Operating theatres and covid-19

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Full title

Operating theatres and covid-19
Options for Conversion of existing theatres and the design of new theatres.

Summary

This paper sets out to demonstrate that existing theatres can quickly and cheaply be converted to provide a safe operating environment for the patient, medical teams operating on the patient and a protective environment for staff walking and working in the clean and service corridors and the rest of the operating department.

The converted operating theatre remains fully compliant with industry standards e.g. HTM 03 including the ventilation remaining sufficient to accommodate, summer heat gains, winter heat losses, dilution of bacterial contamination, air movement control ("open door protection"), pressure differences between rooms.

There is no increase of the design supply and extract air flows for the plant and no requirement for additional fans or ventilation plant to be installed to achieve the objective.

The paper also sets out to demonstrate the same strategies and principles can be followed for a new operating theatre.

Objective

To investigate the merits and options for providing a "source protective" environment for the medical teams in the operating theatre and those in the surrounding theatre department. And providing a protective environment for the patient undergoing surgery from the risks of infection from the medical teams caring for and operating on an infectious patient, whilst continuing to protect the infectious patient from the hygiene and infection risks of the surrounding theatre department.

In short, the objective to carry out surgery on infectious or suspected infectious patients are to provide:

- the normal protective environment for the patient undergoing surgery as for non-infectious patients,
- a protective environment to medical teams carrying out surgery on an infectious patient or suspected infectious patient,
- a protective environment preventing infectious agents from entering the rest of the theatre department originating from the infectious patient receiving surgery.

History

Over many years there has been significant research into the effectiveness of using ventilation systems to control to an acceptable level infection.

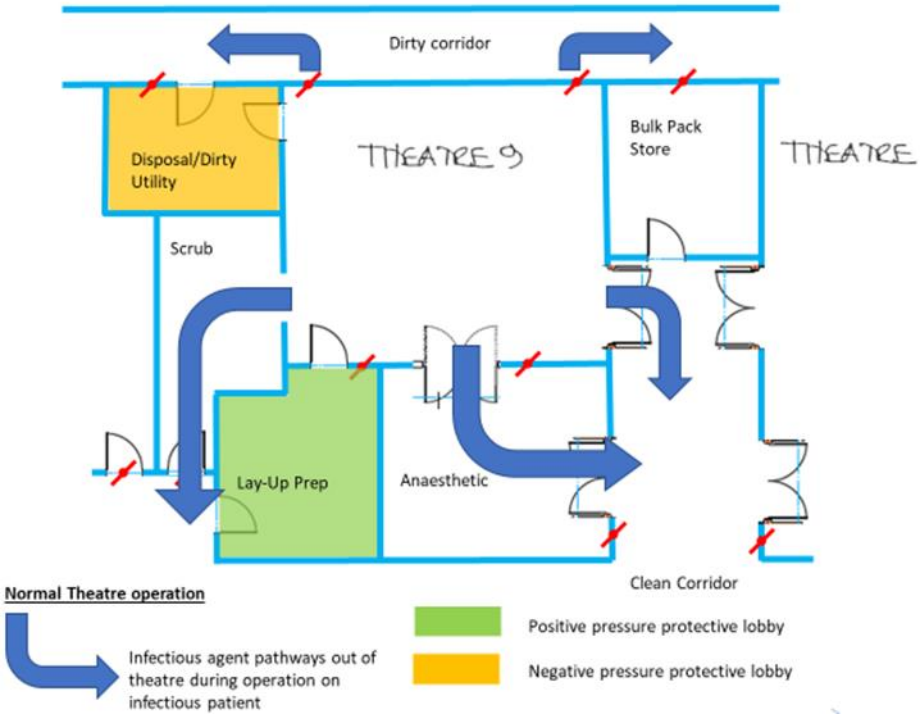
The foundation of this research was carried out by a team of researchers including:

Lidwell OM, Lowbury EJ, Blowers R, Morgan RW, Williams RE, Noble WC, Elson RA, Whyte W, Lowe D.

They published over one hundred research papers on the control of infection by the use of ventilation and related topics.

These research papers form the basis of the earlier DHSS DV4, HTM 2025 and then the current HTM 03-01. Currently chapters 7 and appendix 8 in HTM 03-01 Part A:2007.

The problem



As can be seen from the diagram above most of the air in the operating room passes through doors and pressure stabilisers into the other surrounding rooms and “high foot fall” areas e.g. the clean corridor and service or dirty corridor before being removed through extract terminals mainly in the corridors and often the disposal/dirty utility room. Because of the relatively high ventilation rate required to provide local dilution ventilation to reduce the chance of infection to the patient undergoing a surgical procedure and with an infectious patient additionally to provide similar protection to the surgical team performing the operation on an infectious patient.

There is a growing body of research demonstrating that the airborne risk of viral infection is more significant (Jones 2020)[1] (Beggs May 2020)[2] this research concentrates on Covid-19 infection paths in a single space or room, so is relevant to any room or space where more than one person is present with an infected person.

Whilst the operating room has doors to the other rooms, normally these would effectively form a barrier to air flow between, except for door leakage. In the case of a correctly functioning operating theatre these leakage rates are much higher than say in most other workplaces e.g. offices, this is as a result of the pressure differentials between the various rooms. Air migrating between rooms through closed doors however is small when compared to the air that passes between the operating theatre and most adjacent rooms including "high foot fall" areas such as the circulation spaces e.g. corridors through the pressure stabilisers.

Effectively whilst the doors are closed the amount of air passing to each adjacent room is very high indeed (commonly $0.2m^3/s$ – $0.3m^3/s$), this air contains much of the airborne virus emanating from the patient, this air is only extracted from the terminals in the corridor, disposal and to a relatively small extent the anaesthetic room. The air from the operating room passes relatively quickly into the corridor as a function of the relatively large ventilation volume and relatively close proximity of the corridor for example, studies have shown that infections can travel by the airborne route (Noakes 2015)[3] (Satheesan 2020)[4]

In conclusion it would seem reasonable to conclude that with the air flows from the operating room into for example the "high foot fall" areas that there could easily be sufficient viral material present to infect staff in this area. There also seems to be considerable concern amongst medical teams regarding the potential for infection of staff outside the operating rooms given the interest in "negative" pressure theatres.

[1] Benjamin Jones, Patrick Sharpe, Christopher Iddon, E Abigail Hathway, Catherine J Noakes, Shaun Fitzgerald, Modelling uncertainty in the relative risk of exposure to the SARS-CoV-2 virus by airborne aerosol transmission in buildings. Prepr. Res. Gate (2020)

[2] Clive B. Beggs, Is there an airborne component to the transmission of COVID-19? : a quantitative analysis study, Prepr. Res. Gate May 2020

[3] King MF, Noakes CJ, Sleigh PA. Modeling environmental contamination in hospital single- and four-bed rooms. Indoor Air. 2015;25(6):694-707. doi:10.1111/ina.12186

[4] Satheesan, M.K., Mui, K.W. & Wong, L.T. A numerical study of ventilation strategies for infection risk mitigation in general inpatient wards. Build. Simul. 13, 887–896 (2020). https://doi.org/10.1007/s12273-020-0623-4

Existing solutions

Historically infectious cases theatres have rarely been provided in part because of the assumed higher cost of provision and the comparative lack of patients needing such facilities. Though there is still a legal duty on healthcare organisations to provide a protective safe environment for patients undergoing surgery.

