Operating Room Ventilation: CFU Concentration Measurements

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Abstract

Operating room air quality has a great influence on patient safety. Microbes are often carried to the surgical wound via operating room indoor air. Currently in Finland there is no valid standard for design and implementation of operating room ventilation. Additionally the air quality is not required to be monitored or verified after commissioning. However, European Committee for Standardization (CEN) is working on European-wide standard "CEN/TC156 WG 18" which focuses on hospital air quality and ventilation design. In the standard the indoor air quality is determined on the basis of the microbial concentration, and according to it, operating rooms are divided into two purity classes.

In this study, the microbial concentration of indoor air in Finnish operating rooms was examined during actual surgeries. Samples were taken in ten hospitals in a total of 32 operating rooms. The results were compared to the limits set by the standard in order to determine how well the operating rooms meet the requirements.

Based on the results, the operating rooms meet the limits of the standard well. Most of the samples were inside the Ultra Clean Air limit. Clean Air limit proved out to be so high that all the samples met the value distinctly.

Introduction

Operating room air quality has a great influence on patient safety. Microbes are often carried to the surgical wound via operating room indoor air. (Wang et al. 2010) The basis for designing operating room ventilation is to protect the patient from contaminants from other people. Properly functioning ventilation also protects personnel and the surrounding environment from microbes of the surgical wound. (Dascalaki et al. 2008)

Currently in Finland there is no valid standard for design and implementation of operating room ventilation. Additionally the air quality is not required to be monitored or verified after commissioning. The National Building Code of Finland D2 (2012) determines the minimum requirements for ventilation and indoor climate. However it does not define specific limits for operating rooms. Instead it states that operating room ventilation must be designed individually. Also Finnish Indoor Air Classification (2008) instructs and defines classes for the indoor climate but there are no separate criteria for the ventilation of operating rooms.

However, European Committee for Standardization (CEN) is working on a European-wide standard "CEN/TC156 WG 18" (2017). Its objective is to create common practice for the hospital and healthcare indoor climate in Europe and to set minimum requirements for it. In the standard, the quality of operating room indoor air is determined on the basis of the microbial concentration both operational and at rest. In addition the standard defines acceptable recovery times during which the microbial concentration level must revert back to the rest mode level after the contamination spike of an operation. CFU (Colony forming unit) concentration has been chosen to represent the operating room air quality. A CFU is considered to be a microbe or other particle emitted from a person (excluding the surgery patient).

Operating room air quality has been studied mostly during At Rest mode or simulated surgery. Operational CFU concentration has been measured very little. It raises a question how well Finnish operating rooms align with the limits of the standard.

In this study, the microbial concentration of indoor air in Finnish operating rooms was examined during actual surgeries. The objective was to measure various rooms extensively throughout Finland and compare the results with the limits of the standard. The results would possibly provide more information to the CEN draft standard project group.

Draft Standard CEN/TC156 WG 18

"CEN/TC156 WG 18" (2017) is a draft standard whose purpose is to create European-wide standards and regulations for healthcare indoor air. Part 2 of the standard examines the specialties of operating rooms and can be further divided into two parts based on the content. The first part defines common performance requirements for operating rooms. It defines the design criteria for the ventilation and the purity criteria for the rooms. The second parts aims to unify the verification and testing methods of the operating room ventilation. Thus it orders hospitals to monitor, test and maintain the whole operating suite system often enough in order to ensure that everything functions correctly.

"CEN/TC156 WG 18" classifies operating rooms into two levels according to the microbe concentration of the indoor air. Those levels are normal risk of infection level "Clean Air" and high risk of infection "Ultra Clean". The health care personnel, often a surgeon, decides which level of purity is required. The maximum CFU concentration limits during operation are set for both levels. Those levels are:

- Clean Air < 100 CFU/m^3
- Ultra Clean Air < 10 CFU/m^3

The standard also defines operational microbe concentration as the factor for designing the ventilation of the operating room. When the ventilation is functioning properly and as designed, people are the only source of contamination in the surgery. Thus the number of personnel and the quality and type of clothing have a huge effect on the supply air flow rate.

Research methods

Air quality was measured in 32 operating rooms in ten hospitals throughout Finland. The measurements were performed in 2017 – 2018. The primary measuring parameter was operational CFU concentration but in addition other supportive surveys were performed. The purpose of the support surveys was to ensure that the ventilation is working as planned.

