# **Clinics in Surgery**

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# Air Quality in the Periphery of Operating Rooms during Surgery

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# Abstract

**Background:** Most European ventilation standards and guidelines for infection-prone clean surgeries are developed to determine the size and the air quality of the protected (ultra-clean) area. The periphery of the Operating Room (OR) is not taken into account by most standards and guidelines. However, sometimes the periphery is used to partly position microbiological sensitive instrument tables. The aim of this study was to determine the air quality in the periphery of the OR by means of measuring the number of Colony Forming Units (CFU) during surgery.

**Methods:** CFUs were measured in the periphery at start incision, at several moments during surgery and at the end of the surgery. The recovery time was measured in an 'at–rest' situation.

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**Results:** During 58 surgical procedures the number of CFUs in the periphery was measured. At start incision and during closure of the wound the mean number of CFU/m<sup>3</sup> was 7.0 (SD 10.7) and 6.2 (SD 9.5), respectively. The number of CFUs in the periphery, measured during surgery, did not exceed the international accepted level of <10 CFU/m<sup>3</sup> in 82.4%. The mean CFU value in the periphery of all CFU measurements during surgery (between incision and closure) was 5.9/m<sup>3</sup> (SD 5.8). The mean 100-fold reduction was 6.0 (SD 1.2) minutes in an 'at-rest' situation.

**Conclusion:** The number of CFUs did not exceed 10 CFU/m<sup>3</sup> in 82.4% of the measurements in the periphery of the OR during surgery. The air quality in the periphery might be good enough to safely position instrument tables in case the protected area of the ultra-clean ventilation systems is not large enough.

Keywords: Operating room; Colony forming units; Infection prevention; Ultra clean ventilation systems; Instrument tables; Surgical procedure

### Introduction

Ultra Clean Ventilation (UCV) systems are used in the Operating Room (OR) to reduce the quantity of airborne bacteria in the ultra-clean area and to reduce the incidence of Surgical Site Infections (SSI). When the number of Colony Forming Units (CFUs) in the ultra-clean (protected) area is too high, this is considered a risk factor for SSI [1-3]. SSIs are influenced by many factors. For many SSIs, the responsible pathogens originate from the patient's endogenous flora [4,5]. Exogenous factors like OR staff discipline [6], type of OR clothing [7,8], air cleanliness [9], ventilation effectiveness [10] and the type of ventilation system [3,11] might contribute to the incidence of SSIs.

Underneath a Uni-Directional AirFlow (UDAF) UCV system the number of CFUs, in general, is <10 CFU/m<sup>3</sup> during surgery. However, for large surgical infection prone procedures, the realized protected area of an UDAF is sometimes too small to contain all sterile instrument tables and to allow enough additional space between sterile staff and instrument tables [12-14]. When instrument tables are located (partly) outside the protected area it should meet also the required cleanliness level of <10 CFU/m<sup>3</sup> [5,15].

is properly cited.

To date, standards and guidelines [16-19] focus only on-air quality of the UDAF in the protected area. Air quality in the periphery outside the protected area of the UDAF is not taken into account.

Therefore, the aim of this study was to determine the level of CFUs during surgery in the periphery in order to determine whether instrument tables can be positioned safely in the periphery outside the protected area of the UDAF when the protected area of the UDAF is not large enough.

# **Methods**

Peripheral CFU measurements were performed at two different locations of one hospital organization in the Netherlands between 2014 and 2021. Type of surgery was noted and described as infection prone surgery or generic surgery.

The operating rooms included in this study were equipped with a Unidirectional Air Flow (UDAF). The UDAF system introduces the air directly (and only) above the protected area and not directly into the periphery (Figure 1). All ORs were equipped with an UCV UDAF system. The staff present during surgery wore modern scrub suits made out of 99% polyester and 1% carbon fibers [7]. The source strength using this type of clothing was 2.9 (0.9-5.7) CFU/s per person [7].

Data of the OR location, room sizes, air changes and type of ultraclean ventilation system can be found in Table 1.

#### **CFU** measurements

CFU measurements were performed on two fixed locations in the periphery (Figure 2) outside the protected area of the UDAF with a bioMerieux SAMPL'AIR air sampler. This location was chosen since it is often, at this hospital, the location of instrument tables during (large) surgical procedures. CFU measurements were performed based on the Swedish standard SIS – TS 39: 2015 [5].

We defined four moments to measure the number of CFUs: Patient on table (during positioning of the patient, before surgery starts), at incision, between incision and closure (in this study defined as "during surgery") and during closure of the wound.

The measurement cycle of each sample at the location measured was 2.5 min. During 2.5 min 250 dm<sup>3</sup>/min was sampled. The air sampling started directly after the incision was made and was repeated several times during surgery. The last measurement took place during closure of the wound. A measurement technician was present in the OR (periphery) and exchanged the Agar plates after 2.5 min. The Agar plates (bioMerieux COS) were incubated aerobically for  $2 \times 24$  h at 37°C. During the measurements the number of staff present, number of door openings and duration of surgery were noted.

