Review

Ventilation design conditions associated with airborne bacteria levels within the wound area during surgical procedures: a systematic review

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SUMMARY

Without confirmation of the ventilation design conditions (typology and airflow rate), the common practice of identifying unidirectional airflow (UDAF) systems as equivalent to ultra-clean air ventilation systems may be misleading, but also any claims about the ineffectiveness of UDAF systems should be doubted. The aim of this review was to assess and compare ventilation system design conditions for which ultra-clean air (mean <10 cfu/m^3) within 50 cm from the wound has been reported. Six medical databases were systematically searched to identify and select studies reporting intraoperative airborne levels expressed as cfu/m^3 close to the wound site, and ventilation system design conditions. Available data on confounding factors such as the number of persons present in the operating room, number of door openings, and clothing material were also included. Predictors for achieving mean airborne bacteria levels within <10 cfu/m^3 were identified using a penalized multivariate logistic regression model. Twelve studies met the eligibility criteria and were included for analysis. UDAF systems considered had significantly higher air volume flows compared with turbulent ventilation (TV) systems considered. Ultra-clean environments were reported in all UDAF-ventilated ($N = 7$) rooms compared with four of 11 operating rooms equipped with TV. On multivariate analysis, the total number of air exchange rates ($P=0.019$; odds ratio (OR) 95% confidence interval (CI): 0.66—0.96) and type of clothing material ($P=0.031$; OR 95% CI: 0.01—0.71) were significantly associated with achieving mean levels of airborne bacteria <10 cfu/m^3. High-volume UDAF systems complying with DIN 1946-4:2008 standards for the airflow rate and ceiling diffuser size unconditionally achieve ultra-clean air close to the wound site. In conclusion, the studied articles demonstrate that high-volume UDAF systems perform as ultra-clean air systems

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and are superior to TV systems in reducing airborne bacteria levels close to the wound site.

Introduction

The pioneering study by Sir John Charnley in 1964 [1] paved the way for the universal use of unidirectional airflow (UDAF) systems in modern operating rooms by reporting a significant reduction in surgical site infection (SSI) rates following hip replacement procedures in UDAF-equipped operating rooms compared with operating rooms with traditional ventilation systems. Several years later (1969), a study lead by the same author [2] identified a strong correlation between SSI rates and the number of airborne bacteria sampled close to the wound site in total hip replacement procedures. A similar narrative was followed by the findings of the Medical Research Council (MRC) study published in another landmark study in 1983 by Lidwell *et al.* [3], containing data on intraoperative air contamination rates sampled close to the wound during 8055 hip and knee replacement operations. The MRC study reported a substantial benefit in reducing SSIs if the concentration of airborne bacteria near the wound did not exceed a geometric mean of 10 cfu/m^3, which was only achieved with the use of UDAF systems. Following these conclusions, many national standards today [4–6] define a threshold value of 10 cfu/m^3 close to the wound site during surgical activities, i.e. the generally accepted requirement limit for defining ultra-clean operating rooms. Despite the growing evidence from recent years correlating SSI rates with the number of airborne bacteria sampled close to the wound site [7,8], recent systematic reviews and meta-analyses of registry studies [9,10] have initiated a debate on the use of UDAF systems in operating rooms and their (in)efficiency on reducing SSI rates. It should be noted that the vast majority of the registry studies included in these reviews did not contain information on ventilation design conditions, such as the total airflow rate or diffuser size of UDAF systems. The minimum requirement for the total airflow rate defined by the German standard DIN 1946-4 [5] in operating rooms with UDAF systems has increased by more than threefold: from 2400 m^3/h in 1999 to 9000 m^3/h in 2008. These values indicate that the minimum size of the diffuser has increased by the same factor (given the same air velocity), and the new guidelines require the size of the ceiling to be larger than 3.2×3.2 (10.24) m^2. In support of these revisions, the use of high-volume UDAF systems with large-size diffusers has been shown to reduce the microbiological contamination within operating rooms compared with smaller sized UDAF systems [11–13]. Therefore, without confirmation of the ventilation design conditions the common practice of identifying UDAF system as an equivalent to ultra-clean air ventilation system may be misleading, and at the same time any claims about the ineffectiveness of UDAF should be doubted.

For a more comprehensive perspective of the role of operating room ventilation systems in achieving ultra-clean air standards, other personnel-related factors influencing intraoperative air contamination should also be considered [14]. A systematic review from 2016 on intraoperative staff behaviour in operating rooms [15] found a correlation between both the number of persons and the number of door openings with operating room airborne contamination. This relationship has been supported by more recent observational operating room intraoperative studies reporting traffic flow and door openings [16,17]. Another factor that significantly affects intraoperative airborne contamination is the use of body exhaust suits or surgical helmet systems [18]. However, an absolute and comprehensive comparison of measured airborne bacteria levels from different studies in the critical zone cannot be performed without careful consideration of the sampling devices used [19]. Following these conclusions, we decided to select all the studies reporting both operating room ventilation system characteristics and airborne contamination levels within the operating room critical zone, including available information on the activity level, the number of persons present in the operating room during surgery, clothing material, and use of special suits/exhaust gowns. After finalizing the selection, this study aimed to identify the relative contribution of ventilation design conditions (i.e. type and total volume flow) and personnel-related factors on the airborne bacteria levels sampled close to the wound site during surgical procedures.

Methods

In this study, a systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines [20].

