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# Operating room ventilation and the risk of revision due to infection after total hip arthroplasty: assessment of validated data in the Norwegian Arthroplasty Register

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## SUMMARY

**Background:** The air in the operating room is considered a risk factor for surgical site infection (SSI) due to airborne bacteria shed from the surgical staff or from patients themselves.

**Aim:** To assess the influence of validated operating room (OR) ventilation data on the risk of revision surgery due to deep infection after primary total hip arthroplasty (THA) reported to the Norwegian Arthroplasty Register (NAR).

**Methods:** Forty orthopaedic units reporting THAs to the NAR during the period 2005–2015 were included. The true type of OR ventilation in all hospitals at the time of primary THA was confirmed in a previous study. Unidirectional airflow (UDF) systems were subdivided into: small, low-volume, unidirectional vertical flow (lvUDVF) systems; large, high-volume, unidirectional vertical flow (hvUDVF) systems; and unidirectional horizontal flow (UDHF) systems. These three ventilation groups were compared with conventional, turbulent, mixing ventilation (CV). The association between the end-point, time to revision due to infection, and OR ventilation was estimated by calculating relative risks (RRs) in a multivariate Cox regression model, with adjustments for several patient- and surgery-related covariates.

**Findings:** A total of 51,292 primary THAs were eligible for assessment. Of these, 575 had been revised due to infection. A similar risk of revision due to infection after THA performed was found in ORs with lvUDVF and UDHF compared to CV. THAs performed in ORs with hvUDVF had lower risk of revision due to infection compared to CV (RR = 0.8; 95% CI: 0.6–0.9;  $P = 0.01$ ).

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**Conclusion:** THAs performed in ORs with hvUDVF systems had lower risk of revision due to infection compared to THAs performed in ORs with CV systems. The perception that all UDF systems are similar and possibly harmful seems erroneous.

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## Introduction

Infection after total hip arthroplasty (THA) is devastating for the patients and generates high public costs [1]. The air in the operating room (OR) is considered a potential source of contamination and subsequently a risk factor for surgical site infection (SSI) due to airborne bacteria and other viable microorganisms (colony-forming units (cfu)) shed from the surgical staff or from patients [2–7]. The number of cfu in the OR may be altered by staff behaviour such as the number of personnel, door openings, and physical movement, and by the use of other preventive measures such as impermeable gowns and space helmets [8–10]. Previous studies have postulated that the density of cfu is correlated with the rate of postoperative infection, but the findings are controversial as the isolated effect of air cleanliness is hard to assess [6,11–15]. Other studies show that air contamination is not directly associated with wound contamination and periprosthetic joint infection [16,17].

Unidirectional airflow (UDF or UDAF) systems (formerly known as laminar airflow (LAF) systems) have been used during ultraclean surgery since the late 1960s, as they were thought to reduce the incidence of SSI by reducing the cfu density [13]. UDF systems work by sending parallel, filtered air streams with constant velocity directly on to the surgical field to intentionally displace and reduce the flow of less clean air from the rest of the OR to the surgical field. This is in contrast to the conventional ventilation (CV) systems, which use the dilution principle. CV systems supply turbulent air in order to dilute airborne contamination, mixing polluted air with clean air, and are often termed turbulent and/or mixing ventilation systems [18].

Unidirectional airflow as a prophylactic measure against SSI has been supported ever since Lidwell and colleagues published their randomized, clinical trial in the 1980s [19]. For THA and total knee arthroplasty (TKA), they found lower risk of ‘deep joint sepsis’ after arthroplasty performed in ultra-clean air (UCA; cfu <10/m<sup>3</sup>) with a relative risk (RR) of 0.4 compared to a control group with non-ultra-clean air. The study has been criticized for having methodological weaknesses, but both historic and recent re-evaluations of the study confirm the validity of the findings [15,20–23]. Subsequent observational studies from the same decade, controlled for antibiotic prophylaxis, found no convincing influence of OR ventilation on the rate of SSI [24,25]. More recently, studies from surveillance registries have suggested that LAF actually may increase the risk of infection after arthroplasty [26–28]. Two recent systematic reviews, based partly on these registry studies, conclude that UDF systems should not be installed in new ORs [20,29]. One of the reviews includes an observational study from the Norwegian Arthroplasty register (NAR), not studying the effect of UDF specifically, using ventilation only as an adjustment variable in the study of infection trend [30]. In a

