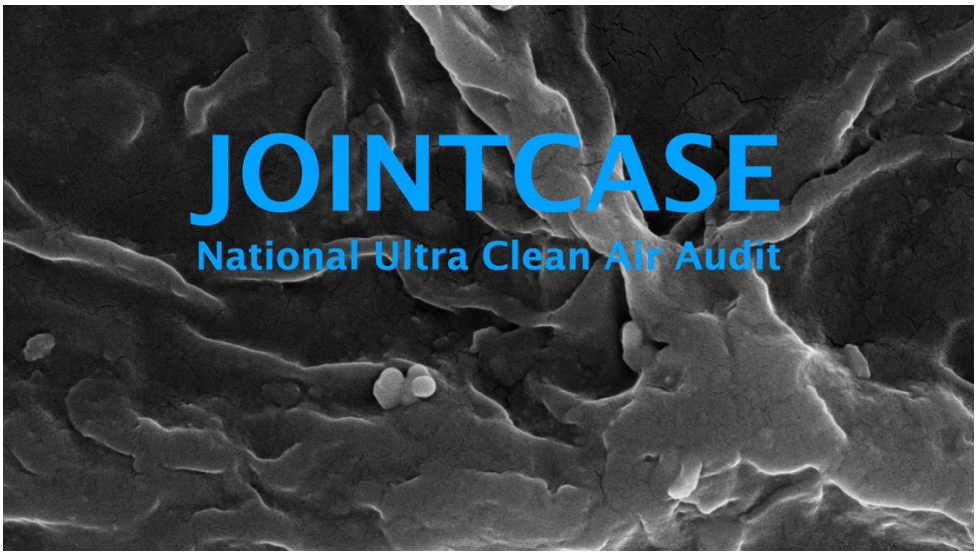
NITCAR
National Infection Trainee Collaborative for Audit and Research

British Orthopaedic Association

UK Health Security Agency

JOINTCASE:

Joint Orthopaedics and Infectious diseases National Theatre Clean Air Service Evaluation



Protocol V2.3; 20-11-2023

Full Title:

Joint Orthopaedics and Infectious diseases National Theatre Clean Air Service Evaluation

Short title: JOINTCASE

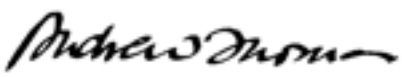
Protocol version and date:
2.3; 20-11-2023

Signatures:

The undersigned confirm that the following protocol has been agreed and accepted. I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Lead: Mr. Andrew Thomas

Signature:  Date: 20/11/2023

Contents:

1. Study Management Group

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2. Study summary

Full Title:
Joint Orthopaedics and Infectious diseases National Theatre Clean Air Service Evaluation

Short title: JOINTCASE

Study design: National prospective audit

Study duration: 12 months

Study participants: Patients undergoing elective primary hip or knee joint replacement

Study question/Aim(s): To investigate the microbiological quality of ultra clean air in operating theatres during joint replacement procedures nationally in the United Kingdom.

3. Funding and support:

This audit will receive no central funding for set up costs. Data collection and recording will be provided by NHSE/UKHSA, administered by Dr Neil Cunningham, with support from Dr Colin Brown. Materials will be funded locally from audit budgets or trust funds. The project will be coordinated via the study management group.

4. Protocol contributors:

The study was suggested during a meeting between the British Orthopaedic Association, and Professor, Susan Hopkins, Chief Medical Advisor, UKHSA. The protocol has been developed by the study management group, under the supervision of Mr. Andrew Thomas.

5. KEY WORDS:

Arthroplasty, orthopaedics, microbiology, ultra clean air

6. Background and rationale

Hospital acquired infections are associated with significant morbidity. They may result in extended length of hospital stay, pain, discomfort and prolonged or permanent disability [1, 2]. Infections of the surgical site account for approximately 16% of all hospital acquired infections (HAI), are estimated to double the length of post-operative stay in hospital and significantly increase the cost of care [3, 4]. The National Joint Registry documented 1260 revision procedures, arthrodesis and amputations for infected hip and knee replacements in 2021 [5]. Additionally, patients may be treated by surgical debridements and long-term antibiotics. The complication results in a dreadful cost in human suffering, and a drain on NHS resources.

The relationship between the microbiological quality of operating theatre air and infection rate is well established. The issue has particular importance in the field of joint replacement surgery. The relationship between air quality and deep infection rates was suggested by Charnley's original investigations and subsequently confirmed by the MRC trial of ultra clean air [6, 7]. Microbiological air quality is likely to be important in other types of implant surgery such as neurosurgical valves and vascular grafts, however these procedures have not been studied systematically. Recent genomic studies have shown that operating theatre air quality is important in clean, soft tissue surgery [8].

