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ORIGINAL PAPER

The management of air contamination control in operating theaters: the experience of the Parma University Hospital (IT)

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Abstract As part of the overall management of a Hospital, the Hygiene Unit has specific tasks including the improvement in the levels of hospital safety by air quality monitoring in hospital environments to control the sources of infection and assessing the healthiness of hospital facilities. Operating theaters (OTs) and cleanrooms air quality control can represent a focal point considering that environmental contamination depends on not only factors such as characteristics and level of maintenance of Heating, Ventilation and Air Conditioning systems (HVAC), but it also depends on the number of people present, their behavioral habits, sanitation and disinfection procedures adopted. Several studies demonstrate a high variability in microbial air contamination in different OTs with similar HVAC, suggesting the need for achieving strict control over the factors affecting air quality. The control of air contamination, as an indicator of the quality care provided, therefore sets precise objectives, accuracy from a scientific point of view including planning, analysis and interpretation of results to propose corrective actions. However, there are no generally accepted standards for sampling nor threshold values on microbial air contamination. Aerobiology skills can improve the approach to involved issues. The monitoring plan of air quality assessment at the Parma University Hospital, by the Laboratory of Aerobiology, involves approximately 80 environments equipped with turbulent or mixed air flow. This paper describes the practical approach to air contamination control of the Hospital Hygiene Department at the Parma University Hospital as an example of how Health Departments can improve safety standards for patients and operators.

Keywords Aerobiology · Operating theaters · Contamination control · Air quality

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1 Background

Healthcare is a complex system where there are specialized skills with health, professional, technical, economical and administrative roles. All elements must be integrated and coordinated to achieve the primary goal: patient care guaranteeing high-level performances and equally high safety standards for patients and operators. Hospitals are one of the most complex systems constituted by man with high risk situations. As part of the overall management of a Hospital, Health Department and Hygiene Unit have specific tasks including increasing efficiency and performance, improving the internal and external

image of the hospital also taking care of legal medical aspects, improving the levels of hospital safety also intended as a work environment, decreasing direct and indirect health costs, including those deriving from infections related to hospitalization and among these the surgical site infections (WHO 2016; Buttazzi et al. 2018). Considering that several studies demonstrate a high variability in microbial air contamination in operating theaters (OTs) with similar forms of Heating, Ventilation and Air Conditioning systems, HVAC, (Agodi et al. 2015), the need for air monitoring in critical hospital environments and a strict control over the factors affecting air quality can be suggested. From this point of view, air monitoring can constitute a means of checking the sources of infection and assessing the healthiness of the hospital facilities and it represents an indispensable tool for maintaining proper management. Unfortunately, the context of the air monitoring activity has not always been encouraged; indeed, it has even been discouraged (Eickhoff 1970, 1994), and even now the orientation is not unambiguous. The role of air as a vehicle for infection, particularly in OTs, the usefulness of its biological monitoring and the methodology to be used have always been the subject of great interest and discussion. Air quality control takes on particular significance within the OTs and cleanrooms that represent a focal point as they concentrate the majority of nosocomial risks, including the biological one, in a small space. Lidwell et al. (1982) established relationship between airborne bacteria and surgical infections (in arthroplasty). Whyte et al. (1982) estimated that 98% of the microorganisms that are deposited on a surgical wound (arthroprosthesis) carried out in the conventional OTs derive from air. Of these, 30% is deposited directly, and the remaining part can arrive indirectly through surgical instruments, canvases, etc. So, in OTs, air biological quality is, however, one of the parameters to be kept under control for the prevention of surgical wound infections, in particular in clean operations.

Environmental contamination depends on several factors: characteristics, effectiveness and efficiency of the HVAC, characteristics of the surgical intervention, surgical duration, sanitation and disinfection procedures adopted, number of people present and their behavioral habits, etc.

So it is important to verify and guarantee efficiency and effectiveness of the plants and hygiene and cleaning procedures (*as built* and *at rest* conditions) and in addition the procedures and behaviors of surgical staff (*in operation*). Industries, such as microelectronics and pharmaceutical, benefit from the control of airborne contamination regarding their specific processes, in cleanrooms. OTs are considered « cleanrooms » and therefore must meet International cleanrooms standards, in particular for airborne particle contamination, with appropriate threshold.

The British guidelines (National Health Service 1994, 2007) and UNI EN ISO 14644:2001 represented the reference (microbiological and particle monitoring, respectively) for the Italian ISPESL guidelines (1999, 2009). In Italy, UNI 11425:2011 referring among others to the particle monitoring is another important reference for air quality in OTs. ISPESL guidelines do not take into account all the aspects that affect the monitoring in every day as the interpretation of the results of fungal detection. For this purpose, to refer to SF2H (2015) and to CCLIN Sud-Ouest (2016) and both referring to NFS 90351 (2013) can help.

Cleanrooms monitoring referring to GMP annex1, 2008, must be compliant with the ISO 14644 cleanrooms standards. In addition, referring to UNI EN ISO 14644:2016, monitoring activity cannot ignore risk assessment that must precede and direct the monitoring activity itself. Risk assessments examine holistically two main aspects, that are, the likelihood that an event may occur and if it does what the consequences are. Monitoring activity must have clear objectives, accuracy and must include planning, proper analysis and the interpretation of results. Despite the verification of the good functioning of the plants *at rest*, risk factors for particle contamination of air in OTs *in operation* should be considered. A well-designed HVAC provides for the effective dispersion and removal of particulate contamination, but in operation, the frequency of door opening remains the main negative predictor for the presence of dust particles. Furthermore, OTs are characterized by constant exchange between airborne and surface contamination. Airborne pathogens settle on surfaces and surface-bound microbes are released into the air. Surgical site infections caused by intra-operative contamination mainly originate from microbes carried by airborne particles, which settle on the surgeon's hands and instruments.

