THE ROLE OF ULTRACLEAN AIR IN CONTROLLING BACTERIAL INFECTION IN THE OPERATING THEATRE

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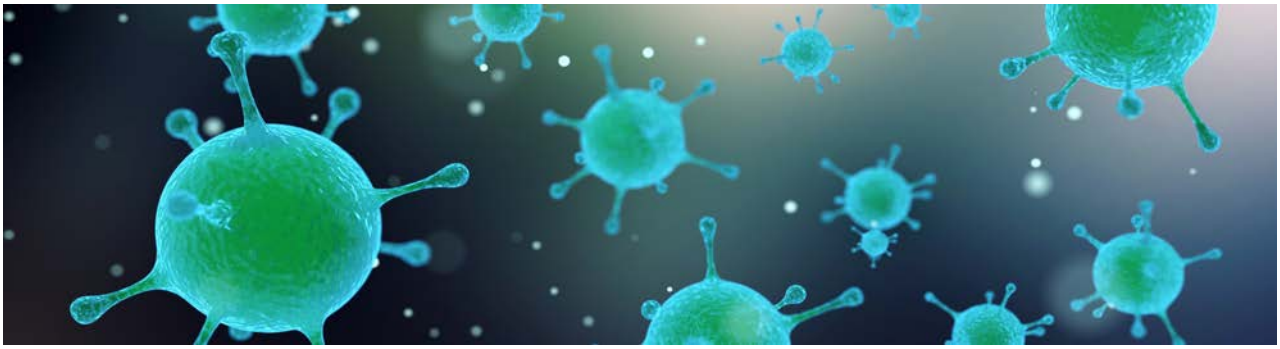


Deep wound infection rates for primary hip and knee replacements currently range from 0.5 to 4%. If all hospitals achieved 1% this would transform the lives of 6,000 patients and save the NHS £300m per year.
Operational Productivity and Performance in English NHS Acute Hospitals, Lord Carter of Coles

In Quality Standard 61, NICE estimates that 300,000 patients a year in England acquire a healthcare-associated infection (HCAI) as a result of care within the NHS. Surgical site infection (SSI) accounts for 15.7% of all HCAI, putting it in the top three after respiratory infections and urinary tract infections. Such is its severity that The Lancet recently called SSI "the next frontier in global surgery".

HCAI places a massive clinical and financial burden on the NHS, and is estimated to cost the NHS in excess of £1 billion annually. It leads to longer hospital stays, costly remedial surgery that puts extra pressure on already busy theatre lists, increased use of antibiotics, and untold distress for the patient and their family. It's little surprise then that infection prevention and control is a key priority for the NHS.

What is SSI?

SSI is a type of healthcare-associated infection in which a surgical incision site becomes infected after a surgical procedure. It is associated not only with increased morbidity but also with substantial mortality.

Skin is a natural barrier against infection, so any surgery that causes a break in the skin that allows bacteria or germs to get through can lead to an SSI. These bacteria can come from three sources:

- Bacteria already on the skin that spread to the surgical wound
- Bacteria inside the body or from the organ on which the surgery was performed
- Bacteria in the environment, for example in the air or on infected surgical instruments

SSI is a global issue and has been the subject of many studies. In its Global Guidelines on the Prevention of Surgical Site Infection, the World Health Authority shows that SSI threatens the lives of millions of patients each year. It also has some astonishing statistics: in low- and middle-income countries, 11% of patients who undergo surgery are infected in the process and in Africa, up to 20% of women who have a caesarean section contract a wound infection.

Even in wealthier countries, SSI represents a major problem. In America, it contributes to patients spending more than 400,000 extra days in hospital at a cost of an additional US$ 10 billion per year. In one study, 77% of the deaths of surgical patients were related to surgical wound infection.[1] Each SSI is associated with approximately 7-10 additional postoperative hospital days and patients with an SSI have a 2-11 times higher risk of death, compared with operative patients without an SSI.[2,3]

SSI and Antimicrobial Resistance

SSI also contributes to antimicrobial resistance (AMR), often referred to as a global crisis. Antibiotic prophylaxis is effective for preventing SSI in certain procedures, but the use of antibiotics carries a risk of adverse effects and increased prevalence of antibiotic-resistant bacteria. The effective use of an antimicrobial agent is undermined due to the possible tolerance or resistance developed from the first time it is used.

