



Otology: a graduated return to the provision of elective ENT services during the COVID-19 pandemic

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OTOLOGY

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Introduction

This guidance has been developed to assist clinicians in their return to elective otological practice during the COVID-19 pandemic. The recommendations contained within this document are based on current knowledge, but it is accepted that the clinical setting in which we work and the evidence base for our practice are constantly changing and this guidance **is changing** over time. This document focuses on return to elective otological outpatient work and to elective otological operating. It has been prepared with the clinical needs of patients and the safety of both patients and personnel in mind. These are guidelines only and may need to be adapted dependent upon local circumstances and changing government policy.

The initial drafts of this document were written by the four named authors. Opinion was obtained from personal communication with a wide range of other stakeholders (Appendix 1) and professional organisations, and government, as well as a review of the literature. The authors have endeavoured to develop guidance that is consistent with recommendations from these other organisations, but the stated opinions are those of the British Society of Otology (BSO). Once completed a final review was undertaken by the full BSO Council and the ENT UK committee overseeing the development of these guidelines.

Outpatients

Triage

BSO recommends that all new and follow-up patients are triaged by a senior clinician. They may then be seen face to face, in virtual clinics, or discharged. **It has become increasingly clear that virtual appointments may have a place in the long-term strategy of many departments and we encourage this option both to be explored and expanded. The use of video consultations will require an appropriate private setting and the correct technology to be provided. The time required for such appointments is likely to be similar to face to face consultations.**

We do not recommend appointments are re-dated without clinical staff having seen either the referral letter or recent clinic letters. Time should be allocated for this. Each ENT department will need to work closely with their administrative staff to generate Consultant-level outpatient waiting lists. This will include patients whose clinic appointments have been deferred since the lockdown and those going forwards who have appointments booked to the end of the calendar year. In addition, a list of the outstanding new referrals that have as yet not been allocated an outpatient date due to the lock-down will be required. This will no doubt generate a substantial list for each Consultant with their senior trainee to actively manage with regards to triaging but will serve to confer ownership and responsibility to each Consultant.

Virtual clinics

These may be undertaken either by telephone or secure video link. There is good published evidence of their usefulness. For example, Healy et al. concluded *"The majority of patients discharged from a surgical service could be better followed up by a virtual clinic with a significant proportion of patients reporting a preference for and a greater satisfaction with such a service."*

These appointments should be undertaken by an experienced clinician in an appropriate protected environment. It is likely that most new otology referrals will need a face to face appointment subsequently for audiometry and examination of the ear. The virtual appointment will allow triaging of urgency, initiation of treatment, and review with investigation results. This will generate reduced hospital visits.

Follow up appointments can be particularly suited to a virtual setting and many patients may be discharged after this. This type of consultation may become part of routine practice in the long-term but we would advise caution when considering serial virtual appointments particularly for wet ears, although it is reasonable to request an ear swab is obtained in the community and treated appropriately to reduce hospital attendance.

Balance clinic appointments can also be successfully undertaken virtually and asking patients to use their smart phones allows a significant amount of the examination to be completed,

including Hallpike's test. **How to run such a clinic can be viewed until early-August on the RSM website (search: RSM/BSO outpatient Webinar).** However, caution will be needed and until further evidence is available most patients are likely to require face to face appointments at some stage.

Face-to-face appointments

For most new otology referrals, in the absence of local spikes in COVID-19 infection, and allowing for individual patient and clinic circumstances, increasing the number of face-to-face consultations will be appropriate.

Appropriate PPE and clinic precautions will need to remain in place, and fewer patients may be able to be seen in clinics depending on local circumstances.

General advice on PPE in outpatients

Although rapid, sensitive antigen and antibody testing for COVID-19 infection is becoming increasingly available, **and the prevalence of COVID-19 is reducing in most areas of the UK,** we still recommend taking appropriate precautions to limit the risk of viral transmission between patient and surgeon and vice versa, even in patients that have tested as COVID-19 negative. For consultation only (no examination, testing or treatment) this constitutes the following:

- Limiting appointments to asymptomatic patients who have had no contact with known COVID-19 positive individuals in the last 2 weeks. Patient selection will have to be more cautious than in the past and individual patient risks assessed against needs. In particular careful consideration will be needed as to whether it is justifiable to bring older patients, or those with other COVID-19 risk factors, into an acute hospital setting.
- Minimising patient waiting time within the department prior to their appointment.
- Social distancing of two metres wherever possible, including the waiting area and inside the consulting room.
- Avoidance of relatives and friends attending with the patient where possible.
- Use of the most spacious and well-ventilated consulting room available.
- **The surgeon should consider wearing theatre clothing if not wearing additional PPE.**
- Standard ANTT precautions, i.e. bare below the elbow (including rings and watches) should be maintained.
- FFP3 masks are not required for consultations. Protection should be within national and local guidelines.
- **Patients should be required to wear a mask. This should also follow national and local guidelines. The challenge of mask wearing in hard-of-hearing patients (who make up 1 in 6 of the population and a much greater proportion in the otology clinic) needs consideration. We have written to the Secretary of State for Health on this issue and await his reply (P. Rea, N. Kumar, S. Saeed, A. Narula, 28 May 2020). Clear masks are being delivered in small numbers to the UK, but most are not CE marked as yet. Options will include the surgeon wearing a visor without a mask and keeping two**

metres from the patient while they wear a mask, and the use of translation software. Such software is now of excellent quality and even when wearing a mask can offer instant printed translation of speech onto a tablet for the patient to read where possible. Departments may wish to explore investment in this technology going forwards.