Search strategy

The following databases were searched for original articles: Medline, EMBASE, Ovid, Web of Science, Cochrane, and WHO regional medical databases. A comprehensive list of search terms, i.e. "operating rooms", "airborne contamination", and "bacterial load", was used, including Medical Subject Headings (MeSH). The search was limited to English-language articles. The last search was conducted on 24th July 2020. Two independent reviewers screened the titles and abstracts of the retrieved references for potentially relevant studies. The full text of all potentially eligible articles was obtained and then reviewed for eligibility by the same two authors working independently of each other.

Study selection

The first screening inclusion was developed to select only studies that addressed the operating room environment, excluding other clinical environments such as hospital wards and clinics. Second, the selected studies had to report the outcome of airborne bacteria as cfu/m^3 and type of operating room ventilation system. The third set of eligibility criteria was then used to screen the full texts of the articles in more detail. The inclusion criteria were all studies reporting the following

intraoperative information: (1) airborne contamination count sampled within wound site ($\leq$ 50 cm from the wound) using either Sartorius MD-8 Air Scanner or the Klotz FH series sampler; (2) information about the ventilation system design parameters, including data on at least the total number of air exchanges per hour (ACH) or total or supply airflow rate expressed as the volumetric flow rate (m^3/h or L/s).

The measured airborne bacteria levels from one study should not be compared with those from another without careful consideration of the sampling method. We, therefore, decided to only include studies using either the filter sampler (Sartorius MD-8 Air Scanner) or the slit-to agar sampler (Klotz FH series), as these specific types of air samplers have shown no statistical difference ($P<0.05$) in sampled airborne bacteria (cfu/m^3) close to the wound site during ongoing surgery [21]. Also, both types of air sampling devices are recommended by the Swedish Standard Institute for microbiological cleanliness in operating rooms [6]. Publications not describing a research study (conference proceedings, reviews, letters, and commentaries) were excluded and duplicate publications were removed. The search was limited to articles written in the English language, published between 1990 and 30th April 2020.

Quality criteria

All of the articles included in our review were observational cross-sectional studies. Unlike clinical research in which interventions are assigned to patients, the exposure target in the studies in this review was the air contamination rate or the number of bacteria growing on different types of culture media. Because no patients were involved in the outcome, most of the criteria from the recommended quality assessment tools for cross-sectional studies [22] could not be applied, limiting their usefulness. Therefore, we chose to illustrate the quality of individual studies by reporting key elements of their methodology using eleven criteria from the Quality Assessment Tool for Quantitative Studies (ICROMS) [23]. A study was awarded 2 points if a specific criterion was met, 0 points if the criterion was not met, and 1 point if it was unclear. Based on recommendations from ICROMS, scores <60% of the maximum attainable score for that criterion were labelled as a high risk of bias, scores of 60–80% of the total for that study type were labelled as medium reliability and studies with >80% of the total score for that study type were labelled as high reliability. Given that our objectives were to capture all the relevant literature, we did not exclude data based on the quality of the evidence provided. Two co-authors independently assessed each study against the criteria, and discrepancies were resolved by seeking further opinions and a consensus from other authors. Four studies were written by the co-authors of this review (B.L., B.R., R.T.); none of the authors were involved in the quality assessment of their papers.

Data collection

Data from the included studies were extracted by one researcher and checked by a second using a predesigned spreadsheet. From each study, the following information was extracted: source details, authors, year of publication, study type, type of procedure, number of procedures, type of air sampler, the position of air sampler relative to the wound, number of personnel inside the operating room, use of surgical helmets or body exhaust suits, number of door openings, type of ventilation system, and outcome air contamination reported in cfu/m^3. When we found multiple publications from a research group, we determined whether their reports were from the same study population based on the time frame of data collection and data sources, and we removed duplicates.

Data analysis

We dichotomized the dependent variable of airborne bacteria close to the wound site as achieving mean levels of <5 cfu/m^3 and 10 cfu/m^3 and max levels <10 cfu/m^3 and <30 cfu/m^3. The independent variables were treated either as continuous variables (number of air exchanges, mean number of door openings, and mean number of persons present during surgical procedures) or categorical (whether surgical helmets/body exhausts were used; woven vs non-woven clothing: non-woven clothing was defined as without cotton material while woven was considered if the clothing material contained cotton. if the type of clothing system was not reported, it was assumed that the surgical clothing was made of conventional non-woven material). Each potential independent variable was compared separately with achieving the predefined airborne bacteria levels. Fischer's exact test was used to compare categorical variables between groups and binary logistic regression for comparing categorical with continuous variables. If the P-value was less than 0.2, the variable was retained for further analysis in a multivariate logistic regression model. Due to the smaller sample size, a conventional logistic regression was not considered an option. Instead, the recommended penalized logistic regression using the Firth procedure for sparse and rare data was used [24]. The significance was defined as $P<0.05$ (two-tailed). All statistical analyses were performed with Stata version 16 (StataCorp, College Station, TX USA).

Results

Study selection

Our initial search yielded 2,823 articles. After removing duplicates, 1767 unique papers remained, of which 1267 were excluded after the abstract review. The remaining 91 studies underwent a full-text review against the inclusion criteria. Of those, 76 were excluded because either the type of ventilation system, active sampling within the operating room critical zone, door openings, or the number of persons were not reported, leaving 12 articles for our final analysis as shown in the PRISMA flow chart (Figure 1). The marked heterogeneity in the study objectives and designs prevented a meta-analysis.