There are some theatres that can be used for carrying out surgery on both infectious and non-infectious patients, these are often based on opening and closing various ventilation dampers in the ventilation system, these theatres when tested have been found to perform very poorly either not meeting the most basic performance requirements or failing to work as the intended design, thereby failing to provide a safe environment for infectious patients.

Earlier in the first phase of the Covid-19 Pandemic, many theatres had their supply ventilation turned off to be used for carrying out surgery on infectious patients (or thought to be infected patients), (some were also used for caring for ICU patients), for both uses it was quickly discovered that turning off or significantly reducing the supply ventilation provided to the theatre resulted in the loss of temperature control in the area, in part due to the heat gains from medical equipment used and external heat gains, over heating was a common complaint.

This general technique also dramatically reduced the amount of dilution ventilation available to protect the medical teams from the infectious agents, so therefore the health care organisation could not demonstrate providing a safe environment for the patient and medical teams.

Also earlier in the first phase of the Covid-19 Pandemic, some theatres were converted into “neutral pressure” theatres where some supply rates into theatres were reduced to about 15ach (air changes per hour) or temporary extract fans installed typically through a doorway into the operating theatre or other limited varied modifications carried out to reduce the release of infectious agents into the remainder of the department, in part by reducing the amount of ventilation air supplied for dilution of the infectious agent. Again, as the earlier ventilation strategy the comparative lack of supply ventilation delivered to the theatre tends to result in overheating and high temperatures in theatre, keeping the operating theatre pressures neutral was also a challenge.

Where local temporary extracts were introduced to collapse the theatre pressure, these tended to remove air through an open doorway and therefore say a quarter of the room, benefited from improved dilution ventilation protecting both patient and medical teams, the rest of the operating room dilution ventilation, the main protective measure for medical teams and patient performed less well.

Given the number of theatres temporarily modified to carry out operations on infected patients, there was clearly need for these facilities.

Many of these theatres were converted to answer the immediate need of medical teams; as the requirement to carry out surgery on infected or thought to be infected patients is known to be needed, therefore the provision of operating theatres that do meet the needs of medical teams and meet the requirements of statute are required.

Internationally there are some published papers on the conversion of operating theatres for operating on infectious patients these adopted the strategy of making the operating theatre

pressure negative[5], typically collapsing the operating room pressure by installing additional extract or extracts[6,7] installing electric doors and additional plant, the airflows in the patient and surgical team was modelled by (Computerised Fluid Dynamics) CFD and microbiological samples were taken with one person in the room. Clearly for this solution the works needed would have taken some time to carry out and left the operating room "open door protection" none existent, risking dirty air from outside the theatre entering (an important requirement of UK guidelines e.g. HTM 03 and previous UK guidelines for safe ventilation). Carrying out limited microbiological testing (to undisclosed standard) these tests[8] are either carried out with an empty theatre or during a full operation with the patient and the surgical team present, so are inconclusive in demonstrating a safe environment.

Similar to some examples in the UK in another solution, the supply ventilation is reduced to the Operating Room (OR)[9] the terminal dampers were closed and then further to reduce the supply air volume duct cleaning access doors were opened successfully reducing the supply air delivered to the OR and reducing the room pressure to -4.7pa. With the resultant negative pressures in the OR and adjacent Anteroom air was drawn into the rooms from the relatively dirty corridor, thereby compromising the ventilations dilution abilities and therefore protective environment for the infectious patient.

The requirements.

HTM 03-01[10] does not offer guidance on the design or operation of infectious diseases theatres, the only guidance is for infectious diseases isolation rooms, requiring the room to have extract only with 10ach and a negative pressure of 5Pa.

The HTM recommends in clause 7.62 in part A, "balanced flow theatres for infectious cases" and earlier in the same clause recommends returning to first principles when developing a solution. Earlier in this section of the HTM it recommends following the guidance in appendix 8 of the HTM. Following these guidelines results in similar supply air volumes to a normal operating room, but as a result of the significantly increased extract in the operating room. "Open door protection" is completely lost for the operating room as there is no supply or extract volume difference and similar for other rooms; without further increasing the extracts in the other rooms and associated supply. Whilst academically operating ventilation systems in "balanced" operation, (equal supply and extract) is simple, operationally though this is rarely achieved, the fans in the plant are operated at fixed speed (approximately 95% of systems in UK Healthcare[11]); so, as filters get dirty and or the external weather conditions change, the balance between supply and extract changes is not achieved. In the operating theatre and other rooms, there is a clear imbalance of air flows resulting

[5] Al-Benna, Sammy. "Negative Pressure Rooms and COVID-19." Journal of Perioperative Practice 31, no. 1–2 (January 2021): 18–23. https://doi.org/10.1177/1750458920949453.

[6] T.T. Chow, A. Kwan, Z. Lin, W. Bai, Conversion of operating theatre from positive to negative pressure environment, J Hosp Infect VOLUME 64, ISSUE 4, P371-378, DECEMBER 01, 2006 https://doi.org/10.1016/j.jhin.2006.07.020

[7] Chow, Tin-tai PhD; Kwan, Anne FANZCA; Lin, Zhang PhD; Bai, Wei MSc A Computer Evaluation of Ventilation Performance in a Negative-Pressure Operating Theater, Anesthesia & Analgesia: October 2006 - Volume 103 - Issue 4 - p 913-918 doi: 10.1213/01.ane.0000237404.60614.24

[8] Public Health England, Examining food, water and environmental samples from healthcare environments, Microbiological guidelines, February 2020, Table 11

[9] Park, J., Yoo, S.Y., Ko, JH. et al. Infection Prevention Measures for Surgical Procedures during a Middle East Respiratory Syndrome Outbreak in a Tertiary Care Hospital in South Korea. Sci Rep 10, 325 (2020). https://doi.org/10.1038/s41598-019-57216-x

[10] health Technical Memorandum HTM 03-01 Specialised ventilation for healthcare premises:2007

[11] Authors own observations.

in air entering or leaving the various rooms increasing infection risk either to the infectious patient undergoing surgery or infectious agent leaking into the adjacent rooms including the theatre department corridors. From a practical delivering point of view, this method for ventilation is very difficult to change from one type of operation suitable for operating on infectious patient to operating on non-infectious patients which makes these theatres expensive to operate or only be used for infectious patents. Additionally, very few hospitals normally have sufficient patients for this niche use. With the complexity, cost and use these theatres are rare.

Relatively early on in the Covid-19 pandemic, Public Health England (PHE) suggested that theatres should be used with their ventilation systems operating normally circa 25ach a positive pressure of 25pa the air being vented to most of the rooms of the theatre suite and the “clean” and “dirty” corridors, the air being extracted in the main part from the corridors and the “disposal” or “dirty utility”.

