Rethinking the Design of Operating Rooms to Benefit from Cleanroom Standards

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Factors causing surgical site infection are multifarious. Several studies have identified the main patient-related (endogenous risk factors) and procedure-related (external risk factors) factors that influence the risk of SSI. The rate of surgical wound infections is strongly influenced by operating theatre quality, too. A safe and salubrious operating theatre is an environment in which all sources of pollution and any micro-environmental alterations are kept strictly under control. This can be achieved only through careful planning, maintenance and periodic checks, as well as proper ongoing training for staff (Spagnolo, 2013).

Hospital operating rooms (ORs) are among *one* of the most infection-sensitive environments in health care facilities. The rate of surgical site infections (SSI) is strongly influenced by operating room quality, which is determined by the structural features of the facility and its systems and by the management and behavior of healthcare workers. Surgical procedures increase patient vulnerability to pathogens transmitted from surgical personnel, surgical equipment, the air and a patient's own skin flora. The pathogens isolated from infections differ, primarily depending on the type of surgical procedure. In clean surgical procedures, in which the gastrointestinal, gynecologic, and respiratory tracts have not been entered, Staphylococcus aureus from the patient's skin flora is the usual cause of infection. When mucous membranes or skin is incised, the exposed tissues are at risk of contamination by endogenous flor (Mangram. 1999).

Despite advancements in surgical techniques and infection-prevention methods, two out of every 100 surgeries in the U.S. result in surgical site infections, according to the Centers for Disease Control and Prevention (CDC). Unfortunately, these statistics have not changed a great deal to date. During surgical procedures, dust particles, textile fibers, skin scales, and respiratory aerosols loaded with viable microorganisms are released from the surgical team and the surrounding into the air of the operating theatre. Bacteria settling on surgical instruments or entering directly into the surgical site may result in surgical site infection (Diab-Elschahawi, 2011).

In 1985, Howarth noted that clinical trials carried out in Britain, Europe, and the United States confirmed that between 80 and 90% of bacterial contaminants found in the wound after surgery come from colony forming units (CFU) present in the air of the operating theatre. With respect to bacteria transmitted to the surgical site through the air, squames (or skin scales) are the primary source of transmission (Brown, 2009)

Sutherland (1993) showed that the probability of post-operative sepsis is directly related to the number of air-borne bacteria in the vicinity of the wound. The air flow distribution plays a major role in controlling the occurrence of postoperative infection. Many sources note that the cost of treating postoperative complications is significant. However, the payback period on an investment in systems that improve air flow and reduce infection rates is often very short (Partridge et.al., 2005; Rosengarten, 2001).

There are no regulated standards for airborne particulate levels in most health care settings in the U.S. ASHRAE Standard 170-2008 does not address airborne contaminant levels. As a result, contaminant levels over the sterile field in an operating room in the U.S. may not be considered because it is not required by standards or codes. However, standards for airborne contaminant control are extremely well-defined in a production cleanrooms to allow no more than a specific number of particles of a specific size to be present in a space at any given time. In meeting these specifications, airflow systems must account for equipment such as lighting, machinery, people and other elements in the space that could otherwise work against creating the desired environment. Aseptic procedures requirements for personnel entering a clean room space are often more stringent than those required for doctors and nurses entering an OR for a surgical procedure. The reason for this is that manufacturers risk the loss of billions of dollars in lost revenue, warranty costs, back charges and liability due to a catastrophic product failure resulting from contaminants present in a sensitive manufacturing environment. It would seem that to prevent possible death from a surgical site infection, more stringent methodologies should be employed in operating rooms along the same lines of clean room specifications.

Both hospital ORs and sensitive manufacturing environments use laminar airflow systems designed to provide uniform, directional airflow that "directs" particles floating in the airstream away from the sterile field to where they can be disposed of and contained through the return ducts and filtration system. In a turbulent environment, particles are allowed to float undirected, which eliminates the ability to predict where they may settle. (Schreiber,2012).

