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To cite this Article: Liljeblad T.-K. 2006. Clinical Needs and Current Standards for Operating Room Air. 37th R³-Nordic Contamination Control Symposium on R³ - Nordic, The Nordic Society of Cleanroom Technology. VTT Symposium 240. Espoo. 243–254, 255-265. ISBN 952-38-6303-4.

URL: <http://www.vtt.fi/inf/pdf/symposiums/2006/S240.pdf>

CHAPTER 41: CLINICAL NEEDS AND CURRENT STANDARDS FOR OPERATING ROOM AIR

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The purpose of this presentation is to introduce some of the current Finnish and international standards for operating room air and critically discuss their implications to aseptic practices aiming to minimize particle dispersion during operation. The criteria for aseptic practice recommendations were created by method of critical incidences by analyzing 18 h of videotaped material including whole time particle count by laser-sampler (VTT, Tampere) in laminar flow paediatric operating rooms. The inductive analysis of the data was divided into three sections 1) the preparations for the operation, 2) the creation of the sterile field, 3) the maintenance of the sterile field. The research findings brought one section more: 4) the discharge of the sterile field. Less incidences causing particle dispersion were found during creation of sterile field than other sections. During the maintenance of the sterile field, the causes of dispersion were 1) handling the items in the sterile field, 2) invasive and 3) non-invasive interventions during the operation and 4) the action of non-scrubbed persons around the sterile field. The amount of particles varied in operations during the discharge of operation. The incidences were tested also by rotated explorative factor analysis (FA) with Maximum Likelihood Method aiming to decrease the number to critical ones. FA strengthened the result of inductive analysis, decreasing 21 incidents to 9 critical ones. The detailed recommendations were reasoned by international evidence. This piece of research will be used in different clinical contexts to test a conceptual model of clinical aseptic practices to be used in perioperative education, research and clinical quality development.

41.1 INTRODUCTION

Operating room (OR) environment has been in the focus of infection control (IC) since mid 1800's when surgeons Lister in Scotland (Cohen 1999) and

Brewer (1915) first in New York and later in Boston, started perhaps the very first evidence based evaluative programmes in OR environment. The concepts like 'asepsis' and 'aseptic technique', and practical norms concerning them, were created to decrease the high numbers of "Nosocomial gangrene" or "wound fever" threatening the effectiveness of the surgery and even the life of surgical patient. In European ORs the environmental aspects were pointing out to the importance of clean air and sterility of items used in operations. Heavy methods of infection control, carbolic vapours and dressings used by surgeons were not available in nursing when Florence Nightingale in Crimean War and Rofaida AL-Islamiah's in Islamic Wars organized groups of women to deliver nursing care for wounded by means of environmental changes and hygiene. According to Meleis (1991) during this stage the mission of nursing was defined as providing care and comfort to enhance healing and a sense of well-being and to create a healthy environment that helps in decreasing suffering and deterioration. At those times nurses defined the patient and the environment to include their domain. In actual perioperative practice nurses are focusing to evidence based practice which in OR means learning, evaluation and development of aseptic practice based on critical use of multidisciplinary knowledge.

In Europe Sweden has long been in the front line of multidisciplinary co-operation and research concerning aseptic practices focusing to the safety of OR air. Since the end of 20th century OR nurse, educator and researcher Barbro Friberg (1998) has developed working standards for OR according to and in co-operation with medical researchers respected as researchers creating basic knowledge concerning air born contamination using experimental design arrangements. Findings of these Swedish and other international research has long been published, but not always been used in a very efficient way when reasoning professionally separated aseptic practices in European ORs. Nominal group decision making model with lacking sources of multidisciplinary IC studies has long been used in reasoning of recommended aseptic practices for OR nurses (AORN 1999). The challenge of evidence based and multidisciplinary aseptic practices in OR is to replace the ritualistic and unreasoned practices with research findings where the evidence strong enough is available (Liljeblad & Sihvonen 2005).

41.2 CURRENT STANDARDS FOR OPERATING ROOM AIR

In Finland findings of Reijula (2005) concerning hospital indoor air showed, that hospital personnel suffers from dry (46%) and stuffy air (40%), noise (30%), draught (27%) and odours (26%) in their working environments. In total 15% of the hospital facilities were estimated to need immediate repair. According to Reijula there are no official regulations for OR air in Finland or in Europe, so the lack of instructions was one of the most common problems with ventilation. The level of local planning and construction of systems like level of air filtration varied a lot between OR's in the research hospitals. Insufficient ventilation was a common problem indoors causes for complaints were draught problems, lack of local exhaust ventilation systems or undeveloped systems, heavy loads of heat or impurities to the indoor air. The immediate need of planning instructions for hospital air was found.