Whilst clearly when the pandemic was in full throw, with no time to make modifications to theatres, these systems, medical practices and their ventilation systems would perform better than the earlier two strategies, to protect other patients and staff from the risk of becoming infected.

Are the requirements clear?

Yes, the PHE guidelines in many respects is clear, use theatres as normal with the medical teams in the operating room wearing various levels of PPE (personal protective equipment) and assume that both the PPE was effective and assume there is a negligible risk of the other staff and patients in the theatre department becoming infected.

The HTM as discussed earlier has no effective guidance for providing a safe environment whilst operating on infectious patients.

Neither demonstrably protect the infectious patient from infection or the medical staff in the rest of the theatre department as well as not being able to demonstrate the legal requirements of COSHH have been complied with i.e. to ensure the ventilation systems cannot result in infection of medical staff for example in the corridors.

Statutory requirements

Apart from the clear medical objectives of providing a protective environment to protect an infectious patient when undergoing surgery as would be the case normally in an operating theatre when non-infectious patients are receiving treatment.

There is in addition, when carrying out surgery on infectious patients there is the real risk to medical teams carrying out surgery on the infectious patient and the possibility of infecting other medical personnel and support staff working in the theatre department.

It is recognised that in other medical environments where infectious patients are accommodated protected source isolation rooms are provided and other facilities are provided to have a protective environment to protect medical teams working in these spaces and adjoining rooms.

The statutory requirements in the UK largely mirror these common safety, engineering requirements, solutions and built environment provided to protect medical teams and patients including infectious patients from infection.

Note, if the healthcare organisation could not have known that they would be expected to treat and provide healthcare to infectious patients, then it just might be possible to say that in the first instance it was not reasonably practicable to put in place:

- work processes,
- systems,
- provide engineering controls,
- control exposure at source,
- providing adequate ventilation and
- organisational measures

and rely on PPE

However, for example the requirements of Reg 7 (COSHH). Should be met when it is reasonably practical to do so
i.e. as soon as reasonably practicable to design and put in place engineering systems including ventilation and appropriate organisational measures in addition to the possible use of PPE if the substance hazardous to health is still not under sufficient control. The ventilation works described in this discussion note are intended to illustrate that existing operating theatres can be converted such they provide a protective environment to the medical teams from infection and also protect the patient from infections arising from the process of carrying out surgical procedures.

Also see appendix A

<u>What is commonly installed in the UK?</u>

The vast majority of operating theatre suites installed in the UK were designed to the HTM current at the time of design, their operating philosophy whatever age is very similar that is the room ventilation rates being set by whichever of the following required the greatest ventilation rate, these are:

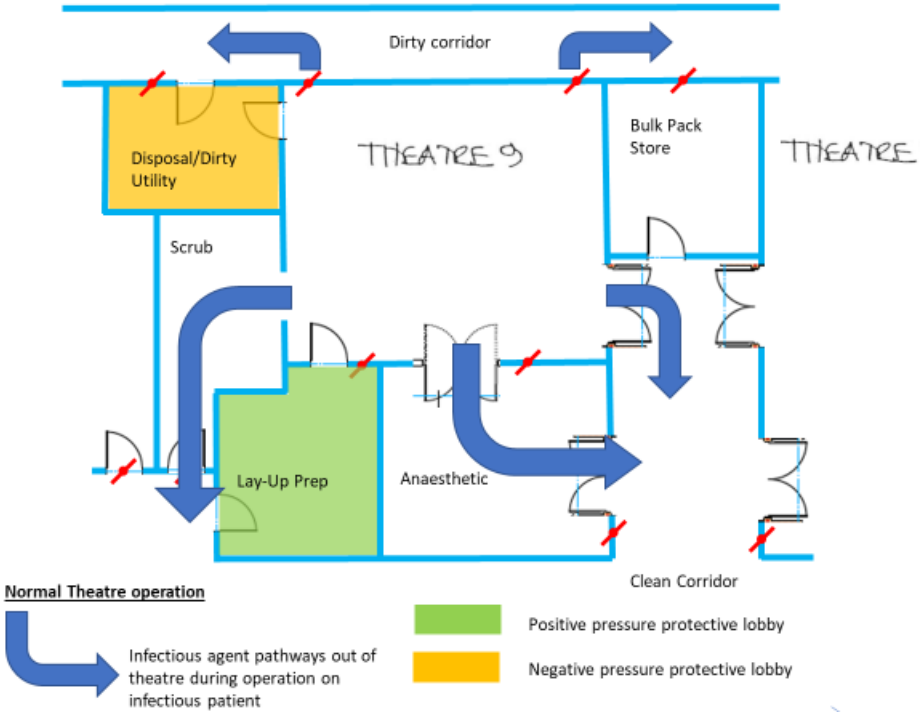
- Summer heat gains
- Winter heat losses
- Dilution of bacterial contamination
- Air movement control (open door protection)[12]
- Pressure differences between rooms

Whilst there are no specific performance requirements detailed in the HTMs the requirements of the Control of Substances Hazardous to Health Regulations[13] (COSHH regulations) must be adhered to e.g. the concentration of chemical (including Viral and biological) agents released in the theatre suite rooms and recovery.

[12] The amount of air needed to flow out of a room when any given door to that room is opened, to prevent dirty or less clean air from the adjacent less clean room.
[13] The Control of Substances Hazardous to Health Regulations 2002 (as amended) Approved Code of Practice and guidance, sixth edition 2013.

When providing a robust and safe ventilation system that is safe for operating on non-infectious or infectious patients these must each be taken into account for each room or space in an operating theatre suite.

The following diagram shows the principle infection routes out of a theatre when an infection patient is undergoing surgery, this is in addition to the risk to the medical team carrying out the surgical procedure.



So as can be seen effectively the air in the operating room exits into the clean and dirty corridors, in the case the air from the operating room is delivered into the clean corridor if there is no dirty corridor as is common for newer theatres. Based on typical theatres designed to the HTM and earlier HTMs 90% is not extracted through the ventilation system until the air has travelled through the clean or dirty corridor for example[14]. Therefore, most of the remaining airborne infectious agent in the operating room will enter the high foot fall areas e.g. the clean and dirty corridors, therefore where it is known there is or could be an infectious agent present, these should be controlled, this also the meeting the statutory requirement discussed earlier. The proposals in this document also demonstrate how this release could be controlled.

Conversion of existing theatres for infectious patients use

The following are the most common drivers for ventilation rates for the various constituent rooms in the operating theatre suite, followed by any alterations needed to make the theatre suitable for carrying out surgery on infectious patients:

- Lay-up preparation room
  These rooms have few heat gains, the heat losses are even smaller, the dilution

[14] In many theatre departments the extract is often out of balance with the supply air, these are rarely reported on as required in verifications, because of the lack of extract air, air from theatres is delivered to the hospital street outside the theatre department.

requirements are set at 25ach from HTM 03-01, “open door” protection requirements for these rooms set the ventilation rate as these are well in excess of the 25ach from appendix 2 of the HTM normally between 35ach and 40ach based on typical standard sized[15] rooms.