previous validation study, we found 12% misreporting of ventilation data to the NAR, questioning the validity of studies based exclusively on ventilation data reported from surgeons or surgical departments [31]. In addition, there are numerous different configurations of UDF systems, and when studying their effect on the rate of postoperative infections it is important to know the dissimilarities between the different UDF systems and that these have evolved over the decades.

Our aim in the present study was to assess the association between validated, factual OR ventilation systems and the risk of revision due to deep infection after primary THA.

## Methods

Since its inception in 1987, the NAR has registered data on primary and revision THAs in Norway. The register form is filled in by the surgeon immediately after surgery, containing information on patient identity, date of operation, indication for surgery and other surgery-related factors. In addition, certain patient-related factors such as sex, age, and comorbidity are registered. Primary THA and any subsequent revisions are linked through a unique person identity number that follows each citizen from birth to death. Revision is defined as removal or exchange of prosthesis parts, whereas revision cause, i.e. deep infection, is determined by the surgeon based on perioperative assessments and clinical evaluation. Cases of revision due to infection are thus reported to the NAR before the culturing of peroperative tissue samples is ready. The data is validated, with 97% completeness of reporting of primary THAs, 93% reporting of revisions, and 100% coverage of Norwegian hospitals [32].

The factual OR ventilation on each hospital was validated and either confirmed or corrected in a previous study [31]. To be included as a UDF system, it had to be verified that the system had been installed with a multistage high-efficiency particulate air (HEPA)-filtered, unidirectional diffuser array. Based on technical data collected, the following classification of ventilation systems was established for further analyses: small, low-volume, unidirectional, vertical flow systems (lvUDVF: volume flow rate (VFR; m<sup>3</sup>/h) <10,000 and canopy size (m<sup>2</sup>) <10); large, high-volume, unidirectional, vertical flow systems (hvUDVF: VFR ≥10,000 and canopy size ≥10); and unidirectional horizontal flow (UDHF). We did not have complete data on the volume of each OR, so we were unable to calculate the exact air changes per hour (ACH). As the ACH also might be dependent on other factors, we did not include ACH in the definition of the different UDF systems. The CV systems included in this study were verified to fulfil the requirement of multi-stage HEPA-filtered air with 20 ACH and positive pressurization [33].

The period of inclusion was 2005–2015, primarily due to the fact that the patients’ American Society of Anesthesiologists (ASA) class, a risk factor associated with infection, was only

reported to the NAR from 2005 and onwards [34]. All patients during this period received systemic, antibiotic prophylaxis.

A separate survey confirmed negligible use of space suits and/or helmets. Three of the hospitals used space suits in very short periods of time, but discontinued the use due to loss of spatial awareness.

Validated ventilation data were obtained for 40 out of 62 public hospitals reporting THAs to the NAR in the inclusion period [31]. Out of 60,298 THAs performed in these 40 hospitals, 2046 were performed in a period of ventilation system exchange or update, and were excluded. A total of 4313 THAs performed in UDVF ventilation were excluded due to lack of detailed information on certain ventilation covariates from parts of the inclusion period, essential for our main analyses, or due to the current UDVF system not fulfilling the defined criteria for lvUDVF or hvUDVF. In addition, 2647 THAs were excluded due to missing patient or procedure covariates. Hence, 51,292 THAs were eligible for analyses.