Guidance on the design, performance and testing of operating theatres in the UK is given in Health Technical Memorandum HTM 03 – 1 [9]. These documents specify the necessary annual engineering checks of the systems, but they do not specify regular microbiological testing of empty theatres, and no microbiological testing of theatres that are in use. HTM 03 – 01 introduces the concept of a ventilation safety group, which can organise or authorise microbiological monitoring during surgery.

This lack of in use testing of operating theatres when in use stands in sharp contrast to pharmaceutical production facilities where microbiological air sampling is carried out during the manufacturing of each batch of product.

The difficulty with not testing operating theatre air during surgery is that, even if the engineering properties of the facility are optimal, the microbiological performance may be suboptimal for multiple reasons such as surgical team numbers, clothing, and behaviours as well as the setup within the theatre, and any ultraclean zone in particular.

Standards for air quality in operating theatres are commonly specified as volumetric standards, for example as microbial carrying particles (MCP's) per cubic metre. Air quality in the operating theatre can be measured by volumetric techniques, most commonly slit samplers, but also with membrane-based samplers. The difficulty with volumetric sampling is that it requires skilled personnel from the microbiology department to bring equipment and attend the operating theatre for prolonged periods of time, which is often simply not practical.

It is also possible to carry out passive sampling using microbiological plates, commonly known as Petri dishes. The plates are opened to expose their nutrient agar for a known time in the theatre. The plates are incubated, and the colonies are subsequently counted. The area of the nutrient agar and the time exposed are used to calculate the microbial deposition rate (MDR) which is reported as number cubic metre per hour or alternatively simply the number of colonies per 90 mm plate per hour.

The advantage of using settle plates is that skilled personnel are not required in the theatre and the technique can be used to measure the number of bacteria carrying particles settling close to the wound or, importantly, the instrument trolleys.

The relationship between volumetric counts and surface counts is reasonably well documented, with a reasonable ultraclean standard of 10 MCP per cubic metre corresponding to account of 1.7 colonies per 90 mm plate per hour, and an optimum standard of one MCP per cubic metre corresponding to 0.4 colonies per 90 mm plate per hour [10,11].

Audit standards for Ultra Clean Air (UCA) theatres are given by the Healthcare Infection Society in the UK, by the Deutsches Institut für Normung (DIN) in Germany and the Svenska institutet för standarder in Sweden [11,12,13].

7. Project question and aims:

7a. Aims

The main aim of this study is to investigate the microbiological air quality in operating theatres during elective total hip and total knee arthroplasty procedures.

The primary observation will be the number of microbial colonies per settle plate, which will be placed in various standardised locations around the surgical field during an arthroplasty procedure.

Secondary measures will evaluate the type of theatre, number of persons in theatre, number of scrubbed individuals in the clean zone, type of clothing used, type of procedure, use of image intensifiers or robots, and use of warming devices.

When microbiological resources permit, we will collect information on the taxonomy of identified colonies.

7b. Objectives

1. To investigate the microbiological quality of theatre clean air in elective joint arthroplasty in the UK.
2. To assess the apparent impact of surgical variables on the microbiological quality of ultra clean air.
3. To assess the apparent impact of personnel variables on the microbiological quality of ultra clean air.

7c. Outcomes:

The following outcome will be recorded for each settle plate:

The number of microbial colonies from each settle plate, after incubation in the microbiology department for 48 hours, using standard incubators, at a standard temperature. Taxonomy of identified colonies, if microbiological resources permit.

8**. Study design**

This is a national, multicentre, prospective audit.

9. Study setting

All elective orthopaedic units in the United Kingdom are encouraged to participate in this study. This includes major elective centres, tertiary units, and district general hospitals. The audit will initially focus on ultra clean air (UCA) theatres used for joint replacement surgery in the UK

There will be an assigned team in each participating centre. The NITCAR system is designed to be trainee run, so there will be one or two trainee leads (Trauma and orthopaedic or microbiology/infectious diseases trainee). The trainees will undertake setup, local approvals and work with supervising consultants in orthopaedics and microbiology/Infectious diseases.

In the future the audit may be repeated elsewhere, to study the outcomes using different types of UCA systems. The techniques are also applicable to neurosurgery, spinal surgery, cardiac surgery and vascular surgery facilities in due course.

10. Audit technique

The audit will be conducted jointly by the local orthopaedic department and the local microbiology/infectious diseases department. Multidisciplinary involvement of Infection Prevention and Control (IPC) teams is welcome and encouraged, but not essential.

