Notes for Boards: Air Sampling within Operating Theatres

April 2024

Version history

Version	Date	Summary of changes
Dv0.2	10 August 2023	Introduction of table and corporate branded formatting
Dv0.3.3	11 September 2023	Testing table included
Dv0.4	16 September 2023	Updated following inclusion of table and internal review
Dv0.5	24 October 2023	Update following additional comments received
Dv0.6	06 November 2023	Update to document with addition of regulatory statement and reference
Dv0.7	30 March 2024	Update following additional engineering input and COAG consultation.

Approvals

Version	Date Approved	Group / Individual
V1.0	04 April 2024	Clinical Assurance Oversight and Advisory Group

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Notes for NHS boards

Introduction

Limited guidance is available regarding air sampling within operating theatres. This document aims to provide best practice and standardised air sampling recommendations for use within Scottish health boards.

Air sampling out with the recommendations listed may give misleading results and is unlikely to be cost effective.

Air Quality Monitoring

Why monitor microbiological air quality?

- To ascertain / confirm the presence of airborne bacteria, fungus (mould) or a combination of both in quantities that may compromise surgical outcomes.
- To confirm that the requirements of the intended use or application of an operating theatre's mechanical ventilation system are being met as part of commissioning process.

When to monitor microbiological air quality

- As part of the standard commissioning process for any new build or refurbishment to assess air quality in an operating theatre.
- Following modifications or remedial works which alter the fabric of the operating theatre, potentially altering the air flow and quality
- Following replacement, modifications, or remedial works to associated ventilation systems, the air handling unit or associated ductwork (including post cleaning and following any fire). e.g., changes to ductwork distribution does require testing, but a routine filter change does not. When Healthcare associated infection(s) (HAI) are hypothesised to have been acquired in an operating theatre / suite which are potentially associated with substandard air quality.
- Targeted air sampling is enacted as part of any enhanced surveillance requests.
- As an enhanced surveillance request to assure the adequacy of dust control measures for nearby construction / renovation activities.

- To meet the requirements of evidence collection connected with a Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) reportable event.

When is monitoring of microbiological air quality not required?

- As routine.
- As part of the routine annual verification process within conventionally ventilated operating theatres.
- For the routine commissioning and validation of UCV operating theatres (provided the system is performing as per SHTM 03-01), as bacteria and fungus are removed from supplied air by the Efficiency Particulate Air (EPA) or High Efficiency Particulate Air (HEPA) filters. Commissioning for UCV theatres should include particle penetration and air velocity testing and not air sampling.

Who can request air sampling?

- The boards Ventilation Safety Group (VSG).
- Project associated VSG.
- Infection Prevention & Control Doctor (IPCD), Consultant Microbiologist & Infection Prevention & Control Nurse (IPCN).
- Consultant in Public Health Medicine (CPHM).
- Incident Management Team (IMT).

Communication with the local laboratory is recommended to take place in advance of any request. If local boards do not have the laboratory facilities to undertake air sampling or the laboratory is not accredited to perform microbiological air sampling tests an external laboratory who provides the service can be used.

Sampling Technique

There is currently no agreed industry standard for air sampling frequency, method, or technique within healthcare buildings (HSPC, 2018).

Air sampling should be performed actively, by a trained operator and via portable devices called slit samplers or sieve impactors which draw in air (and any bioaerosols present) causing its impaction onto standard non-selective agar plates.

This method is subject to less fluctuations and is less time consuming or clinically intrusive than passive sampling methods.

The following good practice points will minimise subjectivity and distortion of air sampling results and their interpretation:

Air sampling should be obtained (as part of conventional theatre validation, in accordance with SHTM 03-01 Part A):

- following confirmation of engineering checks and the achievement of desired ventilation parameters.
- following a deep clean of the operating theatre.
- in an operating theatre which is physically clean and dust free.
- in advance of clinical handover and occupation of the facility.

Air sampling should be obtained (as part of an enhanced surveillance request):

- following review of annual engineering checks and ascertainment that this has achieved the desired ventilation parameters (SHTM 03-01 Part B).
- in an operating theatre which is physically clean and dust free.

Air sampling should be obtained (for both validation and enhanced surveillance requests):

- at a mutually agreeable time (which may include before or after theatre lists or require out of hours access).
- once any post AGP fallow times have elapsed (if the most recent procedure was undertaken on a patient known or suspected to be infectious / indicated by theatre staff).
- in an operating theatre which is empty, and with the ventilation system running at full capacity (which is confirmed not to be in setback mode) for at least 15 minutes.

The air sampling device should:

- be operated as per manufacturer's instructions.
- be physically clean.

