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The following references are divided into categories based on their content and represent a selection of articles, conference papers and reports from organizations that are related to infection control and prevention. Table 1 lists abbreviations used in this document.

Table 1: A list of abbreviations used and their meaning.

Abbreviation	Meaning
SSI	Surgical Site Infection
CFU	Colony Forming Unit
T_cAF	Temperature controlled airflow
LAF	Laminar Airflow
TMA	Turbulent Mixed Airflow
CFD	Computational Fluid Dynamics

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1. **“Surgical site infections are correlated with airborne bacteria levels”**

(a) Charnley, J. (1972). Postoperative Infection after Total Hip Replacement with Special Reference to Air Contamination in the Operating Room. *Clinical Orthopaedics and Related Research*, 87, 167-187.

Sir John Charnley recognized as one of the main contributors to the surgical method for hip replacement also contributed to decreasing the rate of postoperative infections. In 1972 Charnley summarized the results from 5 800 total hip replacements and found that the infection rate fell from about 7-9% in 1960 to below 1% in 1970. The reduction was a result of taking measures to reduce sources of exogenous infection in the operating room, i.e. the usage of clean air technology and body exhaust suits. The use of prophylactic antibiotics was in this study purposely avoided.

(b) Lidwell, O. M. (1988). Air, antibiotics and sepsis in replacement joints. *Journal of Hospital Infection*, 11, 18-40.

In 1973 the Medical Research Council together with the Department of Health and Social Security in the United Kingdom carried out an investigation on the relationship between the reduction of air contamination and the incidence rate of joint sepsis. 19 hospitals in Europe took part in the multicenter investigation and more than 8 000 operations were performed. The results strongly suggest that sepsis in the joint is the result of bacteria introduced into the wound at the time of surgery although an infection might not occur instantly. The study attributes the observed reduction of joint sepsis to ultra clean air systems, occlusive clothing and the use of antibiotics.

(c) Gehrke, T; Parvizi, J. (2013) Proceedings of the international Consensus Meeting on Periprostethic Joint Infection, The Bone & Joint Journal, Vol. 95-B, No 11.

Orthopaedic experts agree that ultraclean air is important as a means to lower the risk for surgical site infections.

2. **“Particles carrying bacteria are continuously spread to the air from people in the operating room or from adjacent rooms in the case of door opening”**

(a) Noble, W.C. (1975). Dispersal of skin microorganisms. *British Journal of Dermatology*, 93(4), 477-485.

Noble summarizes in his review article that each person sheds around 10 000 skin particles per minute into the air when he or she walks. Approximately 10% of these are estimated to carry bacteria. Moreover, a person is estimated to release more than 10^7 skin particles each day.

(b) Benediktsdóttir, E. & Kolstad, K. (1984). Non-sporeforming anaerobic bacteria in clean surgical wounds —air and skin contamination. *Journal of Hospital Infection*, 5(1), 38-49.

Bacteria found on skin scales are either anaerobic, meaning that they do not require oxygen to survive and grow, or aerobic which in contrast implies that they require an oxygenated environment. The contamination of clean surgical wounds with anaerobic and aerobic bacteria was studied in 52 hip operations by Benediktsdóttir and Kolstad. Anaerobic bacteria were found to account for about 30% of the total number of bacteria present in the air inside an operating room on average. Those have the ability to survive long enough in the air to be viable once they reach the surgical wound.

(c) Andersson, A.E., Bergh, I., Karlsson, J., Eriksson, B.I., & Nilsson, K. (2012). Traffic flow in the operating room: An explorative and descriptive study on air quality during orthopedic trauma implant surgery. *American Journal of Infection Control*, 40(8), 750-755.

The study by Andersson et al including 30 orthopedic procedures investigated the air quality in terms of cfu/m^3 during orthopedic trauma surgery in a conventionally ventilated operating room. The effect of traffic flow and number of surgical staff present in the operating room on the air contamination rate was evaluated in the vicinity of the surgical wound. The study concludes that traffic flow has a strong negative impact on the operating room environment and reducing traffic flow is an important measure to prevent surgical site infections. A weaker yet still positive correlation between the number of people present and airborne bacterial count was also found.

(d) Wang, C (2019) Ventilation performance in operating rooms: A numerical assessment, Doctoral Thesis, KTH Royal Institute of Technology

CFD simulations on supercomputers show that door openings have a detrimental impact on the microbiological cleanliness of the OR. The simulations also show that the choice of ventilation impacts the resilience towards this kind of disturbances.

(e) Charles E. Edmiston Jr, PhD,[a] Gary R. Seabrook, MD,[a] Robert A. Cambria, MD,[a] Kellie R. Brown, MD,[a] Brian D. Lewis, MD,[a] Jay R. Sommers, PhD,[b] Candace J. Krepel, MS,[a] Patti J. Wilson, BSN,[c] Sharon Sinski, BSN,[a] and Jonathan B. Towne, MD, [a] (2005). Molecular epidemiology of microbial contamination in the operating room environment: Is there a risk for infection? From the Department of Surgery, [a] Medical College of Wisconsin, and Infection Control Department,[c] Froedtert Memorial Lutheran Hospital, Milwaukee, Wis, and Kimberly-Clark Corporation,[b] Roswell, Ga

Modern operating rooms are considered to be aseptic environments. The use of surgical mask, frequent air exchanges, and architectural barriers are used to reduce airborne microbial populations. Breaks in surgical technique, host contamination, or hematogenous seeding are suggested as causal factors in these infections. Gram-positive staphylococcal isolates were frequently isolated from air samples obtained throughout the operating room, including areas adjacent to the operative field. Nasopharyngeal shedding from person participating in the operation was identified as

the source of many of these airborne contaminants. Failure of the traditional surgical mask to prevent microbial shedding is likely associated with an increased risk of perioperative contamination of biomedical implants, especially in procedures lasting longer than 90 minutes.