Study characteristics

Twelve field studies reported ventilation design conditions and intraoperative air sampling during real-time surgical procedures. Of the 12 studies, eight were published in infection-control journals, three in surgery journals, and one in a pharmacy journal. The study dates ranged from 1990 to 2019, and most studies (8/12) were published in the past decade (2010–2019). The studies were conducted in three countries: Sweden ($N = 10$), Finland ($N = 1$) and Netherlands ($N = 1$). The total number of procedures varied from seven to 250 per study.

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│  Potentially relevant records from databases,        │
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│  screened for retrieval (N = 2823)                   │
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│  Articles included for data analysis and synthesis   │
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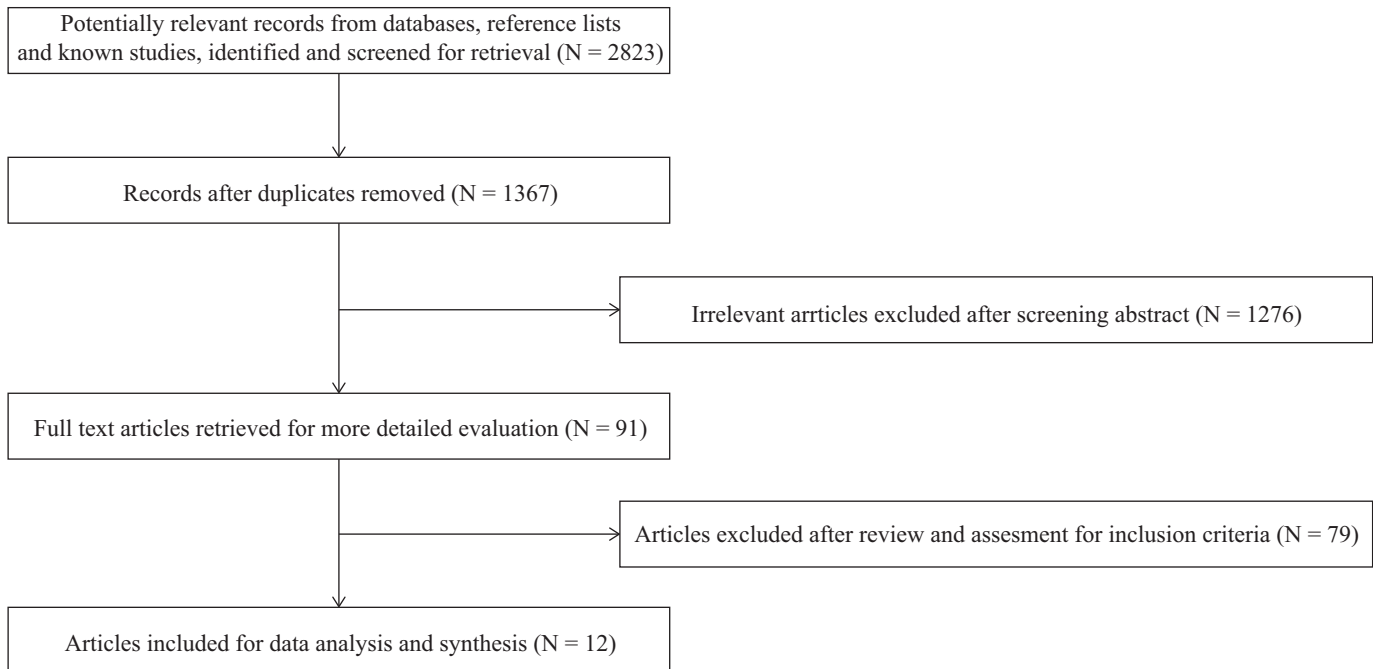
**Figure 1.** Flowchart of the search strategy.

The sampling location relative to the wound varied between 0.2 m and 0.5 m. Seven of nine studies reported information on the clothing type and material, 10 of 12 reported on clothing material, nine of 12 reported on number of persons present during surgeries, seven of 12 reported on number of door openings. If surgical helmets or body exhaust suits were not mentioned, the authors assumed that they were non-existent during the surgical procedures. The total number of air exchange rates (ACH) for each ventilation system was calculated using available data on supply airflow and operating room volume size. In case of missing data on operating room volume size, authors were contacted or the information was extracted through other studies conducted by the same authors in the same operating room. If not reported explicitly, mean values were calculated based on the single measurement results. The quality assessment of the 12 studies is outlined in the Supplementary Data. An overview of the study characteristics for each included study can be found in Table I.

Ventilation and personnel-related conditions associated with ultra-clean air (<10 cfu/m³)

Four different typologies of operating room ventilation systems were identified in the included studies: vertical UDAF (vUDAF) ($N = 8$), turbulent ventilation (TV) ($N = 11$), mobile UDAF in combination with TV (mUDAF + TV) ($N = 4$), temperature-controlled airflow (TcAF) system ($N = 1$). Mean levels below the ultra-clean threshold value of 10 cfu/m³ were reported in all vUDAF ventilated rooms, in four of 11 operating rooms equipped with TV systems, and in three of four operating rooms with combined mUDAF + TV systems (Figure 2). However, it is important to note that mean airborne bacteria levels <10 cfu/m³ were achieved only when non-woven clothing materials were used, the same TV systems exceeded 10 cfu/m³ when woven clothing material was used. On the contrary, UDAF

