Board of Directors of the German Society of Hospital Hygiene (DGKH):

Air Quality in the Operating Room: Surgical Site Infections, HVAC Systems and Discipline

1. The history of heating, ventilation and air conditioning (HVAC) in general

Until the late 1970s little attention was paid to the impact of ventilation systems on the air quality.
It was only in the wake of systematic investigations of e.g. the source of *Legionella pneumophila* and the cause of sick building syndrome (e.g. Kröling 1985) that progress would follow relatively fast. For example, in northern Europe in particular, standards and guidelines were enacted on hygienic planning, implementation and operation of HVAC systems. Since 1999 personnel working with HVAC systems in Germany must be trained by certified bodies (VDI 6022).

In Germany, a conventional HVAC system, e.g. as used in offices just like in hospitals, must be manufactured in accordance with VDI 6022. This calls for, inter alia, an F7 filter (as per the new ISO standard 16890 minimum filtration efficiency ISO ePM2.5 $\geq$65%) at the inlet to the main unit and an F9 filter (as per the new ISO standard 16890 minimum filtration efficiency ISO ePM1 $\geq$80%) at the supply air outlet of the main unit.

2. The history of heating, ventilation and air conditioning in the operating room

For centuries the air has been viewed as the main route of transmission of infectious diseases.
During the 1950s the principle pathogen reservoirs for surgical site infections (SSIs) were thought to be the nasopharyngeal region of the surgical team and the operating room air (Kappstein, 2001).
In the 1960s the first isolated studies (e.g. Charnley et al. 1969) were carried out on the hygienic impact of ventilation concepts.
In the 1980s Lidwell et al. (1982, 1983a, 1983b, 1984a, 1984b, 1986, 1987, 1988) published various studies reporting fewer deep SSIs after total hip or knee replacement operations when laminar airflow (LAF) ventilation was used (around 2-fold reduction) compared with conventional ventilation. The infection rate was further reduced when body-exhaust suits were worn additionally (around 4.5-fold). The reduction was 3-4-fold when perioperative antibiotics were administered, whereby according to Lidwell et al. the effects of the air and antibiotic administration were additive and independent of each other (Lidwell et al. 1984b, 1987)
Likewise, during the 1980s Rüden et al. demonstrated that septic operations were not associated with increased airborne microbial counts (Kappstein, 2001).
In 2001 in a review of the literature conducted on behalf of the DGKH, Kappstein reported that airborne pathogens present as droplet nuclei could only originate from the nasopharyngeal region and from skin scales from surgical personnel. On using HVAC systems with turbulent mixed airflow bacteria could be spread from persons at the periphery of the operating room to the wound. Therefore, HVAC systems would

have to supply the area around the surgical field and instrument table with air with only a low microbial count. The airflow principle would have to be stable laminar airflow (low-turbulence displacement) ventilation Kappstein 2001).

Modern HVAC systems in the operating room have the following main functions:

- They contribute to patient protection and should therefore assure air of an impeccable hygiene quality (with only a low microbial count or even sterile air).
- They should provide thermal comfort for operating room personnel,
- Remove harmful particles, e.g. carcinogenic surgical smoke gases or anaesthesia gases and, furthermore,
- Meet technical process or product requirements (functionality and safety).

Modern HVAC systems as used in the operating room have three filtration stages, whereby in Germany the third is usually a terminal filtration stage mounted flush with the ceiling in the operating room. This filtration stage should be of H13 or H14 quality (pursuant to DIN EN 1822). For laminar airflow ventilation (low turbulence displacement ventilation) a fabric ceiling panel measuring approx. 3.2 x 3.2 m and fitted over a large area with the terminal filters is currently required. The low turbulence is assured by the fabric. For flawless functionality of the ventilating ceiling the incoming air must be somewhat cooler than the ambient air so that it will slowly drop downwards in accordance with physical principle.
That physical principle is assured without further interventions through utilization of the operating room and the heat input from equipment and persons.
For a long time now laminar airflow ventilation has been the gold standard for operating rooms. With the introduction of DIN 1946-4 in 2008 it has been a requirement for a number of operations, something that was difficult to comprehend in certain respects and led to considerable criticism. In 2010 the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (*KRINKO)* adopted a critical stance on that, stating that in view of study findings there was no justification for differentiation into class Ia room (laminar airflow) and class Ib room (swirl diffusers or small LAF ceiling).