Few countries have set bacterial threshold limits in conventionally-ventilated operating theatres, although most recommend 20 air exchanges per hour, so as not to exceed values of 50–150 colony forming units (CFU)/m^3 of air during surgical operations (Cristina 2012).

Our literature review and other reviews found that many countries are either using or amending their OR standards to align with the International Standards Organization (ISO) 14644-1 with ISO 8 and ISO 7 levels published as operating room reference levels, depending on procedural requirements. (Al Waked 2010, Scaltriti 2007, Wan 2011, Charkoska 2008). The ISO 8 level has been promulgated under ISO 14644-1 to describe the minimal standard for cleanroom air, with air exchange and enclosure requirements.

Al Waked (2010) notes that few countries have set bacterial threshold limits in conventionally-ventilated operating theatres, although most recommend 20 Air Changes per Hour (ACH) in order to obtain maximum of 50–150 Colony Forming Units (CFU) per cubic meter of air.

The following includes our findings to date for the use of ISO standards or similar clean room standards in operating rooms (OR) in other countries.

Australia

The Australian/New Zealand Standard of clean rooms has been modified to the AS/NZS ISO 14644.1 (2002) to comply with the international limits (2002). Class 5 of AS/NZS ISO 14644.1 (2002) has approximately 29 Bacterial Cytological Profiling (BCP)/m^3 of particles sizes larger than 5 μm as the maximum allowable density of (BCP) inside the operating theatre. Most theatres tested are falling into the Class 7 and some into Class 6 cleanroom categories – Class 6 being the anticipated standard for ultra clean theatres.

Austria

Austria's regulatory standard is ÖNORM H 6020:2007 Ventilation And Air Conditioning Plants For Locations For Medical Use - Design, Construction, Operation, Maintenance, Technical And Hygienic Inspections. This standard establishes a classification of spaces for their purity as follows:

- (H1) Surgeries on bones and big joints with implementation of foreign material & abdominal surgery, ophthalmic operation, urological surgeries
- (H2) Protective insulation – burn units, clean areas (protection area) in rooms for special treatment (e.g. Bone marrow transplantation)
- (H3) Source insulation (there were no details provided for this category)
- (H4) Other - outpatient procedures, ICU

The mechanical ventilation system in H1 and H2 consist of three-stage filters. Two stages of cleaning are used in classes H3 and H4. All classes use a filter on the exhaust air. Velocity cannot be more than 0.45 m/s in areas with low turbulent flow. The design speed in the laminar flow is 0.3 m/s. Average rate should be 0.24 m/s, and single measurement cannot be less than 0.22 m/s.

When the OR is not in use, the air-conditioning system is switched off; if the system is not used, and the room is empty, it must be enabled no less than 30 minutes before use. The protection zone over the operating table must cover the work area up to 1.2 meters and protect the staff and instruments of the operation. Supply air temperature should be above room temperature to a maximum of 3 degrees. HEPA-filters of at least class H13 must be installed. Turbulence does not exceed 10%.

Requirements that are applied in an LAF system with recirculation include adjustable speed fans, symmetrical arrangement of recirculation units, the lack of roughness in the silencers, silencer should be put before the filter, the use of a filter class F7 as a pre-treatment.

Finland

Standards in Finland are unevenly applied. Individual hospitals develop their own standards. Operating areas for clean surgery (orthopedics, transplantation, eye etc.) generally adhere to ISO class 5 of cleanliness. OR staff regulate the air temperature (+/-3) and relative humidity. Vertical low turbulent flow is used in these operating areas. The OR has 15 Pa over-pressure to surrounding spaces, airflow direction to less clean environments.

Operating areas for general surgery adhere to ISO class 5. OR staff regulate the air temperature (+/-3) and relative humidity. Vertical partial low turbulent flow (perforated diffuser) is used in these operating areas. The OR has 10-15 Pa over-pressure to surrounding spaces, airflow direction to less clean environments.

Areas for outpatient and infection surgery adhere to ISO class 7. OR staff regulate the air temperature (+/-3) and relative humidity. Vertical partial low turbulent flow (perforated diffuser) are used in these operating areas. Infection surgery areas must be at neutral or slight under pressure (10 Pa), outpatient surgery must have over-pressure.