- All surfaces should be wiped down with alcohol-based wipes following the consultation.
- Additional time should be allowed to accommodate the additional infection control activities.
- In suspected or confirmed COVID-19 positive patients precautions, as recommended by PHE, should be taken, i.e. the following should be worn: FFP3 mask, plastic gown and apron, disposable gloves and eye protection (for further information please refer to PHE COVID-19 PPE Guidance). It is vital that fit testing for FFP3 masks is undertaken prior to use.
- Eye protection has been a persistent issue, especially with microscope use in clinic. Some colleagues report the use of soft visors allows adequate approximation to the microscope eye pieces. Others have found close-fitting glasses have been successful. Foam surrounds to the glasses add extra layers of protection (for example Bolle Tracker).

Examination

Otoscopy

As the use of an otoscope requires close face-to-face proximity, where possible the use of the operating microscope or a video otoscope with remote screen should be considered. It is, however, recognised that standard otoscopy may be required at times. In asymptomatic patients with no COVID-19 contacts, if it is necessary to carry out otoscopy then a fluid-resistant mask and disposable gloves should be worn by the surgeon. Some surgeons may also prefer to wear eye protection although this may interfere with the microscope eye pieces. Close fitting visors are less likely to interfere than bulkier eye protection.

In suspected or confirmed positive COVID-19 patients precautions as recommended by PHE should be taken, i.e. the following should be worn: FFP3 mask, plastic gown and apron, disposable gloves and eye protection (for further information please refer to PHE COVID-19 PPE Guidance).

We could find no clear evidence regarding the benefits of asking patients to wear face masks in this setting although breathing does generate some aerosol. There has been a discussion regarding patients coughing and expelling aerosol out the side of the mask during ear examination or suction. An individual decision will be required but on balance the patient wearing a mask seems preferable whilst research data is collected.

Disposable ear specula should be used.

Tuning forks

Should be cleaned after each use.

Testing

BSO has liaised with NHSE-I and Audiology Professional Bodies (see acknowledgements) when making these recommendations to ensure a degree of uniformity and we thank them all for their very helpful engagement. In particular we draw your attention to the following documents: *'COVID-19: Prioritisation within Community Healthcare'*. This is an important document for us. Despite the title this does affect acute hospital settings. This is published by NHS England and NHS Improvement (NHSE-I). *Recommendations for children and young people were updated on 3 June 2020 after NHSE-I consulted widely including with BSO.*

For adult services NHSE-I sought opinion from audiology national bodies and BSO and on 9 May 2020 BSO provided recommendations. However, the most recent update for adult services remains dated 2 April 2020 and still recommends a 'partial stop' to services. This is now unacceptably out of date and is holding back a return to more normal services in NHS hearing and balance clinics.

We wrote to ministers on 25 June 2020 highlighting the delays and received a reply from the Chief of Staff to The Director of Community Health Services (NHSE-I) on 29 June 2020. BSO and audiology national bodies were invited once more to contribute to updating the guidelines which we did by return. However, no update appeared so BSO and ENT UK wrote to Matt Hancock and Jeremy Hunt on 28 June 2020 requesting urgent publication.

BSO received a further email from the Chief of Staff at NHSE-I on 7 July 2020 assuring us this document was going through the final stages of internal approval, but at the time of writing (12 July 2020) nothing has been published. We wrote again on 10 July 2020 highlighting the difficulties delays were causing departments, and some of our most vulnerable patients. We again offered our assistance and urged speedy publication.

Departments should monitor this document carefully. Reference should also be made to: *'Audiology and otology guidance during COVID-19: From the UK's audiology professional bodies. BAA, BSHA, BSA and AIHHP'*. *This document is regularly updated.* However, the guidelines presented in this BSO document are ultimately the opinion of BSO.

As per the above, audiovestibular testing should only be undertaken in patients who are asymptomatic and have not had contact with anyone known to be COVID-19 positive in the last 2 weeks. Again, consideration of additional risk to older patients and those with other COVID-19 risk factors, is required. There is no reason to undertake audiovestibular testing in suspected or confirmed COVID-19 positive patients at the present time.

A fluid resistant mask, plastic apron, eye protection and disposable gloves may be worn. The document 'Audiology and otology guidance during COVID-19: From the UK's audiology professional bodies. BAA, BSHA, BSA and AIHHP' sets out PPE guidance for audiologists. Adult patients should wear a mask where possible.

Testing is likely to take longer due to the longer periods required for cleaning between cases and numbers tested will be reduced. Local discussions regarding staffing factors and the test environment will need exploring.

For audiological assessments undertaken in conjunction with ENT outpatient clinics, some departments recommend that a specific time slot is allocated for testing 30 minutes prior to the allocated ENT outpatient appointment. Other departments prefer the ENT surgeon to assess the state of the ear before testing is undertaken.

Urgent testing for sudden sensorineural hearing loss should continue to be provided in all circumstances. Testing of patients undergoing aminoglycoside or chemotherapy regimens that may induce audio-vestibular injury should not be delayed.

To ensure appropriate triage we recommend testing is requested only by senior clinical staff. We recommend that the following procedures can now be restarted when individual units have appropriate infection control policies in place, and where clear need is present:

Audiometry, tympanometry, stapedial reflexes, ABR, CERA, VNG testing, caloric testing in the presence of intact tympanic membranes, posturography, rotating chair, vHIT and VEMPS.