The hospitals allowed only one sampling person to enter the operating room during surgeries. This person was wearing a clean room suit and under it a surgical clothing provided by the hospital. Prior entering the operating room each sampling device was purified with A12t 80% ethanol mixture. Also the overall shape of the operating room and its ventilation were inspected.

Multiple samples were taken in each operating room. The actual amount of samples depended on the duration of the surgery. Only three samples were taken during short operations and they were all obtained from the critical protected zone which is situated around the operating table. During longer operations up to six samples per room were taken. Two of those were from the operating table, two from the instrument table (also protected zone) and two from the periphery area.

The air sampler was positioned on a table (h=0,7m) and a gelatin filter was attached to it. After that, the table was transferred to the desired location and the sampler was started. The air sampler suctioned indoor air for 10 minutes (50L/s, total of 500 liters) through the gelatin filter. During that time microbes stuck to the filter. When the sampling was finished the filter was removed from the sampler and put carefully to an agar plate. Once all the samples were taken the measurement was finished and the sampling person exited the room.

The objective was to place the sampler as close to the operating table as possible but due to patient safety the surgeon allowed the sampler to be placed approximately 1 – 1,5 meter from the surgical wound. The periphery area samples were taken from notably farther off the table where the air was considered to be as diluted as possible. However the sampling locations varied considerably due to variation in operating room layout, fittings and activities. Instrument table is considered to be protected zone in accordance with the draft standard.

After the sampling the filter filled agar plates were transferred to a laboratory where they were incubated in 35 °C for 48 hours. After that the cultured colonies were counted and analyzed. A closed reference plate was incubated along with the samples from each operating room. This was done to ensure that the samples were not contaminated during the process. Air sampler suctioned 500 liters of air during one sampling so the

smallest observable microbe concentration was 2 CFU/m^3. If the sample did not contain any cultured microbes, the concentration could only be deduced to be less than 2 CFU/m^3.

Results and discussion

The study conducted measurements in a total of 32 operating rooms, 21 of which were laminar air flow systems and 11 dilution mixing systems. A total of 92 samples were taken from laminar operating rooms and 45 from dilution mixing rooms. These systems differ greatly from each other, but the draft standard imposes same operational CFU concentration demands for both systems. The results are displayed anonymously as the information regarding individual hospitals is confidential.

The operating rooms that were measured differed from each other also in other ways: age, size and supply air flow varied plenty. However the air change rate of all the operating rooms exceeded the value of 17. The supply air flows and air change rates are shown in the Figure 1 below.