systems reported mean values within ultra-clean air limits of 10 cfu/m³ regardless of the type of clothing material. Median levels below 10 cfu/m³ were reported in operating rooms with UDAF and TcAF systems, but not in operating rooms with TV. Max values exceeded 10 cfu/m³ in three of eight operating rooms equipped with vUDAF systems, and in all operating rooms with TV systems except for one case. As may be noted in Figure 2, the total number of air exchange rates was remarkably higher for airborne bacteria levels <5 cfu/m³ compared with ACH for bacteria levels higher than 5 cfu/m³. The total average number of persons in the operating room for ultra-clean air ventilation systems (mean <10 cfu/m³) was slightly higher (average 7.26 persons) than the average number of persons in the operating rooms that exceeded the ultra-clean air limit (average 6.9 persons). The use of surgical helmets/exhaust suits was reported in two cases, of which one reported mean values ≥10 cfu/m³. The mean number of door openings was unevenly distributed across the chart; the average number of door openings was higher for mean airborne bacteria levels <10 cfu/m³ (5.91 door openings) compared with cases when airborne bacteria levels exceeded 10 cfu/m³ (average 4.37 door openings).

The bivariate analyses showed that type of ventilation system was significantly associated with all four airborne contamination levels ($P<0.05$), while the total number of air exchange rates was associated with mean airborne bacteria levels <5 cfu/m³ and max levels <10 and 30 cfu/m³, respectively (Table II). When comparing ventilation types between two groups, vUDAF was superior compared with TV for all levels considered ($P<0.05$) and achieved lower airborne bacteria levels compared with combined mUDAF + TV systems for mean levels <5 cfu/m³ and max levels <10 cfu/m³ ($P<0.05$). No significant difference was reported when comparing TV and combined mUDAF + TV systems ($P>0.05$). Personnel-related factors (Table III) did not significantly relate with the concentration of airborne bacteria for any level considered, except
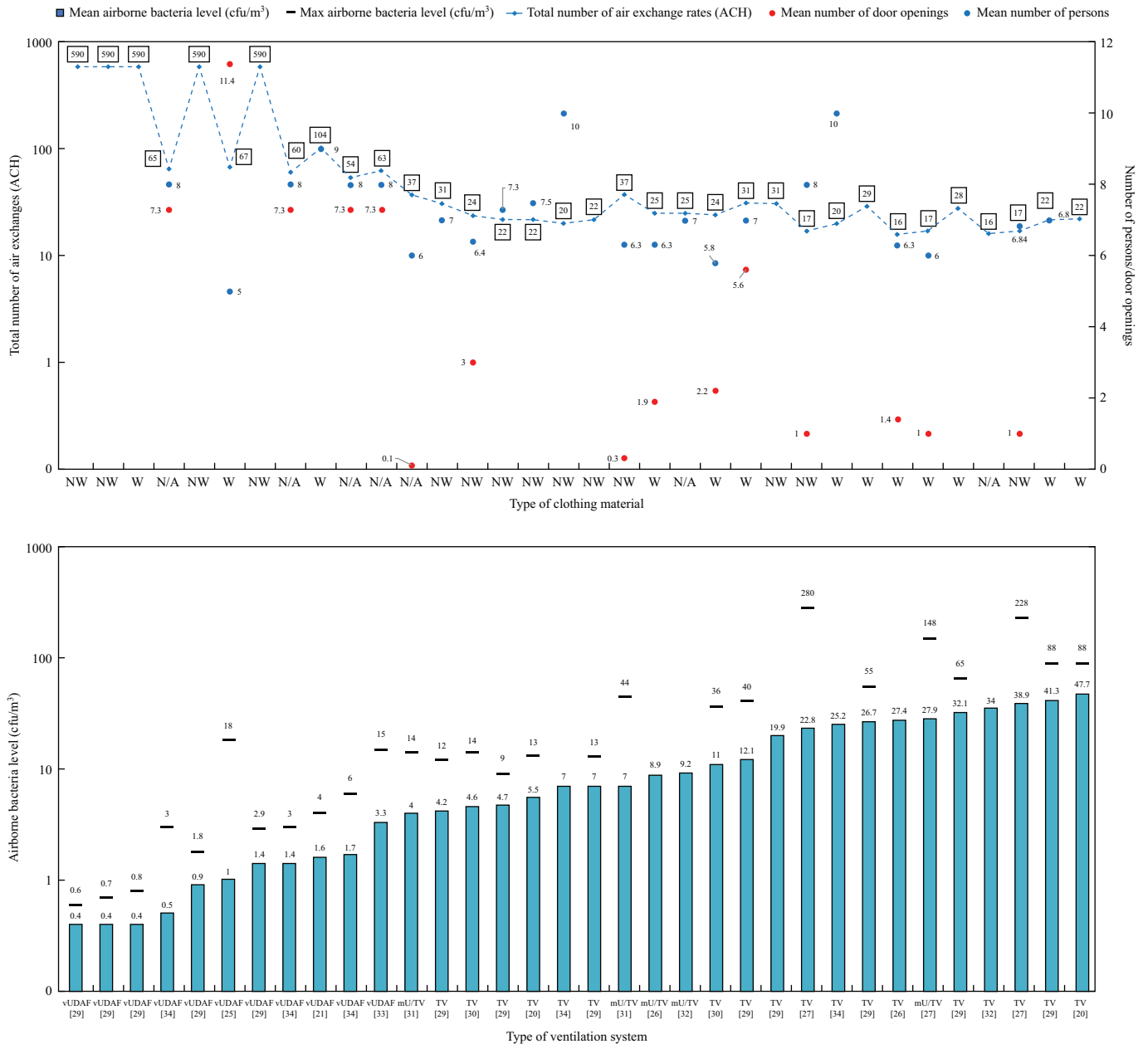
Figure 2. Ventilation systems (the type of ventilation system and the total number of air exchanges – ACH) and personnel-related factors from surgical procedures ranked according to mean and max airborne bacteria levels within ≤ 50 cm from the wound as reported in selected studies [21,25–35]. DO, number of door openings; N/A, not reported; NW, non-woven; PE, number of persons; W, woven.