We do not recommend limiting the availability of these tests as long as appropriate precautions are taken. However, fewer test will be possible due to increased time for cleaning.

We do not recommend undertaking calorics in the presence of a perforation. Careful consideration should be given as to whether or not trans-tympanic electrocochleography is appropriate as this involves piercing the tympanic membrane and may risk exposure to middle ear mucosa.

Despite our recommendations, it is likely many NHS facilities will delay returning to testing until NHSE-I publish their guidelines.

Outpatient treatment

When seeing asymptomatic, unexposed patients who require outpatient otological treatment, a fluid-resistant mask, plastic apron, eye protection (if the surgeon feels appropriate) and disposable gloves should be worn if there is no risk of aerosol generation or viral transmission. The patient should wear a mask.

If there is a risk of aerosol generation or if the patient is suspected or confirmed to be positive for COVID-19, precautions as recommended by PHE should be taken, i.e. the following should be worn: FFP3 mask, plastic apron and gown, disposable gloves and eye protection (for further information please refer to PHE COVID-19 PPE Guidance). Where instruments are required to undertake procedures and treatments, disposable instruments are recommended where possible.

Microsuction

We have considered a number of sources of evidence when considering the safety of micro-suction of the ear in an outpatient clinic.

- The external ear canal is not virus bearing (*personal communication, Dr David Jenkins, consultant medical microbiologist, University Hospitals of Leicester*). Micro-suction of the external ear canal therefore should not generate risk of COVID-19 transmission from the *ear canal* if the tympanic membrane is intact, and it is not considered an AGP with respect to COVID-19 transmission.
- The middle ear and mastoid mucosa may be virus bearing. There is no direct evidence as yet with respect to COVID-19 infection, but there is evidence from previous coronavirus studies. Two papers are worth considering:

The first paper (*Wiertsema SP et al.*) showed that coronaviruses were present in 14.4% of nasopharyngeal swabs of patients with recurrent AOM and OME compared to 6% of healthy controls. The difference did not quite reach statistical significance ($p=0.08$). 4.9% of patients had coronavirus in their middle ear aspirate. There were no controls for this, presumably because healthy controls had no middle ear fluid to aspirate.

The second paper (*Heikkinen et. al.*) did not test for coronaviruses in the middle ear aspirates (it is an old paper) but it does show that when a virus is present in the nasopharynx there is also a high probability of the virus being present in the middle ear (between 4% and 74% depending on the virus).

Microsuction of the middle ear or its contents could therefore in *theory* risk viral transmission in infected patients.

- Concern has been raised regarding the risk of a cough reflex generated by micro-suction. In particular whether asking patients to wear a face mask might direct the cough laterally towards the clinician. The British Academy of Audiology (BAA) sought opinion on coughing and we have liaised with them. Professor Wilson of the Infection Prevention Society recommended the use of a face mask by the patient ('*Audiology and otology guidance during COVID-19. BAA, BSHA, BSA and AIHHP*', 1 May 2020). On balance BSO would also recommend asking the patient to wear a mask during microsuction to reduce aerosol in the clinic room, but this will be at the individual clinician's discretion in the absence of firm evidence.
- It is now recommended that a fan is not used in medical settings for fear of spreading droplets or aerosol.
- It is also strongly recommended that suction equipment in the clinic is reviewed as venting from the machine may be unfiltered. This is particularly true of free standing (portable) suction machines. In theory this could circulate a virus containing aerosol. It is recommended that the filter status of machines is

discussed with the manufacturer, as required, and if necessary additional filters should be fitted.

When undertaking micro-suction or dewaxing in the presence of an intact tympanic membrane the 2-metre social distancing guideline will be breached. To maintain reasonable distance the use of an operating microscope, or video-endoscope with remote screen is likely to be safest. PPE as per otoscopy is recommended. There appears no need to have a period to allow the air of the room to recirculate with such procedures although cleaning of surfaces will be required.

In the presence of a dry tympanic membrane perforation it is reasonable to follow the same recommendations as for an intact tympanic membrane.

If the middle ear is wet intuitively the risk of contamination with virus seems higher. In this situation we would currently recommend the use of a filtering face piece respirator (FFP2 or FFP3). We have no guidance on whether a period of time will be required between patients. PHE imply this is not an AGP, although this depends on the interpretation of the meaning of 'upper respiratory tract'. We would tend to take a more cautious approach and consider the middle ear an extension of the upper aerodigestive tract. A risk assessment will need to be made on each individual patient in line with local guidance.

Because of the risk of generating aerosolised COVID particles during microsuction in the presence of a wet, perforated tympanic membrane we recommend that microsuction, in these cases, is performed in a separate room from the consulting room to allow adequate air change between patients. Where that is not possible, agreement will need to be found between local infection prevention teams and those undertaking suction. Turn around between patients is determined by the speed of air change and in order to facilitate rapid turn around the room used should be well ventilated. Local estates departments can determine the rate of air change and if it is slow the use of HEPA air filtration units can be used to speed up the air change rate.

Avoidance of fenestrated suction is recommended in the presence of a wet ear in order to minimise aerosolisation through the fenestration, and contamination of the surgeon's glove.

Specific scenarios

Wax impaction

Services can resume in outpatient clinics for those with significant symptoms as described above, where appropriate infection control methods are in place.

Otitis externa

Virtual consultations may reasonably request a culture swab of the ear be taken in the community and treated appropriately. Severe pain or failure to settle will need clinic review

as described above. Dry mopping a wet ear to look for a perforation prior to, or in place of microsuction may be helpful.

