ORIGINAL ARTICLE

Safety of Otological Operating During the COVID-19 Pandemic: A National Prospective Audit of 1130 Cases from 79 Centers

Elinor Warner, Reshma Ghedia, Anton Alatsationos, Simon Lloyd, Peter Rea, Felicity Kay Seymour, BSO and BSO Juniors

1The Royal London Hospital, London, UK
2Queen Elizabeth University Hospital, Glasgow, UK
3Manchester Royal Infirmary, Manchester, UK
4Leicester Royal Infirmary, Leicester, UK
5Collaborators listed at the end of the manuscript

BACKGROUND: To assess compliance with guidance produced by the UK body representing all ENT Surgeons (ENT UK) and the British Society of Otology (BSO) on restarting otological surgery after the first wave of the COVID-19 pandemic. Safety was assessed by recording surgical complications and transmission of SARS-CoV-2 transmission during this period.

METHODS: A prospective multicenter audit of otological surgery was conducted over a 12-week period, from June 15, 2020, to September 6, 2020.

RESULTS: One thousand one hundred thirty cases from 79 hospital sites across Great Britain were involved in the study; 91.1% were tested for SARS-CoV-2 pre-operatively, none of whom tested positive; 70.4% were isolated for 7-14 days prior to surgery; 28.2% of surgeons wore full personal protective equipment, compared with 66.6% of anesthetists and 68.2% of scrub staff. The endoscope was used in 75 (6.7%) of all procedures, operations were changed to be performed under local rather than a general anesthetic in 3 cases (0.3%) and the “double drape” to protect against aerosol was used in 321 (27.4%) of cases. Trainees were present in 80.3% of cases. Complications occurred in 4% of cases. No patients or staff contracted SARS-CoV-2 during the audit.

CONCLUSION: ENT UK and BSO guidance was variably followed, with the highest compliance for the use of an FFP3 mask, a negative SARS-CoV-2 swab, and trainee presence in theater. Surgeons did not use full personal protective equipment as frequently as their anesthetic and scrub team colleagues. There were only minimal changes in surgical and anesthetic techniques. Otological operation after the first wave of the SARS-CoV-2 pandemic was performed safely with no reported COVID transmission or increase in major complications despite changes in operating practice.

KEYWORDS: SARS-CoV-2, otology, surgery, pandemic, operating

INTRODUCTION

The SARS CoV-2 pandemic resulted in many challenges for surgical teams across the UK. There were early concerns that otolaryngologists were at high risk. Otologists were concerned that coronaviruses had been shown to be present in the middle ear and mastoid during upper respiratory tract infection, and that powered instrumentation resulted in viral particle aerosolization. On March 25, 2020, all elective ENT surgery was halted due to these concerns.

As the number of COVID-19 cases reduced across the UK, plans for the reintroduction of elective ENT surgery could be formulated. There was uncertainty about the safest way to do this and ENT UK (The UK body representing ENT Surgeons) and the BSO (British Society of Otology) produced guidance titled "A graduated return to the provision of elective ENT services during the COVID-19 pandemic" for surgeons with the following recommendations (referred to as "ENT UK-BSO guidance" forthwith) (Table 1).
Similar changes in operating practices occurred internationally. A global survey of operative practices for otologists and neurotologists during the COVID-19 crisis found that 49.8% reported modifying their surgical technique. Although there were slight differences globally, all techniques followed common themes of aiming to protect patients, and operating theatre staff from viral transmission. Certain countries around the world used the ENT-UK guidance to facilitate their own return to practice, while the American Academy of Otolaryngology--Head and Neck Surgery (AAOHNs) developed their own recommendations. This is the first paper to assess the adherence to the recommendations regarding otology operating during the COVID-19 pandemic.

Objectives
The BSO and BSO Juniors devised a national prospective audit with the primary aim of identifying compliance of operating across Great Britain to the new guidance. Secondary aims were to identify whether changes in practice impacted safety, by reviewing changes in complication rates and any evidence of SARS CoV-2 transmission.

METHODS
This manuscript has been prepared with reference to the STROBE checklist.

Ethical Considerations
The Health Research Authority decision tool determined the study design to fall under the remit of audit and therefore ethical approval was not required.

Study Setting and Design
A prospective multicenter audit of otological surgery was conducted over a 12-week period, from June 15, 2020, to September 6, 2020. There were three 4-week data collection periods (audit periods 1, 2, and 3) with a final 3 weeks to collect follow-up data. A collaborative authorship model was used to recruit data contributors. The BSO council members recruited regional leads, who in turn recruited hospital site leads. Regional and site leads were ENT trainees or non-trainee middle-grades and were responsible for registering the audit with the local clinical governance department. In total, there were 151 possible sites across Great Britain identified. A standardized electronic data collection form was shared with contributors in Microsoft word (Word Software, Microsoft Corporation) (appendix 1).

Data were entered by the site lead or other members of the team (including consultants, middle grades, and more junior doctors and surgeons under the supervision of the site lead).

Participants
All emergency and elective otological procedures taking place in operating theatres across Great Britain were eligible to be included. We excluded any procedures that did not include operating on the ears (even when the indication was for an otological condition, for example, balloon eustachian tuboplasty and those performed in the outpatient department.