for the type of clothing material that was shown to have a significant impact on mean levels <5 cfu/m³ and max levels <30 cfu/m³. Based on bivariate analysis, both ventilation conditions (type and ACH) for all levels defined and type of clothing material for mean levels <5 cfu/m³ and max levels <30 cfu/m³ reached the statistical *P*-threshold value (<0.02) and were therefore entered into the multivariate model. The multivariate analysis (Table IV) showed that the total number of air exchange rates (ACH) was independently associated with all four airborne bacteria levels (*P*<0.05), while the type of clothing material had an impact on whether mean levels of airborne bacteria were less than 10 cfu/m³ (*P*<0.05).

Discussion

Given the solid evidence [1,2,7,8] suggesting that SSI rates correlate with the number of airborne bacteria sampled close to the wound site, reducing microbial air contamination during surgery may be a valuable intervention to prevent SSI. Substantial efforts have been directed towards identifying environmental factors and control strategies that minimize operating room airborne bacteria in past decades, and among these factors, ventilation systems have been considered of major importance. Although previous studies have demonstrated that vUDAF systems outperform TV systems in achieving

Table I

Descriptive summary of included field studies reporting operating room ventilation characteristics, personnel-related factors and airborne contamination levels sampled during surgical procedures

Ref.	Type of procedure	Type of ventilation system	Total air exchange rates (ACH); supply airflow rate (m³/h); inlet size (m²)	No. of procedures	Type of air sampler	Sampling position within critical zone	Number of persons inside operating room	Traffic flow (number of door openings)	Use of surgical helmets/body exhaust suits	Clothing material	Air contamination levels (cfu/m³)
Andersson et al. (2014) [25]	Orthopaedic implant procedures	Vertical UDAF	67 ACH; 9160 m³/h; 3.6 x 3.6 m²	N = 33	Sartorius MD-8 Air Scanner	~30 cm from wound	5 ± 1.1 (mean ± SD); 2—9 (range)	11.4 ± 8.9 (mean ± SD); 2—31 (range)	No	50% cotton, 50% polyester	1.00 ± 2.10 (mean ± SD); 0—18 (range)
Alsved et al. (2018) [26]	Orthopaedic surgeries	Vertical UDAF	100 ACH; 12 000 m³/h; 2.75 × 2.75 m²	N = 15	Sartorius MD-8 Air Scanner & Klotz FH5	≤40 cm from wound	7 (median); 5—9 (range)	3.8/h (median); 1.4/h—11/h (range)	No	69% cotton, 30% polyester, 1% carbon fibre	0.00 (median); 0—16 (range)
		Temperature-controlled airflow	47 ACH; 5600 m³/h;	N = 15			7 (median); 6—9 (range)	2.1/h (median); 0—10/h (range)			1.00 (median); 0—29 (range)
		Turbulent ventilation	27 ACH; 3200 m³/h	N = 15			7 (median); 6—8 (range)	5.6/h (median); 0—11/h (range)			10.00 (median); 0—162 (range)
Friberg et al. (2003) [27]	Groin hernia surgery	Turbulent ventilation	16 ACH	N = 10	Sartorius MD-8 Air Scanner	20 cm above patient's chest	6.3 ± 0.7 (mean ± SD)	1.4 ±1.4 (mean ± SD)	Yes	70 % cotton, 30 % nylon	27.40 ± 9.90 (mean ± SD)
		Mobile UDAF + Turbulent ventilation	400 m³/h; 0.55 × 0.4 m² + 16 ACH	N = 50			5.7 ± 0.8 (mean ± SD)	1.9 ± 1.5 (mean ± SD)			8.90 ± 4.80 (mean ± SD)
Kasina et al. (2016) [28]	Total hip replacement	Mobile UDAF + Turbulent ventilation	220 L/min + 17 ACH; 620 L/s	N = 13	Sartorius MD-8 Air Scanner	~35—50 cm from operating field	6 (mean); 6 (max)	1	No	69% cotton, 30% polyester, 1% carbon fibre	27.90 (mean); 20.0 (median); 1—148(range)
		Turbulent ventilation	17 ACH; 620 L/s	N = 13			6.84 (mean); 9 (max)			Polypropylene/polyethene material	38.90 (mean); 22.5 (median); 0—228 (range)
				N = 11			8 (mean); 9 (max)			Polypropylene	22.8* (mean); 12.0 (median); 0—280 (range)
Ljungqvist and Reinmüller (2012) [21]	Orthopaedic surgeries	Turbulent ventilation	22 ACH; 2736 m³/h;	N = 2	Sartorius MD-8 Air Scanner	~30—50 cm from operating field	7.5 (mean); 7—8 (range)	Not reported	No	69% cotton, 30% polyester, 1% carbon fibre	47.75 *(mean); 27-88 (range)
				N = 3			7.5 (mean); 7—8 (range)			99% polyester, 1% carbon fibre, 120 g/m²	5.5 (mean); 1—13 (range)
		Vertical UDAF	104 ACH 2736 m³/h	N = 2			9 (mean); 9 (range)			69% cotton, 30% polyester, 1% carbon fibre	1.6 (mean); 1—4 (range)
Sanzen et al. (1990) [29]	Total hip arthroplasty	Vertical UDAF	590 ACH	N = 10	Sartorius MD-8 Air Scanner	≤20 cm from the wound	Not reported	Not reported	No	Double layer (cotton scrubs under non-woven operating gown)	1.4 (mean); 1.4 (median); 0.3—2.9 (range)
				N = 10					Yes	Double layer (cotton scrubs under cotton exhaust gown)	0.4 (mean); 0.3 (median); 0.2—0.6 (range)
				N = 10					No	Double layer (polytetrafluoroethylene scrubs under non-woven operating gown)	0.4 (mean); 0.4 (median); 0.4—0.8 (range)
				N = 10					No	Double layer (cotton scrubs under non-woven operating gown)	0.9 (mean); 0.8 (median); 0.5—1.8 (range)
				N = 10					No		