An amended version of DIN 1946-4 was published in 2018, setting out that the class Ia room continued to be justified and that the type of surgery with the most stringent requirements defined the room class of an operating room. But that meant that the class Ia room continued to be the state of the art and would be taken into account in the building design.

3. Verification of HVAC systems

The design of the laminar airflow ventilation systems (low-turbulence displacement ventilation) long used in the pharmaceutical and electrical industries has improved considerably since early 2000 for the creation of a clean zone in operating rooms.
Since early 2000 the German-speaking, Dutch and Scandinavian standards and guidelines have featured comprehensive test methods for verification of the impact of laminar airflow and mixed airflow concepts on the air quality in operating rooms. For example on using laminar airflow the introduction of particles (to which pathogens too can adhere during surgery) must be lower by a factor of at least 100 than for mixed

airflow. To that effect, the degree of protection must be ascertained in accordance with precise specifications for the surgical field with swivel, surgical lighting fixtures (degree of protection $\geq$2). By contrast, for mixed airflow it is more practical to determine the recovery time ($\leq$20 min) of a particle burden in the room after elimination of the particle source through continuous thinning out of the ambient air with inflow of sterile filtered supply air. With laminar airflow the recovery time in the protected area would be less than 2 min because of its directed airflow.

4. Current comments against laminar airflow

In 2016/2017 Bischoff, Gastmeier, Allegranzi et al. published several papers objecting to the installation of laminar airflow ventilation. These papers were published in the *Lancet Infect Dis* (Bischoff et al. 2017a, Allegranzi et al. 2016) as well as one paper by WHO (2016; which served as the basis for the Lancet *Infect Dis* publication in 2016). Below we address specifically the publication by Bischoff et al. (2017a).

The studies on which the publications by Bischoff, Gastmeier, Allegranzi et al. were based reported inconsistent SSI rates for total hip and knee arthroplasties and other operations in relation to the ventilation concept.

The study by Brandt et al. (2008) conducted by the working group headed by Prof. Gastmeier played an important role in the past since for diverse operations with the exception of colon surgery it was unable to find any evidence that laminar airflow had a protective effect, with even increased infection risks predominantly identified. For surgery performed using laminar airflow higher SSI rates were identified for total hip arthroplasty (sign.), total knee arthroplasty, appendectomy, cholecystectomy and hernia operations, but conversely fewer infections for colon surgery. The study included data from the German national nosocomial infection surveillance system (*KISS*) from 2000 to 2004 (99,230 operations with 1,901 SSIs corresponding to 1.9 %). In August 2004, i.e. after data collection, a questionnaire was sent out to the respective infection control teams to obtain information on the HVAC systems. The publication did not include any critical discussion of the findings; in particular, the reasons why laminar airflow should yield better results for colon surgery were not explored.

Assadian et al. (2009) and Kramer et al. (2010) addressed criticism to that study. The latter stated that the technical parameters and configuration of the HVAC systems had not been checked at the start of the survey. Furthermore, it was likely that the requisite ceiling panel of 3.2 x 3.2 m was not assured in the majority of cases since the DIN standard 1946-4 first described that ventilation concept only in December 2008. It was thought that several potential confounders had not been taken into account, for example the surgeons, operating room furnishings, surgical drapes, patient risk factors, perioperative prophylaxis, hair removal or follow-up. Moreover, the postal survey had to be viewed in a critical light since even the technical personnel were often not able to give proper responses regarding the type of ventilation in use, with e.g. perforated sheet ceilings classified as LAF ceilings.

Another critical aspect is that, especially in the case of total prosthesis implantations, the majority of SSIs only manifest after patient discharge from hospital, i.e. at a time

not properly reflected with the *KISS* method. Data from Switzerland (Staszewicz et al. 2014, Troillet et al. 2017) demonstrate that for total hip arthroplasty around 80 % and for total knee arthroplasty around 95 % of SSIs occurred only after hospital discharge. That means that for the knee arthroplasty rates recorded only on an inpatient basis the actual SSI rates are thought to be 20 times higher.