(f) Qiaojie Wang, MD; Chi Xu, MD; Karan Goswami, MD, MRCS; et al (2020) Association of Laminar Airflow During Primary Total Joint Arthroplasty with Periprosthetic Joint Infection

This study suggests that the use of LAF in the operating room was not associated with a reduced incidence of PJI after primary total joint arthroplasty. With an appropriate perioperative protocol for infection prevention, LAF does not seem to play a protective role in PJI prevention. Patients underwent total joint arthroplasty in operating rooms equipped with either LAF or turbulent airflow.

3. **"The majority of the bacteria contaminating the surgical wound are likely to have reached it by the airborne route"**

(a) Lidwell, O.M., Lowbury, E.J.L., Whyte, W., Blowers, R., Stanley, S.J. & Lowe, D. (1983). Airborne contamination of wounds in joint replacement operations: the relationship to sepsis rates. *Journal of Hospital Infection*, 4(2), 111-131.

A correlation between the mean values of air contamination and the number of bacteria isolated from wound wash-out samples as found by Lidwell et al. as well as a correlation between mean airborne contamination and joint sepsis rate. The results indicate that the majority of the bacteria found after insertion of the prosthesis reached the wound by the airborne route, all the way up to 95%. The study concludes that this was especially clear for operations performed in operating rooms with conventional ventilation.

(b) Whyte, W., Hodgson, R. & Tinkler, J. (1982). The importance of airborne bacterial contamination of wounds. *Journal of Hospital Infection*, 3(2), 123-135.

A study of potential sources of bacterial contamination of the surgical wound during hip and knee replacement operations performed in conventionally and laminar airflow ventilated operating rooms was conducted by Whyte et al. From the results it was estimated that 98% of the bacteria in the patients' wounds came directly or indirectly from the air in conventionally ventilated operating rooms.

4. **"Indirect contamination of the surgical wound via medical devices occurs as well as direct airborne contamination"**

(a) Edmiston, C.E., Seabrook, G.R., Cambria, R.A., Brown, K.R., Lewis, B.D., Sommers, J.R., Krepel, C.J., Wilson, P.J., Sinski, S. & Towne, J.B. (2005). Molecular epidemiology of microbial contamination in the operating room environment: Is there a risk for infection?. *Surgery*, 138(4), 573-582.

Via air currents bacteria can be deposited in the surgical wound or onto a surface that might come in contact with the wound. To investigate the potential sources of contamination during operation, air sampling was performed ranging from 0.5 to 4 m from the surgical wound during 70 vascular surgical procedures. This study documents that during operations and under optimal environment conditions, microbial populations were frequently recovered from the sampling points. This is believed to be the result of failure of the traditional surgical mask to prevent microbial shedding which is likely to be associated with an increased risk of perioperative contamination. For example, Staphylococcus aureus was recovered from 64% of air samples, 39% from within 0.5 m from the wound.

(b) Whyte, W., Hodgson, R. & Tinkler, J. (1982). The importance of airborne bacterial contamination of wounds. *Journal of Hospital Infection*, 3(2), 123-135.

An investigation regarding bacterial wound contamination during hip and knee replacement surgery was conducted in an operating suite using either laminar flow or conventional ventilation. It was found that the bacterial count in the air was substantially lowered, representing a 97-fold reduction, when laminar flow ventilation was used. The average number of bacteria that was washed out after surgery was 35 times lower compared to when conventional ventilation was applied. Therefore, a minority of the bacteria that contaminated the wound are estimated to have fallen directly from the air. The rest is assumed to have been transferred to the wound indirectly by depositing on the surgeon's hands, drapes and instruments.

(c) Benen, T., Wille, F. & Clausdorff, L. (2013). Influence on different ventilations systems upon the contamination of medical devices. *Hyg Med*, 38(4), 142-146.

One main aspect of avoiding surgical site infections is to ensure the sterility of the medical devices and instruments in the operating room and their location in the operating room is important. In this study, laminar airflow ventilation manages to maintain ultraclean air within the surgical protection zone but a 55-fold increase of the mean value of airborne colony forming units was observed outside the protected area compared to the value inside.

5. **"Microbiological air sampling is a suitable method for investigating operating room air quality"**

(a) Whyte, W., Lidwell, O.M., Lowbury, E.J.L., & Blowers, R. (1983) Suggested bacteriological standards for air in ultraclean operating rooms. Journal of Hospital infection, 4(2), 133-139.

In this study from 1983, Whyte et al. states that bacteriological standards for the air in ultraclean operating rooms are needed since physical tests alone cannot guarantee satisfactory results. 10 cfu/m3 is suggested as the highest acceptable value for an ultraclean system since a substantial benefit can be obtained if the average concentration of airborne contamination do not is

exceeded. Confirmation that the ultraclean air system has resulted in an acceptable low level of bacterial contamination of the air is therefore an essential precaution.

(b) Cristina, M. L., Spagnolo, A. M., Sartini, M., Panatto, D., Gasparini, R., Orlando, P., Ottria, G. & Perdelli, F. (2012). Can particulate air sampling predict microbial load in operating theatres for arthroplasty? *PLOS One*, 7(12)

Measuring airborne particle counts as an indirect indicator of the microbiological air quality in operating rooms is derived from cleanroom technology standards but has seldom been subjected to evaluation. In this study by Cristina et al. including 95 surgical arthroplasty procedures (59 hip replacements and 36 knee replacements), the aim was to determine whether particle counting could predict microbiological air contamination in an operating theatre.

The results did not indicate any statistical correlation between microbial air contamination in terms of CFU/m^3 and airborne particle counts for either of the particle diameters considered (≥0.5µm and ≥5µm) and the study concludes that microbiological air sampling remains the most suitable method for investigating the quality of air in operating theatres.

(c) Sadrizadeh, S., Holmberg, S. (2015) Impact of staff posture on airborne particle distribution in an operating theatre equipped with ultraclean-zoned ventilation. 36th AIVC Conference "*Effective ventilation in high performance buildings*", Madrid, Spain, 23-24 September 2015.