#### **Recovery rate measurements**

On four positions (Figure 3) in the operating room periphery the 100-fold recovery rate was determined with a Lighthouse 3016 handheld particle counter with a flow rate of 2.83 l/min (0.1 ft<sup>3</sup>/ min). For the determination of the 100-fold recovery rate the used methodology is based on the recovery test described in ISO 14644-3; B.12 [20].

Before the recovery rate measurements started, particles were emitted in the whole operating room with a calibrated Topas aerosol generator (model ATM 226, aerosol Emery 3004). The emitting stopped when the particle counter on the measuring locations displayed a background concentration between  $\geq 10^7$  and  $10^9$  particles

per m<sup>3</sup> ( $\geq 0.5~\mu$ m). On each point, at a height of 1.2 m, the particle counter measured the quantity of particles with a particle size of  $\geq 0.5~\mu$ m, with a measuring cycle of 1 min for 10 min. From the number of particles measured at each point the average room periphery 100-fold recovery rate was calculated.

During the measurements, medical equipment, respirators and operating lights (switched on) were positioned in the operational position. The operating lights were positioned according to VCCN RL7 and DIN 1946-4 [16,19].

#### Statistical analysis

Descriptive statistics were used to determine number of CFUs at incision, during surgery and during closure. Scatterplots were used to explore relations between number of CFUs and recovery rate, number of CFUs and length of surgery, number of CFUs and number of door openings during surgery. To explore differences in number of CFUs between infection prone surgeries and generic surgeries a nonparametric Mann Whitney U test was performed.

IBM SPSS version 25 (IBM Corp. Armonk, NY: IBM Corp) was used.

# **Results**

Measurements were performed during 58 surgeries from which 17 surgeries were infection prone surgeries and 41 were generic surgeries. During 29 surgeries measurements were performed at measuring point A (Figure 2). During the other 29 surgeries measurements were performed at measuring point B (Figure 2).

Average duration of the surgery was 56.9 (SD 50.6) minutes. During surgery the average number of staff was 7.6 (SD 1.1, n=54). The number of door openings was 6.4 (SD 8.3, n=53), the 100-fold recovery time was 6.0 min (SD 1.2, n=58).

The number of CFU/m<sup>3</sup> was 36.9 (SD 48.8) during 'patient on table' before the surgical procedure started (n=48). In 35.4% the number of CFUs was <10 CFU/m<sup>3</sup>.

At incision, the number of CFUs in the periphery was in 78.9% lower than 10 CFU/m<sup>3</sup>. After 10 min (SD 10.7, n=37) the number of CFUs was in 83.8% <10 CFU/m<sup>3</sup> and at the end of the surgery (during closure of the wound) the number of CFUs was in 77.8% lower than 10 CFU/m<sup>3</sup>. Results of the CFU measurements in the periphery are shown in Table 2.

During 58 surgeries in total 125 CFU measurements in the periphery were performed, from which 82.4% (103 measurements)



Figure 1: Uni-Directional AirFlow (UDAF) with the UDAF ultra clean (protected) area and periphery.



Figure 2: Measuring locations, dot was the position of the air sampler at measuring location A and B.



Measuring location is mid 'OR wall – UDAF'.

were <10 CFU/m<sup>3</sup>. The mean CFU/m<sup>3</sup> in the periphery was 5.9 (SD 5.8).

No statistical differences were found in the number of CFU/m<sup>3</sup> between generic and infection-prone surgeries.

The scatter plots shown in Figures 4a-4d do not indicate any relationship between measured quantity of CFUs, the Recovery Rate (CRR) (100-fold reduction), duration of surgery and number of door openings in the periphery.

# Discussion

The wound area, the area of the surgical staff and the instrument tables are areas that need to be protected by ultra-clean air [4,21,22–24]. For infection prone surgeries [5] those areas are defined as ultra-clean (protected) areas. Most standards and guidelines for infection-prone surgeries focus on a pre-defined protected area only. However, the size of an UDAF system, described in standards and guidelines [16-18], is sometimes not large enough to position all instrument

tables [12-14] underneath the UDAF system. Therefore, the aim of this study was to determine the air quality in the periphery by means of the number of colonies forming units during surgery.

Our results show that the number of CFUs in the periphery of the operating room between start incision to closure of the wound, did not exceed the international accepted level of <10 CFU/m<sup>3</sup> [1,2] in approximately 82.4% of the cases. In our study, with in total 125 measurements, the highest accepted level of 30 CFU/m<sup>3</sup> [25] was exceeded three times at incision and four times during surgery. 30 CFU/m<sup>3</sup> is the highest number that is accepted for one measurement during a surgical procedure in the SIS-TS39:2015. Possibly the higher numbers during surgery were measured because of activities in the OR like changing the OR team or bringing in equipment necessary for the surgical procedure [21,25-27]. During surgery the surgical staff was wearing modern scrub suits.

