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Guidelines on the facilities required for minor surgical proce and minimal access interventions

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by J. A. Child

Article Outline

physical requirements for facilities in which such surgical procedures may be carried out. Under the auspices of the H Infection Society, we have developed the following recommendations for those designing new facilities or upgrading ex facilities. These draw upon best practice, available evidence, other guidelines where appropriate, and expert consensu provide sensible and feasible advice. An attempt is also made to define minimal access interventions and minor surgica procedures. For minimal access interventions, including interventional radiology, new facilities should be mechanically ventilated to achieve 15 air changes per hour but natural ventilation is satisfactory for minor procedures. All procedure involve a checklist and operators should be appropriately trained. There is also a need for prospective surveillance to a determine the post-procedure infection rate. Finally, there is a requirement for appropriate applied research to develop evidence base required to support subsequent iterations of this guidance.

Keywords: Minor surgery, Operating theatres, Primary care, Surgical site infection, Ventilation

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Introduction

There have been many changes in healthcare delivery in recent years, including the delivery of surgical services in prir or in day centres, previously provided by acute hospitals. Also, some minor surgical procedures continue to be perform outside the conventional operating theatre.

A recent survey of operating theatre ventilation facilities for minimally invasive surgery in the UK found that most proce were carried out in areas without specialist ventilation and/or in facilities that are often referred to as 'treatment rooms'. However, there is a paucity of evidence on whether or not procedures carried out under these conditions are associate increased infection rates, specifically surgical site infection (SSI).

Guidelines to minimize SSI by identifying interventions during the pre-operative, operative and post-operative phases h been published.[2] Although these guidelines apply to all surgical or operative interventions, they do not address the phy conditions under which minor surgical procedures – those carried out under local anaesthesia and that are superficial, minimal access interventions (MAIs), i. e. therapeutic or diagnostic procedures that are not considered major in terms o of the operative site – should take place. Nonetheless, there is confusion among infection prevention and control perso operators and others as to what facilities and practices are required when minor surgical procedures and MAI are carrie the acute hospital sector and elsewhere, such as in primary care.

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History of hospital operating theatres

Over the centuries, surgeons have moved from operating under primitive conditions to an environment which is ventilat specific high standards and considerably advanced from that of their predecessors. The practice of surgery demands training of surgical trainees in the use of masks, sterile clothing and the need to minimize movement into and within the operating theatre.[3] There is also emphasis on minimizing the duration of each procedure as it is accepted, based on ev that prolonged procedures carry increased risk for SSI.[4]

Specialized ventilation systems in operating theatres

Originally, powerful extract ventilation was provided for operating theatres to remove steam from boiling water 'sterilize pulling in air from surrounding areas (i. e. the theatre was at negative pressure), but this led to infections caused by airb bacteria being drawn in from adjacent wards. With the general provision of clean air under positive pressure, clean wou infection rates fell by a factor of 10.[5], [6], [7]

The principle of modern conventional theatre ventilation is to remove airborne contamination generated in the theatre a prevent the ingress of possibly contaminated air from the surrounding areas. This is achieved by actively supplying re clean air into the theatre faster than excess air can be passively removed.

The air escapes through pressure release dampers and any gap in the fabric of the theatre (e. g. around doors) and, outwards, it prevents any air from surrounding areas flowing inwards.

The main source of airborne contamination is the skin of those moving inside the theatre, i. e. the staff.[8] This is diluted b supplied to the theatre, with air then flowing out to less sensitive areas such as corridors, carrying the contamination av it.[8] A classic study of operating theatre ventilation found that counts of airborne microbes increased with the degree of movement and numbers of personnel within the theatre.[9] It was shown later that airborne skin squames carrying micro-organisms in a 'raft-like' fashion are shed from the skin surface; during modest activity, humans can shed microbe-carr scales yielding up to 10,000 colony-forming units (cfu) every minute.[10], [11], [12]

The importance of ventilation in controlling airborne contamination was shown in an early study in England where the comparative rates of infection in hospital ranged from 2% to 7% and the cut-off between a low and high rate was an air 5 cfu/ft^3 referred to in the so-called Lidwell Report, the forerunner of Health Technical Memorandum 2025, 'Ventilation i healthcare premises'.[13], [14]

In 'clean' surgery, surgical sites can be exposed to airborne bacteria, either directly into the wound or indirectly by micr settling onto surgical/operative instruments which will then, on use, transfer this contamination to the surgical site. Thi route probably accounts for the majority of airborne bacteria in a surgical site or wound.[15] The smaller the incision, such during laparoscopy, the greater will be the proportion of bacteria that enter the wound via indirect airborne sources. T instrument contamination contributes proportionally more to surgical site contamination in this scenario.