Organization R3 Nordic: Contamination Control and Cleanroom (Renhetsteknik och Rena Rum) oversees the situation in clean rooms in Denmark, Finland, Norway, Sweden.

France

In France (NF S90-351), the microbiological limits are more restrictive than in Italy (ISPESL 2010) and the UK, with values of ≤20 CFU/ indicated for turbulent and unidirectional airflows, respectively (Cristina 2012).

"Health care – Zones of environment control - Requirements for the control of air pollution" NF S 90-351, is the French standard for clean rooms. Two zones are defined for hospital rooms where procedures are conducted.

- Zone 3 (high class of risk) - reanimation, maternity boxes, surgical department, pediatrics, laboratory. 18

- Zone 4 (very high class of risk) - operational, transplantation, neonatal units, burn centers.

According to the French standard, air should pass three-stage cleaning. The chain of filters shall consist of F6-F7-H13. The old standard humidity level was 45% -65%, but the new version does not have any requirements for the humidity in operating rooms. Pressure difference between rooms with different classes of cleanliness should be 15±5 Pa. The temperature during working time must be from 19-26 °C.

Germany

Germany uses Standard DIN 1946-4-2008 and Standard VDI 2167. DIN 1946-4-2008 provides indicators for mechanical purity of pollution (particles) and for microbial contamination and prescribed classes of rooms e.g. IA, IB and II. Class IA includes aseptic operating rooms with LAF for protecting the operating table area, and Class IB includes all other ORs with a turbulent flow ventilation system.

According to standard DIN 1946-4-2008 class of the clean room can be determined by:

– The quality of filtration (number of purification steps and the quality of the filters)
– Flow type of supply air
– The purpose for which the facilities will be used

Ventilation in class II rooms (with the exception of special facilities, such as laboratories, and pharmacies) two-stage air purification is used. The first filter should be at least F5-F7 to protect the air conditioner, the second F9 is to prevent air pollution particles (stops particles with large diameter ≥ 5,0 µm). DIN 1946-4-2008

Following are German recommendations for concentration of contamination in rooms of a low-turbulence flow of air (air-conditioned operating theatres and other rooms where a very high degree of air cleanliness is required, equipped with an operating theatre laminar flow ceiling with a HEPA filter): (a) dust contamination: recommended acceptable concentration of particles >0.5 µm: 4 000 particles/m3 of air; limit concentration of particles >0.5 µm: 10 000 particles/m3 of air; (b) microbiological contamination: recommended acceptable con centration of colonies of micro-organisms suspended in the air: 4 CFU/m3 of air and limit concentration of colonies of micro-organisms suspended in the air: 10 CFU/m3 of air. Those recommended values were formulated for an operating theatre which has been disinfected and in which operations are not performed during cleanliness inspection. (Charkoska, 2008)

Standard VDI 2167, "Building Equipment In Hospitals. Part 1. Heating, Ventilation And Air-Conditioning" is based on the Swiss SWKI 99-3 Standard. The only difference is that VDI 2167 does not contain the information about ventilation and heating for pharmaceutical manufacturing. The scope of VDI 2167 is for hospital buildings, clinics, rooms for surgery, room for burn patients.

Italy

The standard value for conventionally-ventilated operating rooms in Italy is 180 CFU/ m3 (ISPESL2010).

Poland

At present, Poland has no guidelines for acceptable levels of microbiological pollution in hospitals. The only source of information on acceptable micro-organism concentration is Kruczkowski's publication implemented in 1984 by the Ministry of Health and Social Welfare as an auxiliary source for the design of new hospitals and recommended in the modernization and refurbishment of existing ones. Hospital rooms are divided into three groups, depending on the acceptable level of bacteria in the air: (a) cleanliness class I (minimum level of bacteria) with acceptable bacteria concentration of up to 70 bacteria/m3 of air, (b) cleanliness class II (low level of bacteria) with acceptable bacteria concentration up to 300 bacteria/m3 of air and (c) cleanliness class III (normal level of bacteria) with acceptable bacteria concentration up to 700 bacteria/m3 of air.