Categorical Variable Stratification
Operative procedures were classified into 4 categories (external, hearing, middle ear, and skull base). External included all cases in which did not enter the middle ear or mastoid space. Hearing surgery included ossiculoplasty, stapedectomy, and all implantable hearing aids. Middle ear surgery included any surgery which exposed the middle ear and mastoid respiratory epithelium including mastoidectomy and grommets, excluding those already included in hearing surgery. Skull-base surgeries included those which targeted the inner ear or intracranial contents such as vestibular schwannoma removal.

With regards to race and ethnicity, instruction was not given as to how this should be determined, and contributors may have asked participants, reviewed their electronic records, or made an observation. Race and ethnicity data were collected because of concerns about increased susceptibility to COVID-19 and subsequent adverse outcomes in Black, Asian, and minority ethnic patients. We therefore categorized race and ethnicity into Caucasian and non-Caucasian to attempt to identify any differences.

Statistical Methods
Statistical analysis was performed using R version 3.6.3 with the use of additional software packages: Tidyverse, compareGroup, dplyr, and ggplot2. Non-parametric data were reported as the median with interquartile ranges, and the Kruskal–Wallis rank-sum test was used for analysis. Pearson’s chi-squared test (X²) or Fisher’s exact test was used to assess the categorical data. Statistically significant differences were set at < 0.05. Missing responses were excluded from the analysis.

RESULTS
Patient Demographics
1,130 procedures were captured during the audit period from 79 hospitals out of the 151 identified (52%). Sites did not contribute either because of lack of otology operating or lack of engagement with the audit, 93.9% (n = 1,054) of patients in the study period had no or minimal co-morbidities (ASA 1 or 2). Hypertension was the most frequently encountered co-morbidity (8.69%, n = 97) followed by diabetes mellitus (3.49%, n = 39) (Table 1). In the population sampled, 83.2% (n = 929) were Caucasian, and 16.8% (n = 187) non-Caucasian which is reflective of the UK population and supports generalizability of these results (16). 1% (n = 8) of operations performed during the study were for malignant disease, external ear...
malignancies being the predominant subgroup. Fifty percent of the patients having surgery for a malignancy were ASA 3 or 4, compared to 6.1% \( (n = 69) \) for surgery overall. The proforma was fully completed in 80% of cases.

**Primary aim: Audit Compliance with the ENT UK-BSO Guidance on Returning to Otological Operating During COVID-19 Pandemic**

**Pre-operative Measures**
One thousand twenty-nine (91.1%) patients were known to have a negative COVID-19 status pre-operatively confirmed with a polymerase chain reaction test. COVID-19 status was not reported in 101 cases (8.9%), of which 84% \( (n = 85) \) were pediatric cases (Table 2).

70.4% \( (n = 786) \) of all patients isolated for 7-14 days preoperatively. By the third audit period there was a significant increase in those isolating for less than 7 days \( (P < .05) \).

**Theater Environment**
A total of 25.9% \( (n = 286) \) of patients were operated on at a COVID-free site, while 40.6% \( (n = 449) \) patients were operated on a zoned site where COVID and non-COVID patients were located in separate areas of the hospital (Table 2). There was a decrease in the number of cases being performed at a COVID-free site as the study progressed, with a statistically significant difference between audit periods \( (P < .05) \).

The microscope was used in 880 operations (83.1%), and the endoscope in 75 (6.7%) of all procedures. These rates were stable over the 3 audit periods. The drill was used in 562 (52.6%) of all operations.

The double drape method was used in 321 (28.4%) cases. Other alternatives to prevent spread of aerosolized virus between patient and healthcare team included covering the patient’s face with a surgical mask \( (n = 3) \).

Totally, 34.6% \( (n = 369) \) of cases lasted less than 60 minutes overall. The proportion of cases taking fewer than 60 minutes increased across the study periods, while operations lasting in excess of 3 hours showed a reciprocal decrease \( (P < .05) \).

**Personal Protective Equipment**
Full personal protective equipment (PPE) was defined as FFP3 mask or PAPR in conjunction with eye protection (visor, goggles, or PAPR hood) as advised in the ENT UK-BSO guidance. This was worn by 313 (28.2%) of surgeons (Table 3). There was a decrease in surgeons wearing full PPE across the audit periods \( (P < .05) \). A total of 66.6% \( (n = 703) \) of anesthetists and 68.2% \( (n = 754) \) of theater scrub team members wore full PPE for cases overall.

Surgical challenges included poor visualization (fogging of eyewear and the double microscope drape impeding visualization) (8.8%, 99/1130) and communication difficulties (0.3%, 3/1130).

**Anesthetic Changes**
Seven hundred sixty-three cases (67.5%) were performed in the surgeon’s usual hospital setting. 965 cases (87.2%) were performed in a positive pressure environment. Local anesthetic was used in place of general anesthetic in 0.3% \( (n = 3) \) cases.

Changes in anesthetic practice compared to pre-pandemic were reported in 13.8% \( (n = 156) \) of procedures, including anaesthetizing patients in theater, longer turnaround times, and extubating the patients under a plastic cover.

**Surgical Prioritization**
The number of otology procedures performed progressively increased across the three study periods (Table 1, Figure 1A). Middle ear procedures were the most frequently performed (69.1%, \( n = 781 \)) while hearing procedures accounted for 15.3% \( (n = 173) \) of cases. Pre-lingual cochlear implantation rates increased initially, with adult cochlear implantation showing a subsequent greater rise in cases. The types of hearing implant and the demographic of recipients are shown in Figures 1B and 1C.