Furthermore, there is doubt about the quality of hospital-based (inpatient) recording of SSI rates as done with the *KISS* module. In Sweden in a group of 1,215 patients healthcare-associated (HAI) /nosocomial infections were diagnosed by the hospital's infection control team as well as in parallel by external experts, albeit citing rates of 9.3 % (hospital team) and 13.1 % (external experts), respectively. Differences in the quality of data collection were also identified on comparing the Swiss findings (Swissnoso) with the German data (*KISS* and external quality assurance). Below a number of examples of HAI rates:

Operation	**Switzerland (Swissnoso)**	**Germany (*KISS*)**	**Germany (external quality assurance)**
Total hip arthroplasty	1.6 %	1.1 %	0.32 %
Total knee arthroplasty	2.0 %	0.7 %	0.14 %
Laparoscopic appendectomy	3.6 %	0.64 %	
Open appendectomy	4.8 %	4.46 %	
Cholecystectomy	3.0 %	1.3 %	
Colon surgery	12.8 %	8.8 %	
Caesarean section	1.8 %	0.5 %	0.11 %
Heart surgery	5.4 %	2.9 %	
As per IQTIG 2017, Swissnoso 2013			

Table 1: Comparison of HAI rates using different infection recording systems

Hence, Switzerland was found to have in most cases two- to threefold more postoperative SSIs than Germany (KISS), whereas the findings by the external quality assurance team in Germany for Caesarean section, total hip and knee arthroplasties were around four- to fivefold less than the *KISS* rates. Since it is not thought that the Swiss healthcare system is poorer that its German counterpart, the differences must be due to methodical disparities, e.g. data recorded for variable periods after patient discharge (in Switzerland 90 % for over one year).
It must therefore be assumed that in the study by Brandt et al. the reported infection rates were underestimated.

The criticism levelled at the study by Brandt et al. led to a follow-up study by Breier et al. (2011 – Germany). This retrospective cohort study based on data from the *KISS* data pool included 33,463 total hip arthroplasties and 20,554 total knee arthroplasties covering the years 2004 to 2009. That was followed in 2009 by an online survey

when hospitals were also asked about the size of the LAF ceiling panel. It was revealed that only 35-40 % of operating rooms had a LAF ceiling measuring at least 3.2 x 3.2 m. Again, some of the operations performed using laminar airflow had higher infection rates but these were markedly less than in the study by Brandt et al. (2008). For total knee arthroplasties laminar airflow was even found to have a protective effect, albeit that was not significant. One limitation cited was that – as in the study by Brandt et al. – data on perioperative antibiotic prophylaxis were not recorded and post-discharge data recording was not "systematically" conducted with the *KISS* method. Hence, the SSI rates were far lower than in the study by Brandt et al. or laminar airflow was even found to have a protective effect for total knee arthroplasties. Besides, further limitations were identified for the investigation method (inadequate post-discharge data collection, perioperative antibiotic prophylaxis (PAP) not taken into account, ceiling panels too small in most operating rooms), hence the study cannot be used as a valid basis for assessment of LAF ceilings with the current standard dimensions of 3.2 x 3.2 m.
Another problem is the lack of standardized qualification of laminar airflow systems prior to 2008. The methods for operating room qualification were first published in 2008 with the introduction of DIN 1946-4. Therefore, reliable functionality of laminar airflow systems before 2008 cannot be assumed.
It must be pointed out that in the German-speaking countries the greatest changes in the design of operating room ventilation systems for class Ia rooms were ushered in only as from 2002 and 2008, with the introduction of new standards in Switzerland (SWKI 99-3:2002), Austria (ÖNORM H 6020:2007) and Germany (DIN 1946-4:2008). Only in the aftermath of these publications has a minimum size 3.2 x 3.2 meters been required for LAF ceiling panels; furthermore, the acceptance terms for the air quality have been greatly tightened and brought into line with real life conditions. Until then it was only possible to install, as indeed was the case, mainly much smaller ceiling panels (e.g. 1.8 x 2.4 m), which had a considerably reduced supply air flow rate.