Cleanliness Class I rooms include highly aseptic operating theatres (for transplantations, heart operations, treatment of severe burns, brain operations), sterile boxes, infusion liquids laboratories, the filling box and special wards (for patients with burns). Cleanliness class II rooms include aseptic operating theatres, septic operating theatres, plaster rooms in operating suites, intensive care units and wards, postoperative rooms, premature infant wards, patient preparation rooms (next to operating theatres) and surgeon preparation rooms, "clean" and "dirty" corridors, and sterilization rooms in operating suites. Cleanliness class III rooms include, among others, delivery rooms, treatment rooms (operating theatres and plaster rooms in

emergency wards), “clean” and “dirty” parts of central sterilization rooms, endoscopy rooms, light-treatment rooms, electro-treatment rooms, X-ray rooms, X-ray control rooms, blood drawing rooms in blood donation centers, photographic laboratories, diagnostic laboratories and apparatus rooms. (Charkowska, 2008)

Russia

Russia’s standard ‘Air Quality In Hospitals‘- RUSSIA:GOST R 52539 - 2006 establishes requirements for the air in the clean room. Russia defines 5 types of rooms based on the number of maximum allowable airborne particles (according to International Standard 14644-1) and the maximum permissible number of CFU per 1 m^2 of air.

Group 1 (ISO 5, SO 6) - the latter include operating. The cross sectional area of unidirectional airflow should be less than 9 m^2. The air flow velocity is in the range 0,24 -0,3 m/s. Allowed recirculation of indoor air. Laminar flow area must be equipped with vertical laminar flow and length of it must be not less than 0.1 m and the distance from the floor to the lower edge is at least 2.1 m. The maximum number of CFU per 1 m^2 of air equal to 5 for the zone of the operating table and 20 for the area surrounding it.

Group 2 (ISO 5, ISO 6) - Requirements for group 2 are similar to the requirements of the first group. However, the second group is the room with the patients. There must be airlocks (protected environments in which dust, dirt particles, and other contaminants are excluded partially by maintaining the room at a higher pressure than the surroundings).

Group 3 (ISO 8) - In these areas recommended to install a unidirectional flow with a smaller cross-section (4,3 m^2). The air must pass a three-stage filtration, including HEPA filter on the output. It is recommended that facilities in accordance with the requirements for Group 1. The maximum number of CFU per 1 m^2 of air is 100.

Group 4 - Emergency room, waiting room. These spaces generally use natural ventilation. The maximum number of CFU per 1 m^2 of air is 500.
Group 5 (ISO 8) - Insulators. Separate ventilation system is required for these areas with minimal air change rate 12 h-1 and the presence of the airlock. Air recirculation is not allowed and maximum number of CFU per 1 m2 of air is 100. 22

In Russia ventilation for clean rooms is regulated by different standards: SNIP 41-01-2003 "Heating, Ventilation and Air Conditioning", GOST 52539-2006 "Air quality in hospitals', SanPin 2.1.3.2630-10 "Sanitary - Epidemiological Requirements For Organizations Engaged In Medical Activities", SanPin 2.1.6.1032-01 "Hygienic requirements to ensure the quality of ambient air in populated areas", SanPin 2.1.3.1375-03 "Hygienic requirements for the placement, installation, equipment and operation of hospitals, nursing homes and other health care hospitals", GOST 51251-99 "Air cleaning filters. Classification. marking ", SNIP 06-31-2009 "Public buildings and facilities”.

South Africa

Operating theatres are considered “cleanrooms” and therefore subject to International cleanroom standards.

In January 2006, the Kwa-Zulu Natal Department of Health, issued a policy document statement entitled “Policy Document for the Design of Mechanical Installations” (Core Standards, 2006).