Usually, operating room ventilation performance is determined without considering the influence of staff-member posture and movements. Results indicate that bending posture increases the overall number of suspended particles in the surgical area by disrupting the particle-free airflow.

(d) Zielke, B., Hofer, V., Rotheudt, V., Rischmüller, S., Brockmann, G. & Kriegel, M. (2017) Experimental Investigation of Airborne Particle Distribution in Operating Theatres under Realistic Load Configuration: A – Developing an Operating Personnel Dummy with Realistic Posture and Particle Emission. Presented on Healthy Buildings 2017 Europe, Lu

To evaluate different airflow patterns regarding their ability to protect the patient from airborne contamination, the use of realistic contamination sources, flow obstacles and heat loads is fundamentally important. Over-simplistic arrangements are often used to evaluate the effectiveness of OR ventilation. For example, according to the German standard on operating rooms (DIN 1946-4), it is assumed that the personnel stand upright beside the patient and that the particle sources are located on the floor. Thus, for the evaluation of an OR air flow concept, the use of a realistic personnel dummy is essential for two reasons: firstly, because the personnel are the main source of germs and those are distributed not only at floor level, and secondly because the personnel have a significant effect on the airflow by being an interruption into the path of air when bending over the patient.

(e) Rotheudt, H., Lichtner, E., Brockmann, G., Hofera, V., Askan, T., Hartmann, A., Zielke, B. & Kriegel, M. (2018) Distribution of Microbial Contamination in Operating Theaters and Healthcare Environments. In: Proceedings 24th International Symposium on Contamination Control and Cleanroom Technology, The Hague, Netherlands, Sept 23-26.

Most investigations and the standard acceptance test cases consider particle contaminant of small particle size that is completely airborne without gravitational effects. Brownian diffusion has the greatest impact on small particles. Bacteria carrying particles are mainly in the range of medium sized particles that are affected by turbophorensis and interception, or in the range of large particles that are highly influenced by gravity. Microbial contaminants are thus affected by their gravitational settling and do not perfectly follow the airflow motion. Gravitational forces lead to significantly increase their deposition behavior. Therefore, investigations that consider the microbial particulates as completely airborne have limited validity to predict the surface contamination inside patients wound field or on medical instruments.

6. **"The size of airborne particles carrying microorganisms are in the order of a few micrometers"**

Noble, W. C., Lidwell, O. M. & Kingston, D. (1963). The size distribution of airborne particles carrying micro-organisms. *The Journal of Hygiene*, 61(4), 385-391.

This article by Noble et al investigated the size distribution of particles carrying different species of bacteria and fungi. Particles were collected with an air sampler which divided the collected particles into four size ranges and deposits the airborne particles onto a Petri dish containing the agar medium. The article summarizes that organisms associated with human disease or carriage are usually found on particles in the range 4-20 µm equivalent diameter. The equivalent particle diameter is here referred to the diameter of a sphere of unit density which has a settling rate in air equal to that of the particle in question.

7. **"The main measures to prevent SSI are antibiotics, the use of suitable ventilation, surgical clothing, staff number and behavior"**

(a) Lidwell, O. M., Lowbury, E. J., Whyte, W., Blowers, R., Stanley, S.J. & Lowe, D. (1982). Effect of ultraclean air in operating rooms on deep sepsis in the joint after total hip or knee replacement: a randomized study. *British Medical Journal* (Clin Res Ed), 285(6334), 10-14.

Lidwell's previously mentioned randomized study, see 1b, involved 8,000 patients undergoing knee or hip replacement surgery. All patients were then followed up for 2 to 3 years for evidence of post-operative wound sepsis. The reduction of joint sepsis rates was attributed to air cleanliness, special operating suits and the use of antibiotic prophylaxis which reduced the sepsis rate independently. More specifically, the use of antibiotics resulted in a four-fold reduction of the incidence rate. The use of occlusive clothing halved the rate further and so did the use of ultra clean air.

(b) Burman, L. G. (2006). Att förebygga vårdrelaterade Infektioner–ett kunskapsunderlag. Stockholm: Swedish National Board of Health and Welfare., ISBN 91-85482-14-5

The report from Swedish National Board of Health and Welfare informs that deep postoperative infection is a consequence of bacterial contamination during surgery. This is believed to apply for other postoperative wound infections as well. The number of bacteria carrying particles in the operating room air depends on the number of people, their activity and routines, clothing and the type of ventilation used. To limit the rate of postoperative infections actions regarding these are important apart from the use of prophylactic antibiotics, good hygiene, and a suitable design of the operating room that minimizes unnecessary traffic and allows for proper transportation of the patient, staff and goods in and out of the operating room.

(c) Sadrizadeh, S., Tammelin, A., Ekolind, P. & Holmberg, S. (2014). Influence of staff number and internal constellation on surgical site infection in an operating room. *Particuology*, 13, 42-51.

The number of surgical personnel and their positions influence the ventilation airflow and thereby the concentration and distribution of colony forming units in an operating room. The influence on airborne bacteria distribution within the critical surgical zone was investigated using a numerical model and the results imply increasing concentrations of colony forming units when the number of staff was increased. From the results, it can also be concluded that the number of staff located in the critical surgical zone should be kept to a minimum since the concentration increase with decreasing distance.

(d) Buhl, S., Eschenbecher, N., Hentschel, S. & Bulitta, C.(2016) Multiple factors influencing OR ventilation system effectiveness In: *Current Directions in Biomedical Engineering*, 2(1), 333-335. DOI: https://doi.org/10.1515/cdbme-2016-0074

In this study clothing and three types of ventilation systems have been investigated and their ability to reduce airborne bacterial counts in the operating room was assessed. The clothing evaluated were German and Swedish operating gowns. The main difference was that the Swedish clothing had tightened cuffs and a closed neck region to avoid unintentional spreading of particles. The results in the study favored the Swedish clothing regarding cfu-levels. The ventilation systems tested were temperature-controlled ventilation, laminar airflow and turbulent mixed ventilation. The temperature-controlled system provided the lowest overall mean value for the three different measurement sites.