According to Finish national infection control guidelines for OR air (Tarvainen & Rantala 2005), the critical amount of particles in air is defined at level of 100 CFU/m³, the temperature 22±3°C, humidity of the air 35–45% ±10% and the pressure model should be directed from clean to less clean (from aseptic zone to periphery). The filtration of air should be performed by HEPA- (high efficiency particulate air)-filtration during basic ventilation model of 20 air changes per hour (ACH), and conventional turbulent ventilation model of 20–25 ACH, from which at least 20% should be fresh air. The vertical laminar flow is preferred as more efficient than horizontal laminar flow. The laminar-roof-model is considered most efficient ventilation model with 60 ACH. The increase in amount of personnel in OR and opening of OR doors decreases the efficiency. Local exhaust models were mentioned as an occupational means of prevention with laser surgery. In www-pages of local office for occupational safety, the exposure to biomaterials but not to surgical smoke was mentioned (<http://www.tyosuojelu.fi/fi/biologisetvaarat> / 19.1.2006). In Finland the follow up of empty OR is recommended to be performed by sampling particles over 2–3 µm. This does not follow the recommendations stated by U.S. Department of Labor, Occupational Safety & Health Administration (OSHA).

OSHA Technical Manual recommends as the 'walk around inspections for health hazards' in OR 1) handling of waste anaesthetic gases, 2) air conditioning, 3) humidity of 50% and 4) static electricity control. Controls and

preventions concerning OR air include a demand of adequate ventilation to remove contaminants with adequate filtering when the air is recirculated. Local ventilation, like portable ventilation, should be used during laser surgery to remove contaminants and mixing of methyl metacrylate should be done in a closed system. In the morgue, but not in the OR the local vacuum systems should be in place for power saws and shields should be used when significant splash hazards are anticipated. OSHA's recommendations for good working practices in OR include immediate and proper disposal of bio hazardous waste and care taken of not to create aerosols. The air sampling should be taken place during normal exposure time not in empty OR like in Finnish recommendations.

CDC (2003) recommends maintaining higher pressure of the air in OR than in surrounding environment. From the recommended 15 ACH, more than 3 should be fresh air. All recirculated and fresh air should be filtered with filters of at least 90% of dust-spot-tested air. In environments with no laminar ventilation available, the intake of conventional ventilation should be from ceiling and, the exhaust from floor level. Ultraviolet germicidal irradiation (UVGI) is not recommended to use in OR. The doors of OR should be kept closed and unnecessary traffic should be minimized. In environments where laser is used, the personal protective devices (PPE) like N95 or N100 respirators and smoke wall-suction evacuators should be used. Mechanical smoke evacuator with high-efficiency-filter should be used with excessive smoke when handling tissues of patients contaminated with human papilloma-virus (HPV) or extra pulmonary Tuberculosis.

41.3 MEASURING THE CRITICAL INCIDENCES CAUSING PARTICLE DISPERSION IN STERILE FIELD

To find out the clinical needs to control air born particles of OR air the criteria for aseptic practice recommendations were created by method of critical incidences by analyzing 18 hours of videotaped material including whole time particle count of particles size over 0.3 μm by Metone-laser-sampler collected by research group of VTT in Tampere in laminar flow ventilated paediatric operating rooms during four open heart operations. To minimize the threats of reliability in data collection and analysis, the time of particle figure dictation from the screen was limited to maximum 30 min and the periods of reanalysis was done. The requirements of accuracy and objectivity in the later judgements

were aimed to reach by using the Friedman's test, principle component analysis, factor analysis and rotated factor analysis to study the hierarchical structure of the critical incidents during these operations.

In operations 1 and 4 the barrier drapes used in sterile field were disposable and extra drapes cotton. In operations 2 and 3 all sterile drapes were made of polyester microfibre. In operation 1 where used several non-sterile cotton bedclothes. During all operations the cotton sponges were used.

After classification of the collected data to reach the demand of normal distribution, the principal component analysis of 21 critical incidences in connection with high particle counts was performed. The analysis aimed to explore the possible grouping variables describing aseptic practice during the operations. The correlations between 21 critical incidents were low. The loadings of critical incidents varied from 0.282 to 0.730. The power of principle component analysis to explain the total variance of critical incidents with nine principal components was 57.2%.

