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Indoor environmental quality in Operating Rooms: An European standards review with Regard to Romanian Guidelines

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Abstract

Operating Rooms require efficient Heating Ventilating and Air Conditioning systems to secure the highly demanding indoor environmental quality for patients and medical staff. In this article we are passing in review the main European Standards on design, indoor thermal conditions, and operation, of Heating Ventilating and Air Conditioning systems for Operating Rooms. The commonly encountered problems on real sites include insufficient indoor air exchange, poor control on indoor thermal conditions, ventilation system operation and poor operation. The principal conclusion is that there is a lack of specifications and uniformity in the existing standards, which, in most of the cases, do not impose very strict values as it would be advisable for this kind of indoor environment. This applies to both International and Romanian standards. In conclusion, there is needed a new re-evaluation on the standards regarding indoor air quality domain in hospitals. This approach should be based on existing standards built around previous experience and benefit from nowadays survey studies that underline on-site problems. This will lead to improved, high quality medical units with low airborne infection rates, where the environment will be comfortable for both, patients and medical staff.

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1. Introduction

The health care units must provide a suitable environment to treat ill people. An over deterioration of the patients' health caused by nosocomial infections may seem an ironic idea, but it is unfortunately an encountered situation, especially in developing countries. There are countries that suffer high Postoperative Infection Rates (PIR) in their hospitals, in Brazil, for example, 15% PIR being reported while in Europe and United States the highest PIR is in general 5% [1-3]. Of course, the incidence of nosocomial infections depends on many considerations, like the type of operating room (OR), the ventilation system or the type of the medical procedure. The risk of hospital acquired infection is present in all medical procedures, especially when referring to surgery and it can be particularly serious in certain types of operations, i.e. joint replacement [4]. There are many factors involved for this risk, like patient factors (risk to infection i.e. low immune system), room factors (cleanliness and substances used in the environment), surgical factors (thermal plume from site) or HVAC (heating, ventilation and air conditioning) factors which involve an airborne route [5, 6] (air change rate and direction of airflow). All these causes influence the recovery of the patient during hospitalization. An inappropriate HVAC system can seriously affect the post-operative healing process by bringing pathogen agents in the incision zone [7].

It is very important to maintain a good Indoor Environment Quality (IEQ) in the medical facilities in order to ensure health and safety for both the patients and the medical staff, or any other occupant of health care buildings. Their state of health can be seriously affected by multiple exposure types, which can either have sensitizing or allergenic properties or even toxicological and infectious effect. IEQ refers to the quality of an occupied space in relation to the health and wellbeing of its users. IEQ is determined by many factors, including air quality, thermal comfort, and lightning. Even if lightning is very important for Operating Rooms, we will however refer here to Indoor Air Quality and Thermal Comfort in the following. In accordance with ASHRAE [8], the IEQ of a space is determined by the level of indoor air pollution and other features, including the air temperature, relative humidity or air speed. In this conditions, setting these parameters in a medical unit means to specify proper air-conditioning and ventilation scheme for an optimal indoor environment.

The Chapter 65 of the Indoor Air Quality Handbook [9] presents at the beginning the exposure types that might occur in hospital facilities in general and in operating rooms in particular. These exposures are affecting in equal manner the patients, the medical staff and the visitors. We see here different effect categories: sensitizing and allergenic agents, irritants, direct toxins, mutagens and teratogens and infectious aerosols. In fact, the great majority of chemical substances used normally in the healthcare facilities can easily lead to allergies, poisoning, while infectious aerosols are representing a potential hazard for wounds and might cause infectious diseases. This way a good control of the air quality means a significant consideration of the aerosols, anesthetic gases and surgical smoke. The emerging hazards are then quickly reviewed in the following: anesthetic gases, the surgical smoke and certain aerosols being the causes that affect indoor air quality.