Various critical remarks can be made about the studies evaluated by Bischoff et al. (2017a), while raising the following issues:

- While the cohort study by Kakwani et al. (2007 - UK) with a total of 435 patients was small, it demonstrated a significant reduction of the hemiarthroplasty infection rate from 5.8 % to 1.4 % on using laminar airflow. A particularly positive aspect of the study was that the follow-up period was at least one year.
- The study by Hooper et al. (2011 – New Zeeland) is an evaluation of the Dutch Joint Registry, showing higher infection rates with laminar airflow, but the panel sizes were not reported. However, only "early infections" were reported hence it is probable (see above) that these were greatly underreported. For example, for 51,485 total hip arthroplasties only 46 infections and for 36,826 total knee arthroplasties 50 infections were diagnosed. That corresponds to 0.09 % and 0.14 %, respectively. Hence, the rate for total hip arthroplasties, at least, was markedly less than the values identified by the German external quality assurance team at 0.32 % (IQTIQ 2017), which themselves have little validity and no doubt reflect too low infection rates (see above). The data of the Dutch Joint Registry are therefore not plausible and should not be used for evaluation of LAF ceiling panels.

- The study by Pedersen et al. (2010 – Denmark) is an evaluation of data from the Danish Hip Arthroplasty Registry for the years 1995 to 2008. The mean follow-up period was five years (range: 0 to 14 years). With 80,756 operations, there were 597 infections corresponding to 0.7 %. With laminar airflow there were fewer infections (crude risk ratio (RR) 0.81, adjusted RR 0.90), however, the differences were not significant.
- The study by Namba et al. (2012 - USA) likewise evaluated registry data, the Kaiser Permanente Total Joint Replacement Registry, with a reported follow-up period of one year. From the 30,491 total hip arthroplasties carried out between 2001 and 2009, there were 155 infections corresponding to 0.51 %. The hazard ratio with laminar airflow at 1.08 was not significant. As pointed out below, laminar airflow in the USA is not necessarily comparable with laminar airflow ventilation as used in Germany.
- Dale et al. (2009 – Norway) published a study on hip arthroplasty infections based on data from the Norwegian Arthroplasty Registry for the period 1987 to 2007. Out of 97,344 cases there were 614 infections corresponding to 0.6 %. The follow-up period continued to the time of patient death, relocation or to the end of 2007, with a range of 0 to 20 years. Laminar airflow was associated with an increased risk with RR of 1.3 (significant with p=0.006).
- Bosanquet et al. (2013 - UK) published a retrospective evaluation of a “single consultant”, over a period of one year, who investigated SSIs in 170 vascular patients. There were 23 SSIs corresponding to 13.5 %. With laminar airflow there were fewer infections – 11 % compared with 33 % (p=0.034).
- The study by Jeong et al. (2013 - Korea) was a cohort study of gastric surgery in 10 hospitals with 2,091 patients. The follow-up period was one month. There were 71 SSIs corresponding to 3.4 % - albeit, the rates for individual hospitals were between 0 and 15.7 %. Overall, there were fewer infections with laminar airflow at 7.2 % compared with 36.6 % (significant). The major differences in SSI rates among the various hospitals were very conspicuous. Furthermore, data were collected separately on laminar airflow and HEPA filters, suggesting that laminar airflow in Korea need not necessarily be the same as that in Germany.
- Miner et al. (2007 – USA) investigated the rate of deep SSIs following 8,288 total knee arthroplasties in 256 hospitals based on Medicare claims. On using laminar airflow an RR of 1.57 was calculated (not significant).
- Song et al. (2012 – Korea) conducted a retrospective cohort study in 26 hospitals between 2006 and 2009, recording SSIs after total hip and knee arthroplasties. Here a distinction was made between operations performed under laminar airflow, operations with HEPA filter alone and operations with no mechanical ventilation. Laminar airflow was used as reference. For the other two ventilation types increased risks were seen in most cases, and were significant for total knee arthroplasties conducted in operating rooms with HEPA filter alone, with odds ratio (OR) of 1.83.

The publication by Bischoff et al. (2017a) reported on a meta-analysis of the included studies which appear to have had different weightings. For example, the study by Brandt et al. with 28,633 patients was assigned a weight of 16 %, the study by Dale

et al. with 93,958 patients a weight of 17.1 % and the study by Hooper et al. with 51,485 patients a weight of 10.1 %. These weightings are not plausible.
For total hip arthroplasties data evaluation yielded an OR of 1.29 and for total knee arthroplasties of 1.08 – neither is significant despite the enormous sample sizes.

For the meta-analysis of non-bone operations the OR calculated was 0.75 (not significant) in favour of laminar airflow. In the Discussion the authors elaborated "… it seems that laminar airflow does not reduce the risk of overall SSIs…" for these operations (meaning the non-bone operations – the authors) – the opposite is the case based on their meta-analysis.

