CONCISE COMMUNICATION

A Road Map to a Comprehensive Regulation on Ventilation Technology for Operating Rooms

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Among strategies to reduce surgical site infection (SSI) risk, we concentrate on the optimization of the air quality through the heating, ventilation, and air conditioning (HVAC) system. Current ventilation standards applied by some European countries have been compared and show uncertainty in the criteria for dimensioning the HVAC system. The development of a comprehensive regulation needs further discussion.

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Hospital infection rates, and particularly the surgical site infection (SSI) rate, are important indicators of the quality of health service delivery. SSI rate is currently one of the most widely used hospital-quality indicators worldwide.[1] The reduction of airborne contamination has been shown to be important for the minimization of SSIs, especially in implant surgery.[2,3] The most important source of airborne contamination is represented by particles dispersed from persons in the operating room (OR) and the movements of those particles.[4] The heating, ventilation, and air conditioning (HVAC) system addresses the issues related to environmental comfort and health protection. The features of health protection are control of chemical contamination (anesthetic gases) and removal of airborne bacteria. In addition, the HVAC system offers a comfortable indoor environment by controlling the temperature and humidity of the room. Two types of ventilation dynamics are investigated in the literature: the unidirectional or laminar airflow (LAF) system and the turbulent or conventional system, with some combination of the two schemes also possible. In surgical rooms that use turbulent airflow systems, conditioned air is supplied through diffusers installed on the ceiling. The incoming air is quickly and evenly mixed with air in the environment, with the purpose being to dilute pollutants in the whole room volume. In the systems that supply unidirectional airflow, a low-turbulence downward displacement of air is delivered by a large surface over the operating area, which is intended to create a protective airflow around the patient.

METHODS

The following 4 technical standards have been analyzed: the French standard NF S 90-351:2003-06,[5] the Italian standard UNI 11425:2011-09,[6] the German standard DIN 1946-4:2008-12,[7] and the British standard HTM 03-01:2007.[8] Particular attention has been given to the model of air distribution inside the OR and to the type of the qualification adopted to prove that the ventilation system achieves the operating performance originally specified. Different classifications of the ORs have been explored with respect to indoor air quality, and numerical values for some of the most important design parameters applicable to newly built facilities have been reported for ORs that require the highest sterility of the air.

RESULTS

According to the analyzed standards, the airflow pattern inside the OR is specified on the basis of the required protection level. Turbulent or mixed airflow is normally used in general surgery ORs. It is not recommended for specialized surgery (ie, surgery with prosthetic implant, organ transplantation, complex surgical oncology, neurosurgey, cardiovascular surgery [eg, vascular prostheses], and surgery with very high incision-to-closure time). A unidirectional airflow is recommended for interventions associated with a high risk of infection (eg, those mentioned above), with air changes per hour depending on the country (Table 1). Inside the OR, the best possible condition of asepsis must be created in the protection area, which is a standard-size area of 9 m^2, including instrument tables and the operating site.

Criteria for OR classification that are considered by the analyzed countries are particle contamination, recovery time, and microbiological contamination. Limits for these parameters are provided for ORs at rest on the basis of cleanroom classes specified by ISO 14644.[9] For example, an ISO 5 cleanroom class means that less than 3,520 particles (0.5 microns in size) are present per cubic meter. Germany and the United Kingdom provide limits for particles and microbiological concentration, respectively, for ORs in activity (Table 1). They also give specific procedures for the qualification of the OR that are based on measuring the particle concentration in the protection area while the OR is loaded with a reference particle load. People (such as the surgical team and anesthesist), equipment, and surgical lamps are also simulated in the test OR specified by the German document. The most relevant physical parameters for the OR environment are specified in Table 2.

