate and insufficient ventilation and airflow. Keeping windows open has the practical consequence of having cold rooms. Keeping doors open does not permit adequate patient confidentiality. Keeping doors open may

also allow the potential venting of infected air into the corridor or waiting room in the event of a potential aerosol generation.

Many clinics created a separate room for endoscopy with additional ventilation during the height of the pandemic. There is therefore a choice according to local circumstance, local microbiological advice and clinical preference.

There should be an option for continuing to use a suitably ventilated endoscopy room (see below for details) according to the wishes of the clinician.

4.4 How to manage a potential AGP incident

If an AGP incident did occur during endoscopy, then the room air/possible infected aerosol needs time to clear. The clearance of air within a room is governed by the principles of ventilation documented below and will depend upon the room's ventilation characteristics. With regard to the timeframe needed to clear the room of aerosol, this will vary according to the room used for endoscopy, and local advice should be sought. However, such events will be infrequent.

4.5 Medical student teaching and support staff during endoscopy

During the peak of infection, it was deemed dangerous to have extra personnel in the room during endoscopy, and clinicians found themselves on their own throughout the whole procedure.

This now seems over cautious, but it was introduced at the peak of infection because of fear and a lack of understanding of the true risks involved.

There should be no reason for clinicians to have lack of support in the current situation. It is strongly recommended that clinicians should always have an attending nurse present, to act as a chaperone and most importantly for patient safety in case of a vasovagal episode.



It would be wise for support staff to maintain the wearing of PPE during the procedure.

Should an AGP incident occur, staff and students should ideally leave the room quickly if they are not wearing an FFP3 mask.

4.6 Additional safety measure in the event of another SARS-Cov-2 wave

Should numbers of Covid episodes start to increase again within local communities, performing a Lateral Flow Test on the patient prior to endoscopy may help protect health care staff during endoscopic assessment of the upper respiratory tract. The sensitivity is 77% when performed by a health care professional and rises to 95% should there be a high viral load.

Key principles and revised recommendations

1 Key principles

- 1.1 A designated, suitably ventilated, endoscopy room should be available within the outpatient clinic suite.
- 1.2 It is acknowledged that few upper airway endoscopies will generate an aerosol. If an aerosol is generated, this will be clearly recognised by the endoscopist at the time.
- 1.3 A facemask worn by the patient will help to contain an aerosol should this be induced during endoscopy.
- 1.4. All clinical personnel in the vicinity will need to wear appropriate PPE.
- 1.5 PPE items include a facemask, visor, gown, plastic apron and gloves. The priority is to protect against inhalation of an infective aerosol.

Essential

- FFP3 mask recommended as the best antiviral protection.
- Surgical face mask offers some protection (improved with the addition of a visor).



• Disposable gloves.

Recommended but not mandatory

- Gown recommended for endoscopist.
- Plastic apron offers limited protection.

2 Revised recommendations

2.1 The endoscopy room

- The designated room should, at the very least, be well ventilated
- Ideally, the endoscopy room should have mechanical negative ventilation with a known rate of air changes per hour (ACH)
- If the clinician is happy to proceed with endoscopy in the clinic room, this is acceptable with low-risk patients and adequate ventilation. However, there is a risk element should an aerosol incident occur, and this needs to be carefully considered.

2.2 The patient

- The patient should wear a surgical mask covering his or her mouth and ideally nose during the procedure.
- Patients should be asked to avoid sneezing or coughing during the procedure, but if this cannot be controlled, they should give a non-verbal warning to the endoscopist to enable the surgeon to keep their distance.

2.3 The endoscopic procedure

• The surgeon should wear suitable PPE as described in section 1.5.



• The ENT surgeon should be fully supported by nursing/ancillary staff during the procedure.

2.4 Action to be taken in the event of a potential aerosol generation

- Should the patient cough or sneeze during the procedure whilst wearing a surgical mask, any aerosol generated should be relatively contained.
- Should a potential aerosol be generated by the patient, the staff and students should leave the room immediately.
- The ENT surgeon may need to leave the room if PPE is deemed non-protective.
- The patient should vacate the room after the procedure.
- The room should be left empty and fallow for a period of time, based upon local microbiological advice and clinician input. The exact mechanism of allowing clearance of the aerosol produced will depend on the room ventilation characteristics (e.g. mechanical air extraction, or natural ventilation).