Still more interesting is the last sentence in the article, stating:
"Very low-quality evidence suggests that compared with conventional ventilation, laminar airflow ventilation does not reduce the risk of deep SSI after total hip and knee arthroplasties. Inadequate evidence suggests that laminar airflow does not reduce the overall SSI when compared with conventional ventilation after abdominal and open vascular surgery. Conventional operating room ventilation systems appear to provide air that is clean enough for procedures involving orthopaedic implants. Given the available evidence shown by this systematic review and the previous cost-effectiveness analyses – which found laminar airflow systems to be more expensive than conventional ventilation systems - … should not install laminar airflow equipment in new operating rooms."
All meta-analyses identified non-significant results which the authors, on one occasion, evaluated as being of "very low-quality evidence" and, in another instance, as "inadequate evidence".
Noteworthy is furthermore that the authors themselves graded their "evidence" as being of low quality or even classified it as inadequate but, nonetheless, concluded that laminar airflow should be rejected. The reasons for that were the costs which tilted the balance against laminar airflow. The authors themselves cited one study by Kramer and colleagues which calculated additional costs of €3.24 per procedure on using laminar airflow. Hence, laminar airflow whose negative effects were not substantiated by the literature review was rejected because of a cost advantage of €3 per patient. Other indisputably positive technological features of laminar airflow (personnel protection) were not taken into consideration.

A letter to the editor on the publication by Bischoff et al. (2017a) was submitted by a Dutch group of authors who cast doubt on the reliability of the responses in the questionnaire. They, too, stated that medical personnel were generally not capable of stating the correct type of ventilation in use and that, besides, data from arthroplasty registries, likewise cited in the publication by Bischoff et al, underestimated the incidence of SSIs by up to 40 %. Hence, in the Netherlands orthopaedists would continue to use laminar airflow (Jutte et al., 2017). By way of response the Bischoff et al. authors acknowledged that, indeed, many experimental studies had shown that laminar airflow reduced bacterial and particulate contamination of the air. However, the causal link between microbial air contamination and SSIs had not been demonstrated to date (Bischoff et al. 2017b) – please see below.

The WHO Recommendation likewise elicited a commentary from a German group of authors (Büttner-Janz et al. O.J.) who stated that laminar airflow with ceiling panels of appropriate dimensions should be the ventilation of choice until such time as better

findings were available. That had been shown to offer patients and personnel enhanced protection against pathogens and surgical smoke.

5. Differences in HVAC ceiling panels between Germany and the USA - Non-comparability

Based on the publication by Wagner (2014) and the experiences of the authors of this paper, laminar airflow is understood in a different context in the USA versus Germany, and apparently perceptions also differ within the various European countries. Whereas in Germany the third filtration stage is in principle a terminal fitting, i.e. it is installed in the operating room ceiling, that is not necessarily the case in the USA, where the third filtration stage may also be fitted in the main unit (based, inter alia, on personal communication from Candice Friedmann and Frank Wille, 2018) or may not be installed at all (ASHRAE 170). That clearly demonstrates, at least on comparing Germany and the USA, that there are different variants and perceptions of laminar airflow systems – not to mention the size of the ceiling panels – hence epidemiological studies from countries that do not take account of that are not comparable.

It is also thought that there are no uniform regulations and concepts on HVAC systems or ceiling panels in other countries and continents (Korea, see above), hence a comparison of international studies is only possible if the design of the laminar airflow system in use is precisely stated. Important factors for evaluation would be the number of filtration stages, filter type, configuration of the filtration stages, ceiling size, air quantities, airflow stabilizers, surgical lighting, type and extent of qualification.

6. HVAC systems with laminar airflow reduce pathogens and particulate contamination

Myriad studies have demonstrated that pathogens and particulate contamination are considerably reduced by laminar airflow (e.g. Ljunggvist and Reinmüller 2013, Andersson et al. 2014, Whyte et al. 1982). In particular, surgical smoke, which may contain carcinogenic substances and viruses (papillomaviruses) Christie et al. 2005, Hensman et al. 1998), is also rapidly eliminated (Hansen et al. 2005, Popp and Hansen 2006, Andersson et al. 2014).