With the existing supply air being provided to these rooms, this room effectively becomes a positive pressure room or lobby, preventing any infectious agent from passing through the room to the rest of the theatre department, so requires no alteration.

- Sterile Pack Store (SPS)
  These are similar to the Lay-up preparation room, though the dilution ventilation rate is much lower at 10ach from appendix 2 of the HTM. “open door” protection is nil except where the room has a door to a less clean room such as the “clean corridor”.

  With supply air being provided to these rooms, this room effectively becomes a positive pressure room or lobby, preventing any infectious agent from passing through the room to the rest of the theatre department, if for example the room has a door to the corridor the transfer grille is covered.

- Operating room
  These rooms have some heat losses, the dilution requirements are set at 25ach, “open door” protection requirements for these rooms set the ventilation rate at between 20ach and 15ach for correctly sized theatres at the time of design. Heat gains from principally medical equipment drive the ventilation rate up significantly, normally increasing the air change rate above 25ach, a common reason for unplanned theatre closures because of the resultant high temperatures or humidities more commonly in the summer months for theatres operating between 75% and 100% of the values (25ach) given in HTM 03-01. Therefore the ventilation rate for operating rooms is set by the heat gains from equipment and summer outside temperatures (not the base line of 25ach from appendix 2).

  With supply air being provided to these rooms, this room provides effective dilution ventilation to provide protective ventilation through the supply of relatively clean air to dilute infectious agents from the medical teams and the same from the infectious patient being operated on to protect the medical team (wearing PPE). With the operating theatre ventilation rate and operating at the customary positive pressure, the excess supply air from the room will need to be vented away to a safe place through the adjoining rooms; this is discussed and solutions found, see discussions on adjacent rooms.

- Equipment room
  Similar to the sterile pack store.

- Scrub room
  These rooms have few heat gains, the heat losses are even smaller, the dilution requirements are set at approximately 13ach[16], “open door” protection requirements for these rooms increase the ventilation rate to approximately 37ach (0.28m^3/s), therefore the ventilation rate is set by “open door” protection.

  With extract air being transferred from the corridor and reinstalled to extract air from this room, the room effectively becomes a negative pressure room or negative pressure lobby,

[15] Based on a more typical room height of 2.4m (used in HBN 26:1991 to calculate the ventilation rate in HTM 2025 for an anaesthetic room for example) not the 3m used in the later HTM 03-01.
[16] Appendix 3, 0.1m^3/s for example from HTM 03-01

preventing any infectious agent from passing through the room to the rest of the theatre department, if for example the room does not have a door then a door will be needed either to form a small lobby with a new pressure stabiliser for the air to be extracted or at the entrance from the theatre.

- Anaesthetic room
  These rooms have some heat gains, the heat losses are even smaller, the dilution requirements are set at 15ach, "open door" protection requirements for these rooms increase the ventilation rate to approximately 45ach (≈0.57m^3/s) or higher for smaller older anaesthetic rooms, therefore the ventilation rate is higher set by "open door" protection, typically provided from the operating room.

  With extract air volume being transferred to extract air from a new exit bay, the anaesthetic room pressure increases to above that of both the operating theatre and remains higher than the adjacent clean corridor forming a positive pressure room or lobby, thereby preventing any infectious agent from passing through the room to the rest of the theatre department, the pressure stabiliser in the wall to the "clean corridor" is covered.

- Disposal, theatre sluice or dirty utility
  These rooms have few heat gains, the heat losses are even smaller, the dilution requirements are set at greater than 20ach[17], "open door" protection requirements for these rooms increase the ventilation rate to approximately 37ach (0.47m^3/s) based on correctly sized rooms[18], therefore the ventilation rate is set by "open door" protection.

  With extract air already in place, this room is already effectively a negative pressure room or lobby, preventing any infectious agent from passing through the room to the rest of the theatre department. To vent excess air from the theatre a new pressure stabiliser will be needed to vent air into the disposal room.

- Dirty corridor/service corridor
  This corridor has variable heat gains, the heat losses are also variable, there are no dilution requirements[19] , "open door" protection requirements for these rooms set the ventilation rate the amount of air changes varies with the size of the corridor.

  This corridor often has no doors to the operating theatre, however this corridor often does commonly have air vented from the operating theatre through pressure stabiliser(s), these would need to be covered (this air vented typically through the new stabiliser into the Disposal room/ theatre sluice or dirty utility from the operating room.

- Clean corridor
  This corridor has relatively small heat gains, the heat losses are also very small, the dilution requirements are set at greater than 7ach [20], "open door" protection requirements for these rooms increase the ventilation rate the increased air changes varies with the size of the corridor.

[17] Appendix 2, for example in HTM 03-01
[18] Based on a more typical room height of 2.4m (used in HBN 26:1991 to calculate the ventilation rate in HTM 2025 for an anaesthetic room for example) not the 3m used in the later HTM 03-01.
[19] HTM 03-01 Part A
[20] Appendix 3, for example in HTM 03-01, therefore the 75% rule for verification does not apply as it is not listed in appendix 2.

The Clean corridor typically has one set of doors from the operating room, many theatre suites have a short corridor outside the theatre doors linking to the main clean corridor for the theatre department. Infectious air from the theatre will enter the clean corridor to control this an exit bay lobby can be constructed (a common room forming a part of a theatre suite in 1950s and 60s). Again commonly there will be an existing extract terminal in this part of the clean corridor or very near, this provides a source of extract air to this new negative pressure lobby, additionally the extract air from the anaesthetic room is diverted into this lobby, excess air from the theatre is extracted from this lobby, some air however also enters from the clean corridor, resulting in the lobby being negatively pressured with respect to the clean corridor and the operating room.

From the modifications described above, the protective environment is provided by altering the ventilation arrangements to provide either positive or negatively pressurised rooms (lobbies), in rooms that adjoin the operating room, a common strategy adopted for ward isolation rooms in the IK and many other counties.

It should be clearly understood the doors to these rooms are not interlocked to prevent more than one door from being opened in each room (or lobby); therefore, as in any medical environment including operating theatre suites, doors should not be left open, this remains just as important when a suspected infectious or infectious patient is receiving treatment.