The 'golden era' of antibiotics, starting with penicillin in 1929 and streptomycin in 1943, gave rise to many hugely effective therapeutic agents. This era came to an end in the 1960s because researchers could not maintain the pace of antibiotic discovery in the face of emerging resistant pathogens - no new classes of antibiotic have been discovered since the 1980s. Persistent failure to develop or discover new antibiotics and non-judicious use of antibiotics are the main factors associated with the emergence of antibiotic resistance.

In January 2019, the UK government launched its 5-year national action plan to support the UK's 20 year vision for antimicrobial resistance, which seeks to 'strengthen stewardship programmes' by ensuring antimicrobials are only used when essential. Clearly, reducing SSI would reduce use of antibiotics and, in turn, AMR.

Airborne Bacteria in the Operating Theatre

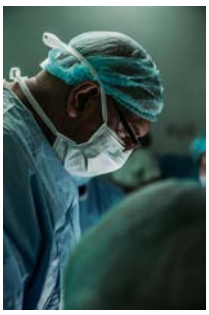
The air around us is full of particles such as dust, dirt, soot, smoke and liquid droplets. Some of these particles will be bacteria-carrying, also called 'colony forming units' (CFUs).

Bacteriologically, the air in an operating theatre is as dirty as the air anywhere else, only it matters more because of what is happing in the space. The microbiological contamination or bio-burden of the air in the operating room is generally considered a risk factor for SSI, even during surgery on a clean wound (an incision in which no inflammation is encountered in a surgical procedure, without a break in sterile technique, and during which the respiratory, alimentary and genitourinary tracts are not entered).

The number of CFUs that are present in the air at the wound site and on exposed surgical items is dependent on several factors, but ironically it is the very people helping the patient that are most likely to introduce bacteria into the room, with staff members closest to the operating table carrying the greatest chance of contaminating the wound.

There are several key 'best practice' procedural guidelines, but there is no getting away from the fact that a person sheds 1 billion skin cells a day and up to 10% of these carry bacteria, floating round in the air ready to settle on the wound site or surgical instruments, laid out ready for use.[4,5] Research carried out at Yale University showed that one person's mere presence in a room can add 37 million bacteria to the air every hour, much of which is material left behind by previous occupants and stirred up from the floor.[6] Another study into sources of bacterial joint sepsis concluded that 62% of the initial infection was carried by skin.[7]

One proven way to address this is through the installation of an ultraclean ventilation system, a specialised form of ventilation used in primary patient treatment areas such as operating departments and critical care areas and also in laboratories and cleanrooms in order to achieve and maintain specific conditions.



Ultraclean Ventilation

Modern operating rooms should be aseptic environments where the use of preventive measures and tools, such as surgical masks, frequent air exchanges and architectural barriers, are recommended to reduce airborne microbial populations.

Ultraclean ventilation (UCV), or laminar flow, is a highly effective way to minimise contaminants at the wound site and has been shown to reduce SSI following certain orthopaedic procedures. Its use is recommended in the guidelines contained within HTM 03-01 Specialised Ventilation for Healthcare Premises – Part A. Ultraclean air is defined as that containing not more than 10 CFU/m^3.

The design philosophy of a conventionally ventilated operating suite is based on the need to dilute contaminants and control both the condition and movement of air in an operating suite. Ultraclean ventilation (UCV) is a means of significantly increasing this dilution effect by providing a large volume of clean filtered air to the clean zone under which an operation is performed and sterile items are exposed.