Study	Surgery	Ventilation	ACH / airflow	N	Sampler	Distance	Value A	Value B		Material	Value C
										Double layer (polyester scrubs under non-woven operating gown)	0.4 (mean); 0.4 (median); 0.3–0.7 (range)
Tammelin et al. (2012) [30]	Orthopaedic surgeries	Turbulent ventilation	29 ACH*; 996 L/s	N = 4	Sartorius MD-8 Air Scanner	~20–50 cm from the wound	7.2 (mean); 7–8 (range)	Not reported	No	69% cotton, 30% polyester, 1% carbon fibre	26.75 (mean); 9–55 (range)
		Turbulent ventilation	28 ACH*; 965 L/s	N = 3			6.3 (mean); 5–7 (range)				32.1 (mean); 9–65 (range)
		Turbulent ventilation	31 ACH*; 1050 L/s	N = 3			7 (mean); 7–7 (range)			69% cotton, 30% polyester, 1% carbon fibre	12.1 (mean); 1-40 (range)
				N = 2			7 (mean); 6–8 (range)			99% polyester, 1% carbon fibre, 100 g/m^2	19.95 (mean); 7–40 (range)
				N = 2			7 (mean); 7–7 (range)			99% polyester, 1% carbon fibre, 120 g/m^2	4.25 (mean); 1–12 (range)
		Turbulent ventilation	22 ACH*; 755 L/s	N = 3			7 (mean) 6–8 (range);			69% cotton, 30% polyester, 1% carbon fibre	41.33 (mean); 12–88 (range)
				N = 1			Not reported			99% polyester, 1% carbon fibre, 100 g/m^2	7.0 (mean); 1–13 (range)
				N = 2			7.3 (mean); 7–8 (range)			99% polyester, 1% carbon fibre, 120 g/m^2	4.75 (mean); 2–9 (range);
Tammelin et al. (2013) [31]	Hip arthroplasty	Turbulent ventilation	24 ACH; 845 L/s	N=5	Sartorius MD-8 Air Scanner	~20–50 cm from wound	5.8 (mean); 5–7 (range)	2.2 (mean); 1–3 (range)	No	69% cotton, 30% polyester, 1% carbon fibre	11.00 (mean); 1–36 (range)
				N = 5			6.4 (mean); 6–7 (range)	3 (mean); 2–6 (range)		Polypropylene	4.60 (mean); 0–14 (range)
Tammelin and Blomfeldt (2017) [32]	Total hip and knee arthroplasty	Mobile UDAF + Turbulent ventilation	1300 m^3/h; 0.69 × 0.73 m^2 + 29 ACH; 996 L/s	N = 7	Sartorius MD-8 Air Scanner	~20–50 cm from the wound	6.28 (mean); 6–7 (range)	0.28 (mean); 0–1 (range)	No	Double layer Polypropylene/polyester-viscose material	7.00 (mean); 0–44 (range)
				N = 8			6.0 (mean); 6–6 (range)	0.125 (mean); 0–1 (range)	No	Triple layer Polypropylene	4.00 (mean); 0–14 (range)
Thore and Burman (2006) [33]	Varices, umbilical hernia, and groin hernia procedures	Turbulent ventilation Mobile UDAF + Turbulent ventilation +	16 ACH 400 m^3/h; 0.55 × 0.4 m^2 + 16 ACH	N = 5 N = 6	Sartorius MD-8 Air Scanner	In the pubic area of the patient (wound area)	Not reported	Not reported	Not reported	Not reported	34.00 (mean); 9.17* (mean);
Traversari et al. (2019) [34]	Pacemaker implants, two heart valve replacements, Endovascular aneurysm repair (EVAR) procedures, constricted blood vessel procedures and angioplasty	Vertical UDAF	65 ACH; 15550 m^3/h; 3 × 6 m^2	N = 5	Klotz FH6	≤50 cm from the wound	8 (mean); 3.75–11.1 (range)	7.3 (mean); 0–22 (range)	No/not reported	Not reported	0.5 (mean); 3 (max)
		Vertical UDAF	60 ACH; 17250 m^3/h; 3 × 4 m^2	N = 3							1.4 (mean); 3 (max)
		Vertical UDAF	54 ACH; 16000 m^3/h; 3 × 4 m^2	N = 3							1.7 (mean); 6 (max)
		Vertical UDAF	63 ACH; 9030 m^3/h; 2.8 × 2.8 m^2	N = 5							3.3 (mean); 15 (max)
Verkalla et al. (1998) [35]	Elective coronary artery bypass surgery	Turbulent ventilation	20 ACH	N = 9 N = 8	Sartorius MD-8 Air Scanner	30 cm above wound	10 ± 2 (mean ± SD)	Not reported	No	Cotton Polypropylene	25.2 (mean) 7.0 (mean)

EVAR, Endovascular aneurysm repair; UDAF, unidirectional airflow systems.