The critical areas within the operating theatre suite are the operating theatre itself and the preparation room, where ste instrument packs may be opened and exposed to the air before use. The soiled utility room is under negative pressure inward airflow) so that it does not contribute to airborne contamination in theatre.

There is a need to define procedures in terms of the susceptibility of the surgical or operative site to contamination and the basic physical requirements of facilities in which many minor surgical procedures and MAI may be carried out.

Aetiology of post-operative infections in minor procedures and MAI

In the National Institute for Health and Clinical Excellence (NICE) guidelines on SSI, no distinction is made between mi surgical procedures, MAI and conventional surgical operations.[2] However, it is not always clear what is meant by minor procedures or MAI and the individual perception of this may vary according to background and professional practice. Laparoscopic procedures are associated with lower infection rates than those after open procedures but patients who u laparoscopic procedures may be pre-selected and have a lower risk of infection as more complicated cases are carried conventional surgical operations.[16], [17]

Surveillance data of orthopaedic procedures from the Health Protection Agency revealed that *Staphylococcus aureus* accounted for 39–44% of the bacteria responsible for SSI in these procedures followed by Enterobacteriaceae in 14–19 cases.[18] The bacteria recovered from specimens taken from infected wounds following laparoscopic abdominal surgery hand surgery or day surgery, largely reflect the endogenous flora of both patients and staff, and appear to be no differe those following conventional surgical operations.[19], [21] For example, *S. aureus* was responsible for 44% of infections of and *Pseudomonas aeruginosa* and other Gram-negative bacilli are more likely to be responsible for infections arising fr laparoscopic gastrointestinal procedures.[19], [20] Therefore there does not appear to be any difference in the causative m of post-operative infection whether carried out as a conventional surgical operation or as an MAI/minor surgical proced

Interventional radiology

The major recent developments in radiology/imaging include therapeutic interventions in the vascular and non-vascular Interventional radiology was originally pioneered by Charles Dotter (1920–1985) who saw the potential for treatment, a diagnosis, with the use of catheterization.

Endovascular procedures are now often considered before open surgery and these techniques can be used in the mar of a range of cerebrovascular, cardiovascular and oncological conditions. Biocompatible materials, e. g. stents includ covered with graft material used in the modern management of aortic aneurysms, coils, particles and inferior vena cava may be implanted. Some procedures require access to the arterial system by an arteriotomy, but the majority can be pe by a percutaneous approach.

In the non-vascular arena, there are a variety of procedures, such as computed tomography and ultrasound-guided tun ablation instead of open surgery and osteoplasty which instills cement into weakened bone without the need for an ope approach. A variety of percutaneous catheters and stents are used for drainage of obstructed urinary and hepatobiliary systems.

Interventional radiology is likely to be the initial treatment for many diseases in preference to open surgery in the future
date, anecdotal reports seem to indicate that infection rarely occurs following these procedures. Every effort is used t
sterility, including only opening the intervention kit when it is about to be used, but the ventilation and other facilities in
interventional radiology departments are not as yet equivalent to those of an operating theatre. It is recommended tha
endovascular aneurysm repair should only be performed in a dedicated endovascular suite of operating theatre standa
appropriate ventilation and support facilities, because of the severe consequences when infection complicates this proc

Surgical issues

The operational standards under which minor surgical procedures or MAI are carried out in the outpatients department,
emergency department or elsewhere outside the theatre have not been defined but should maximize patient safety whi
feasible in terms of facilitating access to clinically required procedures. There is increasing emphasis on some surgical
procedures being carried out as day procedures; for some, a specialist ventilated theatre is not currently used, e. g.
nail bed and vasectomy.[24] A current trial of patients undergoing vasectomy in conventional operating theatres and in pr
rooms with no mechanical ventilation shows no difference to date in post-procedure infection rates but this trial is ongoi
Nevill, personal communication). The pressure to carry out more procedures in primary care, where it may be cheaper,
obvious advantages for some patients in terms of ease of access mean that more procedures may take place outside h
and under non-ventilated conditions. For example, it is suggested that a variety of procedures such as carpal tunnel
decompression, the removal of a ganglion from the dorsum of the wrist, and haemorrhoid injections may be carried out
general practitioners with enhanced surgical experience in a 'modified treatment room/operating theatre'.[25] Although th
guideline is helpful in indicating which procedures can usually be carried out in primary care, the precise definition of th
facility remains unclear.