The anesthetic gases used in ORs should be considered when considering the unnecessary exposure of healthcare workers, who inhale anesthetic agents from leaking. Anesthetic gases are released into the environment or because the patient exhales or either because of problems caused by equipments. Exposure measurements taken in ORs during the clinical administration of inhaled anesthetics indicate that waste gases can escape into the room air from various components of the anesthesia delivery system [10]. Potential leak sources include valves, high- and low-pressure connections in the system, connections in the breathing circuit, defects in tubing, hoses, bags, and ventilator bellows, and the Y-connector. Moreover, some anesthesia techniques or improper practices such as leaving gas flow control valves open and vaporizers on after use, leaks of liquid inhaled anesthetics, and poorly fitted face masks or can allow of waste anesthetic gases into the OR atmosphere. However some gases, for example NO2, will continue to be exhaled by the patient for up to one hour after the surgery is finished [11]. During surgery high concentrations of gas can be found at floor level, so the movements of the occupants can lead to a mixing with the room air which is inhaled by the medical personnel.

Gas concentration level in the operating room is critical and must be controlled, otherwise the procedures' quality of the surgical team can decrease and in medium to long term health problems may arise, leading even to occupational diseases [10]. Certain types of anesthetic gases can have a high toxicity and can affect the central nervous system [12, 13]. The gas concentration is controlled by the air change rate by dilution to acceptable levels.

The surgical smoke can be generated by electro, laser or ultrasonic surgery, those kinds of procedures being used more and more frequently. A laser operation involves a smoke thermal plume which contains particles and small tissue fragments, but also gases released from the incision zone. Research studies have confirmed that this smoke plume can contain toxic gases and vapors such as benzene, hydrogen cyanide, and formaldehyde, bio-aerosols, dead and live cellular material and viruses. The smoke may cause eye and upper respiratory system irritation of the personnel and might create visual problems for the surgeon. The smoke has unpleasant odors and a mutagenic potential [14]. The authors in cigarettes [15] explain that 1 g of tissue would create a smoke plume with a mutagenic effect equivalent to smoking 6 unfiltered Furthermore, the pathogenic characteristics of the organic particles were studied, and it has been shown that malignant cells may exist in the plume [16] and infectious particles may spread out from the incision with an unknown level of potential hazard [17].

When talking about aerosols, we consider any solid and liquid particles or even microorganisms, dispersed in the air. While patients are often the main source of infectious agents, the hospital environment is also a source of pathogenic agents, given the repeated exposure to high enough concentrations of substances for the occupants. In the operating rooms the main sources of aerosols are the patients, surgical team and the equipment used. The infectious aerosols are a potential hazard to both patients and employees as common infectious diseases, but the most unwanted effects are the post-operative wound infections. The medications that are supplied as aerosols and delivered via inhalation to the patients require an additional attention due to the fact that is was proven in time that longer exposure to these substances can have side-effects [18]. The aerosols sources could also be introduced from outside when the filters are not efficient, or because of air infiltration due to improper room pressurization. Using an appropriate filtration module for these types of pathogen agents, the ventilation system is responsible for the adequate dilution of the pollutants concentration.

The ventilation system has an important role in assuring a proper environment for medical procedures. In operating rooms and other healthcare facilities, there are four strategies proposed for the health protection regarding to IAQ: the number of air changes per hour, the air distribution, the room pressurization and the filtration. In all international guidelines it is recommended in general a low velocity unidirectional flow, which was proven to be in most of the cases a better solution to minimize the spread of airborne contaminants.

On the other hand thermal comfort is a sensitive concept depending on all the factors that influence the exchange of heat between the human body and its environment. It can be differentiate between factors connected with the human organism like the age, gender, weight, metabolic rate, type of activity, etc., factors connected with the clothing like thermal resistance, material structure, number of layers, and factors connected with the environment like air temperature, velocity, humidity, pressure and turbulence intensity and frequency [19, 20]. Extensive investigations and experiments involving numerous subjects have resulted in methods for predicting the degree of thermal discomfort of people exposed to a still thermal environment. The most well known and widely accepted methods are: Fanger's "Comfort Equation" and his practical concepts of "Predicted Mean Vote" and "Predicted Percentage of Dissatisfied" [21] and the two-node model of human thermoregulation [22, 23]. We have to note that most work related to thermal comfort has concentrated on steady state conditions. Because of the interactions between building structure, occupancy, climate and HVAC systems, pure steady-state conditions are rarely encountered in practice [24, 25]. This issue is even more obvious in the case of special situations such as OR where special requirements are defined in order to meet the needs of the patient, of the surgical team and also to ensure the security aspects of the infection control.