In the case of cholesteatoma, the disease was more advanced than expected in a total of 5.2% of cases \( (n = 59) \).

**Impact on Training**
Trainees were present for 80.3% \( (n = 907) \) of cases, the largest proportion of which were coded as supervisor-trainer scrubbed (a code.

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**Table 1. ENT UK-BSO Guidance**

| Pre-operative | a. Pre-operative negative COVID test  
| b. Patients should self-isolate for 14 days prior to surgery |
| Theater environment | a. Surgery to be performed in a COVID-free area (COVID-free or a “zoned” site)  
| b. Endoscopic ear surgery preferred to mastoid drilling (where surgeons suitably trained)  
| c. Double draping techniques to help minimize aerosolization of tissues | |
| Personal protective equipment (PPE) | a. Full PPE for otological surgery including FFP3 mask or powered air-purifying respirators (PAPR) and goggles or a visor |
| Anesthetic changes | a. Local anesthetic preferred to general anesthetic |
| Surgical prioritization | a. Most elective ENT procedures were classified as priority level 4 (safely deferred for 3 months) except for cochlear implantation in pre-lingual children, posterior fossa/lateral skull base pathology if brainstem compression, acute worsening of existing conditions including facial nerve palsy and vertigo and acute mastoiditis not responding to conservative management.  
| b. Mastoidectomies for cholesteatoma should be prioritized over tympanoplasty, myringoplasty, ossiculoplasty and stapedectomy |
| Training | a. Trainees are no more at risk of COVID-19 than their consultant and so should be allowed to carry out sections of an operation under consultant supervision but timely completion of surgery should be a priority |
used for the procedure that indicates that the trainee took a lead part in the majority of the surgery) (34.3%, n = 388). Trainee presence is shown according to region of Great Britain in Figure 2.

SECONDARY OUTCOME MEASURES

Complications

There was a total of 49 complications in 46 patients (4%) reported post-operatively (Figure 3). Two patients required a return to theater, 1 for washout of a temporal lobe abscess (after a combined approach tympanoplasty), and the other for repositioning of a cochlear implant electrode.

There were 2 intracranial infections, 1 detailed above, and a subdural empyema managed conservatively. Cranial nerve neuropraxia was reported in 8 cases; a sixth nerve palsy after translabyrinthine vestibular schwannoma (VS) resection, and seven seventh nerve palsies, 2 of which presented late. One of the reported facial nerve palsies had not resolved by the conclusion of the audit, although this was expected following VS surgery. A cerebrospinal fluid leak occurred in 2 cases, following a retrosigmoid approach to VS and after a mastoidectomy with blind sac closure. Post-operative vestibular dysfunction and bleeding each occurred in 4 patients and was managed conservatively. BIPP allergy and taste disturbance was reported in 3 patients each. There were 3 complications reported as “other,” a