- have confirmed, up to date 3rd party validation.
- be calibrated to obtain optimal volumes of 1 cubic metre per 1000L of air.
- nutrient agar plates which are sealed, sterile, in date and have been stored between 1 and 8 degrees Celsius. Incubate for 48hours at 37 degrees Celsius. The consultant microbiologist/ICD may advise on any additional agar plates if required.
- be placed on the operating table/procedure trolley (ideally at least 1m above floor) and left in the theatre on its own for 15 minutes prior to remote activation.
- be activated once 15 minutes have elapsed and left running for 5 minutes to enable sequential averages of optimal air volumes at 1cubic metre / 1000L

Repeat the sampling process and obtain 2 sample sets per theatre where possible.

Plates should be returned to the testing laboratory as soon as possible following sample collection (max 24 hours) (consult local laboratory for sample transport policy).

Any variation to the good practice points listed here should be considered suboptimal and environmental conditions at the time of sampling should be recorded on the laboratory request form to aid their interpretation.

Interpretation of Results

Final air sampling results should always be reviewed and interpreted by a Consultant Microbiologist

Where the conditions for air sampling, described above, cannot be met locally, or an external laboratory is to be used, this will require operational consideration and the generation of a suitable risk assessment supported by the Ventilation Safety Group (VSG). The purpose of this assessment will be to decide suitability of the external laboratory, ISO accreditation for air sampling, the process to be followed for the procedure and aid the interpretation and validity of results.

The accuracy of results may be affected by:

- the presence of ultraviolet light or electromagnetic radiation.
- temperature, moisture & humidity.
- an unclean or defective theatre environment.

- the presence of people or any physical activities being undertaken.
- The ingress of air due to a faulty or incorrectly fitted filter, or a fault that allows air to bypass the filter.

Final air sampling results should then be shared with the following for oversight, interpretation and action where applicable;

- the IPCD
- the IPCN
- CPHM (if applicable)
- IMT (if applicable)
- VSG (if applicable)

Acceptable levels

- Clean, empty, conventionally ventilated operating theatres, achieving the optimal engineering parameters by design should achieve an air quality with a bioburden of <10 aerobic colony forming units (CFUs) of bacterial and / or fungal CFUs per cubic metre.

Action levels:

Bacterial and fungal counts of > 10 CFU –

- Check if the sampling process and engineering parameters are assured and bacterial or fungal counts of > 10 CFUs are accurate.
- Results identified as true require further intervention, investigation, remediation, the establishment of control measures and corrective actions.
- The higher the CFU count from 10 onwards, the higher the level of contamination present at the time of sampling.
- Bacterial, fungal or a combination of both >10 CFU are unsatisfactory consider suspension of theatre activity temporarily to identify the problem, resample and undertake necessary rectifications.

Table 1 Public Health England guidance (page 40) should be used to support interpretation of results Testing requirements and interpretation of results for operating theatre air quality (PHE 2020)

- Filter grades used within Scotland must align with BS EN ISO 16890 and SHTM 03-01 Part A
- Criteria stipulated within SHTM 03-01 are desirable, however SHTM 2025 (part 3 section 5.3) should also be considered when interpreting results of sampling obtained for systems which have been installed before 2007.

Table 1: *Engineering causes checklist*

Checklist should be used by estates personnel to investigate possible causes of ventilation failures in conjunction with the theatre annual verification report as required by SHTM 03-01 Part B.

The findings of this investigation should then be discussed with the Authorising Engineer (Ventilation) for review and consideration for remedial actions.

Engineering causes checklist				
Problem	Yes	No	Potential causes (not exhaustive)	Comments/Actions
Air volume or airflow pattern is insufficient?			Sub-optimal or total loss of supply air, as per original design due to failed plant or other causes.	
The air handling unit (AHU) and or ductwork has visible dirt, debris or pooling water?			• condensation, • faulty drainage or other identifiable cause.	
Filters issue identified?			• wrong filter fitted, • unsuitable filter grade fitted, • filter is fitted incorrectly, • filter is visibly damaged, • there are visible gaps in filters or filter housing, or	

Engineering causes checklist				
Problem	Yes	No	Potential causes (not exhaustive)	Comments/Actions
			• filters are visibly soiled or dirty.	
There is a reverse airflow pattern identified?			• interlocking of supply and extract incorrect supply or extract plant failure, • a damper failure, • temperature gradient is too big at doorway between clean to dirty, • unbalanced extract grilles, • short term pressure surges due to helipad in vicinity of intake or discharge.	

Hoffman et al 2002, SHTM 03-01 v3 Feb 22

Further information on infectious agents which may be suggestive of ventilation associated infection are available: [2019-08-ventilation-crib-card-v1.pdf (scot.nhs.uk)]

References

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