Table II
Bivariate analysis of ventilation conditions related to different airborne contamination levels

	Types of ventilation systems				Total number of air exchange rates (ACH)
	vUDAF/mUDAF +TV/TV	Comparison between two types of ventilation systems			
		vUDAF/TV	mUDAF +TV/TV	vUDAF/mUDAF +TV	
Mean <5 cfu/m^3	$P<0.001$	$P<0.001$	$P>0.05$	$P=0.001$	$P=0.025$
Mean <10 cfu/m^3	$P<0.001$	$P<0.001$	$P>0.05$	$P>0.05$	$P=0.107$
Max <10 cfu/m^3	$P<0.001$	$P<0.001$	$P>0.05$	$P=0.005$	$P=0.003$
Max <30 cfu/m^3	$P=0.001$	$P=0.001$	$P>0.05$	$P>0.05$	$P=0.039$

mUDAF, mobile unidirectional airflow system; TV, turbulent ventilation; vUDAF, vertical unidirectional airflow system; OR, odds ratio.

lower airborne bacteria levels in the operating room [11,36], the use of UDAF systems in operating rooms has been disputed in some recent review studies [9,10]. A problematic issue that may arise when interpreting the conclusions of such studies is the lack of information on ventilation system characteristics and personnel-related factors (e.g., amount of air, filtration grade, size of the canopy, activity level, number of people, clothing system) reported. Without information on the ventilation system characteristics and actual measured performance (degree of protection, at rest), any claims about the ineffectiveness of UDAF as an ultra-clean air system should be seriously doubted [37]. A more clarifying concept of what should be considered ultra-clean air systems in terms of the type of ventilation system and its specific design conditions is needed. Such classification may only be obtained through a detailed review of all studies reporting both intraoperative cfu/m^3 levels in operating rooms and containing descriptive information on operating room ventilation systems.

However, the lack of an internationally agreed standard for microbial air quality in operating rooms makes it difficult to interpret the results against a single threshold value. The British standard Health Technical Memorandum 03-01 [4], German standard DIN 1946-4 [5], Austrian Önorm H6020 [38] and Swiss SKWI VA 105 [39] have the most strict requirements for so-called ultra-clean air during surgical procedures: the maximum airborne bacteria level cannot exceed a single value of less or equal to <10 cfu/m^3. The Swedish standard for high-risk surgeries requires defines a minimum mean airborne bacteria level of 5 cfu/m^3 while the maximum threshold value for single measurements is 30 cfu/m^3. The findings of this systematic review showed that UDAF systems outperform TV systems when compared with the limit levels defined by the British & German (max <10 cfu/m^3) and Swedish guidelines (mean <5 & 10 cfu/m^3 and max <30 cfu/m^3). All UDAF systems achieved mean levels <5 cfu/m^3 and few cases reported maximum levels >10 cfu/m^3. The multivariate analysis showed

that the total number of air exchanges rate is the crucial parameter in achieving low airborne contamination levels. It may be therefore important to interpret the vUDAF systems analysed in our study as high-volume uDAF systems as all of them exceeded the minimum requirement for the total airflow rate defined by the German standard DIN 1946-4 [8].

The observations made thus far about airborne contamination rates and the total number of air exchanges would be far more interesting if interpreted through the lens of a very recent publication on the influence of ventilation systems on SSIs reported by the Norwegian Arthroplasty Register (NAR) [40]. This publication reported a significantly lower risk of SSI reported in operating rooms equipped with validated high-volume UDAF systems ($>10,000$ m^3/h and diffuser size >10 m^2) than in those with TV systems. This finding was observed when grouping all the UDAF systems under one term to compare with TV systems. The conclusion of the registry study by Langvatn *et al.* [40] is even more compelling given that all TV systems exceeded ultra-clean air close (mean >10 cfu/m^3) to the wound in studies selected for this review. It is also important to note here that vUDAF systems have better potential to deliver high-volume airflow compared with to TV systems due to the low supply velocity (<0.3 m/s) induced over a large-sized canopy inlet. This may not be the case with TV systems that supply a larger volume of air through smaller openings with higher supply velocity, as it has been shown that the thermal comfort of surgical staff is negatively affected by velocities higher than 0.3 m/s [41]. It is important to note here, that the vUDAF that reported the lowest airborne bacteria levels were achieved with the outdated Charnley-Howorth UDAF systems characterized by very high air exchange rates with plastic walls enclosing the downflow up to 1.1 m above floor level. These systems disappeared from the market by 1976 and were replaced with UDAF systems similar to the systems previously used [25,26,34], surrounded by partial walls or no walls at all and with lower supply flowrates.