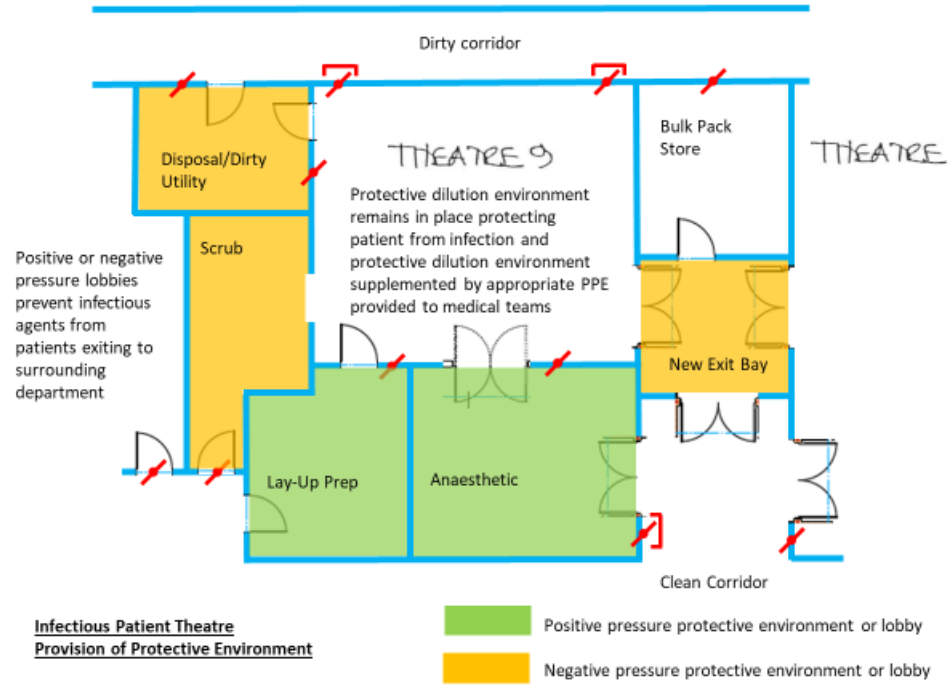


Diagram showing how the Provision of protective environment for conversion into convertible infectious patients for an existing operating theatre could be achieved

See Appendix B for detailed the engineering air flow management for a typical theatre.

List rooms and work content needed for conversion

The following is a description of works needed for the sample theatre described in this discussion note, retaining compliance with the design requirements of HTM 03, with respect to for example heat gains, open door protection pressure cascade etc.

- Lay-up preparation room
  No works.

- Operating room
  Block up the two low level stabilisers to the “dirty” corridor, the air from these is diverted into the “dirty” utility through a new low-level pressure stabiliser.

- Scrub room
  Existing, extract air being transferred from the corridor and reinstalled to extract air from the scrub room, this room effectively becomes a negative pressure room or lobby, fit a new door to the opening into theatre with low level pressure stabiliser, alternatively fit a new door with pressure stabiliser at high level at the end of the short passage to the clean corridor.

  Note to allow the theatre to be easily converted back to conventional operation, leave existing terminal in situ and install change over damper in ceiling (install lock to ensure no unauthorised changes are made).

- Anaesthetic room
  Block off existing pressure stabiliser to corridor.
  The existing extract air is transferred to extract air from a new exit bay, the anaesthetic room pressure increases to above that of both the operating theatre and the adjacent corridor forming a positive pressure room or lobby.

  Note to allow the theatre to be easily converted back to conventional operation, leave existing terminal in situ and install change over damper in ceiling (install lock to ensure no unauthorised changes are made).

- Disposal, theatre sluice or dirty utility
  See operating room

- Dirty corridor
  See operating theatre

- Clean corridor
  See Scrub room and install new doors to form a new small exit bay, either retain or relocate if required the existing extract terminal in this stub corridor.

- New Exit Bay
  See clean corridor

- AHU ventilation plant and other parts of the ventilation system
  No works, including controls.

Plant modifications, as the air volumes supply and extract remain unaltered, there are no works to the plant.

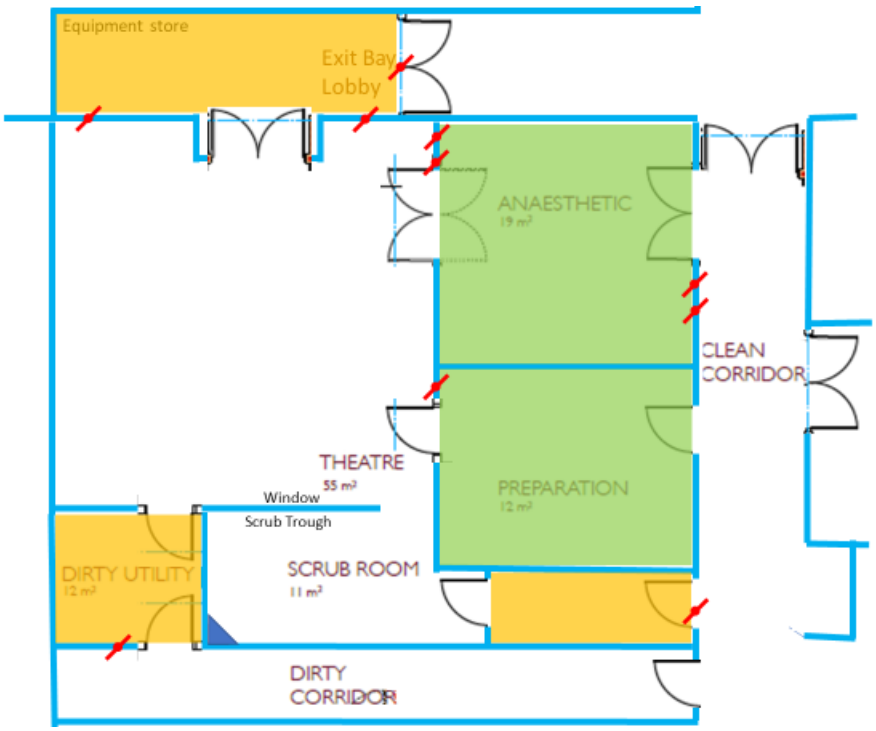
For the conversion, it is suggested that the selected theatre has an extract air termination that discharges to a safe place or an exclusion zone is established. The extract ductwork should be identified to highlight the infection risk as would be done for an any isolation room extract.

Conversion of other theatre layouts

The principles above can be adapted to achieve the desired objectives.

Additionally, in the earlier text solutions have been added, for the adaptions needed for some other rooms e.g. a sterile pack store. Can these adaptions be automated? the manual dampers and pressure stabiliser covers can be replaced with motorised dampers; these being operated by a single switch on the surgeon's panel in theatre.

New theatres



As can be seen from the above these adaptions described can be installed in a new theatre; therefore, one or more new theatres could be designed from concept at a very minimal cost.

For a new theatre the additional doors can be installed and exit bay lobby designed in, the changeover damper operation and the closing of the pressure stabilisers can be done by motorised dampers. These operated from a button on the surgeons' panel.

Additionally, with the installation of room pressure sensors and an alarm on the surgeons panel can

be raised if a door is left open for more than two minutes (this would also be good and cheap to carry out for any operating theatre).

Some or all of the above could also be installed for a temporary solution as none of the components are on long deliveries. For new theatres suites air flow management strategies, see appendix D.

UCV or “Laminar flow” theatres

These solutions could easily be adapted for this type of theatre for either the temporary or for a new theatre.

Conclusions

As discussed earlier, the objectives of this discussion note are to understand the requirements for carrying out surgical procedures in terms of protecting the patient and medical teams and meeting the serious statutory requirements and continuing to comply with the UK HTM and most other aims and objectives of guidelines in other countries, without resorting to negative pressure operating rooms that allow “dirty” air from the rest of the department. Then outline how this could be done, with an existing common theatre layout (circa 1970s in this case) and then for new theatres and UCV theatres.