In the overall management vision of a health care company, the possible legal implications of this control system must not be neglected, and this can allow the Hygiene Unit to protect itself by demonstrating that it has met all the standards required for the proper management of cleanrooms.

A monitoring system intended as a management system, especially if aimed at safety, must be appropriate to the company size, to the activities carried out, to present risk. It must have an organizational structure, precise responsibilities and well-defined procedures, and it must be carried out by motivated, qualified, specially trained and continuously updated personnel. It is important that adequate procedures are defined for the communication of results and corrective actions, in case of anomalous situations, must be planned. The decision to use a management tool like that of microbiological and particle air monitoring must, therefore, takes place in a pragmatic way, and it is essential to pay particular attention to the involvement of health workers.

2 Air contamination control at the Parma University Hospital

At the Department of Hygiene and Preventive Medicine of Parma University Hospital a dedicated team, consisting of the Laboratory of Aerobiology, has been established. The monitoring team carries out its activities in close collaboration with surgical and cleanrooms teams. The activity has an annual schedule shared with the technical department that deals with ordinary and extraordinary maintenance of what refers to physical parameters. The microbiological and particle monitoring plan of air quality in Parma University Hospital involves (i) 22 turbulent flow OTs; (ii) 5 mixed flow OTs; (iii) 14 turbulent flow outpatient surgeries; (iv) 7 bone marrow transplantation care rooms; (v) 15 labs for cancer chemotherapy preparation; (vi) 8 labs for medically assisted procreation; (vii) 3 stem cell labs; (viii) 2 sterilization labs; (ix) 2 transfusion labs; (x) 2 neonatology isolators. For each OT, outpatients' surgery or cleanrooms, monitoring activity is scheduled at least every 12 months, or it is carried out after refurbishment, maintenance or change of HEPA filters, however, when it is deemed necessary. On the date established for each OT or laboratory, subsequent cleaning and environmental disinfection, according to the specific hospital protocol, were done. At the end of cleaning, access to the premises, until the execution of microbiological monitoring of air and surfaces and of airborne particles, is forbidden. The clearance for the recovery of the care activity is issued only after the verification of the results of the samplings and the consequent requalification of the plants.

For instance, we report the results of *at rest* air monitoring carried out in 2017 in: 22 turbulent flow OTs, 5 mixed flow OTs and 14 turbulent flow outpatient surgeries. Particle sampling points and volumes recorded were calculated according to the UNI EN ISO 14644-1:2016. Active microbial air sampling was carried out according to UNI EN ISO 14698-1:2004 and UNI EN ISO 14698-2:2004. Tryptic Soy Agar (TSA) and Sabouraud Dextrose Agar (SDA) were used for total and fungal count, respectively. TSA plates were incubated at 36 ± 1 °C for 48 h and the SDA plates at 25 ± 1 °C for 120 h. After scotch test of fungal colonies, the slides were stained with lactophenol blue for microscopic observation and recognition. Operational clean corridors were sampled as experimental controls.

Table 1 summarizes the results of *at rest* monitoring plan carried out at University Parma Hospital in OTs and outpatient surgeries showing how planned monitoring activity contributes to obtain good standing air quality well below not only the recommended limits, but also the proposed benchmark (Pasquarella et al. 2012).

Results are shown as median: particles/m^3 491 in mixed flow OTs, 372.5 in turbulent flow OTs, 1166 in turbulent flow outpatient surgeries; ISO Class 5 in all sampled environments; total CFU/m^3 0 in mixed flow OTs, 0 in turbulent flow OTs, 0.25 in turbulent flow outpatients' surgeries and 37 in corridors (*in operational*); fungi CFU/m^3 0 in all sampled environments. Rarely, in corridors and only in one outpatient surgery, 1 CFU/m^3 of *Penicillium* spp. and *Aspergillus* spp. was observed.

3 Conclusions

The control of air contamination therefore sets precise objectives: (1) to evaluate the efficiency of the HVAC; (2) to represent a tool for staff training, verifying the behavior of health workers; (3) to check the cleaning

Table 1 Particle, total microbial and fungi air contamination of air and ISO classification in *at rest* OTs and outpatient surgeries at rest during in 2017: minimum, median and maximum values

OT	Particles ≥ 0.5 μm			ISO class			Microbial total count CFU/m^3			Fungi CFU/m^3		
	Min	Median	Max	Min	Median	Max	Min	Median	Max	Min	Median	Max
Mixed flow	51	491	1016	3	5	5	0	0	0.25	0	0	0
Turbulent flow	26	372.5	52,089	4	5	7	0	0	2	0	0	0
Turbulent flow Outpatient surgeries	136	1166	121,907	4	5	7	0	0.25	10.2	0	0	1
Corridors (in operation)	ND			ND			12	37	93	0	0	3

In operation Corridors as experimental control

ND not done

and disinfection procedures; (4) to guide preventive interventions. Air monitoring can be an indicator of the quality of care provided by a healthcare facility and a quality control system for OTs and other cleanrooms, as a process indicator. Carrying out air monitoring in environments at greatest risk, also highlighting the efficiency of HVAC, may represents an instrument that also certifies the correct management for the purposes of the accreditation request and for legal aspects.

The monitoring activity carried out by the Parma University Hospital over the last 20 years can be a useful example of how Health Authorities can identify a path aimed to the prevention and knowledge of airborne contamination in OTs to manage it properly. The Hospital Hygiene Department plays a central role to check environmental quality and infectious risks in hospital cleanrooms by a multitasking approach and multidisciplinary dedicated teams.

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