In this document, revised in January 2013, guidelines are established on the standards that are to be adopted and applied to operating theatres. The document further states that the Operating Theatre shall be validated on completion to ensure compliance with the Filtration and Airflow Requirements for Operating Theatres. This is done by means of a particle count and airflow measurements. Particles are measured according to their size and distribution. The particle count shall conform to ISO 14644 -1 [Cleanroom Classification Standard] HEPA filters and Laminar flow installations are required for Bone surgery, Heart surgery, Vascular, Neuro - Surgery and Transplants. All of the above theatres must conform to level 5 of the ISO 14644-1 standard. Minimum airflow rates shall be 0.35 m/s in laminar flow and 0.2 m/s in general theatres.

Sweden

Contrary to Germany where the air quality and cleanliness is evaluated by the DIN 1946-4: 2008-12 and is based on the measurement of particles in the operating theatre, in Sweden, the focus is on biological contamination and the use of microbiological methods for the assessment and surveillance of the OR ventilation (SIS-TS 39: 2015) and is qualified by detecting the number of ‘germs’ in the air (Kruczkowski, 1984).

Switzerland

Switzerland adopted Swiss Guideline SKI Bulletin 4, to regulate air quality in operating rooms. It is based on the German standard DIN 1946, Part 4 (Ventilation in hospitals, 1963). (Brunner. 2012). This was followed by a standard "Guidelines for the construction operation and maintenance of air treatment systems in hospitals". (Komfort life). This standard establishes several groups of rooms by the number of particles in them. A new 2003 standard updated and adopted SWKI 99-"Heating, ventilation and air conditioning systems in hospitals (design, construction and operation)" for ventilation in hospitals. In this standard, they abandoned traditional methods for assessing air quality. Instead the recommendation was to assess air quality by the concentration of microbiologically contaminated (CFU). (Alexander, 2010)

The Swiss standard divides operating rooms into the following microbiological cleanliness classes: I (a very low level of microbiological contamination) with the acceptable quantity of micro-organism colonies of ≤10 CFU/m3 (colony forming unit per cubic metre) of air, IIb (a low level of microbiological contamination) with the acceptable quantity of micro-organism colonies of 50 CFU/m^3 of air, II (a low level of microbiological contamination) with the acceptable quantity of micro-organism colonies of 200 CFU/m^3 of air and III (a

normal level of microbiological contamination) with the acceptable quantity of micro-organism colonies 200 CFU/m^3 of air.

Swiss guidelines classify hospital rooms as follows: (a) class I, operating theatres used for transplants, orthopedics, cardio-surgery; intensive care units for patients undergoing immunosuppressive therapy after bone marrow transplantation; rooms for patients with extensive burns; and specialist laboratories (serum production, preparation of transfusion fluids); (b) class II, operating theatres of lower requirements, also at emergency wards; preoperative rooms; corridors in operating suites; premature infant wards and delivery rooms; intensive care units for surgery and internal departments; and rooms for patients with less severe burns and (c) class III, intensive care units for patients with coronary diseases, delivery rooms and children's wards, central sterilization rooms, surgeries and wards, changing rooms, X-ray rooms and control rooms, gym halls, central bed stations, sterile storerooms, laboratories, corridors, kitchens and laundry rooms. In the ORs with LAF, the surface area of laminar ceiling shall not be less than 9 m^2, air passes through three stages of cleaning filters. The surrounding laminar ceiling aprons must end at a height of a door or at 2.1 meter from the floor. Supply air velocity in LAF should be in the interval 0,23-0,25 m/s. The air temperature must be regulated and vary within 19-26 C. (Clean room technology 2001)

United Kingdom

In the UK, the limit is 35 cfu/m^3 for an empty operating theatre. In an active OR it should not exceed 180 cfu/m^3 for an average of 5 min period. In an ultra-clean air OR, the limit is set at less than 10 cfu/m^3 sampled within 30 cm of the wound using conventional clothing. The limit is set at less than 1 cfu/m^3 of air when total body exhaust gowns are used (NHSE, 1994). With the use of HEPA filters in operating theatre ventilation, there is a tendency to apply clean room technology standards used in industry for hospitals (Al Waked 2010). British Standard 5295-1 (1989) is based on measuring the presence of particles of varying sizes and number.