| Table 2. Basic Demographics and Comorbidities | [ALL] | External | Hearing | Middle Ear | Skull Base |
|-----------------------------------------------|-------|----------|---------|------------|------------|
| Gender                                        |       |          |         |            |            |
| Female                                        | 523 (46.3%) | 71 (50.4%) | 84 (48.6%) | 355 (45.5%) | 13 (37.1%) |
| Male                                          | 607 (53.7%) | 70 (49.6%) | 89 (51.4%) | 426 (54.5%) | 22 (62.9%) |
| Age                                           | 250 [8.00;50.0] | 9.00 [4.00;42.0] | 22.0 [4.00;55.0] | 26.0 [10.0;49.2] | 50.0 [41.5;63.0] |
| Age category                                  |       |          |         |            |            |
| <18                                           | 474 (42.0%) | 89 (63.1%) | 76 (43.9%) | 309 (39.6%) | 0 (0.00%) |
| 18-49                                         | 360 (31.9%) | 22 (15.6%) | 45 (26.0%) | 276 (35.4%) | 17 (48.7%) |
| 50-59                                         | 110 (9.7%) | 7 (5.0%) | 13 (7.5%) | 84 (10.8%) | 6 (17.1%) |
| 60-69                                         | 89 (7.9%) | 5 (3.5%) | 15 (8.7%) | 63 (8.1%) | 6 (17.1%) |
| >70                                           | 96 (8.5%) | 18 (12.8%) | 24 (13.9%) | 48 (6.1%) | 6 (17.1%) |
| Ethnicity                                     |       |          |         |            |            |
| Caucasian                                     | 929 (83.2%) | 113 (81.3%) | 142 (83.5%) | 646 (83.7%) | 28 (80.0%) |
| Non-Caucasian                                 | 187 (16.8%) | 26 (18.7%) | 28 (16.5%) | 126 (16.3%) | 7 (20.0%) |
| Not reported                                  | 14    |          |         |            |            |
| Diabetes                                      |       |          |         |            |            |
| No                                            | 1078 (96.5%) | 129 (93.5%) | 164 (94.8%) | 754 (97.8%) | 31 (88.6%) |
| Yes                                           | 39 (3.5%) | 9 (6.5%) | 9 (5.2%) | 17 (2.20%) | 4 (11.4%) |
| Not reported                                  | 13    |          |         |            |            |
| Hypertension                                  |       |          |         |            |            |
| No                                            | 1019 (91.3%) | 129 (93.5%) | 156 (90.2%) | 705 (91.6%) | 29 (82.9%) |
| Yes                                           | 97 (8.7%) | 9 (6.5%) | 17 (9.8%) | 65 (8.4%) | 6 (17.1%) |
| Not reported                                  | 14    |          |         |            |            |
| Vascular disease                              |       |          |         |            |            |
| No                                            | 1068 (95.8%) | 132 (95.7%) | 159 (91.9%) | 745 (96.9%) | 32 (91.4%) |
| Yes                                           | 47 (4.2%) | 6 (4.3%) | 14 (8.1%) | 24 (3.1%) | 3 (8.6%) |
| Not reported                                  | 15    |          |         |            |            |
| Immuno-suppression                            |       |          |         |            |            |
| No                                            | 1098 (98.5%) | 134 (97.1%) | 171 (98.8%) | 761 (99.0%) | 32 (91.4%) |
| Yes                                           | 17 (1.5%) | 4 (2.9%) | 2 (1.2%) | 8 (1.0%) | 3 (8.6%) |
| Not reported                                  | 15    |          |         |            |            |
| ASA                                           |       |          |         |            |            |
| 1                                             | 742 (66.1%) | 99 (71.2%) | 97 (56.1%) | 530 (68.2%) | 16 (47.1%) |
| 2                                             | 312 (27.8%) | 31 (22.3%) | 57 (32.9%) | 208 (26.8%) | 16 (47.1%) |
| 3                                             | 65 (5.8%) | 9 (6.5%) | 17 (9.8%) | 37 (4.7%) | 2 (5.8%) |
| 4                                             | 4 (0.3%) | 0 (0.00%) | 2 (1.2%) | 2 (0.3%) | 0 (0.00%) |
| Not reported                                  | 7     |          |         |            |            |
| Audit period                                  |       |          |         |            |            |
| 1                                             | 240 (21.2%) | 28 (19.9%) | 40 (23.1%) | 159 (20.4%) | 13 (37.1%) |
| 2                                             | 425 (37.6%) | 47 (33.3%) | 67 (38.7%) | 296 (37.9%) | 15 (42.9%) |
| 3                                             | 465 (41.2%) | 66 (46.8%) | 66 (38.2%) | 326 (41.7%) | 7 (20.0%) |
| Nation                                        |       |          |         |            |            |
| England                                       | 969 (85.8%) | 106 (75.2%) | 160 (92.5%) | 669 (85.7%) | 34 (97.1%) |
| Scotland                                      | 130 (11.5%) | 16 (11.3%) | 12 (6.9%) | 101 (12.9%) | 1 (2.9%) |
| Wales                                         | 31 (2.7%) | 19 (13.5%) | 1 (0.6%) | 11 (1.4%) | 0 (0.00%) |
pulmonary embolism (n = 1); failure to site a cochlear implant correctly (n = 1) and sigmoid sinus thrombosis requiring heparinisation (n = 1). There were no mortalities.

Transmission of SARS CoV-2 Between Patients or Staff
No staff or patients reported testing positive for SARS-CoV-2 during the audit.

DISCUSSION

Patient Demographics
The rates of co-morbidities including hypertension and diabetes were lower than identified in the UK population as a whole, reflective of a younger population in our audit.12

Pre-operative Measures
No known COVID-19-positive patients were operated on during the study period, therefore complying with the ENT UK-BSO audit standard. This may be explained by the low prevalence of COVID in the general population at the time of the study and the apparent small number of emergency cases included. We identified 12 emergency cases by reviewing all cases individually. These included 3 ear laceration repairs, 3 mastoidectomies for mastoiditis, and 6 drainages for an abscess or hematoma. We did not include foreign bodies in the ears as emergency operating (no cases of a button battery were identified). The majority of patients where the COVID-19 status was unknown were pediatric cases (84%), where pre-operative testing may not have been feasible. 70.4% of patients reported self-isolating for 7-14 days prior to surgery. The UK body representing ENT Surgeons and the British Society of Otology guidance was that patients should isolate for 14 days prior; however, NICE subsequently produced guidance in July 2020 that a 3-day isolation period was adequate before elective surgery. The publication of this new guidance CORRELATED with an increase in patients’ isolating for 7 days or less by audit period 3.13

Theater Environment
Zoned sites or COVID-free sites were used for operating in 66.4% of cases. A higher compliance rate may have been difficult to achieve due to logistical restraints.