In a UCV theatre, air is discharged above the operating zone via a UCV canopy, with the airflow creating two effects:

1. Within the clean zone: downward displacement purges the clean zone around the clinical team and patient so it is free from contaminants and particles, replacing the air 500 times each hour
2. Outside the clean zone: particles are prevented from entering the clean zone (entrainment)

In this way, anything that is sterile when it enters the clean zone remains sterile, and bacteria shed by the surgical team is displaced by the airflow, carried away from the wound site through the return air plenum before being filtered through the HEPA filters and supplied back into the operating theatre.

Thanks to the UCV system, the risk of infection due to airborne CFUs is dramatically reduced in surgeries carried out under an ultraclean ventilation canopy.

Bacterial Infection of Surgical Instruments

What happens outside the controlled clean zone is a different matter entirely.

In his 2019 presentation to the Infection Prevention Society entitled Update on SSI Prevention in Orthopaedics, consultant orthopaedic surgeon Mike Reed stressed the importance of keeping kit inside the UCV canopy to avoid contamination. He calculated the rate of particle increase in the air the

further equipment is moved out of the clean zone – in a working theatre, at just 10cm out of the clean zone, particle counts >0.3 micrometers per cubic meter increased to 300,000 and by 60cm, it was over 600,000, with the assumption being that some of these particles will be carrying bacteria.

So let's go further away from the clean zone, right back into the instrument preparation room where surgical instruments are laid up before being taken into surgery.

The process starts when surgical instruments are cleaned in an ultrasonic washer before going to a cleanroom, where they are put into sealed packs. The packs then go into the autoclave to be sterilised. The ideal scenario is that when needed the sterile surgical instruments are unpacked within the operating theatre clean zone, with the UCV system operating at full duty, and with enough space to comfortably accommodate the trolley and laying up procedure.

However, this potentially slows down throughput as instruments cannot be prepared in advance, and anyway not all surgery is carried out under a UCV canopy. So what usually happens, and is completely within guidelines, is that instruments are unpacked from their sterile packaging in the preparation room and covered in a sterile cloth before being taken into theatre.

The air in a preparation room is clean, but not ultraclean. And although the preparation room must be located very close to the theatre, the journey will be through 'dirty' air. Once under the canopy, the velocity of the ultraclean air is non-turbulent (it moves in a downward direction at 0.2m per second, which is less than walking pace) and therefore will not, as it were, blow any bacteria off the instruments, which may then sit on the instrument trolley for minutes or even hours.

This is a key issue. When instruments are awaiting use, up to 50% of their surface area is exposed to the air, providing an ideal place for CFUs to settle. When used, these bacteria are then transferred directly from the surgical instrument to the wound site. Sources have estimated that up to 90% of bacterial contaminants in the wound come from the air, with 70% of these coming from contaminated surgical instruments.

Mobile Laminar Flow Solutions

At MAT, we believe we have found a way to bridge this gap in infection control – mobile laminar flow solutions.

There is an urgent need for new preventive methods that will lower the risk of infection during surgery. Considerable efforts are made to prevent direct contact contamination, by, for instance, sterile draping of equipment and surgical instruments. These measures alone will not suffice if the air surrounding everything in the operating theatre is allowed to contain airborne, sedimenting, bacteria-carrying particles.
Tomas Hansson, Toul Meditech

- **The Steristay Mobile Instrument Table**

The most widely used variant is the trolley design, a unit combining a surgical instrument table with a positionable HEPA filter air device that provides an ultraclean environment with <5 CFU/m^3 air around the surgical instruments. Its use ensures that instruments remain sterile and free from SSI-causing bacteria during preparation and throughout the operating procedure.

400m^3 of air is cleaned every hour through the HEPA filter, meaning that the trolley provides a much cleaner environment than that found in a preparation room and sufficient air filtration to allow

instruments and implants to be laid out, covered and wheeled easily into the operating theatre without leaving their dedicated clean zone. The technology also reduces particle concentration and bioburden in the entire theatre.

The Steristay Mobile Instrument table can be used in all types of operating rooms and surgical preparation rooms, independent of ventilation system where sterile instruments are handled. Setting up the table in advance under safe and secure hygienic conditions minimises set-up time between surgeries and increases productivity.