The variance of these nine principal components varied from 8.4% to 4.88%. The principal components formulated were 1) simultaneous activity with tissue handling in the sterile field (8.4%), 2) the activity of scrubbed an un-scrubbed personnel near the sterile field (7.4%), 3) handling of sterile items in the sterile field (7.2%), 4) the activity of un-scrubber personnel near the sterile field (6.4%), 5) the handling of the skin of the patient (6.1%). In component number 6) all the criteria (6.0%) were secondary and the principal component number 7) handling of cotton sponges (5.4%) was negative. Next were the 8) incision-component (5.2%) and component describing 9) handling of tissues (4.9%). Critical incident of diathermia use got strong negative loadings in third component like did the suturing of tissues and sawing of the sternum in eight components. The results indicate the critical incidents to be good variables to be used as them selves and the trend of principal component analysis to create larger matrix than factor analysis (Hazard Munro 1997).

The inductive analysis of the data was divided into three sections 1) the preparations for the operation, 2) the creation of the sterile field, 3) the maintenance of the sterile field. The primary analysis of the data brought one section more: 4) the discharge of the sterile field. Unlike earlier Finnish findings

of Verkkala et al. (1990) less incidences causing particle dispersion were found during creation of sterile field than other sections. During the maintenance of the sterile field, the causes of dispersion were 1) handling the items in the sterile field, 2) invasive and 3) non-invasive interventions during the operation and 4) the action of non-scrubbed persons around the sterile field. The amount of particles varied in operations during the discharge of operation. The incidences were tested also by rotated explorative factor analysis (FA) with Maximum Likelihood Method aiming to decrease the number to critical ones. FA strengthened the result of inductive analysis, decreasing 21 incidents to 9 critical ones (Table 41.1). The detailed recommendations were reasoned by international evidence.

The invasive interventions during the operation caused highest dispersions during the whole observed period. Dispersion during incision were less than $10000000000 \text{ p/m}^3$ in all operations. The use of diathermia caused highest maximal dispersion in operation 4 ($730650000000 \text{ p/m}^3$) with significant operation related variation (Khi2 = 127853, $p = 0.000$, $N = 204$). The sawing of sternum caused highest dispersions of range $1610000000\text{--}264395000000$, mean $55798370000 \text{ p/m}^3$ in operation 2. The variation between operations were significant (Khi2 = 11.80, $p = 0.008$). Suturing the tissues and making knots increased the particle amount highest in operation 3 (range $0\text{--}124460000000$, mean 100622000 p/m^3) with very significant statistical variations between operations (Khi2 = 89.696, $p = 0.000$). During the suturation of the skin the difference between operations was significant (Khi2 = 38.069, $p = 0.000$), the highest was $10180000000 \text{ p/m}^3$. When performing simultaneous activities with tissue handling in the sterile field the variation was between 0 and 36875000000 , mean 777970000 p/m^3 in operations 1 and 4, and between 0 and 8255000000 , mean 733430000 p/m^3 in operation 2 and 3. Differences were almost significant (Khi2 = 8.753, $p = 0.033$).

Table 41.1. Critical aseptic incidences as results of rotated factor analysis.

Loadings and explanatory power of critical aseptic incidences
1. Cleaning the skin of the patient after operation (0.984 / 5.307%)
2. Moving the sterile drapes by scrubbed person (0.989 / 5.217%)
3. Sawing the sternum of the patient (0.991 / 5.207%)
4. Moving the sterile drapes by unscrubbed person (0.988 / 5.180%)
5. Actions exposing the sterile field to contamination (5.106%) – removing of the surgical glove in the presence of sterile field (0.880) – moving the OR lamp (402)
6. Actions exposing the sterile field to contamination (4.771%) – moving the OR table (0.692) – removing of the surgical glove in the presence of sterile field (0.318) – coughing in the sterile field (0.546)
7. Handling cotton sponges in sterile field (0.690 / 4.142%)
8. Opening sterile packages (0.521 / 2.68%)
9. Several simultaneous actions in the sterile field – handling the tissues of the patient (0.387 / 1.592%)

The use of powered instruments caused electrical coronas with increased amount of particles in the sterile field (Table 41.2). The other activities were in connection with handling the skin of the patient, causing turbulent air currents or electrical currents in the sterile field by handling drapes and sterile items or by moving in the presence of the sterile field. The factor of several simultaneous actions was describing the explanative power of other factors.

Table 41.2. Particle dispersions and electrical coronas during use of powered instruments.