Limited advice exists on conventionally ventilated and UCV theatres in the UK Health Technical Memorandum (HTM) 2025.1 The HTM gives limits on the microbiological (bacterial and fungal) content of air in empty and working theatres, but states in a margin note `precise guidance is inappropriate and will depend on local circumstances'. Whilst this remains true, it is apparent that many would welcome some advice on infection control aspects of these matters

The Joint Working Party On Ventilation In Operating Suites (`The Lidwell Report' 1972) advised that clean areas (operating theatre and preparation room) should have ventilation equivalent to 20 ACH. If theatres are built to the size specifications in HBN 265 and have ventilation rates specified in HTM 2025,1 there should be between 19.5 and 23 ACH in the theatre (i.e., ventilation rates in operating theatres should equate to around 20 ACH or above). The air change rate in preparation rooms used for laying-up sterile instruments should be around 37 ACH; a greater air change rate than in theatres. (Hoffman, 2002)

Wales

The Welsh standard allows local recirculation in the OR using HEPA-filters. The CFU/ m^3 in one cubic meter depends on the number of people in the OR, the use of special staff clothing and the type of ventilation system. HTM 03-01 specifies that the number of bacteria in the air should not exceed 10 CFU/m^3. Velocity in the operating room at one meter from the floor must be within 0.2 – 0.3 m/s, and the relative humidity within 35-60%.

Welsh standard Health Technical Memorandum 03-01: Specialized Ventilation For Healthcare Premises consists of two parts:

- Part A. Design and validation;
- Part B. Operational management and performance verification.

Rooms in the Health Technical Memorandum are divided into sterile (preparation room, operating room, scrub bay), clean (sterile pack bulk store, anesthetic room, scrub room), transitional (recovery room, clean corridor, general access corridor, changing rooms, plaster room) and dirty (service corridor, disposal) (HTM 03 01 Part A).

Final Thoughts

The difference in the design of the laminar airflow systems in hospital ORs and facilities designed to meet ISO requirements can be radical. In ISO Class 1 to Class 4 cleanroom environments, nearly every square inch of ceiling space is utilized, ultimately forming a single large diffuser, to optimize airflow and particle containment. Maximizing the amount of surface area in the space from which supply air is flowing is critical to achieve the ultimate goal of laminar airflow—minimize turbulence to produce predictable movement of particles away from the sterile field.

In comparison, hospital OR systems typically consist of multiple laminar flow diffusers arranged in a variety of arrays intended to optimize airflow, temperature and humidity control in the space. In most cases, the arrangement of these diffusers over the operating table—with large gaps in airflow delivery for light troffers and other components—would be unacceptable by ISO Class 1 to Class 4 cleanroom standards. The gaps produce low pressure areas that the surrounding airflow will flow into, ultimately resulting in turbulence.

Given the quality of care, economic and public relations consequences of SSIs, consideration should be given to rethinking the requirements for the operating room to include some measure of aerobiological quality standards. The technology and design practices have already been successfully implemented by semiconductor, pharmaceutical and other critical-process manufacturers facing similar consequences in a different context. International standards currently exist that identify the size and quantity of particulates allowed in a given space over a given amount of time.

Granted, many obstacles exist within the operating environment that challenge the feasibility of achieving 100 percent laminar airflow. Booms, lights, monitors and other equipment in the operating room can interfere with ideal airflow conditions. But facing these challenges head-on to advance the typical operating room beyond current design standards can prove to be a worthy venture toward improving the quality of patient care and benefitting the financial bottom line of healthcare facilities.

For example, an operating room requires a minimum of ISO Class 7, which allows 352,000 particles per cubic meter in the size range from >=0.5 µm. An ultra-aseptic operating room can require ISO Class 5, which allows 3,520 particles in this particle size range. In comparison, the ambient air outside in a typical urban environment contains 35 million such particles (Schreiber, 2012)

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