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International Journal of Current Research
Vol. 6, Issue, 05, pp.6871-6874, May, 2014

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

ISSN: 0975-833X

RESEARCH ARTICLE

COMMISSIONING OF OPERATION THEATRE AT A TERTIARY CARE CENTRE – MICROBIOLOGICAL PERSPECTIVE

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ARTICLE INFO

Article History:
Received 25th February, 2014
Received in revised form
10th March, 2014
Accepted 16th April, 2014
Published online 31st May, 2014

Key words:
Commissioning,
Operation Theatre,
Fogging,
Microbiological evaluation.

ABSTRACT

Purpose: Commissioning must occur before an operating theatre (OT) is first used and after any substantial modifications that may affect airflow patterns in preexisting theatres (as part of a re-commissioning process). It is important that the infection control team (ICT) or microbiologist is involved at all stages from pre-design through to opening and that adequate time for commissioning is built in to the schedule, including an allowance of time for microbiological assessments. In the present study special emphasis laid on the process of commissioning OT with respect to microbiologist perspective.

Material and Methods: The study was carried at the tertiary care hospital to commission newly built 6 OTs and one CATH lab. The sterilization of all 6 OTs and CATH lab was done in 3 cycles. First formaldehyde fumigation was done followed by two cycles of fogging using hydrogen peroxide. After fumigation, the sterile surface swabs were collected from representative areas from all OTs and CATH lab. The air sampling was done by settle plate method. Then all the swabs were processed in microbiology laboratory according to standard guidelines for aerobic, anaerobic and fungal cultures.

Results: The OT and CATH lab surfaces were free from anaerobic contamination. The samples which were taken from door side AC duct in CATH lab grew *Aspergillus niger*. The settle plate did not yield any growth.

Conclusion: It is necessary to perform Microbiology evaluation of the newly built OT before commissioning to ensure that ventilation system in the OT are functional, environmental parameters and the microbial load in the theater environment are at the acceptable level. It forms the integral part in the process of commissioning the OT.

INTRODUCTION

The Operation Theatre (OT) has been considered heart of the hospital. Modern operation theatres must fulfill standards of design and ventilation. Asepsis being the vital factor for the success in modern surgery, it is therefore imperative that a scientific, detailed planning should be done while designing an OT. Cleanliness of the hospital environment is the best starting point to achieve the highest patient safety. Infection control is the key to achieve the objective of good patient outcome in hospital. There is need to decrease the bioburden present in the environment in an operating room. Sapna (2011) Standard cleaning, disinfection and sterilization procedures, good theatre practice and discipline can provide a microbiologically safe environment in the theatre. Mehta (2005) In the operation theatre the source of infection may be either endogenous (from the patient himself) or exogenous from the theatre environment. Ayeliffe (1991) In the present article special emphasis is laid on cleaning, sterilization/disinfection and microbiological evaluation done on newly built 6 operation theatres and one CATH lab in our hospital to commission OTs.

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MATERIALS AND METHODS

The study was carried out at the tertiary care hospital to commission newly built 6 OTs and one CATH lab. The 6 OTs are pediatric surgery OT, neurosurgery OT, gastro surgery OT, plastic surgery OT, and 2 additional OTs. All the 6 OTs are ultraclean ventilated (UCV) theaters and the CATH lab is an unventilated room. The commissioning was done just before the use of OTs and CATH lab.

The following steps were followed for commissioning the OTs and CATH lab: Hoffman *et al.* (2002)

1. The interiors were checked for the obvious defects
2. The airflow between the preparation room used for instruments lay-up and UCV OTs was checked
3. The proper installation and functioning of Air Handling Units (AHU) were checked

4. All 6 UCV OTs' were equipped with vertical laminar flow system. High Efficiency Particulate Air (HEPA) filters were checked for proper placement and intactness in the UCV OTs.
5. All OTs and CATH lab were cleaned thoroughly by physical scrubbing with detergents and rinsing with water.
6. Spot cleaning of walls, ceiling and open shelves were performed.
7. All air cooler (AC) ducts were cleaned mechanically by Robotic machine followed by wet mopping with detergent. Then AC duct was fogged using hydrogen peroxide as the disinfectant by fixing fogger machine to the AC duct.
8. Then sterilization of all 6 OTs and CATH lab was done in 3 cycles. First formaldehyde fumigation was done followed by two cycles of fogging using hydrogen peroxide.