Intra-tympanic injections for Sudden Sensorineural Hearing Loss (SSNHL) and Endolymphatic Hydrops

In the presence of an intact tympanic membrane there appears no significant risk to the clinician from the injection itself. This is not an AGP. PPE should be used in line with that described for microsuction. In the presence of a perforation the provision of ear drops might be considered as an alternative if steroids are being used. We would recommend the patient is not asked to spit after the injection as was traditional practice prior to COVID-19, and patients can swallow.

In our earlier guidance on otology surgery we discussed the concerns over the use of steroids in potential COVID-19 infection. The evidence that steroids cause harm is now less clear. Indeed, dexamethasone has been shown to reduce mortality in seriously ill COVID-19 patients.

We currently recommend that intra-tympanic steroid therapy is safe for the treatment of SSNHL and endolymphatic hydrops and see no reason not to offer this form of treatment at the present time. The systemic dose of steroid following intra-tympanic treatment is significantly lower than that of oral treatment and it is therefore likely that the impact on COVID-19 outcomes (if detrimental) will be less. We acknowledge that there is no evidence base for this assumption. With SSNHL there will remain uncertainty as to whether the hearing loss arose from a lesion of the nerve (where systemic therapy may be more effective) or cochlea (where injections may be more effective). Given the emerging evidence of benefit from systemic steroid therapy in COVID-19, the balance of risk has tilted towards providing both intra-tympanic and systemic steroids for SSNHL following an appropriate discussion regarding risk with the patient. If concern is present using only intra-tympanic steroids for SSNHL would seem reasonable.

SSNHL should be treated as a medical emergency and treated at the earliest possible opportunity.

Necrotising otitis externa (NOE)

This should be managed as per local protocol. BSO have published guidelines on the general management of NOE on the ENT UK website. Where practical, we would recommend an increased use of intra-venous therapy at home for as much of the duration of treatment as possible.

Bell's Palsy

In idiopathic facial palsy, the use of oral steroids should be discussed with the patient. Evidence from the Scottish Bell's Palsy study suggests that the use of oral steroids improves recovery from 85% to 96% (*Sullivan FM et al.*). The potential risks and benefits of oral steroid use during the current pandemic need to be made clear and a balanced decision made. **For patients with known COVID-19 infection discussion with your infectious diseases department prior to the use of high dose steroids may be sensible.** For those not believed to be infected the balance of risk may weigh towards treatment with oral steroids.

Adult otitis media with effusion

In adults with effusions lasting six weeks or more, investigation should be initiated. Patients may require a nasal endoscopy and the risk of this to surgeon and patient now seems extremely low. If there is concern regarding possible COVID-19 infection, and in the absence of nasal symptoms, an MRI of the nose, post-nasal space, and skull base may be considered as an alternative.

Chronically infected mastoid cavities

The risks of coronavirus in an infected mastoid cavity with an intact tympanic membrane appear low. The cautions described for microsuction should be employed. Consideration may be given to leaving antiseptic creams in the ear for longer periods.

Surgery

Introduction

In light of the changing demands on acute NHS Trusts, we believe we are now in a phase of the current pandemic when recovery plans for provision of elective ear surgery can be formulated and ear surgery can begin to be safely reintroduced. Practice varies considerably around the world at present reflecting the uncertainty **(and for the next month worldwide views can be watched on the RSM/BSO otology series webinar (search the RSM website for the session Chaired by Chris Aldren).** The precise timing of this will vary to some degree from department to department but the over-arching principles are applicable. There are however a number of considerations.

There is evidence of viable virus particles in the middle ear mucosa during viral acute otitis media in a high proportion of individuals as described in the outpatient section above. It is, however, unclear if COVID-19 produces middle ear inflammation and whether viral particles are present in the middle ear during COVID-19 infection with or without middle ear inflammation. Nevertheless, based upon the current literature there is a significant risk that viable COVID-19 producing virus particles are present in the middle ear mucosa during systemic infection with the virus. In contrast, bone and blood are believed to contain minimal viral material in coronavirus infection as this is an infection of the respiratory mucosa.

Tympano-mastoid surgery should currently be considered a high risk AGP due to the aerosol and particles of mucosa, fluid, and bone dust created by the drilling which might contain viral particles. Our knowledge is, however, incomplete on this point. However, a literature is beginning to develop (*Chen et al.*). This poses a risk of exposure to the surgeon and theatre staff.

Prioritisation of otological surgery

Based on the ENT UK, Federation of Royal Colleges and NHS England statements (Appendix 2, and below), the majority of elective ear surgery was categorised as priority Level 4 (elective surgery can be deferred beyond three months) at the start of the COVID-19 pandemic. Three months have now passed since the initial recommendations were made. Both the clinical environment we work in, and the needs of those patients already waiting significant times for their surgery, have changed. The prioritisation guidelines have recently been updated and we refer you to these, published on the ENT UK website.

We recommend that all otological cases are re-triaged on a case-by-case basis if they reach the end of their allocated priority time frame, for example at three months for priority 4 patients. The indications for surgery, co-morbidities, patient preference, and the time patients have already been waiting for surgery should be reviewed. It is anticipated that some patients will be upgraded to a higher priority level following their review. For example, some cholesteatoma patients who were prioritised as category 4 at the outset of the pandemic may now be upgraded to category 3. Given that it was not uncommon for mastoid procedures to wait up to 12 months prior to lockdown, realistic targets for surgical waits will be required. Where appropriate, patients should be contacted to explain why their operation date is still pending. If required, face-to-face appointments should be arranged to facilitate risk assessment and to update pure tone audiometry. A small number of patients may require re-imaging to assess disease progression, particularly those with cholesteatomas.