The review of the principal European standards regarding IAQ and thermal comfort in ORs that we propose in the following shows that there is no coherence between the guidelines, the prescriptions and the national regulations.

2. European standards

In Europe several directions were used to indicate the guidelines for the design of HVAC systems in healthcare facilities. While UK is related more to the American standards, the Centre Europe has its own regulations, by merging German, Austrian and Swiss standard. Other standards from France and Spain are discussed further.

In Germany several technical associations proposed different guidelines along the years, but first regulation is DIN 1946-4 [26]. This standard had several revisions, in 1989, in 1999 and finally in 2008, when serious changes were made in the newest form of the standard DIN 1964-4/2008 [27]. In parallel institutes from Germany, Switzerland and Austria have issued a common general guideline. In 2000, the 'Robert Koch-Institute' published a new guideline on hygiene [28] which recommended an unidirectional airflow ventilation, resulted from an appropriate size of the ceiling. To develop technical guidance for HVAC systems in hospitals, the German Society for Hospital Hygiene [29] sets out several recommendations for healthcare facilities and also a set of requirements for operating rooms, together with their partner organizations.. A very important recommendation is to avoid air contamination in the area immediately surrounding the operating table and equipments that could lead to direct or indirect pollution of the surgical site. These areas could be separated from surroundings by a steady stream of air that has been filtered to remove particles, leading to the use of dynamic protected area maintenance principle. A vertical low-turbulence displacement flow with a degree of turbulence intensity less than 5% is considered to be an appropriate flow for the operation area. Furthermore, a "laminar" vertical air flow is highly recommended. The air diffuser should be around 3m x 3m, in order to ensure the proper protection for the operating and the instrument table. Particulate class H14 (efficiency ε=99.995%) filters are recommended as a terminal filter stage, while the retention capacity of impact filters might be of lower classes H10 (ε=85%) to H13 (ε =99.95%). It is recommended also to provide temperatures from 18°C to 24°C (sometimes as high as 27°C for pediatric surgery) in terms of comfort aspects and the humidity level below 50%. There are also recommendations for: the temperature of the supply air that has at most 0.5 °C lower than the ambient temperature and the outdoor air flow between 800m3/h and 1200 m3/h due to the anesthesia gases.

The Dutch recommendations regarding hospitals are presented in [30], a general guideline design criteria involved for ORs. Many details are discussed, including the types of ventilation systems applicable in The Netherlands and some requirements for the IAQ. The “laminar” down flow plenum with three different shapes (rectangle, T and octagonal) is the recommended type of ventilation system. This system will lead to different protection levels for the patient because of the airflow dynamics and even allows having different temperatures in the supplied air. The recommendations are: filter F5 (ε =40-60%), F7 (ε =80-90%); F9 (ε >95%) and H13 (ε =99.95%); supplied air temperature of 21°C ± 3°C. Because of the different activity level of the medical personnel in the OR, there are different temperatures suggested for the surgical staff: 18 °C for the surgeon and 22 °C for the anesthesiologists, being one of the few recommendations in the world which mentions different parameters in the surgical field in order to obtain maximum comfort for all the occupants involved. One missing point in this document is information about other parameters like relative humidity and air velocity.

In the French norm NF S90-351[31] the ORs are classified in four levels of risk area (from low risks to high risks). The risk is defined in terms of the medical procedure (duration, complexity, etc.) or the patient’s state of health and not through the type of surgery like in other cases. As an example some recommendations for level 4 of risk are: international classification for air purity ISO 5, Bacteriological class B10, minimum filtration chain – F6 (ε =70-80%) then F7 (ε =80-90%) and H13 (ε =99.95%). A ceiling diffusion and unidirectional flow (laminar) is recommended, with more than 50 h-1 air change rate, while for other classes like 2 and 3 significantly lower values are needed: 15 to 25 h-1 air change rate, respectively 25 to 30 h-1 air change rate.