### Statistics

The association between OR ventilation and revision due to infection was estimated by Cox regression analyses. Relative risk (RR), as a measure of hazard rate ratios, was calculated with 95% confidence intervals (CIs). End-point was date of revision due to deep infection. Further, adjusted four-year survival rates were calculated, as well as Kaplan–Meier four-year survival rates, and cumulative survival curves with OR ventilation as strata. In the multivariate analyses, we adjusted for sex, age at primary surgery, indication for primary THA, ASA class, method of fixation, modularity of the prosthesis, and duration of surgery. Year of primary THA was included as an adjustment variable to account for unknown time dependent confounding. Additional analyses were made with one- and two-year follow-up. Further, additional assessments were performed to adjust for spatial orientation of the wound in the OR, whether the wound was oriented upwards or to the side, based on an evaluation of patient positioning and surgical approach as potential risk factors. The analyses were performed in concordance with the guidelines for statistical analyses of arthroplasty register data [35].  $P < 0.05$  and non-overlapping 95% CIs were considered statistically significant.

Statistical analyses were performed using SPSS version 24 (SPSS Inc., 2004) and R (R Foundation for Statistical Computing, 2014). The study was performed in accordance with the RECORD and STROBE statements.

### Ethics

The registration of data and further assessment were performed confidentially following patient consent and according to Norwegian and EU data protection rules.

### Results

Among the 51,292 eligible THAs, 575 (1.1%) had been revised due to infection. Demographics and distribution of risk factors in the different ventilation groups are presented in Table I. All patients received systemic antibiotic prophylaxis and all cemented THAs had antibiotic loaded bone cement. The distribution of the risk factors was similar for the four ventilation

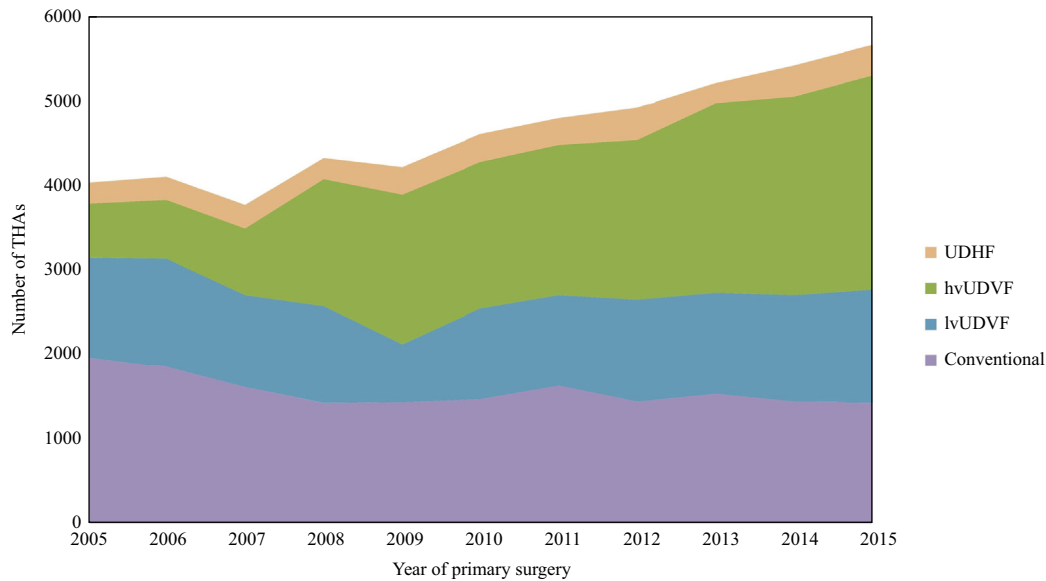
**Table I**

Baseline characteristics for the total hip arthroplasties performed in the different ventilation systems