We continue to recommend the sub-categorisation of category 4 in to those patients that could wait longer than three months but not indefinitely (4a) and those patients that can safely wait indefinitely (4b). Patients in category 4a should have a target date for surgery, determined locally and based on local clinical and patient circumstances. However, it is recognised such targets may often be unachievable due to a lack of elective capacity.

The following should be regarded as the ideal standard for each type of surgery when comparing urgency to cases in other specialities, but recognising that services may not be able to meet this elective capacity at times:

Priority 1a (Emergency procedures to be performed in <24 hours)

- Ear button battery removal
- Life threatening middle ear conditions.

Priority 1b (Urgent procedures to be performed in <72 hours)

- Acute mastoiditis, or severe complications of cholesteatoma, not responding to conservative therapy:
We recommend minimum drilling, and subsequent curettage to reduce generation of bone dust (see ENT UK guidelines for otology surgery). Drilling should be at low speed with reduced irrigation. Consideration may be given to needle aspiration in place of surgical drainage for acute mastoiditis (*Bakhos et al.*).
- Facial nerve palsy secondary to trauma/cholesteatoma
- Cochlear implantation:
 - Patients with meningitis where medically possible
 - Removal of an infected implant.

Priority 2 (Procedures to be performed in <1 month)

- MDT directed otological cancer surgery
- Baro-traumatic perilymph fistula
- Organic foreign bodies in the ear
- Cochlear implantation:
 - Pre-lingually deafened children
 - Device failure leaving user without hearing
 - Post-meningitis
 - Other profoundly deaf children meeting NICE criteria may be placed in this category, based upon the clinical team's assessment, and theatre availability.

Priority 3 (Procedures to be performed in <3 months)

- Cochlear implantation in other post-lingually deafened children, and profoundly deaf adults
- Active chronic suppurative otitis media without cholesteatoma may be priority 3 or 4.

Priority 4 (Procedures to be performed in >3 months)

- Cholesteatoma – uncomplicated.
- All ossicular surgery/middle ear implants/BAHA
- Tympanoplasty
- Grommets (exceptions include where PNS biopsy is required which is priority 2, and where significant speech delay is present which may be priority 3)
- Meatoplasty
- Vestibular Surgery
- Most non-organic foreign bodies in ears (except button batteries or where causing pain or infection).

Vestibular schwannoma surgery (Priority 1-4)

- It is not possible to group all VS surgery into a single category. Very large tumours with impending or actual complications may be category 1b or 2. Small, slowly growing tumours may be regarded as category 4.

Cholesteatoma surgery (Priority 2-4)

- It is not possible to group all patients with cholesteatoma in to the same category as individual circumstances differ. Those with impending complications should be category 2. Actively discharging disease with evidence of extensive cholesteatoma should be regarded as category 3. It may be reasonable to consider early cholesteatoma priority 3 before erosion develops. Dry low activity cholesteatomas may still be regarded as category 4.

Interdependencies for reinstatement of elective ear surgery

The reintroduction of elective otological surgery will be dependent on the availability of the following: Imaging; audiology; PPE stocks; advice from PHE; advice from related specialty associations, e.g. BAA, BSA, BCIG, RCoA, RCS; local circumstances, e.g. availability of staff and facilities (we are aware many anaesthetic colleagues have been redeployed and theatres reconfigured. It may take time for more elective practice to return); and a safe operative environment.

The need for preoperative imaging and audio-vestibular testing remains unchanged (see section on clinics). Clear consenting explaining the rationale for undertaking the elective procedure and the risk – benefit balance in the presence of 1) a very small risk of the patient having asymptomatic COVID-19 infection just prior to admission and 2) a small risk of transmission during hospitalisation; must be undertaken and documented (see section on consenting). Alternative management options including non-surgical treatment should be discussed (please also refer to ENT UK guidance on consent). **The additional COVID-19 consent form should be completed (this can be found on ENT UK website).**

Pre-operative considerations

- Pre-operative COVID-19 testing is essential to minimise viral transmission as much as possible. We would recommend that the patient should be asymptomatic, **have a negative COVID-19 antigen test taken 48 hours pre-operatively**, and have self-isolated for 14 days prior to surgery. One or both parents will need to self-isolate with the child in the case of paediatric surgery. This should be checked by the admissions team on the day of surgery. These criteria may vary across hospitals according to local policy.
- The optimal length of time to postpone surgery after a positive swab is unknown. Given that increased mortality is described with GA following COVID-19 infection a considerable gap may be required. Discussion with your anaesthetic team will be required.
- As we progress through the pandemic the risk of operating on an asymptomatic patient should decrease rapidly. **At the time of writing approximately 1 in 3,000 of the**

population is infected, with significant local variation. Pre-admission protocols generally mean that surgery will only be undertaken on asymptomatic patients who have self-isolated for two weeks and who have had **one or two consecutive negative swabs**. The likelihood of operating on an infected, but asymptomatic patient is therefore already likely to be several thousand to one against. This will continue to fall assuming no second wave. It is not possible to provide guidance on what is, and what is not, a safe level of risk. However, in producing this document opinion has been taken from around the world and there are a number of otologists working in Europe and the USA, in areas where the prevalence of COVID-19 was relatively high but has fallen, who are now undertaking major ear surgery with only an N95 face mask and goggles or visor. Others are limiting themselves to tympano-ossicular surgery and avoiding drilling, whilst many have yet to restart elective work.