(e) Wang, C (2019) Ventilation performance in operating rooms: A numerical assessment, Doctoral Thesis, KTH Royal Institute of Technology

Mixing ventilation cannot reliably maintain an ultraclean environment and therefore is generally not recommended for infection-prone surgeries.

(f) Qiaojie Wang, MD; Chi Xu, MD; Karan Goswami, MD, MRCS; et al (2020) Association of Laminar Airflow During Primary Total Joint Arthroplasty with Periprosthetic Joint Infections.

This study suggests that the use of LAF in the operating room was not associated with a reduced incidence of PJI after primary total joint arthroplasty. With an appropriate perioperative protocol for infection prevention, LAF does not seem to play a protective role in PJI prevention. Patients underwent total joint arthroplasty in operating rooms equipped with either LAF or turbulent airflow.

8. **"Postoperative infections not only cause suffering - they are also costly"**

(a) Leaper, D. J., Van Goor, H., Reilly, J., Petrosillo, N., Geiss, H. K., Torres, A. J. & Berger, A. (2004). Surgical site infection – a European perspective of incidence and economic burden. *International Wound Journal*, 1(4), 247-273.

This study reviewed data from 48 studies and estimated the economic costs of surgical site infections in Europe to range between e 1.47–19.1 billion. Furthermore, the review suggests that the economic burden is likely to have been underestimated since the infection rate reported is believed to represent an underestimation.

(b) Burman, L. G. (2006). *Att förebygga vårdrelaterade Infektioner–ett kunskapsunderlag*. Stockholm: Swedish National Board of Health and Welfare., ISBN 91-85482-14-5

The previously mention report from the Swedish National Board of Health and Welfare, see 7b, states that the cost of care is increased by nosocomial infections. Patients that are victims to nosocomial infections, which lead to an extended length of stay, spend 500 000 days extra in hospital each year. This consequently leads to increased costs of 3700 million SEK corresponding to e 388 million annually, according to an estimation by the authors.

(c) American College of Surgeons and Surgical Infection Society (2016). *Surgical Site Infection Guidelines*, 2016 Update. http://www.journal acs.org/article/S1072- 7515(16)31563-0/pdf

SSIs accounts for 20% of all hospital-acquired infections in the US and are reported as the most common and costly of all hospital-acquired infections. The incidence of SSI is 2% to 5% in patients undergoing inpatient surgery. The estimated annual incidence varies widely and ranges from 160,000 to 300,000 in the US although this is likely to represent an underestimation due to the surveillance challenges after discharge. The cost for surgical site infections is mainly associated with extended length of stay, emergency department visits and read missions. The annual cost of SSI in the US is estimated at $3.5 to $10 billion in this report.

(d) Sveriges kommuner och landsting. (2017). Vårdrelaterade infektioner. Kunskap, konsekvenser, kostnader. Stockholm: Sveriges kommuner och Landsting. ISBN 978-91-7585-475-5

https://webbutik.skl.se/sv/artiklar/rapport-vardrelaterade- infektioner.html

65 000 patients each year suffer from hospital-acquired infections (HAI) in Sweden, and HAI is the most common and expensive type of event that causes injury to patients. It leads to a prolonged length of stay that costs 6.5 billion SEK each year. The length stay increases with ten extra days on average. Estimations show that between a third to half of these could be avoided. The most common HAI is urinary tract infection followed by postoperative wound infection.

(e) William, J. O´Brian; Kalpana Gupta; Kamal M.F Itani (2019) Association of Postoperative Infection With Risk of Long-term Infection and Mortali, JAMA Surg. Dpi: 10.1001

At any given point during the follow-up period, patients with 30-day postoperative infection had a 3.2-fold higher risk of 1-year infection and a 1.9-fold higher risk of mortality compared with those who had no 30-day infection. Cost-benefit calculations for surgical infection prevention programs should include the increased risk and costs of long-term infection and death. Preventive efforts in the first 30 days postoperatively may improve long-term patient outcomes.

9. "Antimicrobial and antibiotic resistance is an increasing threat"

(a) World Health Organization (2014). *Antimicrobial resistance: Global report on surveillance.*

Antimicrobial resistance threatens the effective prevention and treatment of an increasing range of infections caused by bacteria, parasites, viruses and fungi. WHO establishes that this is an increasingly serious threat to global public health, development and food security that requires action across all government sectors and society. Furthermore, antimicrobial resistance leads to higher medical costs, longer hospital stays as well as increased mortality. The report states that measures can be taken at all levels in society to limit the impact and spread of antimicrobial resistance and that global surveillance generating reliable data is urgently needed. In all WHO regions, very high resistance rates have been observed for common bacteria, such as Escherichia coli and Staphylococcus aureus, that cause common nosocomial and community-acquired infections.

(b) World Health Organization. (2016). *Antibiotic Resistance*. http://www.who.int/ mediacentre/factsheets/antibiotic-resistance/en/ [2017-08-21]

WHO informs in their fact sheet from 2016 that antibiotic resistance is rising to dangerously high levels in all parts of the world. New resistance mechanisms are emerging and spreading globally which threat the ability to treat common infectious diseases. Resistance is enhanced by poor infection prevention and control, misuse and overuse of antibiotics. WHO points out that without urgent action, we are heading for a post-antibiotic era in which common infections and minor injuries can pose a deadly threat. Organ

transplantation, chemotherapy and major surgical procedures such as caesarean sections or hip replacement will become much more dangerous without effective antibiotics for the prevention and treatment of infections.