The Spanish norm UNE100713 from 2003 and its late version form 2005[32] classifies the medical environments in class I or II (high or normal risk) with two levels for filtration for class II and three levels for class I (F5, F9 and H13). The other recommendations are: air flows between 10 and 30 (m3/h)/m2, air temperature between 22 and 26 °C and a humidity of 45-55%.

In UK several recommendations are used, from which we underline HTM 03 Part 1[33], CIBSE guidelines and the American ASHRAE Handbooks. HTM 03-01/2007 is replacing the well known HTM 2025 [34], by modifying radically the values recommended: higher air changes per hour, from 6 to more than 25 h-1, or a range of air temperatures from 18 to 28 °C. The filtration level is indicated for the area envisaged, the recommendations being: F4, G7, H10 or H14. It is interesting that natural ventilation is encouraged where relevant and full fresh air for the mechanical ventilation – no recirculation.

A draft of and European standard CEN/TC 156/WG 13 Ventilation in Hospitals issued in 2008 in order to homogenize the requirements in hospitals.

3. Romanian standards

The C253-0-94 norm from 1994 [35] for designing clean rooms (including post operatory therapy rooms and rooms for immune depressed patients) and the Design Norm NP-015-97 from 1997 [36] for Hospital Buildings and the corresponding equipment. These standards recommend for OR an air temperature of 20–22°C in winter, and maximum 26 °C in the summer for the air velocity 0.275 m/s (this temperature could reach at most 28°C at an air velocity of 0.45m/s). The amplitude of the temperature variation has to be less than 1°C in the winter and less than 3°C in the summer. However for special situations such as OR and other facilities for patients with polyarticular rheumatism or highly burned, the air temperature has to be maintained between 30-32°C. The relative humidity has to be correlated with the air temperature and has to be in the limits 30-60%, excepted being the situations related to highly burned patients when it has to be kept between 60-85% or polyarticular rheumatism patients – 30-35%. Other special condition patient facilities are to be defined by the project's specifications if needed. The hospital spaces are classified in three types: Class I, Class II and Class III, in accordance with the type of procedure and equipment used. Class I is represented by spaces in OR for special condition patients like: highly burned patients, open cord operations, other OR for immuno-suppressed patients. Class II is the ordinary OR and Class III concerns all the other spaces in hospitals.

For the OR, depending on the situation, special equipment has to be used for the air diffusion in order to achieve aseptic adequate conditions. These can be: air diffusers on the upper part of the wall corresponding to the patient's feet, with the air flow oriented towards the operation theatre, perforated modular panels on the ceiling, simple or with air curtains around the operation table, perforated modular panels combined with grille diffusers generating two air jets for the flow stabilization, ceiling filter system (HEPA) with air guide curtains and high recirculation. The evacuation of the air has to be done through grilles at the floor level for at least of 75% from the total air volume and through ceiling grilles for the rest of the air volume. The design norm recommends also maintaining the ventilation system in function outside the periods of use of OR with reduced volumetric rates at 50% from the nominal rates.

There are no new updates to these two Romanian standards even if the standard concerning the ventilation and air conditioning of general purpose buildings has been changed in 2011 according to the new European energetic constrains.

4. Discussion

It could be observed from the standards review proposed above that minimum and maximum values of temperature recommend for the standards are different. Some important differences between the standards put in difficulty the design engineer to choose which recommendation is better and to ensure safety for the patient and the surgical team. Low temperatures for instance can result in risks for the patient. To prevent hypothermia in the patient a high ambient temperature in the OR should be recommended as suggested by [37] a temperature between 24ºC and 26ºC is suitable, while temperatures below 21ºC put the patient in risk of becoming hypothermic. However, according to others [38], a temperature above 23ºC is in general hardly supportable by surgeons. Some authors [38] recommend in the OR a temperature between 20ºC and 22ºC for the staff while other authors [39] recommend 23-24.5ºC for the anaesthesiologist, 22-24.5ºC for nurses, and 19ºC for the surgeon. A range of air temperatures for the auxiliary personnel was not recommended even if they occupy the same zone as the surgeons. The maximum relative humidity is recommended to be in a range of maximum 60% and a minimum of 30%. These limits are connected to the growing rates of certain microorganisms. It would be also important to evaluate the influence of the relative humidity to the thermal comfort, and if the relative humidity of 30% would not result in some problem for the staff, like the sensation of dryness and irritation of skin and mucous tissues as indicated in EN14449 [40].