Theatre considerations

- It is likely that the turnaround time for patients will be significantly extended. We would recommend assuming a doubling in duration of the patient's surgical pathway initially. This is an important consideration and teams should be realistic in terms of the number of cases that can be safely undertaken in each surgical session. Re-organisation of theatre lists to 2 or 3 session lists may be more efficient in terms of case throughput and utilisation of resources such as theatre staff and PPE.
- The number of staff in theatre should be kept to a minimum.
- Theatre staff familiar with the procedure being undertaken is critical in order to maintain efficiency.
- Safe, fast and efficient surgery is important in order to minimise the risk of exposure and optimise the use of PPE. It should therefore be undertaken by an experienced otologist.
- The use of endoscopic ear surgery in preference to mastoid drilling may be appropriate for suitably trained surgeons in certain cases.
- Novel draping techniques may help in limiting aerosolisation of tissues during surgery and are already being introduced in to clinical practice (Hellier *et al*; ENTUK COVID-19 guidelines web page). It is likely that further design improvements and alternatives will emerge. Particular care will be needed when removing these drapes at the end of surgery.
- **High resolution 3D exoscope technologies are increasingly available and may offer the opportunity to have excellent surgical visualisation whilst wearing full PPE.**
- The theatre needs to be appropriately cleaned post-operatively to ensure minimisation of residual particulate material on surfaces. Similarly, optimisation of theatre ventilation is critical in order to clear aerosolised material as promptly as possible.
- The use of drills, lasers and electro-cautery has been considered. This has been reviewed in a paper by *Thamboo et al*. The laser reviewed was a CO2 laser and there was no data on KTP lasers. Nor was there any comment about the viability of virus particles following lasering. Drills, lasers, and electro-cautery all produced aerosol and so caution is required. There is evidence from papilloma surgery that great caution is required when using lasers in the presence of virus bearing material.

PPE requirements

Not all ear surgery will generate significant aerosols, for example, stapedectomy or routine myringoplasty in a dry ear. Nevertheless, we recommend the following PPE as a minimum for all otological surgery:

- Fit-tested FFP3 mask or powered air-purifying respirator (PAPR) or equivalent
- Goggles or Visor
- Water proof gown
- Double gloving
- Non-fenestrated suction

Standard donning and doffing procedures should be adhered to.

We have considered at length the optimal design of visor and face mask to take into account the difficulties of working with a microscope in PPE. It is not possible to give individual recommendations as different mask designs fit different individuals faces and interact differently with the microscope. Similarly, it is difficult to make specific recommendations for eye protection. **The Bolle Tracker glasses have been recommended as a useful option as they fit close to the eyes. And hoods with soft shields have been found to be particularly comfortable but their availability is variable.**

Two types of contamination should be considered. Droplets are likely to be blocked by visors. However, aerosol will not. Whilst an FFP3 mask should protect the surgeon from inhaled virus it will not protect from contamination of the conjunctiva which may be a significant portal of entry of infection. Appropriate eye protection is therefore critical. This is one of the major challenges for recommencement of otological practice as most of the forms of eye protection available interfere with the use of the microscope. A number of possible eye protection options that might offer adequate protection whilst allowing use of the microscope are currently under assessment across the UK and abroad. There is not enough information at the time of writing to make recommendations on their use. It is likely that most full-face masks will not be compatible with microscope use. Close fitting wrap around visors may be easier to use, but they may not protect the conjunctiva from aerosol. The microscope and eye pieces may offer some degree of protection in themselves from droplets. Some surgeons may prefer to operate from a screen, particularly in conjunction with an endoscope or state of the art exoscope technologies. These technologies may allow a wider range of masks, hoods, and visor options.

The practicalities of eye protection have been explored and no ideal solution as yet has been found (Clamp et al).

Consideration should also be given to some of the other difficulties faced when wearing this equipment for prolonged periods including discomfort, claustrophobia and CO2 build up (there are reports of surgeons unaccustomed to tight fitting masks and visors losing concentration in long procedures, so practice and experience are needed).

It is recommended that all surgeons familiarise themselves with the PPE available in their hospital and undertake “dry runs” to ensure it is appropriate for them whilst maintaining an appropriate fit.

Anaesthetic considerations

- The Royal College of Anaesthetists have a COVID-19 website that can be referred to for specific anaesthetic advice.
- We would recommend that patients having general anaesthesia are woken in the operating theatre.
- All appropriate steps to avoid coughing on waking should be taken. Similarly, precautions to minimise aerosolisation with coughing should be taken. This should be discussed with the anaesthetic team.
- Local Anaesthetic may be preferred in some procedures to reduce aerosol generation and to reduce patient risk from general anaesthesia.
- Otological surgery should be carried out as a day case (including mastoid surgery and auditory implantation) in a designated COVID-19 free area wherever practical in order to minimise the duration of time in hospital and avoid exposure to potentially COVID-19 positive areas of the hospital.