Microbiology settle plates (pack of 10) will be distributed around the surgical field during each joint arthroplasty procedures. The audit is of the air quality in the ultra clean zone, not in the periphery of the operating theatre, so the plates are only placed on the instrument trolleys, and next to the wound.

The necessary packs of microbiology plates will need to be ordered by the orthopaedic department using local clinical audit funding. Packs of 10 plates, which can be peeled apart for easy dispensing onto surgical instrument trolleys have been developed by Cherwell labs. The packs of 10 plates can be opened aseptically, using the Cherwell peel apart packs, and dispensed onto the instrument trolleys for the scrub person to manage during the procedure.

The packs of 10 plates are filled with tryptone soya agar, which is a standard medium for this type of environmental study. Similar packs of plates are available from other suppliers, however, they may be more difficult to dispense in a sterile manner, if they do not come with a peel apart wrapping. Note: The study group, do not have any financial or consultancy relationship with Cherwell Labs.

The pack of 10 settle plates should be distributed on the instrument trolleys and near to the wound during the setup procedures, but not opened at this stage. Experience has shown that the instrument trolleys are commonly so crowded during joint replacement operations that it may be difficult to find space for all 10 settle plates. It is clearly of interest to monitor airborne contamination close to the wound.

A good compromise is to have two plates next to the wound and, for example, 2-4 plates on each of two or three instrument trolleys, depending on the trolly set-up. The plates should be placed as evenly as possible, typically between instrument containers. The plates must all be inside the clean zone, which should happen nauurally as all the trolleys should be inside the clean zone as a matter of routine.

For the plates near the wound it is easy to fix them using a rolled up sticky strip, which is freely available in orthopaedic theatres. For the plates next to the wound it is important that they are as horizontal as possible. This is generally not too difficult in a total hip replacement. In a total knee replacement, it is more practical to have the plates in the region of the contralateral hip, which will not move during the procedure, and should be out of the way of the assistant.

In order to standardise the technique, the plates should be placed in position during the preparation for surgery. They should be opened at or soon after the time the incision is being made. This is partly for consistency with other studies. Also, it is known that the prepping and draping stage of the procedure results in temporary high levels of airborne contamination which will be short lived and highly variable, and therefore not well measured using settle plates.

The plates should be closed after one hour. A member of the circulating staff is encouraged to set an alarm on a mobile phone. When the alarm goes off, the plates should be closed and handed over to the circulating staff by the scrub person.

The plates should be marked with the date and time and whether they are from the wound or from the instrument trolleys (although the plates from the wound will usually have residual sticky strip on them).

The 10 plates from each procedure should be stacked and secured with Micropore or similar type, which is freely available. The plates on the trolleys should be marked with a “T” using a black magic marker, and any plates from the wound should be marked with a “W”. The pack of 10 plates should then be placed in a plastic bag, together with a theatre paper form with basic details for the microbiology department.

The theatre paper form is designed for speedy filling during a busy list. The nature of the microbiology request documentation will need to be agreed locally. If a clinical lab is used, they may require a standard microbiology form in addition to the paper form.

In the microbiology department, the plates will be incubated for 48 hours using standard incubators, at a standard temperature, and the colonies counted.

The microbiological data should be expressed as microbial colonies per 90 mm plate per hour. If all 10 settle plates are exposed on the instrument trolleys, then the data can be logged as number of colonies per 10 plates per hour. If the plates are split, then the data can be expressed as number of colonies per eight plates per hour on the instrument trolleys and number of colonies per two plates per hour on the wound margins. The data collection tool will allow investigators to submit the number of microbial colonies individually per plate, or collectively.

The data on the paper form from the theatre and the colony counts will be entered electronically by the microbiology department on an NHS form. The data entry from microbiology can be batched and done at the convenience of the infection trainee.

11. Audit standards

Guidance from the expert working group of the hospital infection society [10] recommend the following standards in ultra clean air theatres:

1. Air sampled close to the wound site during procedures, within 300mm of the wound, should on average contain less than 10CFUs/m^3 of air using conventional cotton clothes. Levels less than 1 CFU/m^3 can be expected when using occlusive clothing or body exhaust systems.

   1 CFU/m3 is the equivalent of 0.4 colonies/9cm plate/hour, so that is the audit standard. A pilot study for this project suggested that the 1 CFU/m^3 standard should be achieved for most of the time.

12. Study period

The data collection period will last for 12 months, to control for seasonal variations. During this time, sites will identify and capture data on all eligible patients.