Characteristic	Type of operating room ventilation			
	Conventional	lvUDVF	hvUDVF	UDHF
No. of THAs	17,297	12,639	17,960	3396
Sex				
Male	34%	33%	34%	33%
Female	66%	67%	67%	67%
Age group (years)				
<45	2%	3%	3%	3%
45–54	6%	7%	8%	7%
55–64	22%	23%	23%	22%
65–74	36%	36%	36%	35%
75–84	28%	27%	25%	28%
>85	5%	5%	5%	5%
Indication for primary THA				
Osteoarthritis	82%	75%	77%	83%
Inflammatory disease	3%	3%	2%	2%
Hip fracture	3%	2%	3%	1%
Complication after hip fracture	6%	6%	6%	5%
Complication after childhood hip disease	5%	12%	10%	6%
Necrosis of the femoral head	2%	2%	3%	3%
ASA class				
1	22%	18%	19%	19%
2	57%	63%	61%	62%
≥3	21%	19%	20%	19%
Method of fixation				
Uncemented	20%	9%	29%	64%
Cemented	80%	91%	71%	36%
Modularity of the prosthesis				
Monoblock	5%	5%	4%	0
Modular	95%	95%	96%	100%
Duration of surgery (min)				
<70	20%	20%	27%	18%
70–99	51%	41%	36%	48%
100–129	21%	28%	27%	27%
>130	8%	11%	10%	7%

lvUDVF, small, low-volume, unidirectional vertical flow systems; hvUDVF, large, high-volume, unidirectional vertical flow systems; UDHF, unidirectional horizontal flow systems; THA, total hip arthroplasty; ASA, American Association of Anesthesiologists.

groups, except for more uncemented THAs in the two hospitals using UDHF (one rural and one regional hospital). In the remaining three ventilation groups, rural, regional, university, and specialized elective hospitals were evenly represented. During the study period, four hospitals converted from CV to hvUDVF and one hospital converted from lvUDVF to hvUDVF between 2006 and 2009. From 2009, 16 hospitals used CV, nine used lvUDVF, and 13 used hvUDVF systems. The annual distribution of THAs within the different groups of ventilation system is presented in Figure 1. The risk factors and confounders in the adjusted analyses are presented in Table II. Sex, age, ASA class, and duration of surgery were associated with risk of revision due to infection.



**Figure 1.** Annual number of primary THAs in the four different ventilation groups during 2005–2015. UDHF, unidirectional horizontal flow systems; hvUDVF, large, high-volume, unidirectional vertical flow systems; lvUDVF, small, low-volume, unidirectional vertical flow systems.

Assessing the UDF group as one encompassing entity, primary THAs performed in ORs with such unclassified UDF had a risk of revision due to infection similar to that of CV (RR: 0.9; 95% CI: 0.7–1.2). The risk of revision due to infection after THAs performed in ORs with lvUDVF and UDHF was similar to those performed in CV (Table III, Figure 2). THAs performed in ORs with hvUDVF had a lower risk of revision due to infection than those performed in CV (Table III, Figure 2). No UDF system was associated with higher risk of revision due to infection after THA compared to CV.

Adjusting for wound spatial orientation and reducing follow-up time to one year and two years had only minor influences on the results. We did not have complete data on the spatial volume of all ORs in order to calculate the exact ACH, but adjusting for operating room volume in analyses of the available ORs had negligible impact on the results.

## Discussion

The risk of revision due to infection after primary THA performed in ORs with hvUDVF was 20% lower than after THA performed in CV, whereas THA performed in ORs with lvUDVF or UDHF had a risk of revision due to infection similar to that of THA performed in CV. No UDF system was associated with higher risk of revision due to infection after THA compared to CV.

Recent registry studies as well as systematic reviews and meta-analyses are questioning the effect of LAF/UDF as a prophylactic measure against postoperative infection, as they suggest for arthroplasty an increased risk of SSI and revision due to infection [20,26–30]. This is in contrast to the results from our study on validated ventilation data. Recent World Health Organization (WHO) guidelines, though conditional, recommend not to use UDF systems to reduce the risk of SSI in arthroplasty [36]. The WHO recommendation is based partly on

a few observational studies with some methodological issues: no UDF system differentiation or definition based on technical specifications, limited documentation of validation on the UDF systems, and limited information on coverage or completeness of reporting of the end-point SSI or revision due to infection [21,22,31,37]. Some of these studies had only six months to one year follow-up, and others had no systematic post-discharge surveillance. This has been a point of debate as low-grade infections caused by airborne contaminants might be excluded as they may present at a much later stage [21,22]. Coagulase-negative staphylococci (CoNS) are the most frequent bacterial cause of revision of infected THA [38]. Since CoNS are regarded as commensal bacteria and since CoNS have also been shown to be the most frequent bacterial cause of late infection, this may suggest that direct contamination from primary surgery is the likely mechanism of THA infection, even in infection more than two years after primary THA [38]. Haematogenous seeding of CoNS is possible, but is less likely to occur as this requires substantial bacteraemia [39,40]. We studied the effect of OR ventilation with four years follow-up, comparable to the Lidwell studies [21,41].

