Letter to the Editor of the Journal of Hospital Infection

Criticisms of the study of ultra clean air systems in operating theatres by Teo et al

Sir

We read with interest the article written by Teo *et al* entitled 'Laminar flow does not affect risk of prosthetic joint infection after primary knee replacement in Asian patients'[1]. We compliment the authors on their article and their contribution to the ongoing debate in this journal about the effectiveness of ultraclean air systems in reducing joint infections after total joint arthroplasty. However, we offer some criticisms.

In this letter we do not use the term 'laminar airflow (LAF)' as these ventilation systems do not employ 'laminar' airflow [2]. We use the name 'ultraclean air (UCA) system', for a system that uses a unidirectional airflow (UDAF) ventilation system as well as occlusive clothing that reduces the dispersal of microbe-carrying particles (MCPs) from the surgical team.

The Medical Research Study (MRC) of UCA systems concluded that an airborne MCP concentration of $1/m^3$ was required to minimise joint infection caused by airborne MCPs, although $10/m^3$ would give a worthwhile reduction [3]. Agodi et al [4] measured the airborne MCP concentration in operating theatres of 14 hospitals and showed that many of the UCA systems failed to achieve a concentration of $10/m^3$, let alone $1/m^3$, and some were no better than conventional mixed airflow OTs. Therefore, it should not be concluded that UCA systems are ineffective in reducing deep joint infection without demonstrating that the UCA systems studied are able to achieve the correct UCA conditions. This problem occurs in Teo et al's study and in other studies on the same topic.

Teo at al's study did not give information about whether their UDAF systems are enclosures, have no walls, or have partial walls or air curtains round the perimeter. This information is required to understand how well the unidirectional air supply is constrained to give sufficient air velocity at the sterile working area, as well as preventing outside contamination being entrained into the clean air zone. Also, no information was provided about the surface area of the UDAF filter bank to show if it was likely to protect exposed surgical instruments from airborne contamination, in addition to the wound.

It is clear from the article by Teo et al's that the bank of air filters in their UDAF systems were monitored regularly for leaks. However, knowing the air supply is free of MCPs is only part of ensuring the correct performance of a UDAF system. It is essential to show that the filtered air has sufficient velocity and correct airflow pattern to remove effectively MCPs from the sterile working area and minimise the entrainment of contamination from outside the clean zone. Tests to show this are described in HTM 03-01 [5].

Of greatest importance in confirming the effectiveness of UCA systems is the measurement of airborne MCP concentrations at the wound and surgical instruments during surgery. Teo et al reported concentrations of airborne particle ($\geq 0.5\mu m$) and MCPs but did not state if they were measured during surgery or, as we suspect because the low particle concentrations, in an unoccupied OT. If measurements are carried out in an unoccupied operating theatre, then only one tester is likely to be present and unlikely to be within the UDAF system. In this situation, the airborne particle concentration should be close to zero. However, during surgery, airborne contamination will be dispersed by the surgical team, who will also disturb the UDAF airflow and reduce its effectiveness. This will result in the concentration of airborne contamination being very much higher than in the unoccupied condition. Teo at al also provide no information about the sampling location. Owing to the unidirectional nature of airflow of the air, it is relatively easy to obtain low airborne concentrations of contamination in air that comes directly from filters. Measurements must, therefore,

be taken at locations where the airborne contamination directly affects wound contamination, namely, next to the wound and adjacent to surgical instruments.

Teo et al gave little information about what type of surgical clothing was worn. This is important, as occlusive clothing can contribute a further 10 to 20 fold reduction of MCPs in UDAF systems [6] Well-designed and maintained UDAF systems are likely to produce an acceptable average MCP concentration at the wound of 10 MCP/m^3 when conventional clothing made from cotton or polycotton fabric is worn. However, to obtain the preferred average concentration of 1 MCP/m^3, occlusive clothing is required and, therefore, information should be given about the type of clothing worn. Tests are described in IEST CC 003 for determining the air permeability and pore size of fabrics to show their effectiveness in preventing the penetration of MCPs [7]. Also described is a body box used to obtain the dispersal rate of airborne MCPs from people wearing different types of clothing [7].

We agree with Teo et al's opinion that national surveillance databases give low-quality information about wound infections and that studies into the effect of UCA systems should be obtained in the same hospital to avoid an imbalance of conditions that affect infection rates. However, the number of patients studied by Teo et al is too few to support their conclusion that UDAF systems do not affect deep infections. There is a Type 11 statistical error.

The required number of patients in each group operated on in different ventilation system can be obtained from the following formula, which assumes a two tail distribution [8].

$$n = \frac{p_1(1-p_1) + p_2(1-p_2)}{(p_1-p_2)^2} \,.\, f(\alpha,\beta)$$

Where,

n is the required number of patients in each group studied,

p_1 is the proportion of patients that have joint infections after surgery in conventionally ventilated OTs,

p_2 is the proportion of patients that have joint infections after surgery in UCA systems, and,

f (α,β) is a value calculated from the statistical confidence level (α) and chance of the results being correct (β) that are given in Table 1.

Table 1 Common values of f(α,β)

α	**β**		
	95%	**90%**	**50%**
95%	13.0	10.5	3.8
99%	17.8	14.9	6.6

The infections rate in the conventional operating theatre found by Teo et al's was 3 in 1000 (i.e. a proportion of 0.003). The information given in the MRC study of UCA systems [9] suggests that a halving of the infection rates might be expected from an effective UDAF system. If you wish to have a 90% chance of showing a difference at a 95% level of statistical confidence (f (α, β) = 10.5), the number of patients in each group studied can be calculated to be about 21, 000 (i.e. a total of 42,000 patients). Therefore, Teo et al's study is short of about 40,000 patients. A smaller reduction in the rate of infections would require more patients.

In conclusion, we suggest that any study that compares the effectiveness of UCA systems with conventional mixed airflow OTs should describe the UDAF system and surgical clothing. Information should also be provided about its performance in terms of physical tests, as well as MCP concentrations during surgery which should preferably average less than 1 MCPs/m^3. If the system fails to give ultraclean conditions, no conclusions can be drawn about the ineffectiveness of UCA systems in reducing deep infections. In addition, the study should avoid a Type 11 statistical error.

References

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