(c) U.S. Centers for Disease Control and Prevention. (2013). *Antibiotic resistance threats in the United States.* https://www.cdc.gov/drugresistance/threat- report-2013/pdf/ar-threats-2013-508.pdf [2017-08-22]

The U.S. Centers for Disease Control and Prevention estimates in their report from 2013 that there are about 2 million people who become infected by bacteria or fungus that are resistant to antibiotics and 23000 deaths resulting from these infections each year in the United States. The estimation is reported to represent a minimum. When antibiotic resistance grows, the ability to fight routine infectious diseases is weakened and it will also impair treatment of infections complications in patients with other diseases. Many of the modern advances in medicine are dependent on the effectiveness of antibiotics to fight infections. For example, patients that undergo complex surgery such as cardiac bypass or joint replacement are subjected to the risk of SSIs. Prophylactic antibiotics is often used to prevent such infections but if the effectiveness of antibiotics is lost, so is the advantage of these modern medical advances.

10. **"Downward airflow is effective regarding reduction of airborne bacterial counts and velocities of at least 0.3 m/s are needed to break body convection"**

(a) Whyte, W., Shaw, B. H. & Barnes, R. (1973). A bacteriological evaluation of laminar-flow systems for orthopaedic surgery. *Epidemiology & Infection*, 71(3), 559-564.

In 1973 Whyte et al investigated the efficiency of unidirectional airflow in operating theaters where both horizontal and vertical flow were evaluated. Conventional surgical clothing was used, and the investigation concluded that vertical airflow velocities in the region 0.3-0.4 m/s is enough to keep the mean value of airborne bacterial counts measured at the wound site below the limit for ultraclean surgery. Furthermore, it was concluded that the vertical airflow was about 11 times more efficient regarding airborne bacteria count than horizontal.

(b) Nielsen, P. V. (2009). Control of airborne infectious diseases in ventilated spaces. *Journal of the Royal Society Interface*, 6(6), 747-755.

Experiments with heated manikins indicate that downward air velocities up to 0.25 m/s preserves isothermal smoke released from above the standing manikin at head height. The thermal plume above a person has an upward velocity of approximately 0.25 m/s and down- ward air velocities of at least 0.30 m/s are needed to break the body convection.

(c) Wang, C (2019) Ventilation performance in operating rooms: A numerical assessment, Doctoral Thesis, KTH Royal Institute of Technology

Ultra-clean air is not only a result of high airflow rates – the type of airflow distribution is of critical importance in reducing cfu levels and different ventilation techniques have very different ventilation efficiency. The highest efficiency was shown by Temperature Controlled Airflow (TcAF).

11. **"Thermal comfort in operating room must be achieved for all members of the surgical staff"**

Van Gaever, R., Jacobs, V. A., Diltoer, M., Peeters, L., & Vanlanduit, S. (2014). Thermal comfort of the surgical staff in the operating room. *Building and Environment*, *81*, 37-41.

The indoor environmental quality in an operating room affects not only the patient health but also the well-being of the surgical staff. However, a surgical environment restricts the ability for people to adapt to the climate in the environment by prescribing specific clothing and environmental regulations. International technical HVAC standards and guidelines control the indoor air quality by prescribing the use of a LAF system for infection-sensitive surgery. Therefore, the design parameters of the LAF play an important role in the thermal sensation of the staff. This article states that it is impossible to achieve thermal comfort for all members of the surgical staff with the current design parameters of the LAF system, according to ISO 7730. By performing a survey at four major Belgium hospitals this discrepancy between the technical HVAC standards and thermal comfort standard has been revealed. The results show it is not possible to achieve thermal comfort for each member of the surgical staff by only revising the HVAC standards but an adaptation of the ventilation and surgical luminaire system to meet the thermal needs of the surgical staff without losing the protective properties to prevent SSI is necessary.

12. **"T_cAF ventilation keeps the whole operating room ultraclean"**

(a) Alsved, M., Civilis, A., Ekolind, P., Tammelin, Erichsen-Andersson A., Jakobsson, J., Svensson, T.; Ramstorp, M.; Sadrizadeh, S., Lars- son, P.-A., Bohgard, M. Šantl-Temkiv, T. & Löndahl, J. (2017) Temperature controlled airflow ventilation in operating rooms compared with laminar airflow and turbulent mixed airflow. *Journal of Hospital Infection*, DOI: http://dx.doi.org/10.1016/j.jhin.2017.10.013

CFU concentrations were measured at three locations in an operating room during 45 orthopaedic surgeries close to the wound (<40 cm), at the instrument table, and in the periphery. 15 of these operations corresponding to 250 samples, were performed in operating rooms equipped with T_cAF - ventilation. The study resulted in a median value of 1 CFU/m^3 in the vicinity of the wound for the T_cAF system. Median values at the instrument table and in the periphery were also well below the limit required for infection-prone surgery 10 CFU/m^3.

(b) Bulitta C., Schlautmann B. (2020) Relevance and implications of positioning analysis for infection-preventive effectiveness of ventilation systems with low-turbulence dis-

placement flow

Ventilation technology in German operating rooms is regulated by DIN 1946-4. Since the release of the latest version in 2018, a positioning analysis (worst-case scenario with the largest space requirement) for determining the required protected area in class 1a operating rooms is mandatory. The aim of this investigation was to use typical workflow scenarios to assess existing installations regarding the match of the required and the built size of the protected area. Positioning analyses were carried out together with the on-site staff for various clinical procedures in 2 hospitals to assess the built versus required protected areas. In all cases, the positioning analysis revealed that required protected areas need to be significantly larger than provided by the existing setup. The size of the protected area that is actually required can only be determined by individual positioning analysis. Most existing installations of low turbulence displacement flow systems (TAV) are likely to be too small. The larger protected areas actually require significantly larger rooms in order to maintain proper thermodynamics. Furthermore, significantly higher volumetric flow rates are required. Finally, the current mismatch between actual and necessary protected area would be a possible explanation for the controversial data situation regarding the infection preventive effects of TAV systems.