One possible explanation for the reported contrary effect of UDF could be improper positioning and movement of personnel, theatre lamps, etc. in the airflow [18,42,43], thereby abolishing the preventive effect by creating more turbulence. This might especially be the case in the boundary areas due to insufficient size of the protected UDF zone. Studies have shown impact of canopy size on bacterial counts in the surgical area, where the minimum size of a UDF ceiling distribution system has been recommended to be at least 320×320 cm for ultra-clean surgery [44–46]. We studied the effect of canopy size on infection risk by defining cut-off for canopy size in accordance with this recommendation.

In addition, the potentially lower tissue temperature and bacterial impingement danger due to disruption of the

**Table II**  
Relative risks of revision due to infection after primary total hip arthroplasties in the Norwegian Arthroplasty Register

Risk factor	Included	Revised due to infection	Relative risk	95% CI	P-value
Sex					
Male	17,144	268	1.8	1.5–2.1	<0.001
Female	34,148	307	1		
Age group (years)					
<45	1334	15	1.2	0.7–2.1	0.5
45–54	3667	27	0.8	0.5–1.3	0.4
55–64	11,584	101	0.9	0.7–1.2	0.6
65–74	18,475	180	1		
75–84	13,669	202	1.5	1.2–1.8	<0.001
>85	2563	50	1.9	1.4–2.7	<0.001
Indication for primary THA					
Osteoarthritis	40,305	448	1		
Inflammatory hip disease	1293	18	1.3	0.8–2.1	0.3
Hip fracture	1180	17	1.3	0.8–2.1	0.3
Complication after hip fracture	2963	39	1.0	0.7–1.4	0.9
Complication after childhood hip disease	4342	31	0.8	0.5–1.2	0.2
Necrosis of the femoral head	1209	22	1.5	1.0–2.3	0.08
ASA class					
1	10,178	60	0.6	0.5–0.8	<0.001
2	30,837	347	1		
≥3	10,276	168	1.3	1.1–1.5	0.02
Method of fixation					
Uncemented	11,974	127	1.0	0.8–1.2	1.0
Cemented	39,318	448			
Modularity of the prosthesis					
Monoblock	2059	11	0.5	0.3–1.0	0.04
Modular	49,233	564	1		
Duration of surgery (min)					
<70	11,405	120	1.1	0.9–1.4	0.4
70–99	22,125	225	1		
100–129	12,935	147	1.1	0.9–1.4	0.3
>130	4827	83	1.6	1.3–1.8	0.002

CI, confidence interval; THA, total hip arthroplasty; ASA, American Association of Anesthesiologists.

Adjusted for sex, age, indication for primary THA, ASA class, modularity of the prosthesis, method of fixation, and duration of surgery, in addition to operating room ventilation and year of primary THA.

wound's own protective, thermal plume, is also claimed to disturb the effectiveness of the UDF [26,47–49]. One recent study identifies the use of UDF as a significant risk factor for hypothermia, thereby being subsequently a risk factor for infection of the wound [50,51]. To counteract these issues, forced air warming (FAW) systems have been used. These are also thought to disturb the laminar airflow [52,53]. However, recent reviews conclude that the evidence for this is sparse [54–56]. A recent experimental study found that the disturbing effect of FAW is counteracted by sufficient air velocity in the UDF systems [57]. As the air velocity of different UDF systems is adjustable, we could not use it as a constant adjustment variable in our analyses. It was therefore indirectly assessed by studying the VFR, varying in the range of 1000–5000 m<sup>3</sup>/h in older, low-volume systems and 10,000–20,000 m<sup>3</sup>/h in newer, high-volume systems. The latter is necessary to create velocities in the desired minimum range of 0.3–0.38 m/s through large area canopies [58].