In addition, the unexpected may occur, for example the removal of an apparent groin lymph node in a hospital operatin
may subsequently become a hernia repair which requires the facilities of an operating theatre.

The use of aseptic techniques with the appropriate facilities is especially important in those areas of surgery where the
consequences of infection can be devastating, for example orthopaedic surgery resulting in an infected implant, or oph
surgery resulting in endophthalmitis. However, intravitreous injections such as in the treatment of macular degeneratior
carried out in treatment rooms with or without specialist ventilation, and the risk of endophthalmitis, when it occurs occa
is related to suboptimal technique.[26], [27]

Basis for design specifications for minor surgery and MAI, including interventic radiology

Health Technical Memoranda in the UK seek to define the optimum parameters in which various forms of healthcare de
should be undertaken. There is a range of ventilation options available, depending on whether a day case theatre, trea
room, endoscopy room, a conventional or an ultraclean theatre is being considered. In all cases the primary requireme
protect the patient from preventable infection. There is also a need to control the exposure of staff to waste anaesthetic
where present, and to ensure that staff work in comfortable conditions.

Traditionally UK operating theatres have been ventilated at ~20 air changes per hour, an 'air change' occurring when a
of air equivalent to the volume of a room has been supplied to or extracted from that room, and the operating theatre is
maintained at a positive pressure to surrounding areas. This air change rate has been shown to be sufficient to dilute
contaminants within the theatre, with the resulting positive pressure ensuring that contaminants from outside do not ent

Current guidelines recommend a design ventilation rate of 25 air changes per hour for new conventional operating thea
The supply air should be filtered to at least EN 779 F7 standard (i. e. 80–90% efficiency against a test aerosol with parti
0. 4 μm) and a positive pressure differential of 25 Pa with respect to outside air.[13] The performance of the ventilation sy
acknowledged to deteriorate over time, but as long as at least 18 air changes are achieved it will remain acceptable.
ventilation requirements for ultraclean theatres are much greater in terms of a more organized air flow at the operating
the supply air being high efficiency particulate air (HEPA)-filtered.

Portable HEPA-filtered auxiliary ventilation units are available, and, when incorporated into an instrument trolley, may p
the equivalent of ultraclean air quality in an ultraclean ventilated theatre but over surgical instruments on the trolley (M.
Thomas and C. A. Mackintosh, personal communication). Freestanding portable HEPA-filtered directional auxiliary vent
units have been evaluated.[29] Their effectiveness is likely to be influenced by their position and direction relative to the
site and discipline of the operating staff.

In rooms where anaesthetic gases may be used, e. g. interventional radiology, a minimum of 15 air changes per hou
for the removal of airborne chemicals.[28]

In designing surgical and operative facilities, there are many other issues apart from ventilation to be considered. The sterile pack storage facilities, separating where possible clean and dirty facilities, the type and location of the scrub and disposal of excised human tissue and surgical waste.

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Recommendations

General principles

The primary objective in formulating standards for facilities is to protect patients from surgical site and other infections. removal of anaesthetic gases and the provision of comfortable facilities for healthcare staff are also important and shou considered.

It is recognized that the risk of infection will vary according to the procedure and the patient. Even where there is a lo infection after a specific procedure, in some circumstances the consequences may be disproportionately serious, for ex infection after arthroscopy resulting in septic arthritis. Consequently, such factors should be considered in deciding whe procedure should be carried out and under what conditions, i. e. conventional operating theatre standards or those c below. Here we make recommendations on the design of new facilities to be used for the carrying out of MAI, including interventional radiology, and minor surgical procedures to minimize post-procedure infections. We also hope to raise of all healthcare staff and patients of the importance of infection prevention.

We recognize that many minor surgical procedures in particular are currently being undertaken in facilities that do not r these standards, and usually without reported adverse consequences in terms of increased infections. However, in re the changing delivery of healthcare, increasingly in the non-acute hospital sector, and in response to requests for guida have produced the following guidelines. These are based on best practice, evidence and current guidelines where avai appropriate, and expert consensus to primarily provide sensible and feasible advice. For existing facilities, consideratio be given to using these recommendations to improve facilities in part or in full over time.