As can be seen by carrying out minor works it can be readily seen that to provide a protective environment for the infectious patient undergoing surgery and for medical teams, these can be delivered in a short timescale and at little cost, with no material performance changes to the capacity or controls to the ventilation AHUs or controls, therefore meeting the core objectives and statutory requirements and reduce the chance of infection of medical teams in the OR, personnel outside the OR and protecting the patient.

Sample engineering solutions

Several engineering solutions are attached these based on the requirements of HTM 03 theatre design requirements, these appendices outline solutions for the conversion of existing theatres and new theatres, as can be seen from these the Staff and Patients in theatre areas around the theatre suite are protected from infection by positive or negative pressure rooms for example:

- Disposal/Utility,
- Scrub,
- Lay-Up Prep.
- Anaesthetic,
- Exit Bay Lobby

The Patient remains protected by provision of a protective environment as normal theatre e.g. clean fresh air, as to are medical teams as a normal operating theatre, additionally medical teams receive additional protection from appropriate ventilation and Healthcare Organisations can demonstrate better compliance with statutory requirements.
Note. Patients should be anaesthetised in the operating room and staff should don PPE before entering theatre through negatively pressured rooms/lobbies during surgery on an infectious patient.

Final designs and modifications should be checked for compliance with the HTM.

Appendix A Statutory requirements

The following are examples of the relevant statutory requirements:

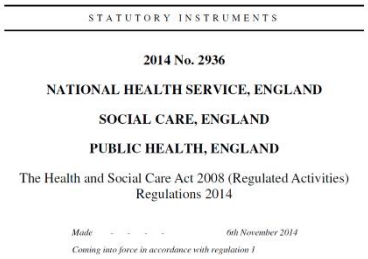
The Health and Social Care Act
requires the following: a safe protective environment for the patient e.g. an operating theatre environment that protects the patient from infectious agents from outside and the medical team operating on the patient.

Department of Health ACoP for the Health and Social Care Act.
Additionally, requires appropriate provision and maintenance of isolation facilities. To protect patients from infection and similarly to protect medical teams and others working in the theatre department from infections from the patient.

Workplace (Health, Safety and Welfare) Regulations
To provide a sufficient quantity of fresh or purified air and to maintain ventilation systems, to protect patients and medical teams both in the operating theatre and in the theatre department.

The Control of Substances Hazardous to Health Regulations
Requires patients and medical teams to be protected from infectious agents including bacterial and viral infections. And where these are present, they are to be controlled by reducing exposure, to a safe level by suitable ventilation and where these cannot be controlled to a safe level the ventilation can be supplemented using suitable PPE.

The Health and Social Care Act
The Health and Social Care Act 2008 and UK SI 2014 No. 2936


STATUTORY INSTRUMENTS

2014 No. 2936

NATIONAL HEALTH SERVICE, ENGLAND

SOCIAL CARE, ENGLAND

PUBLIC HEALTH, ENGLAND

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Made - - - - 6th November 2014

Coming into force in accordance with regulation 1

requires the following:

Regulation 12 Safe care and treatment
(1) Care and treatment must be provided in a safe way for service users.

(2) the things which a registered person must do to comply with—

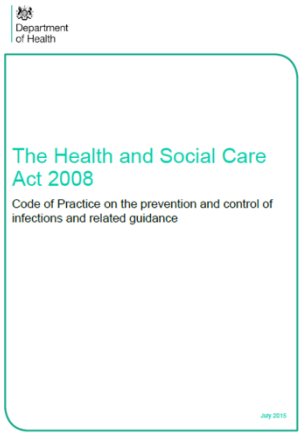
(d) ensuring that the premises used by the service provider are safe to use for their intended purpose and are used in a safe way;

Regulation 15 Premises and equipment
(1) All premises and equipment used by the service provider must be—

(a) clean,
(c) suitable for the purpose for which they are being used,
(d) properly used
(e) properly maintained

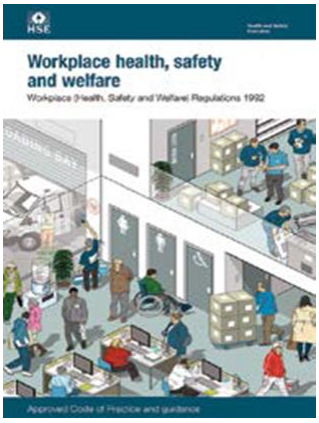
Clearly requiring health care facilities to be safe and suitable for their use, the responsibility of both users and operators of the facilities (e.g. Healthcare Organisations, Medical Teams, Estates Teams).

There are additional requirements in
Criterion 7 of the Department of Health ACoP for
the Health and Social Care Act: July 2015.
Additionally, requiring appropriate provision and maintenance of isolation facilities.



Workplace (Health, Safety and Welfare) Regulations
Workplace health, safety and welfare ACoP L24: 2013
for the Workplace (Health, Safety and Welfare) Regulations 1992 UKSI 1992 No.3004

Regulation 6 Ventilation, requires in
(1) Effective and suitable provision shall be made to ensure that every enclosed workplace is ventilated by a sufficient quantity of fresh or purified air.



Control of substances hazardous to health Regulations
Control of substances hazardous to health (Sixth edition) ACoP and Guidance L5:2013
The Control of Substances Hazardous to Health Regulations 2002 UK SI 2002 No. 2677 (as amended):

Reg 7 Prevention or control of exposure to substances hazardous to health

7.—(1) Every employer shall ensure that the exposure of his employees to substances hazardous to health is either prevented or, where this is not reasonably practicable, adequately controlled.

7.—(2) In complying with his duty of prevention under paragraph (1), substitution shall by preference be undertaken, whereby the employer shall avoid, so far as is reasonably practicable, the use of a substance hazardous to health at the workplace by replacing it with a substance or process which, under the conditions of its use, either eliminates or reduces the risk to the health of his employees.

7.—(3) Where it is not reasonably practicable to prevent exposure to a substance hazardous to health, the employer shall comply with his duty of control under paragraph (1) by applying protection measures appropriate to the activity and consistent with the risk assessment, including, in order of priority—

(a) the design and use of appropriate work processes, systems and engineering controls and the provision and use of suitable work equipment and materials,

(b) the control of exposure at source, including adequate ventilation systems and appropriate organisational measures, and

(c) where adequate control of exposure cannot be achieved by other means, the provision of suitable personal protective equipment in addition to the measures required by sub-paragraphs (a) and (b).

explanatory notes
reg 7.—(1) employers duties to control employees exposure to substances hazardous to health (e.g. chemical, bacteria, Virus) and where this not reasonably practicable, for them to be adequately controlled.

Reg 7.—(2) change or remove or otherwise change working practice such that the substance hazardous to health is not used or present. In the case of an infectious agent, this cannot be removed for example.

Reg 7.—(3) where the employer cannot control/remove the substance hazardous to health the following sub clauses apply, in the following order of priority.

Reg 7.—(3)(a) put in place work processes, systems and engineering controls.
Reg 7.—(3)(b) put in place appropriate control of exposure at source, including adequate ventilation systems and appropriate organisational measures.

Reg 7.—(3)(c) where (a) and (b) cannot be achieved additionally provide personnel protective equipment (PPE).