UDF systems are able to create lower cfu concentrations than CV systems both in air and close to the operation site. This

is shown both in computational fluid dynamics studies and in experimental studies [44,59–66]. Studies have also shown an association between the cfu concentration and SSI, but the question remains whether other risk factors such as the patient's immunological status, bacterial virulence, antibiotic prophylaxis, surgical technique, etc., are indeed much more important [6,11–14]. The latter is supported by studies showing that SSI after elective orthopaedic surgery is more frequently caused by endogenous transmission than previously assumed [67,68]. Further indicating the patients' skin commensals as source of infection are studies on the bacteriology of infected shoulder arthroplasty and postoperative infections after spinal surgery, showing a high proportion of *Propionibacterium (Cutibacterium) acnes* [69–71]. This is a species known to be abundant in sebaceous glands of the skin in such regions, and as the bacteriology of infected total hip arthroplasties is different, dominated by staphylococci, this might indicate that the patients are their own source of infection. If the cleanliness of the air in the OR is the same during different types of prosthetic surgery and a significant source for postoperative infection, why does the bacteriological spectrum of

**Table III**

Relative risks of revision due to deep infection after primary total hip arthroplasty, adjusted four-year survival and Kaplan–Meier four-year survival for the four operating room ventilation systems

Operating room ventilation	THAs included	THAs revised due to infection	Relative risk	95% CI	P-value	Kaplan–Meier four-year survival	Adjusted four-year survival	Censored before four years	At risk at four years
Conventional	17,297	208	1			98.8 (98.6–98.9)	98.9 (98.7–99.0)	1627	12,914
lvUDVF	12,639	138	0.9	0.7–1.1	0.3	98.9 (98.7–99.0)	99.0 (98.9–99.2)	1081	9077
hvUDVF	17,960	175	0.8	0.6–0.9	0.01	99.0 (98.9–99.2)	99.1 (99.0–99.3)	1423	11,860
UDHF	3396	54	1.3	0.9–1.8	0.1	98.4 (97.9–98.8)	98.6 (98.2–99.0)	342	2366

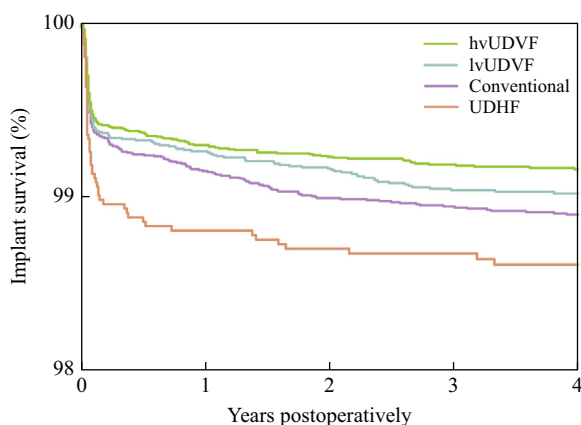
THA, total hip arthroplasty; CI, confidence interval; lvUDVF, small, low-volume, unidirectional vertical flow systems; hvUDVF, large, high-volume, unidirectional vertical flow systems; UDHF, unidirectional horizontal flow systems.

Adjustments were made for sex, age, indication for primary THA, American Association of Anesthesiologists class, modularity of the prosthesis, method of fixation, duration of surgery, and year of primary THA.

infections vary between different regions of the body? This questions the extent of air cleanliness importance. Despite this, and with increasing antibiotic resistance taken into account, it seems logical to reduce the peroperative, bacterial load to a minimum. This will be increasingly important in an era with increasing microbial resistance to antibiotics [72,73].

Our finding of a 20% lower risk of revision due to infection after THA performed in hvUDVF compared to CV is minute, considering also that the incidence of revision due to infection is only around 1%. However, UDF systems can create cleaner air, and, taking our results into account, it seems erroneous to discontinue the use of large, high-volume, vertical UDF systems in the ORs of the future. Technological development and multidisciplinary co-operation with the focus on correct implementation and function of the ventilation systems should be encouraged [22,65,66].