Procedure-specific considerations

- *Grommet insertion:* For otitis media with effusion where other hearing strategies have not been helpful local anaesthetic placement is preferred. Management in out patients may be preferable where facilities allow. For children hearing aids should be considered as an alternative to surgery at present.
- *Tympanoplasty / Myringoplasty/ Ossiculoplasty / Stapedectomy :* (Priority level 4b). As elective work and theatre availability increases these procedures are expected to be increasingly reinstated. Local anaesthesia may be considered in preference to general anaesthesia but there will be a balance, and the longer the case the safer it may be for theatre staff and patient for general anaesthesia.
- *Mastoidectomy:* Deferral will become increasingly difficult with cholesteatoma as time passes. Monitoring of waiting lists is important and should be documented. From a patient safety perspective, it is likely most mastoidectomies for cholesteatoma should be given **priority** over tympanoplasty, myringoplasty, ossiculoplasty, and stapedectomy in stable ears. However, the reverse is true for the safety of the operating surgeon and theatre staff. This is a challenge faced by all otologists and there is no simple answer. Given the high-risk nature of drilling a wet ear, and the current absence of safe and practical PPE when using the operating microscope, some surgeons may prefer to defer mastoid surgery for as long as possible to allow the prevalence of COVID-19 to reduce. **In general cholesteatoma surgery can safely be**

deferred for a number of months, but given the length of delays thus far, a return to cholesteatoma surgery is now required.

- *Middle Ear Implantation:* (Priority level 4b). Whilst the operative considerations are similar to cholesteatoma surgery, like other priority level 4b procedures, middle ear implantation may be deferred to prioritise higher category procedures. The availability of audiology assessments and fittings needs to be considered.

BAHA (Priority level 4b): As above, these procedures may be deferred. They should be regarded as relatively low risk as bone and blood are not believed to harbour significant viral loads. This type of surgery lends itself to day case local anaesthesia. The availability of audiology assessments and fittings need to be considered.

- **Cochlear Implantation:** For new priority levels, see above.
- *Skull base:* Patients with no new symptoms or non-growing pathology such as vestibular schwannoma can be monitored as usual with interval scanning. As described above, patients should be monitored closely and advised to contact the team if new symptoms develop which may result in escalation to priority level 2 or 3 (MDT decision). Rapidly growing tumours or tumours with symptoms or signs of brainstem compression should be regarded as priority level 2 or 3 and appropriately prioritised. All other vestibular schwannomas under consideration for surgery should be regarded as priority level 4a and should be given some degree of prioritisation. Some patients, especially those with risk factors for adverse outcomes in COVID-19 infection, may wish to reassess the decision to proceed with surgery where appropriate. They may prefer to pursue radiotherapy options. This should be discussed with the patient through the MDT. Some centres may prefer a retro-sigmoid approach over a trans-labyrinthine approach in order to minimise drilling time and exposure to middle ear mucosa. Temporal Bone malignancies needing surgery will need prioritising with MDT guidance. Decision making in this group is complex and must take into consideration patient co-morbidities, the prolonged nature of surgery, the need for reconstruction and the prolonged in patient stay. Other options including neo-adjuvant radiotherapy should also be discussed.

Training

- We acknowledge the ongoing need for training and with appropriate protection, trainees are no more at risk of COVID-19 infection than their consultant. It is therefore recommended that trainees should be allowed to carry out sections of an operation under close consultant supervision within tight time constraints, but timely completion of surgery should be a priority, and this will probably result in a reduction in the overall operating time for the trainee. This may vary depending on competencies, seniority and COVID-19 status, and will have to be taken on a case by case basis.
- Observation within the operating theatre should be minimised especially in the presence of AGPs and, where possible, facilities should be made available for live

streaming outside the theatre. The use of pre-recorded and edited operative videos or simulation are safer alternatives to direct observation. Operative simulation training is a good adjunct to operative training, but ultimately one cannot substitute for the other and a lack of operative training may need to be addressed in time.

- The effects on training of the reduced operating time that trainees are likely to experience in the near future will need to be reviewed on an ongoing basis.

Research/audit:

Current BSO projects related to COVID-19

We would be grateful if ENT UK members could inform us of any projects you are undertaking that BSO can add to this 'live' list:

- **Observational study of conservative vs. surgical management of acute mastoiditis, and COVID-19 status.** Iain Bruce for BAPO and Peter Rea for BSO. This project will be released in the coming days and consultants and registrars will be contacted. We would ask all units that are able to please participate in this. Collaborative authorship will be available to local leads.
- **Protective draping in mastoid surgery.** Will Hellier, Tim Mitchell, Seb Thomas
- **Virtual vs face to face outpatient study in balance patients.** Yougan Saman, Louisa Murdin and Peter Rea (Editorial paper submitted)
- **Otologic surgery during the COVID era. A national audit.** Ellie Warner and Kay Seymour with BSO. Recruiting. We would ask all units that are able to please participate in this. Collaborative authorship will be available to local leads.
- **SNHL in COVID-19.** Wendy Smith and Manohar Bance with BSO. Recruiting soon. We would ask all units that are able to please participate in this. Collaborative authorship will be available to local leads.
- **Does middle ear mucosa contain coronavirus?: a histological study of COVID-19 patients.** Peter Rea and others. **In ethics.**

There are many other papers in preparation we will alert you to when accepted for publication.

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- [Re-opening facilities to provide Non-Emergent Non Covid 19 Healthcare Phase I](#)
- Robert Jackler (Covid 19 and Ear Surgery) in www.entnet.org
- [RCS Guidance on Recovery of surgical services during and after COVID-19](#) 29 April 2020.
- [Restarting planned surgery in the context of the COVID-19 pandemic: a strategy document from the Royal College of Anaesthetists, Association of Anaesthetists, Intensive Care Society and Faculty of Intensive Care Medicine](#).