Table 3. Theater Environment and Pre-Operative Requirements

|                      | [ALL]           | Audit Period 1 | Audit Period 2 | Audit Period 3 |
|----------------------|-----------------|----------------|----------------|----------------|
| **COVID-free site**  |                 |                |                |                |
| Yes                  | 286 (25.9%)     | 80 (33.3%)     | 101 (24.5%)    | 105 (23.1%)    |
| *Zoned*/mixed        | 449 (40.6%)     | 89 (37.1%)     | 174 (42.2%)    | 186 (41.0%)    |
| No                   | 371 (33.5%)     | 71 (29.6%)     | 137 (33.3%)    | 163 (35.9%)    |
| Not reported         | 24              |                |                |                |
| **Setting:**         |                 |                |                |                |
| Usual location       | 763 (67.5%)     | 154 (64.2%)    | 289 (68.0%)    | 320 (68.8%)    |
| Alternative within same hospital | 232 (20.5%)   | 53 (22.0%)     | 92 (21.6%)     | 87 (18.7%)     |
| Different hospital   | 135 (12.0%)     | 33 (13.8%)     | 44 (10.4%)     | 58 (12.5%)     |
| COVID Status Preop   |                 |                |                |                |
| Negative             | 1029 (91.1%)    | 220 (91.7%)    | 383 (90.1%)    | 426 (91.6%)    |
| Not reported         | 101 (8.9%)      | 20 (8.3%)      | 42 (9.9%)      | 39 (8.4%)      |
| **Pre-operative Self Isolation** |           |                |                |                |
| Did not self-isolate | 171 (15.3%)     | 39 (16.2%)     | 66 (15.9%)     | 66 (14.3%)     |
| <7 days              | 138 (12.4%)     | 0 (0.00%)      | 10 (2.4%)      | 128 (27.8%)    |
| 7-14 days            | 786 (70.4%)     | 190 (79.2%)    | 333 (80.0%)    | 263 (57.0%)    |
| >14 days             | 22 (1.9%)       | 11 (4.6%)      | 7 (1.7%)       | 4 (0.9%)       |
| Not reported         | 13              |                |                |                |
| **Theater Environment** |             |                |                |                |
| Positive pressure    | 965 (87.2%)     | 205 (85.4%)    | 362 (86.6%)    | 398 (88.6%)    |
| Negative pressure    | 142 (12.8%)     | 35 (14.6%)     | 56 (13.4%)     | 51 (11.4%)     |
| Not reported         | 23              |                |                |                |
| **Duration**         |                 |                |                |                |
| ≤60 minutes          | 369 (34.6%)     | 68 (28.9%)     | 132 (31.7%)    | 169 (40.7%)    |
| 61-120 minutes       | 242 (22.7%)     | 38 (16.2%)     | 101 (24.3%)    | 103 (24.8%)    |
| 121-180 minutes      | 254 (23.8%)     | 66 (28.1%)     | 104 (25.0%)    | 84 (20.2%)     |
| >180 minutes         | 201 (18.9%)     | 63 (26.8%)     | 79 (19.0%)     | 59 (14.3%)     |
| Not reported         | 64              |                |                |                |
likely that surgeons would not CHOOSE to trial new, unfamiliar techniques in an already challenging surgical environment. The reasons for this include the challenges of learning a new technique when visualisation and comfort are reduced in PPE and pressure to complete the cases in a timely fashion in order to reduce the exposure of operating room staff to aerosolised viral particles.

Across the audit, the “double drape” method was used in 28.4% of all cases. The drape was usually only used for cases requiring drilling as surgeons and scrub staff found it difficult to pass instruments and there was a perceived lack of additional benefit of double draping, if full PPE is also being worn.

There was a statistically significant difference in the duration of operations across the audit periods, with the average operation time reducing. As the audit progressed, the surgeon and theater team’s familiarity with COVID safety precautions may have increased resulting in shorter operations over time.

Figure 1. a-c. (a) Operations by category, changes in operating capacity over time. (b) Hearing implant operations, changes in operating capacity over time. (c) Cochlear implantation, changes in population receiving implant over time.
Personal Protective Equipment
Full PPE (FFP3 and appropriate eye protection) was worn by only 28.2% of surgeons overall, and there was a decrease in the number of surgeons wearing full PPE across the audit periods ($P < .05$), perhaps because surgeons could not find a full PPE solution compatible with microscope use. A higher proportion of both anesthetists (66.6%) and theater staff (68.2%) wore full PPE, which supports this conclusion as unlike surgeons, they did not need to use the microscope (Table 4). This may also be reflective of differing attitudes to risk across these professional groups. For surgeons, the relative risk of causing morbidity to the patient from poor visualization may have outweighed the perceived minimal safety risk from operating on a patient who had tested COVID negative.

There were no reports of PPE shortages, and no staff or patients tested positive for SARS-CoV-2 post-operatively. This suggests that the existing guidance with regard to testing, isolation, and PPE use was adequate to protect staff and patients having otological procedures.

Anesthetic Changes
Although the ENT UK-BSO guidance stated that local anesthetic should be used in preference to general anesthetic, this was only achieved in 0.3% of cases, with the majority of surgeons choosing not to deviate from their usual practice.

Surgical Prioritization
Middle ear surgery (69.1%) was the most frequent operation performed throughout the audit, reflective of usual otological practice. Across the audit period, the number of cases of middle ear surgery increased, demonstrating an increase in surgical capacity and as hospital sites re-started operating and theater teams became more familiar with COVID safety measures increasing theater throughput (Table 1). Cochlear implantation for pre-lingual children was prioritized over post-lingual children and adults initially (Figure 1C).

The disease was thought to be more advanced than expected in 5.2% of cases which may have been a result of otology operations being delayed at the start of the pandemic.

Training
Trainees were present in 80.3% of all cases submitted, which is similar to proportions found in the British Rhinology Society COVID-19 audit. However, in many departments across Great Britain, surgical trainees were redeployed to support additional bed capacity in medical wards or the intensive care unit, missing much valuable operating experience, and when they were present in the theater, only 23.2% of cases had a trainee in a leading role in the case (defined as cases coded as supervised trainer unscrubbed (cases where the trainer is present in theatre but not scrubbed for the

Figure 2. Trainee presence in theater by region.