Table III
Bivariate analysis of personnel-related conditions related to different airborne contamination levels

	Mean number of door openings	Mean number of persons inside operating room	Type of clothing material (woven/non-woven)	Use of surgical helmets/body exhaust suits (yes/no)
Mean <5 cfu/m^3	$P>0.2$	$P>0.2$	$P>0.2$	$P>0.2$
Mean <10 cfu/m^3	$P>0.2$	$P>0.2$	$P=0.021$	$P>0.2$
Max <10 cfu/m^3	$P>0.2$	$P>0.2$	$P>0.2$	$P>0.2$
Max <30 cfu/m^3	$P>0.2$	$P>0.2$	$P=0.047$	$P>0.2$

Table IV
Multivariate analysis of ventilation and personnel-related conditions related to different airborne contamination levels

	Type of ventilation system	Total number of air exchange rates	Clothing material (non-woven/woven)
Mean <5 cfu/m^3	$P=0.847$ (OR 95% CI: 0.19−8.17)	$P=0.039$ (OR 95% CI: 0.81−0.99)	−
Mean <10 cfu/m^3	$P=0.069$ (OR 95% CI: 0.01−13.49)	$P=0.019$ (OR 95% CI: 0.66−0.96)	$P=0.031$ (OR 95% CI: 0.01−0.71)
Max <10 cfu/m^3	$P=0.820$ (OR 95% CI: 0.15−4.39)	$P=0.031$ (OR 95% CI: 0.89−0.99)	−
Max <30 cfu/m^3	$P=0.816$ (OR 95% CI: 0.17−9.56)	$P=0.027$ (OR 95% CI: 0.81−0.99)	$P=0.234$ (OR 95% CI: 0.72−2.36)

CI, confidence interval; OR, odds ratio.

Thus far, we have focused on the vUDAF systems because they are the most widely used and discussed vUDAF systems, and most recommendations and standards are based on them. The mUDAF systems used in combination with TV systems achieve operating room ultra-clean air conditions and should therefore be given more attention in both future research and recommendations by national standards. The question remains whether they are effective in delivering clean air outside the wound site, to other critical areas such as the instrument table. Based on the results provided in the literature, TV systems may be considered ultra-clean air systems (<10 cfu/m^3) only in combination with a type of clothing material. Yet, even in this case, vUDAF systems achieve lower airborne bacteria levels regardless of clothing material. To our knowledge, this systematic review is the first to report and assess the associations between the airborne bacteria concentration and complete data on ventilation system design conditions while considering other confounding factors, such as the number of people present in the operating room, foot traffic, and type of clothing. However, the study has limitations. The sampling sizes in the different studies varied considerably. No adjustments were made to account for the sample size or multiple comparisons; thus, the mean and median cfu/m^3 estimates may be biased. Because of the estimated medium to high risk for bias in most included studies and extensive differences regarding sampling sizes among the included studies, we decided that a meta-analysis was not a viable option for this review. The emphasis of this work is on the apparent trends, and accuracy of the numeric estimates of specific airborne bacteria concentrations should be interpreted with caution. However, our evidence that high-volume UDAF systems are associated with operating room ultra-clean air conditions is convincing. The instruments used for active air sampling provide comparable results based on our evaluation of the instruments [20]. Given the low concentration range that is relevant herein (<10 cfu/m^3), the airborne cfu surrogate variable can be used to unconditionally and straightforwardly brand high-volume UDAF systems as ultra-clean air systems, unlike TV ventilation systems. Notably, the conclusions of this systematic review were written only regarding one of the many risk factors associated with the incidence of SSI: the microbiological quality of air. The conclusions were not written to speculate that the use of UDAF systems will necessarily result in lower infection rates generally because too many uncontrollable variables causing SSI are not related to the operating room air environment. Instead, the conclusions of this review should serve as a complementary source of information to the recent findings of the registry study by Langvatn *et al.* [40], implying that ventilation design conditions must be reported when comparing the influence of different types of operating room ventilation systems on SSI rates in future clinical studies.

In conclusion, following an extensive search strategy and strict selection criteria from six medical databases, we collected 12 field studies reporting ventilation system design conditions and levels of cfu/m^3 within 50 cm from the wound. Available confounding factors such as the number of persons present in the operating room, number of door openings, clothing material, and the use of surgical helmets/exhaust gowns were also reported. All studies were observational cross-sectional studies using comparable active sampling techniques for collecting airborne contaminants. The following conclusions were made based on the studied articles: (1) Bivariate analysis showed that the effect of the type and the total number of air exchange rates of ventilation systems and clothing material was significantly associated with an ultra-clean environment (mean airborne bacteria load <10 cfu/m^3) close to the wound ($P<0.05$). (2) UDAF systems are superior to TV systems in reducing airborne contamination levels close to the wound site ($P<0.05$). (3) UDAF systems considered had significantly higher air volume flows compared with TV systems considered. (4) The number of door openings and number of persons present during surgical procedures had no significant impact on achieving an ultra-clean air environment ($P>0.05$). (5) On multivariate analysis, the total number of air exchange rates ($P=0.019$; OR 95% CI: 0.66−0.96) and type of clothing material ($P=0.031$; OR 95% CI: 0.01−0.71) were significantly associated with achieving mean levels of airborne bacteria <10 cfu/m^3 close to the wound. (6) High-volume UDAF systems complying with DIN 1946-4:2008 standards for the airflow rate and ceiling diffuser size unconditionally achieve mean levels <10 cfu/m^3 air close to the wound site. (7) mUDAF systems in combination with background TV can achieve ultra-clean air (mean <10 cfu/m^3) close to the wound site. (8) TV systems may achieve ultraclean air close to the wound, particularly in combination with clothing systems made of occlusive non-woven material.

Conflict of interest statement
The authors have no conflicts of interest to declare.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jhin.2021.04.022.

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