(c) Zhijian Liu, Di Yin, Lina Hu, Junzhou He, Guoqing Cao (2022) Bacteria-carrying particles diffusion in the operating room due to the interaction between human thermal plume and ventilation systems: An experimental-numerical simulation study

During surgery, the release of bacterial-carrying particles (BCPs) by surgeons is one of the major pollution sources in operating rooms (ORs), which may cause surgical site infection (SSIs) or health problems. The human thermal plume emitted by the human body may affect the airflow in the surgical micro-environment, leading to the further spread of BCPs. The experiments of airspeed measurements and biological particle emission were carried out in a standard vertical laminar ventilation operating room. Computational fluid dynamics (CFD) was used to extend the investigation of the different ventilation systems. The TcAF (called TAF in the article) ventilation system was superior to the other three systems in reducing BCPs levels in the air of the operating room.

13. "T_cAF ventilation is energy efficient and provides a comfortable working environment"

(a) Löndahl, J., Ekolind, P., Tammelin, A., Ramstorp, M., Civilis, A. & Larsson, P.-A. (2017). *Energieffektiv ventilation för sjukhus och renrumsmiljöer inom industrin.* (E2B2– ett samverkansprogram mellan Energimyndigheten och IQ Samhällsbyggnad Rapport 2017:04) http://www.e2b2.se/library/3117/slutrapport energieffektiv ventilation for sjukhus.pdf

T_cAF ventilation is in this study observed to consume 28% less energy than LAF, related to the almost double airflow volume in LAF. T_cAF requires lower airspeed than LAF, since the air supplied above the surgical zone has a slightly lower temperature, i.e. higher density than the rest of the room. The higher density of the cooled air causes it to fall at a speed dictated by this temperature difference and lower airspeed is required. The same report also states that the impact of the T_cAF system on the staff work environment from draught and noise levels also were significantly lower compared to laminar airflow which is

primarily due to reduced airspeed.

(b) Alsved, M., Civilis, A., Ekolind, P., Tammelin, A., Erichsen Andersson, A., Jakobsson, J., Svensson, T., Ramstorp, M., Santl-Temkiv, T., Larsson, P.-A., Bohgard, M. & Löndahl, J. (2017). Airborne bacteria in hospital operating theatres during surgery. In: 12. *Ulmer Symposium Krankenhausinfektionen, Epidemiologie Hygienemassnahmen Antibiotikaprophylaxe.* Ulm, Germany, March 15-17, 2017,50-51.

The results from the study above, see 11, were also presented on the conference Ulmer Symposium Krankenhausinfektionen, Epidemiologie Hygienemassnahmen Antibiotikaprophylaxe in March 2017 by M. Alsved from Lund University.

14. "T_cAF ventilation benefits validated using CFD"

(a) Sadrizadeh, S. & Ekolind, P. (2016). A new ventilation system principle for operating rooms: Temperature-Controlled Air Flow. In: *CLIMA 2016 – proceedings of the 12th REHVA World Congress: volume 5.* Aalborg, Denmark, May 22-25 2017.

The performance of a T_cAF ventilation system was evaluated using CFD. The temperature difference between the air supplied from the central and external air showers subdivided a fully equipped operating room into two distinct zones; one in the critical surgical zone that showed a strong unidirectional downward airflow with air velocities high enough to wash of all released bacteria carrying particles above the operating table, and another in the periphery were the external air showers diluted periphery-emitted particles via a mixed airflow. The system proved robust to heat loads as well. A recovery test based on ISO 14644-3:205 showed that the recovery time for the T_cAF ventilation system is well below the limit proposed by the standard.

(b) Sadrizadeh, S. & Holmberg, S. (2014). Comparison of different ventilation principles in an operating suite. In: *Proceedings of 13th SCANVAC International Conference on Air Distribution in Rooms*, São Paulo, Brazil Oct 19-22.

By using computational fluid dynamics, the performance of three different ventilation systems for operating rooms was investigated. The examined ventilation principles were turbulent mixed airflow, laminar airflow and temperature-controlled airflow and each system was evaluated in the same operating suite. Using LAF ventilation, a strong reverse flow pattern was observed in the outer edges of the operating room. The T_cAF ventilation system managed to damp the reverse flow well with the external air showers. Regarding the TMA ventilation, reverse flows occurred in most parts of the operating room as well as airflow stagnation in the corners of the room.

(c) Bulitta, C., Magerl, F., Hartwich, R. & Russwurm, B.(2015) CFD analysis of a

high-tech operating room using Star-CCM+. In: *Magazine DYNAMICS from CD-adapco*, (38), 70-73. https://mdx2.plm.au tomation.siemens.com/magazine/ dynamics-38

The Technical University of Applied Sciences Amberg-Weiden in Germany is equipped with a fully functioning high-tech operating room. A T_cAF ventilation system installed in the operating room was subjected to CFD analysis and the temperature and airflow behavior was examined and compared with experimental data. The results showed good agreement between simulation and measured air velocities as well as temperature distribution which supports the notion of CFD analysis being a good tool to investigate such properties.

(d) Buhl, S., Eschenbecher, N. & Bulitta, C. (2016). Erste Ergebnisse und Erfahrungen mit einem neuartigen OP-Lüftungssystem auf Basis einer temperaturkontrollierten Luftströmung. *Krankenhaus-Hygiene +Infektionsverhütung*, 38(2), 67-73.

A T_cAF ventilation system installed in the research operating room of the Ostbayerische-Technische Hochschule Amberg-Weiden in Germany was evaluated using CFD analysis. It was proven to be less influenced by obstacles in the operating room such as operating lamps. According to Swedish standard for microbiological cleanliness in the operating room SIS-TS 39: 2012 active air sampling was performed under real operating conditions. The results verified that the T_cAF ventilation system is efficient regarding reduction of airborne bacterial contamination.