Trainee present in case

| Region               | Number of cases |
|----------------------|-----------------|
| Wales                |                |
| West of Scotland     |                |
| East of Scotland     |                |
| Yorkshire            |                |
| West Midlands        |                |
| Wessex               |                |
| Thames Valley        |                |
| South Thames         |                |
| Severn               |                |
| North West of England|                |
| North Thames         |                |
| North East of England|                |
| Mersey               |                |
| Kent, Surrey, Sussex |                |
| East of England      |                |
| East Midlands        |                |

Not present | Present
case as trainee performing it independently) or performed (no consultant trainer present).

A Joint Committee on Surgical Training study evaluating the comparative numbers of surgical logbook cases showed that ENT trainees case throughput was 32% compared with the same period the previous year. The involvement of trainees at a time when overall caseloads were low shows enthusiasm for training from trainers and trainees despite the prevailing situation.

Complications and Comparison to Other Studies
Complication rates (4%) are comparable to previous literature, suggesting that otological surgery was being performed safely in Great Britain, despite the pressure of operating within the restrictions necessitated by a pandemic. We compared our mastoidectomy cases (n=342) with a Royal College of Surgeons (RCS) audit of 536 mastoidectomies in 1995 and found no increase in major complications. There was 1 (0.2%) permanent facial palsy compared to their 0.6%, and no (0%) dead ears compared to 1.3% in the RCS audit. Surgical site infection for mastoidectomy in our study (n=8) was less than that detected in a recent study looking at surgical site infections following mastoid surgery (2.3% vs. 3.9%).

Clinical Applicability and Generalizability
This is the first paper to describe adherence to any guidance for otology operating and the findings are generalizable as many of the recommendations were similar to those used internationally. The British Rhinological Society Juniors team performed an almost identical audit of rhinology operating which also found no increase in complication rates or COVID-19 transmission.

Limitations
A limitation of this study was that there were no reports of COVID transmission, therefore comparison of practices that have a significant impact on transmission is not possible. Although there are very large data sets, there are some gaps. First, out of the 151 hospitals we hoped to include in the audit, 79 (52%) did contribute. Second, only a small proportion of emergency cases were captured (n=12) which may have been due to the challenges of collecting data from emergency cases out of hours. Third, as trainees and middle grades collected the majority of the data, there may have been additional cases not captured (by consultants operating in the private sector) in their absence. Finally, 20% of datasets were not completely filled in. We did not provide any training to complete the form and so some
data fields were interpreted differently. For example, free-text data capture for complications gave autonomy to site leads about the threshold of complication data to include. This may have led to the under-reporting of minor complications such as taste disturbance. Despite a 3 week follow-up period, it would have been challenging to assess COVID rates given the rates of asymptomatic cases and the logistical difficulties of following up of staff and patients. The study period in which the data collection was performed was immediately following the end of the first wave of SARS-CoV-2, where the community prevalence of SARS-CoV-2 was low, and before more