2.5 After the procedure

- The surfaces should be cleaned after each procedure.
- The room should be thoroughly cleaned at the end of the session according to local Trust IPC guidance.
- There is no need to have a fallow period if no AGP has been produced.

Summary

i). The current risk of being exposed to a patient infected with SARS-Cov-2 is low.

ii). The risk of upper airway endoscopy inducing an aerosol is low.

iii). The combined relative risk makes exposure to the virus unlikely, but the risk is still present.

iv). We have a duty to ensure the optimum safety of patients, clinical personnel, students, and ourselves.

v). The most important objective is to prevent inhalation of infective air should an aerosol be generated. Whilst a facemask is essential, an FFP3 mask offers the best protection.

vi). The clinical room should be adequately ventilated. Should an aerosol be generated, a room rest period is recommended. The duration of room rest will be determined by the ventilation characteristics and local advice.

vii). The variation of individual practice, clinical rooms, room ventilation and local Covid rates in the community should all be given consideration in the prevention of viral infection. Local safety measures will need to be based on these considerations.



Appendix

The science behind the reasoning

Definitions:

Aerosol: suspension of fine solid or liquid droplets in a gas

Droplet: very small drop of liquid

These basic definitions look simple but aerosol science is much more complex; the definitions cannot therefore be applied as easily as may be expected.

For practical purposes, droplet sizes are categorised as follows:

<5 μm 'airborne' particles >5 μm referred to as a droplet within Infection Control

Droplets that are 40 μ m or less are not visible and would go unnoticed. Droplets of 100 μ m or less are inhalable.

For the purpose of this guidance document, we will refer specifically to respiratory aerosols. These will include a range of droplet size including microdroplets.

Viral particles may contaminate particles of all sizes but the viral load would be greater on a larger droplet.

The behaviour of the aerosol will depend on particle size and the environment. The latter includes temperature and humidity, but room airflow can have a significant effect of maintaining droplets in suspension and spread.

4 Aerosol generation

Endotracheal intubation is the only AGP that is proven to cause aerosolised viral transmission.⁽¹⁾ This was described in a systematic review of the transmission of acute ENT UK at The Royal College of Surgeons of England 11 35-43 Lincoln's Inn Fields London WC2A 3PE Tel: 020 7404 8373 | Email: entuk@entuk.org | Web: www.entuk.org

respiratory infections. Tracheostomy, non-invasive ventilation and bronchoscopy are implicated in aerosol generation, although not proven.

The four national public health bodies advise appropriate PPE, including fit-tested particulate respirators, when undertaking these procedures.⁽²⁾

Flexible and rigid nasendoscopy (NE) have been identified as potential AGPs due to their similarities with bronchoscopy.

NE in itself is not an AGP, unlike intubation, in which high-pressure air forced into a patient's mouth aerosolises moisture from their respiratory tract. In NE secretions can only be aerosolised by sneezing and coughing. Contact transmission can occur from secretions left on the endoscope after use, however the mechanism of this transmission is hand-to-mouth transfer rather than inhalation. Any respiratory infection (RSV, influenza, pneumonia, TB) can be transmitted by aerosolisation or contact transmission, and it is important to note that basic infection control precautions (gloves, hand washing and covering of the face when sneezing) were regarded as adequate before the arrival of Covid-19.

Breathing, coughing and sneezing produces different airflow dynamics dependent on the amount of kinetic energy involved. In descending order, sneezed airflow contains the most energy, followed by coughing and then breathing. The higher the energy involved, the larger the droplets that can be created (up to 400 μ m in sneezing). Aerosols from sneezing also have the highest exit velocity of up to 100m/s.⁽³⁾

Droplets

Both droplet size and exit velocity are important factors that dictate how an aerosol behaves. High-energy airflow, however, does not create exclusively large droplet aerosols. Sneezed aerosols can contain very small droplets too. Small droplets remain airborne and evaporate rapidly without ever landing on a surface (within two seconds

for droplets <50 μ m). Despite very small droplets evaporating rapidly, these high exit velocities can force droplets out to six metres.⁽⁴⁾

Larger airborne droplets (>125µm) are subject to gravity, landing on surfaces before evaporating. In a room with still air, friction prevents these droplets travelling significant distances. They land within two meters in a matter of seconds.^(4,5) As a basic principle the larger the droplet the higher the viral load and theoretically the higher the risk of infection.⁽⁶⁾ These large droplets are the most hazardous which is why social distancing, hand washing and cleaning surfaces are so important.