Formaldehyde fumigation (first cycle)

This method is commonly used to sterilize the OT and other rooms. AHU was switched off. Formaldehyde gas was generated by adding 150gm of KMno4 to 280ml of formalin for every 1000 cubic feet (28.3 cu.m^3) of room volume. The reaction produces considerable heat, and so heat resistant vessels were used. When formalin vapour was generated, doors were sealed and left unopened for 48hours. After 48 hours, the left formaldehyde was neutralized by 300ml of 10% ammonia. Ammonia solution was kept for 2-3 hrs to neutralize formalin vapours. Ananthanaranya *et al.* (2009)

Fogging Method (second and third cycles)

Fogging method involved nebulization of a disinfectant in a sealed OT room until all surfaces were wet by wiping of residual fluid from surface by masked and gowned personnel. Center for Disease control 1972; Otter *et al.* (2003) The hydrogen peroxide was used as a disinfectant for fogging. The fogger machine was switched on; doors were sealed and left unopened for 30 minutes. The AHU were switched off for half an hour.

After Fumigation the sterile surface swabs were collected from representative areas from all OTs and CATH lab as follows:

1. Operation table at the head end
2. Over head lamp
3. Four walls
4. All AC ducts
5. Floor and Roof
6. Floor below the head of the table
7. Instrument trolley

The AHU was operating at all OTs at normal flow rates for 24 hours before sampling. Microbiological air sampling was done by settle plate method. After each cycle of sterilization, blood agar and mannitol salt agar plates with lid opened were kept in the theaters in each corner and one at the centre of OT for 30 minutes. Then secured plates were transported to laboratory and incubated at 37^0C for 24 hours. The plates were observed for the aerobic growth and colony count was calculated according to standard guidelines. Forbes *et al.* (1998); Sehulster *et al.* (2004) After each cycle of sterilization, sterile surface swabs were taken from all the areas mentioned above. The sterile swabs were rubbed over the area to be sampled. From each area 3 swabs were taken, one each for aerobic, anaerobic and fungal culture. These swabs were transported to the microbiological laboratory in a sterile container. All the swabs which were taken after each cycle were processed according to the standard guidelines. They were processed by streaking it on Blood agar for aerobic growth. Robertson cooked meat media (RCM) and Sabouraud dextrose agar (SDA) was used for anaerobic growth and fungal culture respectively. Then aerobic plates were incubated at 37 ^{0} C for 48hours. Quality analysis of the colonies was done using standard bacteriological methods to rule out the presence of *Staphylococcus aureus*. Detection of even a single colony of *Staphylococcus aures* was considered as a risk for infection. Sapna *et al.* (2011); Forbes *et al.* (1998); Sehulster (2004); Favero (1985); Salle (1973); WHO (1978)RCM media were incubated at 37 ^{0} for 9 days and identification of anaerobes were done according to standard guidelines upto genus level. Willis (1977) Sabouraud dextrose agar tubes were incubated at 25 ^{0} to 30 ^{0} C for 7 days to check for fungal growth. Any fungal growth was identified by gross and microscopic examination of the growth according to standard guidelines. Larone (1995)

RESULTS

The engineering parameters were adequate and satisfactory. The OT and CATH lab surfaces were free from anaerobic contamination. The samples which were taken from door side AC duct in CATH lab grew *Aspergillus niger* during first cycle of surface sampling. Following which all air cooler (AC) ducts were cleaned mechanically by robotic machine followed by wet mopping with detergent. Then AC duct was fogged using hydrogen peroxide as the disinfectant by fixing fogger machine to the AC duct. After 3rd cycle of sterilization, it showed no growth. All surface swabs for aerobic culture yielded no growth except in CATH lab. The first cycle of surface samples which were taken from trolley in CATH lab grew *coagulase negative staphylococcus*. The CATH lab was again cleaned in depth and fogged. In 3rd cycle it showed no growth. Air sampling done by settle plate method didn't yield growth in the any of the OTs and CATH lab.

DISCUSSION

Operation theaters must be commissioned before being used, after being built or modified substantially. Hoffman *et al.* (2002) The 6 OTs and CATH lab in our hospital were commissioned after being built and before being used. Commissioning is a process in which the structural and functional integrity of the theaters is ensured by assessing various parameters. The parameters and protocols used to assess them differ depending on the type of ventilation system. Hoffman *et al.* (2002). The operation theaters or the intervention rooms may be unventilated in which there is only single zone and turbulent airflow dynamic is present. This is not a good system for operation theatres as because of turbulence insurance the air is not clean in the area of the patient and on the table of instruments. This type of ventilation

system can present different disposition on the ceiling and sometimes also on the walls. Melhado *et al.* (2006) The CATH lab in our hospital is an unventilated intervention room and hence requires stringent cleaning, followed by sterilization of the room and frequent surveillance. Hoffman *et al.* (2002) The other ventilation systems are conventionally ventilated and ultra clean ventilated theaters. Hoffman *et al.* (2002) The UCV theatres consists of laminar air flow (LAF) systems where in it can be horizontal or vertical. These ventilation systems are combined with the use of the HEPA filters, and a low and uniform velocity. This system, if used alone, can divide the OTs in two zones. However, in the horizontal LAF supply air in OTs usually is disrupted by the surgical team. Dharan and Pittet 2002 The vertical LAF is more effective in OT than the horizontal, because the clean air is supplied directly over the operating table, and also more effective in accordance with some studies. Lidwell *et al.* (1982); Friberg (1998); McCarthy *et al.* (2000); Technology Assessment Team (2001) In our hospital all the 6 OTs where in specialized surgeries were to be performed had UCV vertical LAF system.