Table 4. Personal Protective Equipment and Instruments Used

|                          | [ALL] | Audit Period 1 | Audit Period 2 | Audit Period 3 |
|--------------------------|-------|----------------|----------------|----------------|
| Surgeon mask             | FFP3  | 924 (83.2%)    | 217 (90.4%)    | 351 (84.2%)    | 356 (78.4%)    |
|                          | FFP2  | 54 (4.8%)      | 13 (5.4%)      | 26 (6.2%)      | 15 (3.3%)      |
|                          | Surgical Mask | 133 (12.0%) | 10 (4.2%) | 40 (9.6%) | 83 (18.3%) |
|                          | Not reported | 19         |                |                |                |
| Surgeon eye protection   | Air-tight goggles | 86 (7.7%) | 25 (10.4%) | 29 (7.0%) | 32 (7.0%) |
|                          | Goggles | 69 (6.1%) | 13 (5.5%) | 26 (6.3%) | 30 (6.5%) |
|                          | All in 1 hood | 22 (2.0%) | 8 (3.3%) | 11 (2.6%) | 3 (0.7%) |
|                          | Visor | 154 (13.8%) | 51 (21.2%) | 61 (14.6%) | 42 (9.1%) |
|                          | None | 786 (70.4%) | 143 (59.6%) | 290 (69.5%) | 353 (76.7%) |
|                          | Not reported | 13         |                |                |                |
| Surgeon full PPE         | Yes | 313 (28.2%) | 95 (39.6%) | 118 (28.4%) | 100 (22.0%) |
|                          | No | 796 (71.8%) | 145 (60.4%) | 297 (71.6%) | 354 (78.0%) |
|                          | Not reported | 21         |                |                |                |
| Anesthetist mask         | FFP3 | 898 (83.3%) | 200 (85.8%) | 341 (83.0%) | 357 (82.3%) |
|                          | FFP2 | 44 (4.1%) | 13 (5.6%) | 21 (5.1%) | 10 (2.3%) |
|                          | Surgical Mask | 136 (12.6%) | 20 (8.6%) | 49 (11.9%) | 67 (15.4%) |
|                          | Not reported | 52         |                |                |                |
| Anesthetist eye protection | Yes | 744 (70.2%) | 174 (75.3%) | 279 (69.8%) | 291 (67.8%) |
|                          | No | 316 (29.8%) | 57 (24.7%) | 121 (30.2%) | 138 (32.2%) |
|                          | Not reported | 70         |                |                |                |
| Anesthetist full PPE     | Yes | 703 (66.6%) | 166 (71.9%) | 264 (66.3%) | 273 (64.1%) |
|                          | No | 352 (33.4%) | 65 (28.1%) | 134 (33.7%) | 153 (35.9%) |
|                          | Not reported | 75         |                |                |                |
| Scrub mask               | FFP3 | 885 (79.9%) | 209 (88.2%) | 334 (81.1%) | 342 (74.5%) |
|                          | FFP2 | 58 (5.2%) | 14 (5.9%) | 26 (6.3%) | 18 (3.9%) |
|                          | Surgical Mask | 165 (14.9%) | 14 (5.9%) | 52 (12.6%) | 99 (21.6%) |
|                          | Not reported | 22         |                |                |                |
| Scrub eye protection      | Yes | 836 (75.2%) | 185 (78.1%) | 320 (76.9%) | 331 (72.1%) |
|                          | No | 276 (24.8%) | 52 (21.9%) | 96 (23.1%) | 128 (27.9%) |
|                          | Not reported | 18         |                |                |                |
| Scrub full PPE           | Yes | 754 (68.2%) | 170 (72.0%) | 288 (69.9%) | 296 (64.6%) |
|                          | No | 352 (31.8%) | 66 (28.0%) | 124 (30.1%) | 162 (35.4%) |
|                          | Not reported | 24         |                |                |                |
| Drill use                | Yes | 562 (52.6%) | 144 (62.6%) | 223 (55.3%) | 195 (44.8%) |
|                          | No | 506 (47.4%) | 86 (37.4%) | 180 (44.7%) | 240 (55.2%) |
|                          | Not reported | 62         |                |                |                |
| Visual aids              | Microscope | 880 (77.8%) | 188 (78.3%) | 335 (78.8%) | 357 (76.8%) |
|                          | Microscope and Endoscope | 104 (9.2%) | 25 (10.4%) | 39 (9.2%) | 40 (8.6%) |
|                          | Endoscope | 75 (6.7%) | 16 (6.7%) | 29 (6.8%) | 30 (6.5%) |
|                          | None | 71 (6.3%) | 11 (4.6%) | 22 (5.2%) | 38 (8.1%) |
transmissible variants emerged. The risk of significant complications for the majority of routine otological procedures is minimal and therefore even a large study such as this may be underpowered. This study is unable to address concerns regarding cholesteatoma recurrence rates secondary to visualization challenges while operating.

Summary
This audit has demonstrated variable compliance with the ENT UK BSO guidance produced to guide the restarting of otology operating practice in Great Britain. Pre-operative SARS-CoV-2 testing, wearing FFP3 masks (but not full PPE) by all staff groups, and trainee presence in the theater was satisfactory. Surgeons did not use full PPE as much as their aesthetic and scrub team colleagues. Where surgeons were encouraged to deviate from their usual surgical practice (use of the endoscope or local anesthetic encouraged) the compliance was much lower, suggesting surgeons did not feel the benefits of these interventions to reduce SARS-CoV-2 aerosolization justified the risks of using less familiar operating practices. We also found that the resumption of otological surgery following the first UK wave of the SARS-CoV-2 pandemic has been conducted safely, with no major increases in complications, and without transmission of SARS-CoV-2 to patients or to theater staff.

BSO Study Group
BSO council leads: East of Scotland: Alex Bennett; West of Scotland: Arun Iyer; North East: Dave Strachan; North West: Simon Lloyd; Mersey: Owen Judd; East Midlands: Peter Rea; West Midlands: Peter Monksfield; Yorkshire: Gerard Kelly; East of England: Wendy Smith; Thames Valley: Ian Bottrill; North Thames: Felicity Kay Seymour; South Thames: Mike Wareing; South West: Simon Carr; Severn: Philip Robinson; Wessex: Tim Mitchell; Wales: Steve Backhouse.

Regional leads: East of Scotland: Shiyiing Hey; West of Scotland: Vibha Jaiswal; North East and Yorkshire: Jack Sandemann; North West: Haroon Saeed; Mersey: Richard Siau; East Midlands: Mohammed Hussain; West Midlands: Hannah Lancer; East of England: Anna Kaleva; Thames Valley: Marina Brimioulle; North Thames: Reshma Ghedia; South Thames: Misha Verkerk; South West: Haymar Htun; Severn: Linnea Cheung; Wessex: Katarzyna Monika Konieczny; Wales: James Howard.

Consultant leads and Site leads at contributing centres: Lyris James Howard. BSO Study Group of SARS-CoV-2 to patients or to theater staff.

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Nitesh Patel (Whipps Cross Hospital); Nicola Wooles, Thomas Martin (Worcestershire Royal Hospital); Richard Brown, David Snow (Wrexham Maelor Hospital); Rajesh Anmolsingh, Derrick Siau, Simon Joshua (Wythenshawe Hospital, Greater Manchester); Sridevi Karutheddah, Phillip Moore (Ysbyty Gwynedd Hospital, Bangor).

Ethics Committee Approval: N/A.