DISCUSSION

The comparison among OR ventilation standards highlights different approaches among countries, even if some similarities can be evidenced. Some standards do not present all of the requirements, and there are no standardized limits for

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TABLE 1. Operating Room (OR) Classification Parameters and Ventilation Requirements

	Limits for OR classification parameters					
	Particle contamination			Microbiological contamination		
Standard, airflow distribution system	At rest	In activity, particles/m^3	Recovery time, min	At rest, cfu/m^3	In activity cfu/m^3	Total ACH
NF S 90-351:2003-06, unidirectional	ISO 5	NS	10	10	NS	50 vol/h
UNI 11425:2011-09, NS	ISO 5	NS	NS	NS	NS	15 vol/h
DIN 1946-4:2008-12, unidirectional	NS	3.5×10^5	NS	NS	NS	8,800 m^3/h
HTM 03-01:2007						
Unidirectional	NS	NS	NS	NS	10	11,900 m^3/h
Turbulent	NS	NS	NS	10	180	11,900 m^3/h

NOTE. ACH, air changes per hour; cfu, colony-forming unit; ISO 5, less than 3,520 particles (0.5 μ in size) present per cubic meter; NS, not specified; vol, air volume corresponding to room volume.

the common requirements at present, thus showing uncertainty in the criteria for dimensioning the HVAC system.

Ventilation parameters, such as supply air temperature and air change rate, are different from one country to another, which leads to different ventilation options. In addition, different types of ventilation systems not only have different airflow dynamics and parameters but also have different design, dimensions, applicability, and costs. Hence, in assessing the performance of existing ventilation systems, all of the above aspects should be considered and integrated.

Although both unidirectional and turbulent ventilation systems are sensitive to objects and movements, intraoperative activities performed in an OR with unidirectional airflow, if not correctly managed, have more serious implications with respect to infection control issues, because people and their movements could disrupt the air displacement. This effect is emphasized with increasing volume flow rate. The physical barrier due to extra walls adopted in some countries (eg, the United Kingdom and Germany) can further decrease the versatility of the OR and limit its use to certain surgical procedures. Possible transportation of microorganisms from the floor or the periphery of the room into the operation zone is the main disadvantage of the turbulent system, which has a less protective effect with respect to cross contamination. However, it imposes less restrictive working conditions inside the OR.

Resources put into a specialized ventilation installation can be considerable, especially when high values for the rate of air change have to be achieved. For that reason, the decision regarding which ventilation model is suitable should involve careful consideration of the problem of existing facilities that do not fulfill the specified hygienic requirements.

Another issue to discuss is the method used to check the level of contamination within the OR once the theatre has been put into use. Microbiological sampling is not recommended as a routine test and should be restricted to part of a specific investigation (eg, investigation of an epidemic) and validation procedures of the OR. Particle counts in the operating theaters are recommended as routine procedure by most European countries, although they are based on standards developed for cleanroom technology used in industry,[9] and thus should be performed only in empty theaters. The importance of assessing the OR air quality during operation has been focused on by the regulations from Germany and the United Kingdom. Details given on the hygienic qualification of ORs make the above standards closest to a prospective harmonized regulation. However, some limitations of the qualification tests in reproducing real operating conditions should be further addressed.

On the basis of the above consideration, it can be concluded that it is very difficult to assess how a general, abstract model of ventilation is effective in infection control in the OR, because SSI rate is affected by many other confounding factors, and ventilation performance itself is affected by the great variability of the operating conditions. The applicability of the ventilation system in clinical practice should be discussed by each hospital on the basis of the available resources and ordinary surgical activity.

Although the LAF system is recommended by all countries for surgical procedures associated with a high risk of infection,

TABLE 2. Physical Parameters of Operating Room Environment

Standard	Room temperature, °C	Supply air temperature, °C	Relative humidity	Pressure differential, Pa
NF S 90-351:2003-06	19–26	...	45–65	≥15
UNI 11425:2011-09	20–24	...	40–60	15
DIN 1946-4:2008-12	...	19–26 (adjustable)	...	...
HTM 03-01:2007	18–25	...	35–60	≥25

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clinical studies to support a clear cost benefit for patients are lacking in the literature. The latest clinical studies and a recent meta-analysis have even pointed at the LAF system as a risk factor for severe SSI.[10] In addition, it is worthwhile to remember that the ventilation system is only one of many factors that can contribute to a safe operating environment.

Issues related to architectural requirements and behavioral and hygienic procedures should be more carefully addressed by hospitals, given their role in enhancing the effectiveness of the ventilation. Monitoring and control systems should also be implemented to keep the operating suite within the required environmental parameters. Reliable statistics should then be collected to suggest the suitable ventilation parameters and to prove that the chosen ventilation system is appropriate for the purpose of controlling infection.

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