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Appendix 1

In addition to researching the current publications we have engaged with the organisations listed below. Whilst we have sought consensus the opinions expressed are those of BSO and not necessarily those who contributed advice and opinion. We are very grateful to all who those who have assisted us.

Association Independent Hearing Healthcare Professionals
British Society of Otolaryngology committee members
British Association of Audiovestibular Physicians
British Academy of Audiology
British Skull Base Society
British Society of Audiology
British Society Hearing Aid Audiologists
British Society of Neuro-otology committee members
ENT UK
Local audiology services
Medical microbiology
National Community Hearing Association
NHS England and NHS Improvement (NHSEI)
Royal College of Surgeons of England
AIHHP

Appendix 2

SURGICAL PRIORITISATION IN OTOTOLOGY. 1 JULY 2020 UPDATE.

As of 1 July 2020, limited surgical services for non-emergency and non-cancer cases are returning to most UK hospitals. However available theatre time remains dramatically below levels prior to the COVID-19 pandemic, and our discussions with colleagues suggest the availability of theatre time varies significantly between hospitals. Most otological surgery was classified as category 4 during the peak of the COVID pandemic, when the original otology guidelines were drafted. Exceptions to this were set out in our initial guidance document. Three months have now passed since the initial recommendations were made. Both the clinical environment we work in, and the needs of those patients already waiting significant times for their surgery, have changed. These revised recommendations have been made in conjunction with the Federation of Surgical Specialty Associations and complement advice provided by them. We are enormously grateful for the feedback from colleagues around the UK who have highlighted areas where change will help our patients. Please use these as guidelines. Our own clinical assessment should always take priority over the guidelines. However, it is clear there will be times we will not be able to meet the suggested standards set out below as more urgent cases from our own or other specialities take priority in a health service with such greatly reduced elective capacity, resulting from the unavoidable changes in priority the COVID-19 pandemic has created.

- We recommend that all otological cases are re-triaged on a case-by-case basis if they reach the end of their allocated priority time frame, for example at three months for priority 4 patients. The indications for surgery, co-morbidities, patient preference, and the time patients have already been waiting for surgery should be reviewed. It is anticipated that some patients will be upgraded to a higher priority level following their review. For example, some cholesteatoma patients who were prioritised as category 4 at the outset of the pandemic may now be upgraded to category 3. Given that it was not uncommon for mastoid procedures to wait up to 12 months prior to lockdown, realistic targets for surgical waits will be required.
- Where appropriate, patients should be contacted to explain why their operation date is still pending. If required, face to face appointments should be arranged to facilitate risk assessment and to update pure tone audiometry. A small number of patients may require re-imaging to assess disease progression, particularly those with cholesteatomas.
- We continue to recommend the sub-categorisation of category 4 in to those patients that could wait longer than three months but not indefinitely (4a) and those patients that can safely wait indefinitely (4b). Patients in category 4a should have a target date for surgery, determined locally and based on local clinical and patient circumstances. However, it is recognised such targets may often be unachievable due to a lack of elective capacity.
- The following should be regarded as the ideal standard for each type of surgery when comparing urgency to cases in other specialities, but recognising that services may not be able to meet this elective capacity at times:

Priority 1-4

Vestibular schwannoma surgery.

- It is not possible to group all VS surgery in to a single category. Very large tumours with impending or actual complications may be category 1b or 2. Small, slowly growing tumours may be regarded as category 4.

Priority 2-4

Cholesteatoma surgery

- It is not possible to group all patients with cholesteatoma in to the same category as individual circumstances differ. Those with impending complications should be category 2. Actively discharging disease with evidence of extensive cholesteatoma should be regarded as category 3. It may be reasonable to consider early cholesteatoma priority 3 before erosion develops. Dry low activity cholesteatomas may still be regarded as category 4.

Priority 1a

Emergency procedures to be performed in <24 hours.

- Ear button battery removal
- Life threatening middle ear conditions.

Priority 1b

Urgent procedures to be performed in <72 hours.

- Acute mastoiditis, or severe complications of cholesteatoma, not responding to conservative therapy:
We recommend minimum drilling, and subsequent curettage to reduce generation of bone dust (see ENT UK guidelines for otology surgery). Drilling should be at low speed with reduced irrigation. Consideration may be given to needle aspiration in place of surgical drainage for acute mastoiditis (*Bakhos et al.*).
- Facial nerve palsy secondary to trauma / cholesteatoma.

- Cochlear implantation:
 - Patients with meningitis where medically possible.
 - Removal of an infected implant.

Priority 2

Procedures to be performed in <1 month.

- MDT directed otological cancer surgery.
- Baro-traumatic perilymph fistula.
- Organic foreign bodies in the ear.
- Cochlear implantation:
 - Pre-lingually deafened children.
 - Device failure leaving user without hearing.
 - Post-meningitis.
 - Other profoundly deaf children meeting NICE criteria may be placed in this category, based upon the clinical team's assessment, and theatre availability.

Priority 3

Procedures to be performed in <3 months.

- Cochlear implantation in other post-lingually deafened children, and profoundly deaf adults.
- Active chronic suppurative otitis media without cholesteatoma may be priority 3 or 4.

Priority 4

Procedures to be performed in >3 months.

- Cholesteatoma – uncomplicated.
- All ossicular surgery/middle ear implants/BAHA.
- Tympanopasty.
- Grommets (exceptions include where PNS biopsy is required which is priority 2, and where significant speech delay is present which may be priority 3).
- Meatoplasty.
- Vestibular surgery.
- Most non-organic foreign bodies in ears (except button batteries or where causing pain or infection).