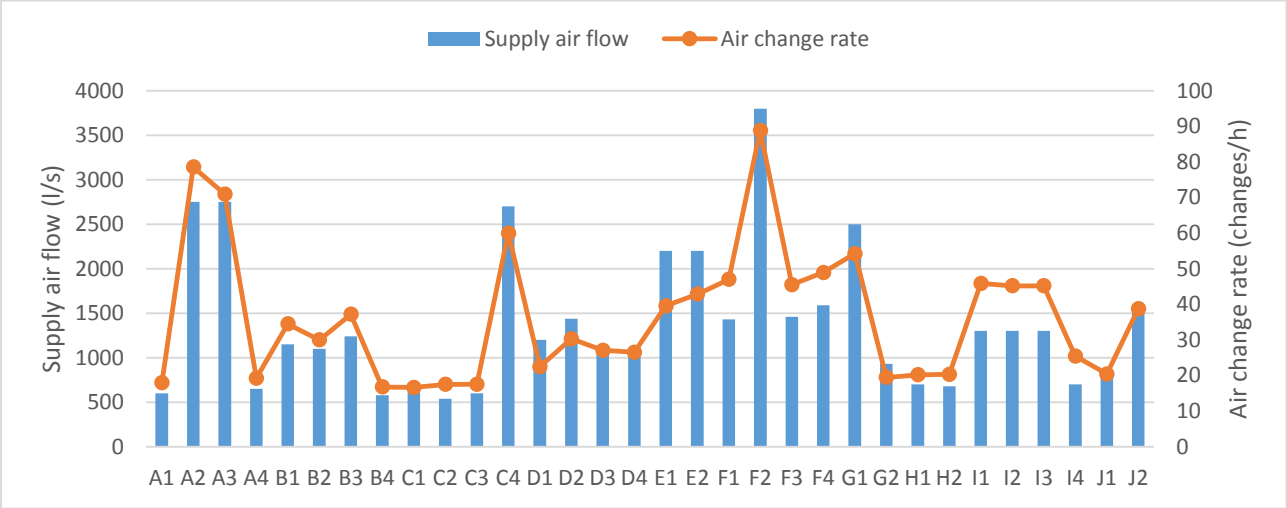

Figure 1. Supply air flows and air change rate of the operating rooms

Operating room has to maintain a positive air pressure compared to its surroundings in order to ensure that the leak air moves away from the room and not vice versa. A suggested positive pressure level is 10–15 Pa. This was achieved in only four operating rooms. These three rooms had tight doors which probably helped to reach this level of pressure differential. Most rooms had a clear 1–2 cm door gap which allowed the leak air to flow through. However, the pressure differentials were positive with the exception of four rooms, two of which was slightly negative pressure and the other two in balance with the surrounding space. The pressure differentials compared to surroundings are presented in Figure 2 with a recommended pressure differential level for operating rooms (10 Pa).

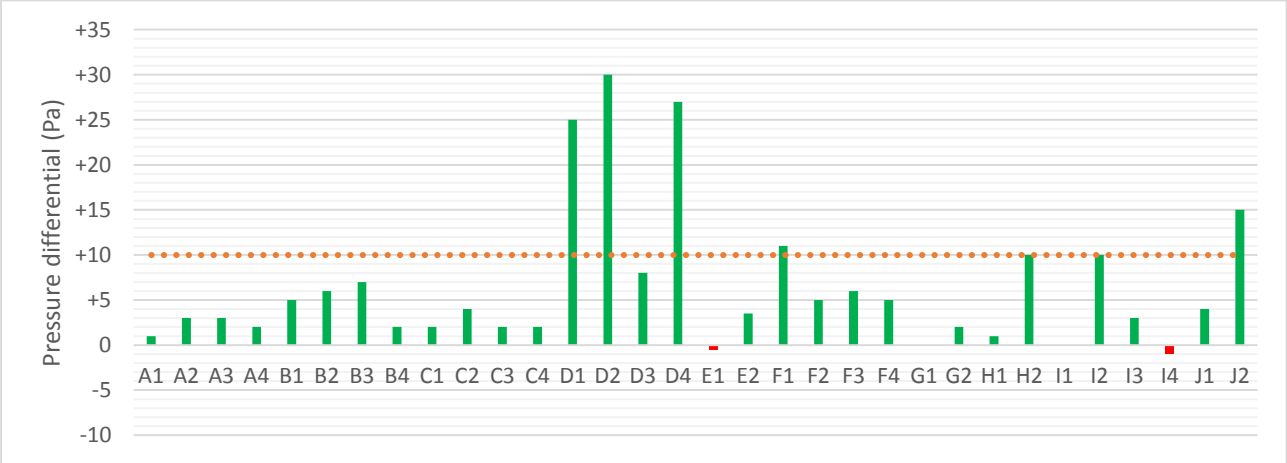

Figure 2. Operating room pressure differentials compared to surrounding area

Air change rate explains how many times indoor air changes during an hour. Thus it is a good indication of the level of ventilation. The higher the air change rate, the greater the amount of air in the room processed through the ventilation system. (Seppänen 2008) It could therefore be assumed that the operating rooms with large air change rate would have a lower CFU content. The measurements showed the indicated assumption to be true, although a direct relationship does not seem to occur. It was also possible to reach very low microbe concentrations with lesser air change rate values.

Every operating room measured reached the Clean Air purity class with considerable margin, based on both average value and peak value. Only two of the rooms had clearly higher values and exceeded the limits of Ultra Clean Air purity class with both average and peak value. The averages of all the other operating rooms were below the limit, and only a few individual samples surpassed it. The mean values and the highest values of the measurement results are shown in Figure 3 together with the limit values of the draft standard.