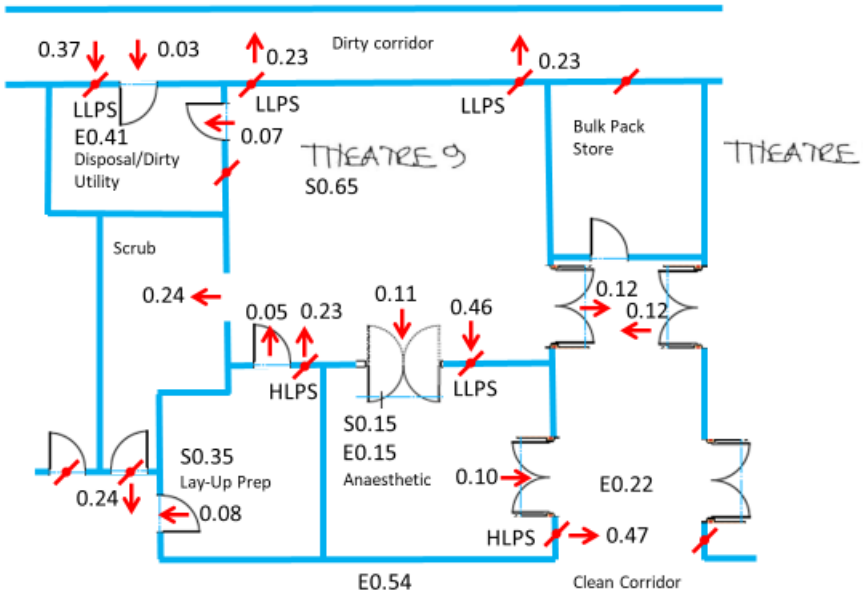
Note, if the healthcare organisation could not have known that they would be expected to treat and provide healthcare to infectious patients, then it just might be possible to say that in the first instance it was not reasonably practicable to put in place:

- work processes,
- systems,
- provide engineering controls,
- control exposure at source,
- providing adequate ventilation and
- organisational measures

and rely on PPE

However, the requirements of Reg 7. Should be met when it is reasonably practical to do so i.e. as soon as reasonably practicable to design and put in place engineering systems including ventilation and appropriate organisational measures in addition to the possible use of PPE if the substance hazardous to health is still not under sufficient control. The ventilation works described in this discussion note are intended to illustrate that existing operating theatres can be converted such they provide a protective environment to the medical teams from infection and also protect the patient from infections arising from the process of carrying out surgical procedures.

Appendix B: Typical air flow management for an existing theatre

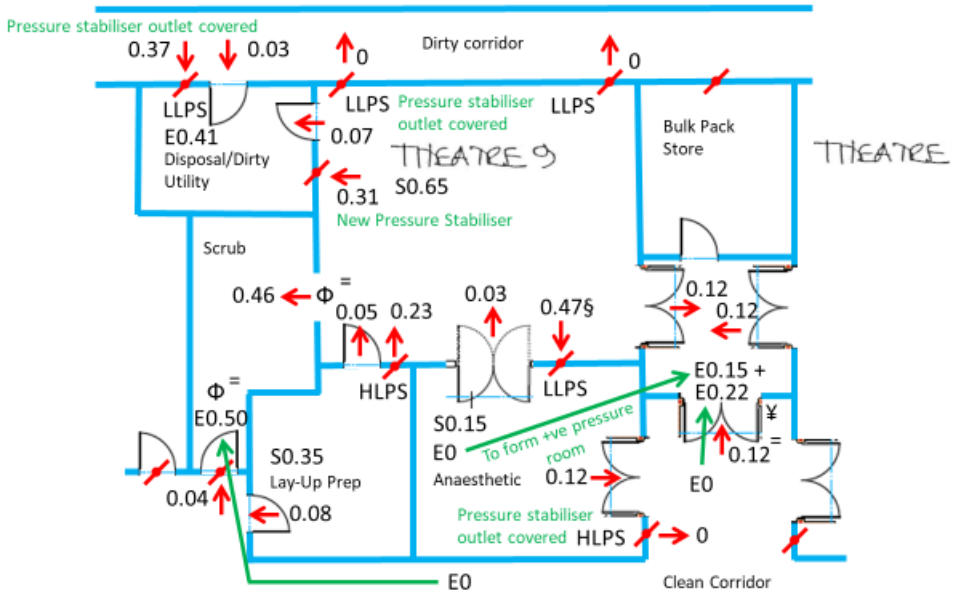


Normal Theatre operation

Legend

E Extract Rate from Room into Terminal in m^3/s
S Supply Rate into Room from Terminal in m^3/s
HLPS High Level Pressure Stabilizer
LLPS Low Level Pressure Stabilizer

Appendix C: Suggested detailed air flow management for a converted temporary theatre



Infectious Patient Theatre Changes and operation

Legend

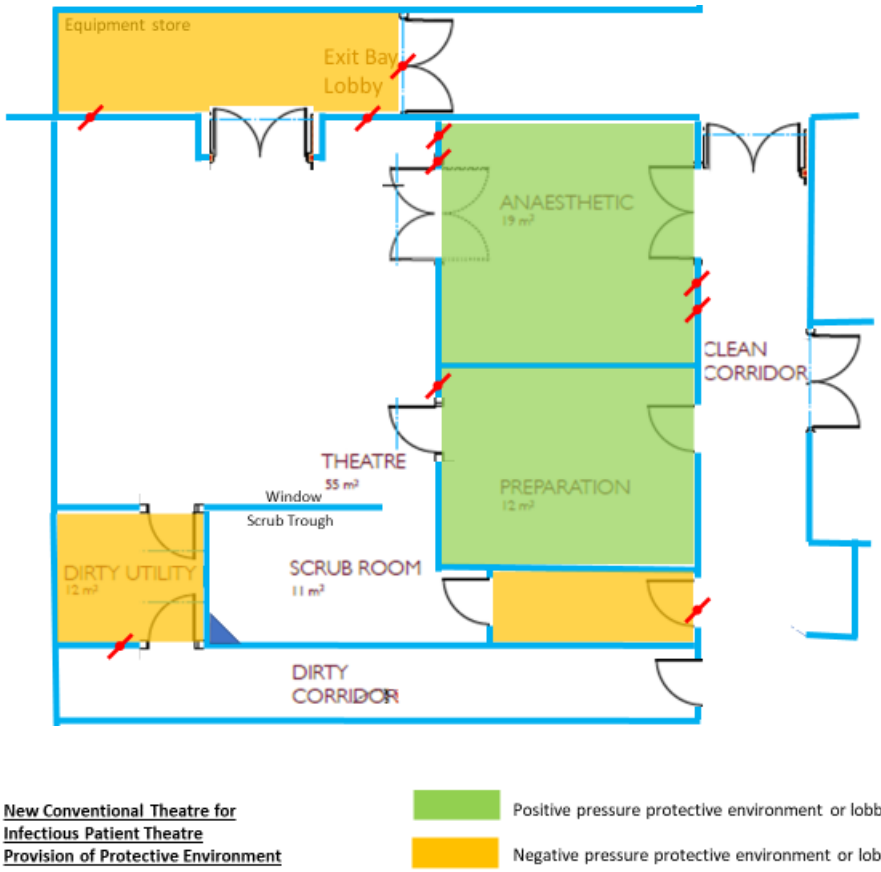
E Extract Rate from Room into Terminal in m^3/s
S Supply Rate into Room from Terminal in m^3/s
HLPS High Level Pressure Stabilizer
LLPS Low Level Pressure Stabilizer
§ When Anaesthetic Door to Corridor is open
Φ New Door in either location and Stabilizer to form -ve pressure lobby
¥ New Door to form an –ve pressure Exit Lobby
= New Doors can remain open when theatre put in "Normal" Use