It is interesting to note that even breathing and talking produces aerosols. Breathing has the lowest airflow velocity and therefore always produces very small droplets less than 8 μ m. They evaporate in a fraction of a second, very close to the subject's face without ever landing on a surface. ^(4,6)

Coughing produces droplets with kinetic properties between breathing and sneezing.

Respiratory droplets are made up of both solution and substrate. The solution (H_2O) evaporates leaving behind the substrate, which is mainly sodium chloride. Factors that improve evaporation theoretically reduce transmission risk. These include high temperature, low humidity and air movement in the room.

In respiratory viral infections the evaporated substrate/dry particulate matter (sometimes referred to as microdroplets) may also carry viral material. These dry viral particles are believed to be less contagious than those in droplets. They can stay airborne indefinitely, but their role in viral transmission is unproven.

Masks

Basic surgical masks (BSM) have been shown to reduce aerosolisation during coughing and speaking by 98.5%.⁽⁷⁾

Respirator masks such as FFP2 (N95) and FFP3 (N99) trap 94% and 99% respectively, of particles as small as $0.3\mu m$.

Put simply, a BSM stops 99% of an aerosol coming out while an FFP3 mask stops 99% of an aerosol being breathed in. Preventing an aerosol with a BSM has the added benefit of reducing air and surface contamination in a room.

5 Ventilation characteristics of rooms used for AGPs

Ventilation for any enclosed workspace is necessary for human habitation (fresh air – replacement of O2 used and removal of CO2 build up). In the healthcare environment it is also necessary for removal of infectious, toxic or otherwise hazardous odours, aerosols, vapours, fumes and dust (Control of Substances Hazardous to Health (COSHH) regulations, and also the dilution and control of airborne pathogenic material.⁽⁸⁾

The Healthcare Technical Memorandum 03-01, published by the DOH (7), states that 'ventilation is installed to protect staff from harmful organisms, and the patients and staff have a right to expect that it will be designed, installed and operated and maintained to standards that will enable it to fulfill its desired functions reliably and safely.' This Memorandum further states that 'the requirements to provide ventilation, implicit under The Health and Safety at Work Act 1974 and COSHH, have been made explicit by the Management of Health and Safety at Work Regulations 1999, the Workplace (Health and Safety and Welfare) Regulations 1992 and the Provisions and Use of Work Equipment Regulations 1998.'

HTM 03-01 mainly deals with the ventilation in a healthcare setting designed to reduce the air contaminants that might affect a patient, for example the design of operating suite ventilation, as opposed to the ventilation needed to remove aerosolised SARS-CoV-2 from a patient who poses a risk to the healthcare worker, and subsequent patients in that room. However, it contains a great deal of information about

principles of ventilation, and is used by all hospital estates departments as their reference document.

6 Types of ventilation

Ventilation may be passive (opening windows and doors) or active with some form of mechanical ventilation. Ventilation may be described by the fixed volume of air supplied to a room, usually expressed in terms of the resulting air changes per hour (ACH), or the volume of air supplied in order to maintain a specific pressure relationship between the room and the surrounding areas, or a combination of both.⁽⁸⁾

Local exhaust ventilation (LEV), describes systems installed to prevent hazardous substances entering the general atmosphere of the room in which they are being used. This may be a capture hood, extractor ductwork or a fan. Examples are fume cabinets in labs, or sometimes in mortuary dissection suites.

6.1 Natural ventilation

Created by the effects of wind pressure, or temperature differences in environments, when doors or windows are open, or when there are vents or gaps in windows and doors. Impossible to maintain consistent flow rates, and ensure minimum ventilation rates will be achieved at all times.

If natural ventilation is 'single-sided', it will usually only be effective for a three-metre depth within the space.⁽⁸⁾ Often purpose fitted vents are needed to allow cross flow of ventilation. Cross flow ventilation can be enhanced by the use of fans (so called mixed-mode ventilation), but the path of the air must be clear, to allow flow.

In modern clinic rooms, window opening is often restricted, and insulation of the room is designed to prevent drafts and therefore airflow.

6.2 Mechanical ventilation

This may be extraction ventilation (e.g. extractor fan), supply only (creates positive pressure room, e.g. operating theatres) or supply and extraction.