Definitions

–*Minimal access interventions* may be therapeutic or diagnostic and are not considered major procedures in terms of th the operating skin site, but may be major in terms of the actual surgery, e. g. laparoscopic colectomy. These are ca using a non-open approach, e. g. laparoscopic surgery and interventional radiology. These may be performed under l general anaesthesia, and, although relatively uncommon, consideration needs to be given to the necessity to quickly a convert from an MAI intervention to an open surgical procedure due to complications or technical difficulties, e. g. lap cholecystectomy.

–*Minor surgical procedures* are those that are carried out under local anaesthesia and that are superficial. The operativ usually limited in size by whether it can be anaesthetized locally. Some podiatric procedures and the debridement of are included in this category. By definition for the purposes outlined below, such procedures are not carried out under s general anaesthesia. Some intraocular ophthalmic procedures are excluded from this category as the consequences o infections are significant and difficult to treat, even if the operative site is small or limited, and carried out under local ra general anaesthesia. A list of some of the procedures that might come under this category is outlined in Table I, which modified from Reference 25. However, this is not exhaustive and some of the procedures listed might be considered as requiring conventionally ventilated operating theatre facilities, e. g. carpal tunnel decompression.

Table I. Examples of minor procedures[a] under various surgical disciplines that may be performed outside a ve operating theatre

Surgical discipline	Procedure
Breast	Percutaneous core biopsy Vacuum-assisted excision biopsy
Ear, nose and throat	Cauterization of nasal septum Polypectomy of internal nose Manipulation of fractured nose

Surgical discipline	Procedure
General	Trans-anal excision of lesion of anus Haemorrhoid injections and haemorrhoidectomy Excision of epidermoid cysts, lipoma (<2 cm), basal cell carcinoma and 'small bumps and lumps' Hydrocele aspiration
Gynaecology	Endometrial biopsy Colposcopy Diathermy or laser treatment of cervical lesions Marsupialization of Bartholin's cyst Insertion of intrauterine device Vacuum aspiration, and dilatation and evacuation termination of pregnancy
Ophthalmology	Excision, biopsy or cauterization of eyelid, e. g. chalazion Laser iridotomy Intravitreal injections Lacrimal sac washouts Subconjunctival injections
Orthopaedic	Excision of ingrown toe nail Intra-articular injection Carpal tunnel surgery
Vascular surgery	Varicose vein injection, sclerotherapy, laser treatment or radiofrequency ablation
Other	Liver, renal and bone marrow biopsy Caudal block Endoscopy via natural orifices, e. g. cystoscopy and gastroscopy Vasectomy Pleural drain insertion Radiologically guided CT or ultrasound drain insertion and biopsies

CT, computed tomography.

aMainly derived from recommendations/discussions in References 24 and 25.

Facilities specifications

(a)Ceiling

This should preferably be made from non-porous material that can be easily cleaned. Suspended ceilings should not b installed in new facilities.

(b)Walls

These should be made from non-porous/monolithic material that can be easily cleaned and occasionally disinfected.

(c)Windows

These should be non-openable where specialist mechanical ventilation is provided.

Where there is natural ventilation using a window that can be opened, there must be a fly screen to prevent the ingress insects.

Where windows are present, these must not compromise patient privacy.

(d)Doors

These should be self-closing with a vision panel (with laser protection where appropriate) to facilitate observation of pro and the movement in and out of the operating room. However, this has to be balanced with the necessity for patient pri

(e)Floors

Floors should be easily cleaned and disinfected according to local policies, and be durable and strong enough to suppo machinery that will be necessary in some operative facilities.

Coving is desirable to facilitate cleaning, contain spills and to avoid damage.

(f)Instruments and sterile pack storage

Single-use instruments may be preferable and their use is encouraged if it is difficult to comply with the requirements fo appropriate decontamination and storage of reusable instruments. Also, for minor procedures in primary care, single-use eliminate the increasingly rigorous requirements to decontaminate surgical instruments to a standard that would be diff comply with outside specialized sterile supply departments.[30], [31]

Dedicated secure facilities should be provided for the storage and collection of re-usable instruments if preferred, inclu endoscopes and their accessories (which require pre-cleaning in a separate sink), to ensure their safety and to avoid d to the instruments themselves.

There should be adequate storage space for instruments with due regard to the range of procedures carried out and th throughput of patients.

The design should minimize the deposition of dust, including appropriate racking or shelving.

Unlike for conventional operating theatres, a separate area for the laying up of instruments is not required, but instrume should only be laid up as required and not in advance.