Critical incident in sterile field during electrical coronas	Amount of particles* during electrical coronas during four operations (n=number of observations)	min	max	mean	SD
Use of electrocautery device	1 (n = 26)	161	6 803 000	10 56 298.8	1 949 937.9
	2 (n = 12)	2 000	2 619 000	253 541.67	746 084.28
	3 (n = 12)	1 000	1 645 000	477 791.67	620 806.42
	4 (n = 187)	0	24 963 000	1 937 067.4	3 714 299.20
Sawing the sternum of the patient	2 (n = 4)	224 000	1 306 000	588 125.0	486 656.00
	4 (n = 4)	227 500	565 500	393 000.0	153 964.82
Use of suction during operation	1 (n = 20)	0	14 000	2 575.0	3 184.15
	2 (n = 8)	1 000	4 000	2 062.5	1 083.56
	3 (n = 20)	0	89 8000	72 000.0	197 375.14
	4 (n = 42)	1 000	26 000	3 809.52	4 462.52
Ensuring the function of pacing electrode	2 (n = 4)	2 500	3 000	2 625.0	250.00

* 1 observed particle is 10 000 particles/m³

41.4 CLINICAL NEEDS TO CONTROL THE AMOUNT OF PARTICLES IN OR AIR

These findings of analysis done in an inductive way are supported by traditional understanding of particle dispersion in the sterile field and also by Friberg (1998) when she describes broadly the classical findings of studies concerning air born contamination in OR. She summarises that the physical mechanisms of movements and sedimentation of particles in OR air has been proved by Whyte concerning the gravitation mechanism and the speed of sedimentation of the particles as mean value of 0.3 m/min and points out that fine particles of size less than 0.5 µm are able to spread out by random diffusion which decreases the speed of sedimentation. The current Finnish recommendation to measure particles of over 2–3 µm in empty OR does not respect the existence of particles this size.

According to earlier strong evidence, several issues should be taken care when optimizing the clean air in sterile field of surgical operation site by decreasing the amount of particle dispersion originated from foreign materials, perioperative patient and personnel. Friberg (1998) summarised that by 1) minimizing the number of personnel in OR, 2) avoiding rapid movements in the sterile field and 3) ensuring intact and healthy skin of OR personnel important factors effecting on the amount of particles in the air of sterile field in OR are controlled. The sources of contamination could be controlled by using personal protective devices, sterile instruments and scrub suits in the sterile field, ensuring the positions and cleanliness of OR lamps, minimizing the dispersion of particles originating from electrocautery devices, materials used in operation site like glove powder and linting textiles and minimizing handling of the instrument. To protect the sterility of the surgical site, the size of the sterile field is recommended to be 2.8 m² covering all the instruments and the whole sterile operation site (Chow & Yang 2005).

These current research findings are supported also by the demands of American operating room nurses in their national conferences (Ulmer 1998) concerning surgical smoke to protect the patient and the personnel in OR not to exposure to the irritating and toxic effects of surgical smoke plume from electrical surgical devices and use surgical laser. The origin of current American recommendations for evacuation of surgical smoke is in “Health Hazard Alert” of National Institute for Occupational Safety and Health in September 1996, where is described that the surgical smoke consists of toxic cases, vapours and particles and vapours causing bio hazardous exposure. Despite of demands of Association of periOperative Nurses (AORN) and American Nurse’s Association (ANA) the Centres for Disease and Control (CDC) has not (yet) published national standards concerning surgical smoke even many pieces of research with strong experimental design arrangements has been published recently. According to Johnsson (2000) the publishing will take place ‘soon’ but they have not been published during year 2003 (Roark, 2003) or spring 2006.

Earlier CDC (2003) has been shortly guided the health care personnel to protect against air born risks in it’s Guidelines for Environmental Infection Control in Health-Care Facilities. There are advices to use portable, industrial-grade HEPA filter units capable of filtration rates in the range of 300–800 ft³/min to augment removal of respirable particles when needed. Portable HEPA filters able to

re-circulate all or nearly all of the room air, and provide the equivalent of > 12 ACH should be selected. In many American hospitals removal of surgical smoke has been taken care by the hospital risk management (Tydell 2002). The recommendations of OSHA, like the location of the nozzle of smoke evacuator line not longer than 2 in from the source of surgical smoke, operation or use related change of filters and lines, and handling of smoke evacuator filters as infected material has been accepted locally.

These results support the need to develop both the occupational infection control and the aseptic practices to decrease air born contamination of the surgical site in OR. In future creating process of European Council Directives for OR air, the exposure of OR personnel to bio-hazardous materials caused by the use of powered instruments should be taken care by proper room and local ventilation and personal protective devices. The exposing time of OR nurses is discussed to be longer than the time of surgeons and anaesthetists, so the occupational risk of at least nurses to pulmonary and infectious diseases should be studied in addition to the risk of air born contaminants like toxic vapours and mutagenic particles.

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