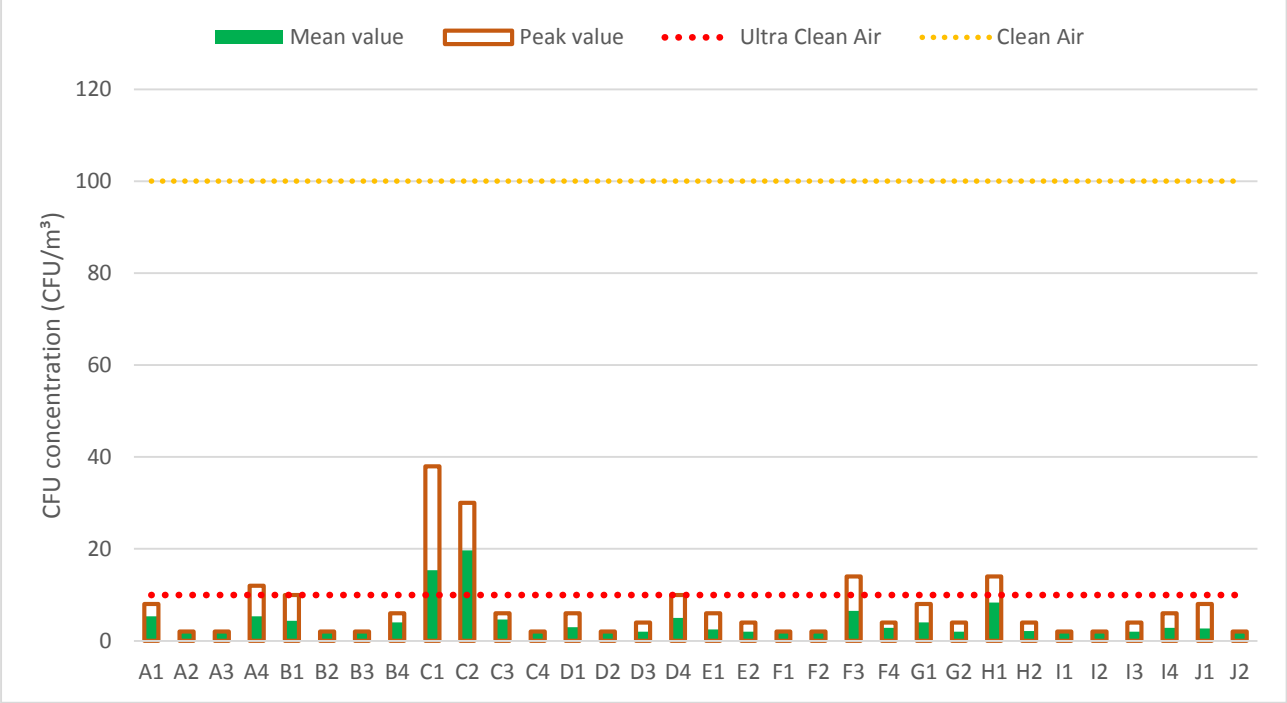

Figure 3. CFU concentrations of the operating rooms and CEN/TC156 WG 18 purity class limits

The highest individual sample included 38 CFU/m^3 while the other higher values were around 30 CFU/m^3. So the Clean Air purity class CFU limit (100 CFU/m3) seems to be very high compared to the measurements.

Conclusions

A total of 32 operating rooms in ten hospitals were measured for the study. Rooms with both dilution mixing and laminar air flow system were studied. The hospitals decided which operating rooms they wanted to be measured, and thus the rooms varied a lot (age, size, air flow etc.). A total of 137 air samples were taken, 3-6 from each operating room. Because of all this variation, operating rooms cannot be directly compared with each other. There are a great deal of variables and their influences to CFU concentration level cannot be directly explained. However the overall level of microbe concentration in Finnish operating rooms can be estimated and the results can be compared with the draft standard purity class levels.

The results show that microbe concentration level in measured operating rooms is quite low compared to the draft standard purity class limits. Most of the rooms reached the Ultra Clean class while the Clean Air class limit seems to be very high as every room reached it with ease even with smaller supply air flows. This raises a question how low supply air flow could be when the CFU concentration approached the value of 100 CFU/m^3. An operation room used for more simple measures has an air change rate of around 10. Would this

be enough to reach Clean Air class if the staff used surgical clothing? Also the pressure level would have to be taken into consideration as the room should be positively pressured compared to surroundings.

All but two operating rooms reached the Ultra Clean class based on mean value. Seven rooms had a peak value of over 10 CFU/m^3. In many of these cases the peak values were only anomalies as the other samples indicated very low concentration levels.

If the results had indicated high CFU concentration levels, a thorough investigation on an operating room is required. In that case it is not enough to examine only the ventilation or cleanliness. Additionally staff behaviour and clothing has to be taken into account as those have a significant impact on the air purity level of an operating room.

Generally the air purity level of Finnish operating rooms is at a good level compared to the draft standard. The results suggest even that Clean Air limit seems to be unnecessary high. The whole topic requires a more specific further research related to microbe concentration, surgical clothing and more in-depth analysis of causal relationship. Additionally it would be advisable to develop clear guidelines which would help to resolve what could be the cause for high microbe concentrations.

Acknowledgements

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