Section 4 of the German Occupational Health and Safety Act (*ArbSchG*) stipulates that occupational health and safety measures shall be taken in accordance with the state of the art and of the provisions of occupational medicine and hygiene/infection control. Moreover, Section 4 of *ArbSchG* states that personal and organizational protective measures shall be subordinated to technical measures. Section 5 of *ArbSchG* calls for hazard assessment, including of the effects of biological substances. Since laminar airflow has been shown to reduce the hazards faced by personnel – from pathogens and carcinogenic surgical smoke – it is one of the primary, occupational health and safety measures to be implemented.

Furthermore, another study demonstrated that operating room traffic, including the number of persons present and number of door openings, increased aerosolized particles and that this could be greatly reduced with laminar airflow (Rezapoor et al. 2018).

7. Evidence of airborne infection transmission

In general it is difficult to conclusively impute postoperative SSI causation to an airborne transmission route. That is because the majority of SSI causative agents are “everyday microorganisms” that can be spread through different channels. One exception is extremely rare pathogens for which other transmission routes can be excluded.

Such is the case for infections caused by *Mycobacterium chimaera* whose only portal of entry into the body is the preceding surgical procedure. Case studies have reported on contaminated heater-cooler systems used for cardiopulmonary bypass (e.g. Walker et al. 2017, Kuehl et al. 2018, German Society … o.J., Schwandtner et al. 2018). That case eminently demonstrates that infections can, indeed, be imputed to airborne transmission.

Likewise, there was a report of a *Trichoderma longibrachiatum* airborne outbreak of SSIs from a defective stool /armchair (Würstl and Stege 2018).

8. Critical limitations of laminar airflow systems

Two aspects of laminar airflow ventilation are very important:

- The size of the LAF ceiling and the resultant area of protection,
- Positioning of instrument tables.

Today, the number of instrument tables used in many operations is so great that they cannot all fit beneath a LAF ceiling measuring 3.2 x 3.2 m. Benen et al. (2013) demonstrated that those instruments exposed outside the Ia ceiling area of protection, especially in Ib operating rooms, have higher microbial counts after a certain exposure time than instruments inside the area of protection. That also demonstrates that LAF ceilings contribute to infection protection. SSIs can also originate from unsterile instruments and implants exposed for a long period of time outside the area of protection afforded by the LAF ceiling or from instruments that had been recontaminated (e.g. Bible et al. 2013, Chosky et al. 1996). To ensure the absence of microorganisms before use, instruments are cleaned, disinfected and sterilized using complex validated processes. It is therefore important that both the surgical field and as many instrument tables as possible are placed within the LAF ceiling area of protection. Often, operating room personnel do not realize this, hence there is a need to foster a greater awareness of that issue.

9. Practical implications are not limited to outcome studies

Bischoff et al. (2017 b) state that outcome studies were unable to furnish proof of an added value of laminar airflow ventilation and concluded that laminar airflow should not be installed. At the same time, they acknowledge that pathogens and particulate contamination can be reduced with laminar airflow but they do not at all take account of that with regard to infection protection and occupational health and safety.

That approach, as such, is not scientifically plausible:

- Outcome studies in the hygiene/infection control setting (see above) are in general of a low quality because of their methodology. By contrast, physical measurements and microbial count measurements (surrogate studies), for example, have a very small margin of error.
- In principle evaluations should be based on epidemiological studies, microbiology tests or experimental investigations, possibly underpinned by theoretical and logical considerations (RKI 2004, KRINKO 2010).

- Such scientific insights are available for laminar airflow, i.e. there is proof that it can reduce both airborne pathogens and carcinogenic surgical smoke. That, in turn, prevents microbial contamination of instruments exposed, and uncovered, for a long period of time on the instrument table. Furthermore, this restricts pathogen entry into open wounds.
- Likewise, it limits personnel exposure to carcinogens in the nasopharyngeal region. In the interest of occupational health and safety alone laminar airflow ventilation must therefore be evaluated in a positive light (Seifert et al. 2017).

10. When do postoperative SSIs occur?

KRINKO (2018) reports that primary wound healing closure without drainage is generally seen after 24 hours and the wound is no longer deemed susceptible to exogenous infection. Therefore the wound dressing can be removed after 24 to 48 hours.

Likewise, during primary wound healing the wound is at risk for endogenous SSIs through haematogenous seeding of bacteria.