Supply and extraction methods (often called balanced ventilation) are often used in treatment rooms, or windowless examination rooms, to maintain consistent air movement.

6.3 Dilutional ventilation

Dilutional ventilation, as it suggests, aims to dilute the hazardous substances by means of room air changes (ACH).

Appendix 1 contains the recommended air change rates for a variety of hospital environments taken from HTM 03-01, as well as the type of ventilation, and whether there is a positive, negative or equal pressure environment.

Of note, a general ward should have an air supply/natural ventilation with 6 ACH; operating theatres should have positive pressure ventilation with 25 ACH; a treatment/minor procedure room should have positive pressure ventilation with at least 10 ACH.

7 Air changes per hour (ACH) and efficiency of removal of airborne contaminants

The efficiency of airborne contaminant removal from a room is shown by data from Universite Catholique de Louvrain, Architecture de Hygeine Hospitaliere (please see Appendix 2).⁽⁹⁾ It details the number of minutes needed to remove 90%, 99% and 99.9% of contaminants at different air change per hour (ACH).

Of note, the data shows the following:

- At 6 ACH, it takes 46-69 minutes to remove 99% and 99.9% respectively (the time taken for almost complete room air change in a ward).
- At 10 ACH, it takes 28-41 minutes to remove 99% and 99.9% respectively (as may occur in a possible treatment room setting).
- At 25 ACH, it takes 11-17 minutes to remove 99% and 99.9% respectively (in an operating theatre setting).

Appendix 3 contains similar data from the American Center for Disease Control and Prevention.⁽¹⁰⁾

8 Clean air paths (CAP)

Dilutional ventilation can be aided by means of clean airflow paths. This is where the air coming into the room flows across the area of hazard, and out through a separate vent. There should be no other object restricting the airflow apart from the hazard.

An example of this is the airflow in anaesthetic rooms where air often comes in through a high wall vent, and out via a low level vent, properly behind the anaesthetic machine to remove anaesthetic gases in the room. The laminar flow (ultra-clean ventilation) system in orthopaedic theatres is another example of clean air flow paths.

It has been reported that the most important contributing factor to contaminant transmission in enclosed and mechanically ventilated environments is the path between the contaminant source and the exhaust, and not the ACH as may be expected.⁽¹¹⁾

9 Validation of ventilation

For any new facility or for the assessment of an older facility, the hospital estates department, often via an external specialist contractor, should validate the ventilation system.



Thus, a designated endoscopy AGP room should be validated accordingly, and clean airflow paths (CAPs) can be identified and assessed. The details of this process can be requested from the hospital estates team.

10 Pragmatic room and ventilation consideration for potential AGPs in ENT

10.1 AGPs in patients not suspected of being Covid-19 positive

There is no fixed advice on the exact environment that is best to perform an AGP on a patient whose Covid-19 status in unknown.

It is now clearly established that patients with Covid-19 could have minimal or trivial symptoms and Covid-19 swabs may show false negative results. Therefore, all patients who undergo upper airway endoscopy should be treated as potentially Covid positive.

10.2 AGPs in Covid-19 positive patients

The WHO recommends that potential AGPs performed on patients with Covid-19 should be performed, whenever possible in negative pressure rooms with a minimum of 12 ACHs.⁽¹²⁾

'Apply airborne precautions when performing an aerosol-generating procedure. Ensure that healthcare workers performing aerosol-generating procedures (e.g. open suctioning of respiratory tract, intubation, bronchoscopy, cardiopulmonary resuscitation) use the appropriate PPE, including gloves, long-sleeved gowns, eye protection, and fit-tested particulate respirators (N95 or equivalent, or higher level of protection). A scheduled fit test should not be confused with a user's seal check before each use.

Whenever possible, use adequately ventilated single rooms when performing aerosolgenerating procedures, meaning negative pressure rooms with a minimum of 12 air changes per hour or at least 160 L/second/patient in facilities with natural ventilation.

18



Avoid the presence of unnecessary individuals in the room'.

11 Further research

Further research is needed to try and assess the safest environment for potential AGPs in ENT. Local exhaust ventilation, air extraction ventilation or portable air filtering units might offer benefit, but further advice and research is needed.

A copy of the full document, including appendices, can be found on the ENT UK website.