Our study is based on data from the NAR with a large number of THAs, with good quality, coverage, and completeness [74–76]. This gives us a unique opportunity to study relatively rare events, such as deep infection after THA, with detailed information on surgery- and patient-related confounders.



**Figure 2.** Survival curves for total hip arthroplasties (THAs) performed with different ventilation systems and revised due to infection. Adjusted for sex, age, indication for primary THA, American Association of Anesthesiologists class, modularity of the prosthesis, method of fixation, duration of surgery, and year of primary THA. lvUDVF, small, low-volume, unidirectional vertical flow systems; hvUDVF, large, high-volume, unidirectional vertical flow systems; UDHF, unidirectional horizontal flow systems.

Other register studies on OR ventilation have been criticized for not making a thorough adjustment of antibiotic prophylaxis, for using surgeon- or surgical department-reported data on ventilation, for not differentiating the UDF systems on technical specifications, and for having a limited follow-up time [21]. All of our cases received systemic, antibiotic prophylaxis and the multivariate analyses were conducted on the basis of validated ventilation data. Further, we did sub-analyses on canopy size and VFR with four-year follow-up. All this adds strength to our study and makes it a substantial contribution to new knowledge in the field.

This study suggests merely the association between OR ventilation and revision due to deep infection after primary THA. There will be unknown confounding such as human behavioural factors in the OR, incorrect implementation and maintenance of the ventilation systems, and other factors potentially disturbing the UDF. We have no information on patient warming systems, use of surgical drapes, number of personnel in the room, number of door openings, etc., but we have no reason to believe that this would be different between the four ventilation groups in our study. In addition, revision due to infection may be underreported, but, as the under-reporting of revision is similar between the hospitals, this will add minimal selection bias and subsequent impact on our results [32,77–79].

There has been an increase in the share of hvUDVF systems over the last 20 years (Figure 1). This increase is parallel to the reported, increased risk of revision due to infection after THA [80,81]. This will necessarily be a time-dependent confounder in our analyses and we have addressed this by adjusting for year of primary surgery as a continuous variable in the analysis.

Only two of the included hospitals used UDHF. In addition, these two hospitals had a higher share of uncemented THAs. This may add selection bias, but the type of fixation was adjusted for.

The modularity of the prosthesis may affect the incidence of reported revision due to infection. Non-modular/monoblock THAs (i.e. Charnley prostheses) were used by some hospitals until 2014. They do not contain modular parts, and hence, infections of such THAs treated with debridement, antibiotics, and implant retention (DAIR) were not reported to the NAR until 2011 from when all DAIRs were reported regardless of component exchange or not. This is in contrast to modular THAs, which contain removable components exchanged during a DAIR procedure. Hence, these debridements were defined as revisions throughout the study period, and were subsequently

reported to the NAR as such. This will potentially lead to an underreporting of revision due to infection after THA with monoblock prostheses, which was addressed by adjusting for modularity.

Forty of 62 public hospitals were included. Most of the excluded hospitals performed primary THAs throughout the whole study period, as did most of the included ones, and with a completeness of reporting of more than 97% [75]. Time trends of reporting are therefore not thought to affect the findings. The reporting of primary THAs was similar in the two groups (included/excluded) and the distribution of hospital types in the two groups was also similar (rural hospitals, regional/university hospitals, specialized elective hospitals). We therefore believe that the impact of selection bias is minimal.

In conclusion, UDF ventilation assessed as one encompassing entity did not influence the risk of revision due to infection after primary THA compared to CV. When differentiating the UDF systems on technical specifications, however, primary THAs performed in ORs with hvUDVF ventilation systems had a lower risk of revision due to infection compared to ORs with CV. Considering also that UDF systems can create lower particle and microbial load than CV systems, our findings support the use of hvUDVF systems for all ultraclean surgery in the future.

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### Conflict of interest statement

None declared.

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