It can be inferred that most exogenous postoperative SSIs are causally linked to the time spent in the operating room and less to the postoperative care, e.g. in the patient room (e.g. also Salzberger et al. 2004, Widmer and Battegay 2010, Uckay et al. 2009).

One possible cause may be inadequate preoperative skin disinfection, especially given that bacteria in the hair follicles may not have been effectively inactivated.

It is also well known that implantation of foreign bodies presents a special risk of SSI (Seifert et al. 2017). It was been demonstrated that the minimum infectious dose required for *Staphylococcus aureus* abscess formation was 10,000-100,000 times lower on implantation of foreign bodies (Napp et al. 2013, Kellersmann et al. 2012). It has been reported that colonization of foreign bodies with even 100 pathogens can trigger infection (Seifert et al. 2017).

From this can be concluded that the majority of SSIs are contracted during the time spent in the operating room (Bechstein 2018) and that implants present a particular risk. Apart from the surgical procedure itself, risks emanate from instruments contaminated with airborne microbes, bacterial shedding from surgical staff as well as inadequate preoperative disinfection, especially in the region of the hair follicles. After all, Charnley reported that already 50 years ago (1969, 1972).

11. The influence of poor discipline in the operating room

That poor discipline of surgical staff increases the SSI risk has been demonstrated (e.g. Beldi et al. 2009).

Already for several years now, the *KRINKO Recommendation for Prevention of Postoperative* SSIs has stipulated that the protective headgear and oronasal mask must completely cover all beard and head hair as well as the mouth and nose (2007, 2018).

Likewise, the standard requirement specified in the literature is that all hair must be fully covered (Seifert et al. 2017).

The following table illustrates bacterial shedding from the body under different conditions:

Bacterial shedding (per hour with slight movement	Normal skin
Undressed	25,000- 40,000
With surgical clothing	14,000–28,000
With clean room overall and high boots	780–2,240
Based on Construction Ministers Conference 2013	

Table 2: Bacterial shedding in relation to different types of clothing

In certain cases it has been possible to impute SSI outbreaks to individual surgeons who were carriers (Wang et al. 2001).
It has been demonstrated that of the parts of the head that (may have) remained uncovered during the operation, the ears were responsible for most bacterial shedding, i.e. three times more than the forehead or the eyebrows (Owers et al. 2004). Besides, it must be noted that in many operations the surgeon's head is very close to the surgical site, often for prolonged periods of time. Attention has been drawn earlier to the importance of wearing proper headgear and a massive rise in bacterial shedding has been demonstrated on omission of headgear (Friberg et al. 2001).

The *KRINKO* requirement that the protective headgear and oronasal mask must completely cover all beard and head hair as well as the mouth and nose can only be fulfilled by wearing an Astro helmet/hood, which together with a properly worn oronasal mask will cover even an extensive beard.
However, it must be ensured that the surgical helmets are of a high standard with regard to particle retention (Markel et al. 2017).
The current real life situation: Often, the hair is uncovered, ears are not covered and even in the case of staff at the operating table the oronasal mask frequently does not fit tightly (DGKH 2017).

12. Skin diseases are an additional risk

The *KRINKO Recommendation for Hand Hygiene* (2016) was the first to draw attention to the problem of chronic skin diseases, suggesting that if necessary through the intervention of the occupational physician colonization with potential pathogens should be investigated and eradication attempted. After all, atopic eczema and psoriasis are both seen in around three percent of adults. More attention must be paid to that problem in the future in the operating room:

- Operating room personnel should be tested for bacterial colonization and, if necessary, efforts made to eradicate highly pathogenic bacteria (MRSA – currently not possible for MRGN and VRE, possibly with the exception of *Acinetobacter* on the skin). Testing must be repeated at regular intervals.
- Risk assessment must be conducted and, if necessary, critical skin sites covered.