(e) Wang. C (2019) Ventilation performance in operating rooms; A numerical assessment, Doctoral Thesis, KTH Royal Institute of Technology

This doctoral thesis investigates the performance of different ventilation technologies using CFC and confirms the performance of Temperature Controlled Airflow (TcAF).

(f) Aganovic, A., Cao, G., Stenstad, L. I., & Skogås, J. G. (2017) Impact of surgical lights on the velocity distribution and airborne contamination level in an operating room with laminar airflow system. *Building and Environment*, *126*, 42-53.

The presence of surgical lights disturbs the flow of ultraclean air in operating rooms (ORs) with vertical laminar airflow systems (LAF) by creating a wake downstream of the lights. The wake may be characterized by velocities low enough to directly influence the level of airborne microbe- carrying particles close to the surgical site in an OR, eventually leading to surgical site infections (SSIs). In order to detect microbiological contamination during operating conditions, four mock surgeries were performed mimicking real surgeries on a porcine tissue. Three of the surgeries were performed under different types of surgical lights and one surgery did not include surgical lights at all. The mean velocity under all three surgical lights was significantly lower (≤0.07 m/s) compared with the mean velocity measured when the LAF was not obstructed by lights (0.24 m/s).

(g) Wang, C., Sadrizadeh, S. & Holmberg, S. (2018) In: Proceedings -Roomvent &

Ventilation 2018. Aalto University, Espoo, Finland, June 2-5 2018

This study numerically investigated the influence of surgical lamps on the airflow pattern and airborne bacteria concentration in two existing operating rooms equipped with, respectively, a laminar airflow system and a temperature-controlled airflow system. Two different lamp shapes were studied: a closed-shape lamp and an open-shape lamp. The closed-shape lamp obstructs the unidirectional airflow in the LAF ventilated OR and results in an increase in the bacteria concentration. The open-shape lamp, in contrast, creates limited disturbances to the airflow and the desired flow pattern can be achieved. TcAF shows good performance in reducing the concentration of airborne contaminant with both closed-shape and open- shape lamps. In the TcAF system, the cooler air falls down to the surgical site from the supply diffusers, forming a relatively unidirectional flow over the surgical site. This buoyancy-driven downward flow is capable of washing off bacteria carrying particles from their sources and preventing them from reaching the patient.

(h) Zhijian Liu, Di Yin, Lina Hu, Junzhou He, Guoqing Cao (2022) Bacteria-carrying particles diffusion in the operating room due to the interaction between human thermal plume and ventilation systems: An experimental-numerical simulation study

During surgery, the release of bacterial-carrying particles (BCPs) by surgeons is one of the major pollution sources in operating rooms (ORs), which may cause surgical site infection (SSIs) or health problems. The human thermal plume emitted by the human body may affect the airflow in the surgical micro-environment, leading to the further spread of BCPs. The experiments of airspeed measurements and biological particle emission were carried out in a standard vertical laminar ventilation operating room. Computational fluid dynamics (CFD) was used to extend the investigation of the different ventilation systems. The TcAF (called TAF in the article) ventilation system was superior to the other three systems in reducing BCPs levels in the air of the operating room.

15. **“Depending on the ventilation principle, surgical lamps can influence the airflow and particle distribution in the operating room”**

(a) Wang, C., Sadrizadeh, S. & Holmberg, S. (2018) In: Proceedings -Roomvent & Ventilation 2018. Aalto University, Espoo, Finland, June 2-5 2018.

This study numerically investigated the influence of surgical lamps on the airflow pattern and airborne bacteria concentration in two existing operating rooms equipped with, respectively, a laminar airflow system and a temperature-controlled airflow system. Two different lamp shapes were studied: a closed-shape lamp and an open-shape lamp. The closed-shape lamp obstructs the unidirectional airflow in the LAF ventilated OR and results in an increase in the bacteria concentration. The open-shape lamp, in contrast, creates limited disturbances to the airflow and the desired flow pattern can be achieved. T_cAF shows good performance in reducing the concentration of airborne contaminant with both closed-shape and open-shape lamps. In the T_cAF system, the cooler air falls down to the surgical site from the supply diffusers, forming a relatively unidirectional flow over the surgical site. This buoyancy-driven downward flow is capable of washing off bacteria carrying particles from their sources and preventing them from reaching the patient.

(b) Zoon, W. A. C., van der Heijden, M. G. M., Loomans, M. G. L. C., & Hensen, J. L. M. (2010). On the applicability of the laminar flow index when selecting surgical lighting. *Building and Environment*, *45*(9), 1976-1983.

Surgical lamps can significantly disturb the flow of clean air. Zoon et al. conducted experimental and numerical studies and found that the infection risk was proportional to the projected area of the surgical lamp. Zoon et al. measured velocities that ranged from 0.10 to 0.20 m/s under three differently shaped and sized surgical lights using hot sphere anemometers in a small-scale experimental chamber equipped with LAF. This study also showed that the velocity was lower under closed shaped lights compared with light-heads with openings.

(c) Aganovic, A., Cao, G., Stenstad, L. I., & Skogås, J. G. (2017). Impact of surgical lights on the velocity distribution and airborne contamination level in an operating room with laminar airflow system. *Building and Environment*, *126*, 42-53.

The presence of surgical lights disturbs the flow of ultraclean air in operating rooms (ORs) with vertical laminar airflow systems (LAF) by creating a wake downstream of the lights. The wake may be characterized by velocities low enough to directly influence the level of airborne microbe-carrying particles close to the surgical site in an OR, eventually leading to surgical site infections (SSIs). In order to detect microbiological contamination during operating conditions, four mock surgeries were performed mimicking real surgeries on a porcine tissue. Three of the surgeries were performed under different types of surgical lights and one surgery did not include surgical lights at all. The mean velocity under all three surgical lights was significantly lower (≤0.07 m/s) compared with the mean velocity measured when the LAF was not obstructed by lights (0.24 m/s).