In terms of the minimum air change rate per hour different values in some standards were given, and in others no recommendation were made. The air change rate minimum is 10 h-1. The maximum reported rate is 25 h-1. The minimum air change rate of 10 h-1, is not specified for a determinate type of surgery, enabling us the question if this rate is enough to ensure security aspects for example, in an orthopedic or eye surgery.

From the comparison we can conclude that it is difficult to set some ideal ranges of parameters in order to satisfy each requirement by category of medical staff of patients but It would be interesting to evaluate how the currently prescribed limits are complying security aspects the patient only, and if they also addresse the thermal comfort and the energy consumption issues.

There are not recommended, for example, values of the air velocity which is very important in the issues of the IEQ and also thermal comfort. The design requirements for a HVAC system are defined in line with standards for the IAQ in hospitals following particular classes of risk and the type of surgery. The standards establish the limits for the temperature, the relative humidity, the rate of air change, the types of filters, the pressure relationship to adjacent areas, and the cases when the air may be recirculated. Some of these variables are related to thermal comfort, others are not. Each type of surgery presents a particular characteristic that requires different care. This phase is very important to evaluate, because the standards present different patient's needs and different limits, for example, for the temperature and relative humidity. This question is particularly relevant for immune suppressed patients like burned patients [41-43]. For such patients the temperature must be kept low enough to ensure that the growth of certain microorganisms cannot take place. In these critical situations the indoor air in OR will be ultra-cleaned. Otherwise, when the surgery is septic, there should be also a higher control in the indoor environment, to protect the adjacent areas.

The type of surgery will define other parameters too, for example, the number and type of equipment, lights, the time spent in OR, the type of clothing worn by the surgical team, and the type and intensity of the work being carried out. The main problem in this type of special spaces like OR, other clean rooms and high care facilities, is that indoor air quality is primarily assessed by minimizing the effects of the rate at which the ventilation distribution system either protects the patient from infection or conversely contributes to infection risks.

While infection control is clearly the main focus in strategies for air distribution, problems of thermal comfort should also play a role in assessing the quality and efficiency of air distribution, even in an environment of health care. This is especially true in what we might consider to be the most critical areas in a hospital - OR - where the thermal comfort of the patient and the medical staff or look very different.

In our opinion, the answer for achieving better air quality and improving thermal comfort is residing in developing innovative air diffusers and terminal air units, as well as air diffusion strategies. In the same time, implementing such strategies requires to integrate and to improve the available advanced measuring techniques according to the specific conditions for qualifying the studied indoor ambiances. Nevertheless, this technical direction of research has to be preceded by the theoretical advances in improving the existing thermal comfort models and experimental evaluation techniques which seem to be inappropriate in many situations [44].

5. Conclusion

A comparative review of main standards used in health care units conception phase has been conducted in order to determine the suitability of the existing regulation concerning the indoor air quality inside hospitals and other medical buildings. Healthcare issues are the same across Europe so why different standards? The principal conclusion is that there is a lack of specifications and uniformity in the existing standards, which, in most of the cases, do not impose very strict values as it would be advisable for this kind of indoor environment. This applies to both International and Romanian standards.

In conclusion, there is needed a new re-evaluation on the standards regarding indoor air quality domain in hospitals. This new approach should be based on existing standards built around previous experience and benefit from nowadays survey studies that underline on-site problems. This will lead to improved, high quality medical units with low airborne infection rates, where the environment will be comfortable for both, patients and medical staff.

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