- **The Operio Ceiling and Operio Mobile Units**

We have already established that in UCV theatres, the ventilation system maintains ultraclean conditions. And while there is an argument that UCV would benefit virtually all procedures, many surgeries are carried out in conventionally ventilated theatres, without a UCV canopy. In this environment, during minor procedures it may be helpful to create a sterile air zone at the wound site. This can be done via an adjustable unit suspended from the ceiling or using the mobile sterile air zone unit, which allows ultraclean air to be directed wherever needed and can be moved easily between rooms as required.

Conclusion

In the operating theatre, everything that comes into contact with the wound site has been sterilised except the air, which comes into contact with everything and is teeming with nearly 2,000 kinds of potentially dangerous bacteria.

The importance of air in the transmission of infection has always held significance for doctors, even when they had it completely wrong – the term 'malaria' literally means 'bad air', for example, though it isn't airborne at all, and 'miasma theory', the belief that diseases such as cholera, chlamydia and even the Black Death were caused by infected air, didn't die out fully until the 1880s with the development of the germ theory of disease.

At MAT, we have developed a range of solutions that deliver air that is not just clean but ultraclean, helping to combat SSI and support the outstanding patient care that our hospitals deliver every day of the year. The ECO-flow canopy will always be our flagship product, but the latest additions to our clean air family, the Steristay Mobile Instrument Table and Operio Ceiling and Mobile units, expand the potential usage of ultraclean technology and complement our core offerings, further confirming our commitment to helping hospitals combat SSI.

Case Study - Evaluation of bacteria-carrying particles (CFUs) over two types of instrument tables in the surgical environment (experiment conducted by Toul Meditech)

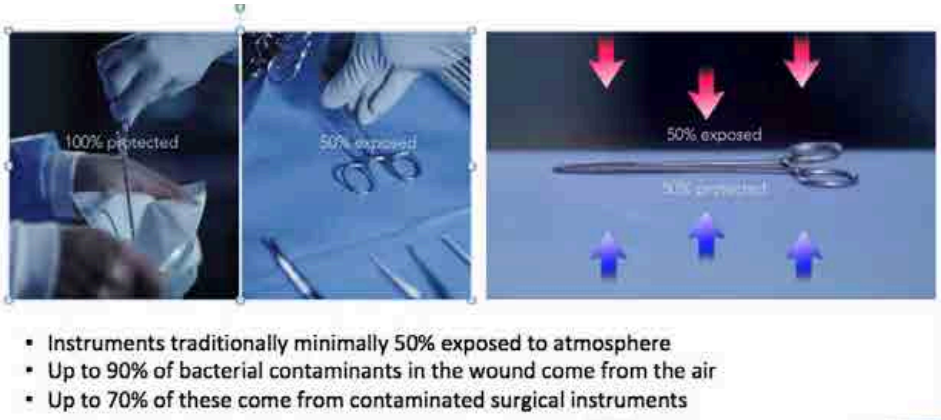
The Steristay Mobile Instrument Table

Purpose: The aim of the test was to evaluate the protective effect provided by the SteriStay Mobile Instrument Table during preparation and the surgical procedure, when compared with a regular instrument table.

Procedure: Two instrument tables were prepared – a regular instrument table and an instrument table supplied with ultraclean air (the SteriStay Mobile Instrument Table). The tables were used for 45 minutes and three people in OR clothing were present in the room. The sterile goods and six agar plates were exposed for two hours in total. The size of the operation room was 20 m^2 with mixing ventilation from the ceiling.

Result: Even though the ambient air contained a large number of bacteria-carrying particles, the level of contamination on the sterile goods placed on the SteriStay table was significantly low, as verified by the result from the agar plates that had been exposed during that time:
Regular instrument table - >120 CFU on all three plates
SteriStay instrument table - 0-5 CFU on all three plates

Conclusion: Good air quality is difficult to maintain and evaluate due to many factors. However, to protect the exposed instruments and sterile goods with an ultraclean airflow minimises the risk of down-falling bacteria-carrying particles, since these particles are present in the operation room at all times.



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