16. "Qualification and modeling of ventilation systems needs to be realistic to minimize the risk of microbiological contamination"

(a) Rotheudt, H., Lichtner, E., Brockmann, G., Hofera, V., Askan, T. Hartmann, A., Zielke, B. & Kriegel, M. (2018) Distribution of Microbial Contamination in Operating Theaters and Healthcare Environments. In: Proceedings 24th International Symposium on Contamination Control and Cleanroom Technology, The Hague, Netherlands, Sept 23-26.

Most investigations and the standard acceptance test cases consider particle contaminant of small particle size that is completely airborne without gravitational effects. Brownian diffusion has the greatest impact on small particles. Bacteria carrying particles are mainly in the range of medium sized particles that are affected by turbophorensis and interception, or in the range of large particles that are highly influenced by gravity. Microbial contaminants are thus affected by their gravitational settling and do not perfectly follow the airflow motion. Gravitational forces lead to significantly increase their deposition behavior. Therefore, investigations that consider the microbial particulates as completely

airborne have limited validity to predict the surface contamination inside patients wound field or on medical instruments.

(b) Zielke, B., Hofer, V., Rotheudt, V., Rischmüller, S., Brockmann, G. & Kriegel, M. Experimental Investigation of Airborne Particle Distribution in Operating Theatres under Realistic Load Configuration: A – Developing an Operating Personnel Dummy with Realistic Posture and Particle Emission. Presented on Healthy Buildings 2017 Europe, Lublin, Poland, July 2-5. https://www.isiaq.org/docs/presentation/0075.pdf

To evaluate different airflow patterns regarding their ability to protect the patient from airborne contamination, the use of realistic contamination sources, flow obstacles and heat loads is fundamentally important. Over-simplistic arrangements are often used to evaluate the effectiveness of OR ventilation. For example, according to the German standard on operating rooms (DIN 1946-4), it is assumed that the personnel stand upright beside the patient and that the particle sources are located on the floor. Thus, for the evaluation of an OR air flow concept, the use of a realistic personnel dummy is essential for two reasons: firstly, because the personnel are the main source of germs and those are distributed not only at floor level, and secondly because the personnel have a significant effect on the airflow by being an interruption into the path of air when bending over the patient.

(c) Sadrizadeh, S., Holmberg, S, 2015. Impact of staff posture on airborne particle distribution in an operating theatre equipped with ultraclean-zoned ventilation. 36th AIVC Conference "*Effective ventilation in high performance buildings*", Madrid, Spain, 23-24 September 2015.

Usually, operating room ventilation performance is determined without considering the influence of staff-member posture and movements. Results indicate that bending posture increases the overall number of suspended particles in the surgical area by disrupting the particle-free airflow.

(d) Whyte, W., Lidwell, O. M., Lowbury, E. J. L., & Blowers, R. (1983). Suggested bacteriological standards for air in ultraclean operating rooms. *Journal of Hospital infection*, *4*(2), 133-139.

In this study from 1983, Whyte et al. states that bacteriological standards for the air in ultraclean operating rooms are needed since physical tests alone cannot guarantee satisfactory results. 10 cfu/m^3 is suggested as the highest acceptable value for an ultraclean system since a substantial benefit can be obtained if the average concentration of airborne contamination do not is exceeded. Confirmation that the ultraclean air system has resulted in an acceptable low level of bacterial contamination of the air is therefore an essential precaution.

17. **"TcAF installation reduces risk for SSI – 3% to 1% in large study"**

(a) S. Vasiuk, Y. Vasylchyshyn, V. Vasyuk, C. Bulitta (2019) Antimicrobial Resistance & Infection Control, Volume 8 Supplement 1, Abstracts from the 5th International Conference on Prevention & Infection Control (ICPIC 2019) P274 Efficacy of Temperature Controlled Airflow (TcAF) Ventilation in the OR

to reduce Surgical Site Infections

The aim of the study was to evaluate the impact of operating room ventilation technology on clinical outcome parameter.

The method was based on a retrospective analysis of 1,000 consecutive cases of primary total joint arthroplasty (hip, knee) before and 1,000 consecutive cases after the installation of an ultraclean airflow ventilation system (temperature-controlled Airflow TcAF System Opragon AB, Avidicare Sweden), in the same operating room was performed. Clinical outcome was evaluated using length of stay and infection rates as endpoints. The proper function of the TcAF system was checked by intraoperative measurement using active air sampling (blood agar plates, Klotz Impactor FH6).

The results illustrated that the intraoperative airborne contamination was always below 5 cfu/m3 of air, which is the threshold demanded according to the Swedish SIS standard for ultraclean air in operating theatres demonstrating proper function of the system. Ultraclean air provided by the TcAF system was associated with a decrease in mean postoperative hospital stay from 11.0 to 8.64 days, a decrease in percentage of patients who stayed inpatient over 14 days after surgery from 7.3 to 2.2 %, and a decrease of infectious complications from 3.3 to 1.1 %.

(b) C. Bulitta, Sergeii Vasiuk, Yaroslav Vasylchyshyn, Volodymyr Vasyuk, Regina Guttenberger, and Sebastian Buhl (2020) Clinical validation and efficacy of a temperature-controlled ventilation system (TcAF) in the OR to reduce surgical site infections

Microbiological burden of room-air in operating theatres is a known risk factor for surgical site infections. However, it is unclear how to best evaluate efficacy and efficiency under routine clinical conditions. Moreover, there still is a lack of data to assess the impact on infection rates. The aim of this study was to evaluate a temperature-controlled ventilation system (TcAF) under routine clinical conditions and assess its impact on infection rates. 10 clinical installations of the TcAF system Opragon (Avidicare AB, Sweden) were assessed during live surgeries according to the Swedish SIS TS 39: 2015 standard.

The study shows positive impact on key clinical outcome parameters in line with previous research by Charnley and Lidwell.