The number of CFU/m<sup>3</sup>, when the patient was positioned on the surgical table before incision was made, was on average 36.9 (SD 48.8). In 35.4% the level of CFUs was below 10 CFU/m<sup>3</sup>. These numbers are high and do not comply with the standards. At incision, these numbers were reduced to <10 CFU/m<sup>3</sup> in 45 of the 57 measurements. However, a decrease of the number of CFUs after positioning the patient might result in a further reduction of CFUs in the periphery at the moment the incision is made. A reduction of the number of CFUs could be achieved when a 'clean-up time' is introduced and/ or the surgical staff is wearing clean air suits [5,7,8]. A clean up time is related to the recovery rate and dependent on the number of air changes in the periphery. A lower number of air changes [28], as advised in some guidelines [29], will result in a longer clean-up time and higher numbers of CFUs [3]. In our study the number of air changes in the periphery was approximately 57 and the average 100fold reduction in the ORs was 6.0 (SD 1.2) minutes. With clean air suits [7,8] the dispersion of bacteria-carrying skin particles from the staff into the air of the operating room will also be reduced [7,24,30].

We explored the relationship between number of CFUs, recovery rate [10,31], duration of the surgery and number of door openings [22,23,32,33]. The scatter plots do not indicate any relationship between measured quantity of CFUs and the recovery rate of the periphery. This could be explained by the fact that all ORs have more or less the same room geometry, equal type of clothing [7], equal amount of air changes, recovery rate [31], number of door openings and surgical staff [22,32,33].

This study has several limitations.

First, CFU measurements were conducted at only two locations in the periphery and during two types of surgical procedures (infection prone and generic). However, in this study the examined locations are locations often used by the hospital to position instrument tables in case instrument tables cannot be positioned in the protected area of the UDAF [13,14].

Second, the recovery rate was measured in a 'at-rest' situation and not during surgery. During surgery there may be locations where air does not reach the measurement location due to obstructions, heat sources, room geometry etc. they influence the airflow patterns [34,35,36].

Third, the sampling volume was not fully executed according to the Swedish standard SIS – TS 39: 2015. The sampling volume is advised to be 100 dm<sup>3</sup>/min for 10 min. In this study we used a



Figure 4: Scatter plots of relation recovery rate and level of CFUs at incision (a), relation recovery rate and level of CFUs during closure (b), relation level of CFUs and operation length (c) and relation level of CFUs and quantity of door openings (d).

Table 1: The OR location, room sizes, air changes and type ultraclean ventilation system.

OR TYPE	Hospital Location	System type (No. of ORs)	Surface UDAF [m <sup>2</sup> ]	OR Length [m]	OR Width [m]	OR Height	Volume OR [m <sup>3</sup> ]	Total air volume [m³/h]	Air changes [no.]
1	Α	UDAF (10)	6.4	7.4	5.9	2.8	123	5,593-7,282	46-59
2	Α	UDAF (2)	5.7	5.4	6.2	2.8	96	5,599-6,013	58-63
3	В	UDAF (10)	7.1	6.8	6.1 -6.9	3	127-142	7,412-8,690	56-68

Table 2: Data and results measurements periphery operating rooms. Results are presented as mean (SD).

CFU Measurements Periphery	Patient on table	At incision	At 10 min.	Closure wound
n	48	57	37	54
Number of CFUs Mean [CFU/m <sup>3</sup> ] (SD)	36.9 (48.8)	7.0 (10.7)	5.0 (6.7)	6.2 (9.5)
<10 [CFU/m <sup>3</sup> ]	35.4%	78.9%	83.8%	77.8%

sampling volume of 100 dm<sup>3</sup>/min for 2.5 min. A shorter sampling time is chosen since we wanted to measure the number of CFUs during the positioning of the patient on the OR table, at incision, after 10 min and at the closure of the wound for that particular event. A longer sampling time would give us insight in the mean number of CFUs after 10 min, however this would gain no insight in the specific activity as for example the incision.

# Conclusion

The number of CFUs did not exceed 10 CFU/m<sup>3</sup> in 82.4% of the measurements in the periphery of the operating room during surgery. The air quality in the periphery might be good enough to safely position instrument tables in case the protected area of the ultra-clean ventilation systems is not large enough.

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# **Authors' Contribution**

J.L., R.T. and N.M. wrote the main manuscript text. T.S., R.T. supplied all CFU and measuring data. J.L. prepared figures 1-3 and table 1 and 2. N.M. did the statistical analysis and prepared figure 4. All authors reviewed the manuscript.

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