(g)Scrub-up facilities

These may be within the operative facility, but, if within the operating room/theatre, should be located such that instrum not get splashed and should be separate from basins used for other purposes.

Taps or faucets should be hands-free.

Disposable towels should be used.

(h)Disposal of waste

The facilities and the procedures for the safe disposal of waste should comply with the current guidelines for holding wa to collection/disposal.[32]

A separate secure area, inside or outside the operative facility, e. g. a lockable bin, should be provided.

(i)Ventilation
(1)Minimal access interventions

It is recommended that new facilities be designed to achieve 15 air changes per hour, as required for the removal of air chemicals/anaesthetic gases and which we believe is microbiologically adequate in this setting.[28] Such a specification i required because of the need to prevent the deposition of airborne contamination on to items that may be introduced in patient, especially where there is implantation of sterile prosthetic devices such as stents, and a need occasionally to c an open procedure. Where there is a perceived increased risk of infection due to the complexity of the patient or the pr a risk assessment should be carried out to determine whether the procedure should be undertaken in a theatre in the c theatre suite.

Supply air should be filtered by an EN 779 F7 filter (see above and Reference 13) for new facilities.

There should be a pressure differential of ≥5 Pa positive pressure between the operating facility and the surrounding ar constructing new facilities.

(2)Minor procedures

Natural ventilation, including the presence of opening windows but with a fly screen, is acceptable.

(j)Room conditions (e. g. temperature)

For mechanically ventilated facilities, these should be within the standard range, i. e. 18–22 °C with relative humidity c 60% unless clinical considerations deem otherwise.

(k)Ventilation status indicator panel

Where the operating facility has specialist mechanical ventilation to the standards above, there should be a clear indica those carrying out the procedure (i. e. within the room such as part of a surgeon's loop panel in a conventional theatre) that t ventilation is functioning correctly.

(l)Lighting

This should be adequate for the task to be undertaken in the facility.

(m)Medical gases

Where MAIs with general anaesthesia are undertaken, 15 air changes per hour are required, similar to that specified fo anaesthetic rooms in conventionally ventilated theatre suites, to minimize staff exposure to anaesthetic gases.[28]

(n)Imaging/IT

Access to Picture Archive and Communications Systems (PACS) is required to optimize the quality and safety of patier

(o)Specimen storage/transport

There should be adequate facilities and space for the collection and storage of specimens, with temperature-controlled conditions, for important or key specimens.

(p)Electrical services

All facilities should have emergency lighting in the case of a loss of power supply and should comply with relevant heal safety recommendations.

Professional practice

If the hands of the operator are not visibly dirty, alcohol hand rubs or equivalent may be used between cases. Howev conventional surgical scrub is indicated at the start of a list, i. e. before the first case or procedure. Sterile gloves ar apron are the minimum personal protective equipment requirement for carrying out minor surgical procedures. Howev precautions, including fresh sterile gowns for each case, are required for MAI, for minor surgical procedures if a sterile being implanted and when there is a risk of significant post-procedure infection, or if there are other factors predisposin infection.

Masks are not usually required except when a sterile device is being implanted, or when there are other issues predisp infection. However, face protection (e. g. mask with eye protection) for operators and other staff who may be affected is required, if splashing is likely. Further details on pre-, peri- and post-operative interventions to minimize SSI can be acc elsewhere.[2]

All surgical procedures should involve a checklist. Those involving general anaesthesia should be modelled on the World Health Organization checklist for safe surgery (http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Checklist_finalJun08.) to include aspects of mechanical theatre ventilation, e.g. checking that the ventilation is working, in facilities for MAI. Modifications to these made for MAI and minor surgical procedures as appropriate.

Training and education

Facilities need to meet the educational needs of students, doctors in training and other healthcare workers, such as those related to understanding infection and sepsis. All staff involved in MAI and minor surgical procedures must be able to provide evidence of competency in aseptic technique and in their knowledge and understanding of the facilities that are provided, e.g. ventilation, safe disposal of waste, etc. Although outside the scope of this document, practitioners carrying out MAI and minor surgical procedures should be competent to do so with appropriate mandatory training and ongoing continuous professional development.

Research and audit

As there is an absence of good data on the risk of infection after MAI and after most minor surgical procedures, prospective surveillance of post-procedure infections is required. Audit is necessary, and should include, as minimum, readmission rates for healthcare-associated infection. There should be access to the results of research and audit, and research in primary care is essential to underpin improvements in patient care. Appropriate support and funding to develop the evidence base is required to support subsequent iterations of this guidance.

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