KEY DATES	SUGGESTED MILESTONE
17/10/2023	Pilot study presented as poster at IPC, Liverpool
14/11/2023	Launch at FIS meeting, Edinburgh
28/11/2023	Launch at BOTA meeting, Edinburgh
07/02/2024	Sites to obtain local approval at their trust. The necessary packs of microbiology plates will need to be ordered by the orthopaedic department.
15/02/2024	Data collection period starts
15/11/2024	Data collection period ends. Final data cleaning queries will be sent to sites soon after this date

13. Participating site teams

Each participating site will be asked to complete a single electronic registration form to take part in this study (https://forms.office.com/e/bA7uQa46GG). The participating team should comprise a name supervising consultant (Trauma and orthopaedic or microbiology/infectious diseases) and up to two trainees (Trauma and orthopaedic or microbiology/infectious diseases). The participating team will be responsible for case identification, recruitment, and data collection. Centres participating in this study will be sent a document bundle comprising an invitation letter, a template audit request form (to submit to their local audit department), study protocol, and an FAQ document.

13a. Local site registration

Centres participating in this study will be requested to register this study as an audit through their local audit department to adhere to governance procedures and gain local trust site approval. Ethics approval is not required as this is an environmental audit (See appendix 1 for HRA decision tool).

14. Recruitment

14a. Inclusion criteria

- Patients undergoing an elective primary total knee arthroplasty (replacement of femoral and tibial components, with or without patellar replacement)

OR

- Patients undergoing an elective primary total hip arthroplasty

14b. Exclusion criteria

- Skeletally immature patients (<16 years old)
- Revision arthroplasty for any reason (e.g. Revision for loosening or instability, revision for infection, revision for periprosthetic fracture)
- Evidence of infection intra operatively
- Tumour or cancer suspected cases
- Patients undergoing a unicompartmental knee replacement
- Patients undergoing a hemiarthroplasty
- Patients undergoing a total hip arthroplasty or total knee arthroplasty for trauma (e.g. For neck of femur fracture or distal femoral fracture)

14c. Recruitment target

The data on a total of at least 15 arthroplasty cases should be submitted by each participating site.

The data on all 10 microbiology settle plates should be submitted for each arthroplasty case, for the results to be accepted for analysis.

14d. Patient identification

Each participating site will decide on how to identify the eligible cases for inclusion in this audit. Only the assigned participating team at the hospital site will access the identifiable data.

15. Data collection and data recording

Data collection will be performed through a secure data entry online form. Sites need to indicate that they have local governance approval in place before submitting data. No patient identifiable information will be recorded on the online data entry form. The names of the surgical team will not be recorded.

The following variables from each arthroplasty case will be recorded on the paperdata collection form in theatre:

- *Date and time of surgery (for the information of the microbiology department, to be retained locally only).*
- *The exact type of theatre, manufacturer and model number.*
- *Number of circulating and anaesthetic persons in the theatre*
- *Number of scrubbed persons in the clean zone*
- *Type of clothing used by the scrub team, i.e. standard disposables, reusable's, battery hood or battery hood with full toga.*
- *Type of procedure, i.e. THR or TKR*
- *Use of either image intensifiers or robots*
- *Use of warming blanket, forced air or resistive*
- *Significant event, such as plate dropped, free text*

The following information will be recorded by the microbiology department:

- *Microbiological data:* expressed as colonies per 90 mm plate per hour, on the trolly plates, and the wound plates, if any.

- Identification of the organisms by the microbiology department is very welcome and encouraged, but not essential. The fact that there should not be more than one colony per plate should help with managing the identification workload.

  The data set on each patient will then be uploaded to the data collection system by the microbiology department, at their convenience.

15a. Missing data

Participating sites will be able to securely access patient data throughout the study period. Any missing or erroneous data can be amended by the local investigators whilst the data collection period is ongoing. Centres are encouraged to try and complete as many of the data points as possible to allow for accurate results. A minimum of 90% of the data must be completed by the participating sites for data to be accepted for analysis.

15b. Data security and data protection

The security of the online data collection system is governed by the policies of the UKHSA. Data management and data security will abide by the requirements of the General Data Protection Regulations (GDPR) and any subsequent amendments. Data will be acquired and stored on the secure data collection form website.

Access to data will be restricted. Each participating site will be given access only to the data pertaining to their local site. All data will be analysed and reported in summary format. No individual will be identifiable.

Site approval will need to be obtained for each individual site, the study to be registered as an audit or service evaluation. Patient information leaflets and patient consent is not required, because this is an environmental audit.

16. Data analysis

Individual orthopaedic and microbiological departments will have access to their own data. They will be able to review their own air quality and take action as necessary.