Change over damper diverts air from Anaesthetic in to exit lobby

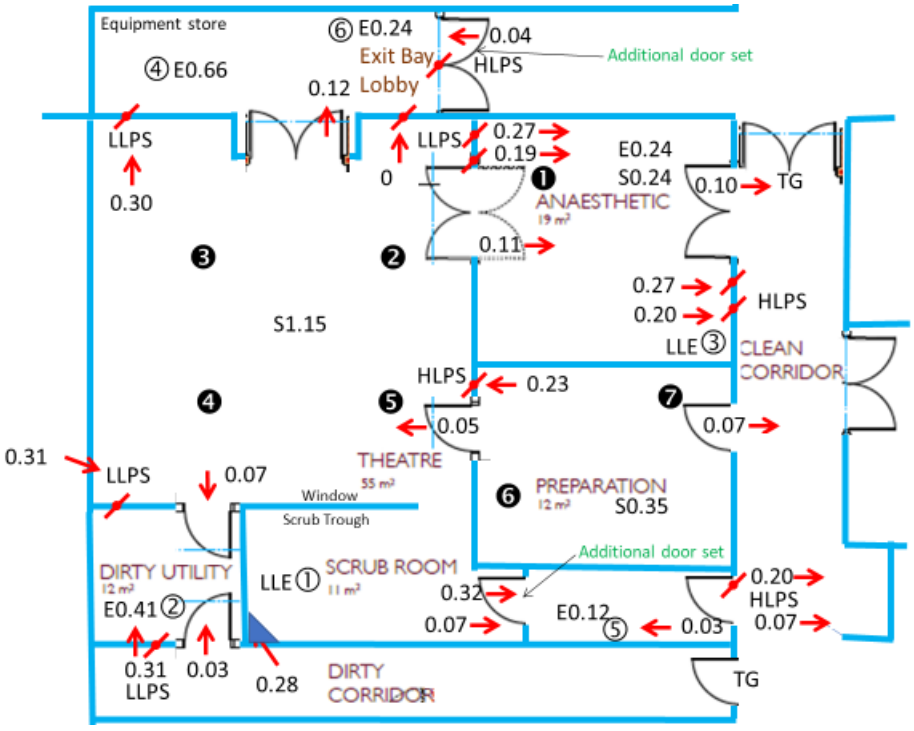
Change over damper diverts air from corridor to new Scrub lobby

Green notes denote modification works

Appendix D: Sample solutions for New Theatre Designs, New Conventional Theatre for Infectious Patient Theatre



Air Flow Management for non-infectious patients use



Legend

E Extract Rate from Room into Terminal in m^3/s
S Supply Rate into Room from Terminal in m^3/s
Sec Secondary Air Extract in m^3/s
HLPS High Level Pressure Stabiliser
TG Transfer Grille
LLPS Low Level Pressure Stabiliser
§ When Anaesthetic Door to Corridor is open
LLE Low Level Extract

Low Level extract air inlet for secondary circulation through canopy

Diffusers ❶ Supply ① Extract (and connections to canopy)

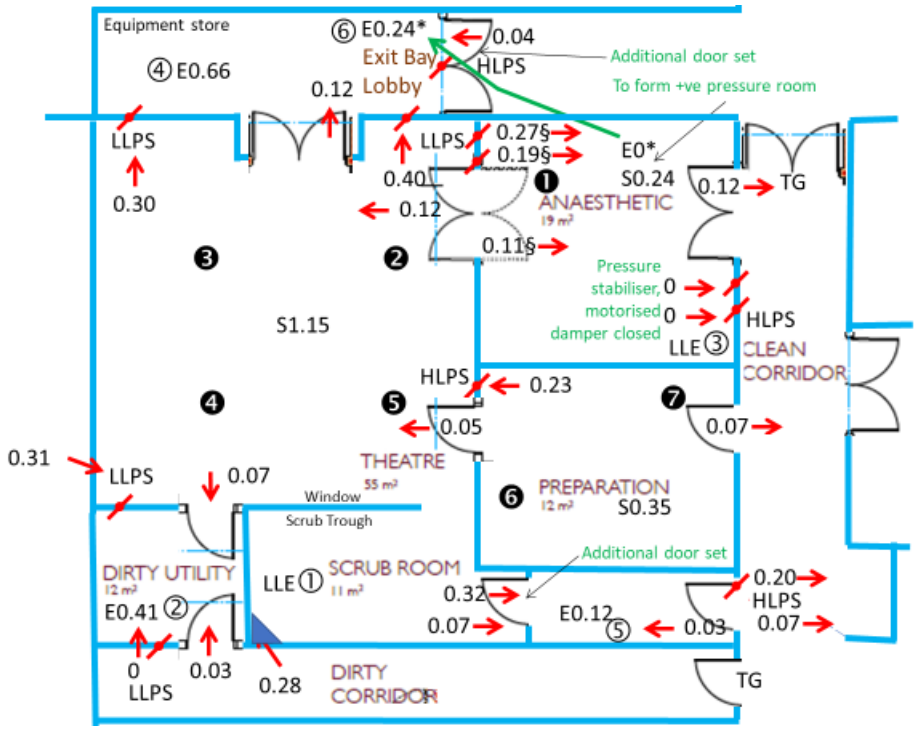
Pressure stabiliser location

0.12 → Denotes possible air flow direction, when for example a door is opened, with direction arrow in m^3/s

* Change over damper diverts extract air from Anaesthetic in to exit lobby

Notes as normal protocol
All doors in theatre suite should remain normally closed when in use

Air Flow Management for infectious patients use



Legend

See earlier in this appendix

Operation

Motorised change over damper diverts air from Anaesthetic in to exit lobby

Motorised damper in wall of anaesthetic room, closes off air flow through pressure stabiliser into clean corridor

These can either be operated manually or electrically with the control switch in the operating room

Green notes denote modification works

Notes

as normal protocol, all doors in theatre suite should remain normally closed when in use
air flow management diagram shows that theatre can be designed to meet HTM objectives including, equal air volumes leaving each corner of the operating theatre; all air out paths are at low level to further improve the dilution performance of the ventilation system as HTM 03-01 and CIBSE Guidance , further protecting patients and medical teams from infectious agents as required by COSHH.

Anaesthetic room should not be used for medical procedures
Medical teams should enter operating theatre through negative pressure lobbies only after donning appropriate PPE
Total Supply and extract air volumes do not change or increase.