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – E.W., S.L., P.R., F.K.S.; Design – E.W., S.L., P.R., F.K.S.; Supervision – S.L., P.R., F.K.S.; Data Collection and/or Processing – R.G., E.W., A.A.; Analysis and/or Interpretation – E.W., R.G., A.A.; Literature Review – E.W., R.G.; Writing Manuscript – E.W., R.G.; Critical Review – S.L., P.R., F.K.S., E.W., A.A.; Analysis and/or Interpretation – E.W., R.G., A.A.; Literature Review – F.K.S.; Supervision – S.L., P.R., F.K.S.; Data Collection and/or Processing – R.G., A.A.; Writing Manuscript – E.W., R.G.; Critical Review – S.L., P.R., F.K.S., E.W., R.G., A.A.

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BSO/ BSO Juniors. Elective Otological Surgery during COVID-19 Audit Questionnaire

Thank you for participating in this audit. Please select all that apply for each question.

Name of NHS Hospital

Name of person entering information:

Patient Demographics

Age (years):

Gender:  □ Male  □ Female

Ethnicity:  □ White  □ Black  □ South Asian (Indian, Pakistani, Bangladeshi)  □ South-East Asian (Chinese, Korean)  □ Mixed Please state ________________________  □ Other Please state ________________________

Comorbidities:  □ None  □ Vascular disease (IHD, stroke or PVD)  □ Diabetes  □ Hypertension  □ Immunosuppression

Anaesthetic performance status (I-V):

Pre-operative management

For how long did patient self-isolate prior to surgery?
  □ Did not self-isolate
  □ 7 days
  □ 14 days
  □ Other. Please state _________

COVID status?  □ Positive          □ Previous COVID
              □ Negative          □ Unknown

Surgery

Diagnosis

Name of procedure

Date of procedure

Setting of surgery:  □ Usual location
                    □ Alternative within same hospital
                    □ Different hospital to usual

Is this a “COVID-free” site?  □ Yes  □ No  □ “Zoned/mixed site”

1  BSO/BSOJ COVID Study 2020
Anaesthetic used: □ General □ Local

Is this a change from the type of Anaesthetic that would have been used pre COVID □ Yes □ No

Type of theatre environment: □ Positive pressure □ Negative pressure

Were any of the following visual aids used?
- □ Endoscope □ Microscope
- □ Loupes □ None
- □ Other: Please state __________________________

Is the visualisation method different from what you would use “pre COVID”?

□ Yes □ No

Please comment: ____________________________________________

Team

Trainee Involvement: □ No trainee present □ Supervised scrubbed
- □ Observation □ Supervised unscrubbed
- □ Assisted □ Performed

PPE Used by Surgical Team:
- □ FFP3 mask □ Double gloves
- □ FFP2 mask □ Single gloves
- □ PAPR Hood □ Other: Please state __________________________
- □ Oxygen tent
- □ Other: Please state __________________________

Please state manufacturer of mask: ____________________________________________

Eye protection Used by Surgical Team
- □ None □ Glasses
- □ Visor □ Airtight goggles
- □ All in one hood state □ Other: Please state __________________________

Please state manufacturer of eye protection equipment: ____________________________

Did Eye protection change throughout the course of the procedure?

□ Yes □ No

Please comment: ____________________________________________

Was it possible to see adequately? □ Yes □ No
PPE Used by Anaesthetic Team:
- FFP3 mask
- FFP2 mask
- PAPR Hood
- Disposable hood
- Other: Please state

PPE Used by other Theatre Staff:
- FFP3 mask
- FFP2 mask
- PAPR Hood
- Disposable hood
- Other: Please state

Were any other protective measures used?
- Double draping of microscope
- Drape over patient
- Other: Please state

Procedure

Instruments used:
- Cold Steel
- Laser
- Drill
- Electrocautery
- Other: Please state

Duration of general anaesthesia:
- ≤60minutes
- 61-120 minutes
- 121 - 180 minutes
- >180 minutes

Was the patient recovered in theatre?
- Yes
- No

Any changes in anaesthetic/surgical technique/practice?
- Yes
- No

Please comment:

Any challenges in performing surgery?
- Yes
- No

Please comment:

Intra-operative complications?
- Yes
- No

Please comment:

Was the disease more advanced than expected?
- Yes
- No

Please comment:
Return to theatre?  ○ Yes  ○ No
If yes, please state reason:

Follow-up (3 weeks)

Patient complications?  ○ Yes  ○ No
If yes, please state:

Was patient subsequently found to be COVID +ve?
  ○ No
  ○ Confirmed COVID
  ○ Suspected COVID symptoms

Patient mortality?  ○ Yes  ○ No
If yes, please state cause of death:

In the three weeks following surgery are you aware of?

a. Staff morbidity/COVID Cases in theatre team?
  ○ None
  ○ Surgical team
  ○ Anaesthetic team
  ○ Theatre staff
  Please state number of people affected and details: ________________________________

b. Did the operating surgeon or assistant develop COVID symptoms or test positive?
  ○ No
  ○ Yes. Please give details ______________________________________________________

Thank you for completing this questionnaire. Please feel free to state any further comments:

______________________________________________________________________________

______________________________________________________________________________
Author Queries

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JOURNAL: JIAO

Q1 Please check the usage of open parenthesis.