The data of individual departments will not be published, to encourage full participation. There will be no formal method for centrally recording outliers, so individual departments must take action to review the situation if they persistently have over 1.7 colonies per plate per hour in a UCA theatre.

17. Confidentiality

No patient identifiable data will be recorded. All data collected about patients will be identified using only a unique study number. This number will be automatically allocated on the data collection tool once a patient record is created on the database. Any correspondence between the study management group and the participating centres will only use this unique study number.
The linkage between the database study ID and the actual patients will be confidentially maintained at the participating site. This data will not be submitted to the study office and will not be sent outside of the participating site. The patients identified for this study will not be identifiable in any future publication that results from this project.

18. Ethical approval

This project is an audit of clinical practice and would not be considered research by the NHS (see appendix 1: HRA decision tool). Therefore, sites may participate once their local clinical audit office has approved this. Patients identified for this study will not undergo additional investigations or follow up after this study has been conducted.

19. Study administration

This audit is under the umbrella of The National Infection Teams Collaborative for Audit and Research (NITCAR), consultant chair Dr Andrew Kirby. The aggregated data will be available for the audit group to review. The review group will include a consultant lead for microbiology, Dr Matt Scarborough, A UKHSA consultant representative, Dr Colin Brown, a trainee lead for microbiology, Dr Neil Cunningham, a consultant lead for orthopaedics, Mr Andrew Thomas, and two trainee leads for orthopaedics, Miss Rachael Clegg and Mr Ahmed Nasser.

19a. Local study teams

Each participating centre will be responsible for identifying a supervising named consultant, and up to two registrars, responsible for identifying eligible patients and collecting data. The role of the local study team is to:

- Facilitate delivery at site
- Liaise with the study management group as necessary
- Ensure appropriate local staff resources are maintained to deliver this study

20. Patient and public involvement

Patients and the public were not engaged in setting up this audit, however, the prevention of complications such as infection has been prioritised by multiple different patient groups.

21. Publication policy

The planned publication policy is provided below, and describes the intended publication policy. This policy may be subject to modification e,g. based on specific journal requirements.

The study management group, and others who may become involved in data analysis and manuscript writing, will be cited as authors for all publications.

If a hospital submits at least 15 patient records (with a minimum 90% completion of the data fields), then two trainee collaborators will be named under a “JOINTCASE collaborative” heading, as collaborators on the manuscript. Additional collaborators may be added if the hospital makes a larger contribution.

Those involved in the study in another form e.g. supervision of trainees, will be listed in the acknowledgements section of a manuscript.

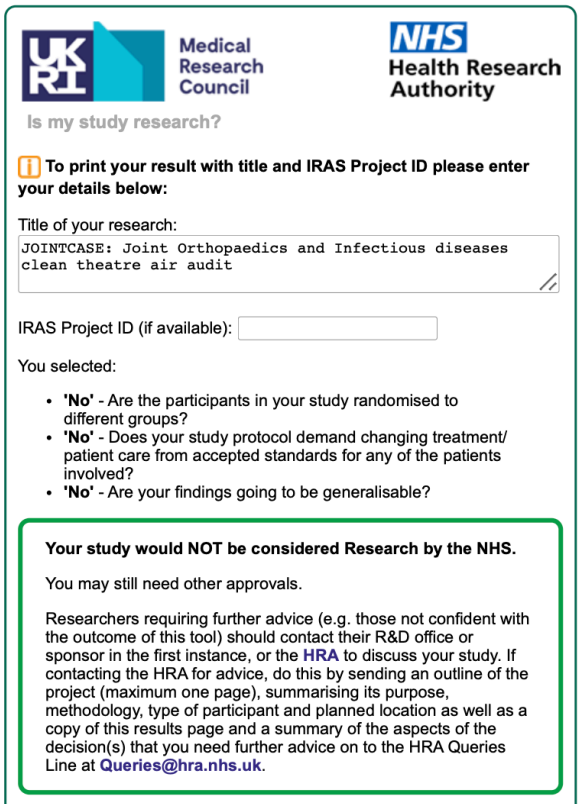
21a. Dissemination of findings:

The results of this study will be submitted to a peer reviewed scientific journal. The results will also be presented at national and international conferences.

22. Finance and funding:

The necessary packs of microbiology plates will need to be ordered by the orthopaedic department using local clinical audit funding. The cost of a pack of 15 sets of 10 microbiology plates is around £150, which should be within the ability of most orthopaedic departments to fund using either clinical audit budgets or local trust funds.

23. Appendix 1 (HRA decision tool)



Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

JOINTCASE: Joint Orthopaedics and Infectious diseases clean theatre air audit

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at Queries@hra.nhs.uk.

24. References

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