13. Operating rooms as clean rooms

On 1 August 2007 the Human Tissue (Quality and Safety for Human Application) Regulations [Quality and Safety of Human Tissues and Cells) came into force in Germany, transposing into national law Directive 2004/23/EC of the European Union from 2004. Since then tissue preparations, which within the meaning of

Section 1a(4) of the Transplantation Act are tissues or are prepared from tissues, are defined as medicinal products pursuant to Section 4(30) of the German Medicinal Products Act (*AMG*).
Tissue preparations include human corneas, human amniotic membranes, skin, cardiovascular tissue such as cardiac valves and blood vessels as well as musculoskeletal tissues such as femoral heads and bone preparations, soft tissues (fascia and tendons) and bone cartilage.
With the new directive, there are now uniform quality and safety standards throughout Europe for donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. When handling and processing tissues in a tissue bank an air quality that minimizes the risk of microbial contamination must be assured. The environment must meet at least class A cleanliness and the background environment class D cleanliness of the EC guide to Good Manufacturing Practice (EU GMP…). In Germany pursuant to Section 64 of *AMG,* tissue banks are inspected by the competent state authorities at least once every two years after award of licence. Increasingly, the state authorities apply the same requirements for tissue procurement as for tissue processing. As such, operating rooms become class A clean rooms, which implies that in operating rooms where tissue procurement / harvesting takes place laminar airflow is needed.

14. Conclusions

The following conclusions can be drawn from the above:

- The publications by Bischoff, Gastmeier, Allegranzi et al. report on various studies which for methodological reasons cannot be used for evaluation of laminar airflow ventilation. These include the studies by Hooper et al. (2011 – implausible infection rates), Namba et al. (2012 – USA: other laminar airflow standards), Miner et al. (2007 – USA, other laminar airflow standards) and Jeong et al. (2013 – probably other laminar airflow standards in Korea). Likewise, the studies by Brandt et al. (2008) and Breier et al. (2011) from Germany have obvious methodological shortcomings. That leaves very few studies, some of which demonstrate the protective effect of laminar airflow but, overall, do not suffice to permit definitive evaluation.
- There is no doubt that laminar airflow is better at reducing pathogens and particles than conventional turbulent mixed airflow and that it also removes carcinogenic smoke more effectively. That contributes to personnel protection and corresponds to the perception in Germany of the primacy of primary protection (technical protective measures) in the workplace, to the extent possible, as in this case.
- Since laminar airflow reduces pathogens and particles it can help to restrict pathogen entry into the surgical site. This is of particular relevance for long operating times.
- Accordingly, laminar airflow confers benefits in operating rooms.
- Likewise, DIN 1946-4 (2018) continues to feature class Ia rooms (laminar airflow) and, as such, laminar airflow reflects the state of the art to be applied to hospital construction in Germany. Therefore, at least some of the operating rooms in new build hospitals should be equipped with LAF ceilings.
- Because of the growing trend towards tissue procurement and associated requirements, it can be assumed that laminar airflow will be mandatory in future

and that the requirements governing the operating room will be upgraded to those of clean rooms.

- The possible causes of SSIs include:
  - Disinfection gaps in preoperative skin disinfection, e.g. bacteria in the hair follicles not effectively inactivated.
  - Bacterial shedding in skin scales and hair from the heads of surgical personnel.
  - Aerosols from the nasopharyngeal region. Hence. the quality and correct fit of oronasal masks play a crucial role here.
  - Contaminated instruments, e.g. those exposed outside the area of protection of the LAF ceiling where they become recontaminated.
  - The surgeon's hands if gloves are damaged or have manufacturing defects.
  - Airborne pathogens (adhering to particles) subjected to turbulence.
  - Haematogenous seeding of bacteria following interventions conducive to bacteraemia.
- Of the regions of the head often left uncovered during an operation in the operating room, the ears are responsible for most bacterial shedding. This means that the ears, too, must definitely be covered with a helmet during an operation. The same applies for all beard and head hair. Astro helmets in conjunction with tight fitting oronasal masks are the only solution for complete coverage of hair, beard and ears. However, attention must be paid to the quality of the helmets since particle penetration through thin helmets may be easier. The hospital's medical superintendent, nursing directors, hospital administrators and operating room management are responsible for implementing an appropriate professional dress code. That, above all, implies acting as role models.

In summary, on no account can a recommendation against the use of laminar airflow ventilation in the operating room be issued. Laminar airflow ceilings assuring an area of protection of 3 x 3 m are superior to conventional turbulent ventilation – they are more effective at reducing pathogens and particles and at removing potential carcinogenic smoke, thus protecting patients, surgeons and exposed instruments. Therefore, as stipulated by the currently valid DIN 1946-4, laminar airflow ventilation should be installed in surgical departments in accordance with the risk of the surgical procedures conducted therein.

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