The parameters and protocol used to assess the structural and functional integrity of the OTs in our hospital were according to the UCV OTs. Hoffman *et al.* (2002) General Cleaning is the necessary first step of any sterilization or disinfection process. Cleaning is a form of decontamination that renders the environmental surface safe to handle or use by removing organic matter, salts, and visible soils, all of which interfere with microbialinactivation. Cleaning, disinfection and sterilization are the cornerstones in ensuring operation theatre asepsis. Fumigation by Formaldehyde inactivates microorganisms by alkylating the aminoacid and sulfhydryl groups of proteins and ring nitrogen atoms of purine bases. Occupational safety health Administration (OSHA) indicated that Formaldehyde should be handled in the workplace as potential carcinogen and set an employee exposure standard for Formaldehyde that limits an 8-hour time- weighted average exposure concentration of 0.75ppm. Fumigation of OT using formalin is not recommended by the Center for Disease Controland prevention. Technology Assessment Team (2001) Fumigation by fogging using hydrogen peroxide, the disinfectant is the newer method and it is non carcinogenic, less time consuming and cost-effective.

Sampling of air can be done by settle plates or using volumetric slit samplers. In the former air borne particles are allowed to settle on exposed plates whereas in the latter a known volume of air is impacted on a given medium. The medium used is usually blood agar. Colonies are counted after incubation and results are expressed in colony forming units, presence of one colony taken to indicate the deposition of one bacteria carrying particle. The presence of pathogens such as *S. aureus*, beta haemolytic streptococci, fungi is recorded. Parker (1978) In the present study, air sampling by settle plate method didn't yield any growth in any of the OTs and CATH lab indicating that ventilation systems (UCV-HEPA filters) were functioning properly decreasing the microbial load in the air circulating inside OT rooms. The rationale for surface sampling is based on the assumption that inanimate sources are important cause of health care associated infections and in no part of the hospital is it more important to have a sterile environment than the operation theatre. Mehta (2005) The utility of the bacteriological assessment of the surfaces of the OTs for the presence of Clostridia is questionable, at best it is an indicator of effective cleaning and housekeeping practices. However the value of this tool for sentinel surveillance is good. Eelkar *et al.* (2003) In our study Clostridia were not isolated in any of the OTs and CATH lab. Health care associated infections attribute to fungi have been documented. Aspergillus is ubiquitous and occurs in soil, water and decaying vegetations. Other opportunistic fungi associated with nosocomial infections are Rhizopus, Fusarium and Penicillium. Overberger *et al.* (1995) All these are capable of proliferating in the wall mounted air conditioning units. The filters utilized in the units can act as nidus for growth and proliferation of the pathogenic fungi. Indoor levels of *Aspergillus*sp. can be greatly reduced by air filtration systems, such as the HEPA system, and this can result in a concomitant decrease in the incidence of invasive aspergillosis. Alberti *et al.* (2001); Araujo *et al.* (2008); Vonberg and Gastmeier (2006) reviewed all cases of invasive aspergillosis and concluded that the fungus is able to cause disease in environments with less than 1 CFU x m-3 of air. They recommended that risk patients should not be exposed to the fungus and concluded that prevention from all routes is critical. Patients staying long periods at clinical units with high degree and long duration of immunosuppression are at the highest risk for developing invasive aspergillosis. Vonberg and Gastmeier (2006) In the present study, there were no HEPA filters in CATH lab and the lab was not operational for long time after construction. This led to growth of fungi in the AC ducts. Following which all air AC ducts were cleaned mechanically by robotic machine followed by wet mopping with detergent. Then AC duct was fogged using hydrogen peroxide as the disinfectant by fixing fogger machine to the AC duct. After 3rd cycle of sterilization, it showed no growth. In the present study, trolly in CATH lab surface sample grew coagulase negative staphylococcus (CoNS). The clinical significance of CoNS continues to increase asstrategies in medical practice lead to more invasive procedures such as the replacement of damaged or missing body parts with synthetic materials and the widespread use of catheters. The most vulnerable to infection by CoNS are hospitalized patients, especially those who are premature, very young, or old and those who are immunocompromised and/or suffering from chronic diseases. The growth of CoNS in CATH lab environment is significant. Kloos and Bannerman (1994) Hence the surface and all the articles in the CATH lab were again cleaned thoroughly, followed by sterilization. Further surface sampling from CATH lab didn't yield any growth.

Conclusion

Commissioning of OTs and other intervention rooms is a process in which various environmental parameters are evaluated. The microbial load in the OTs should be at an acceptable level which is detected by microbiological sampling of the theatres and intervention rooms. If any microbiological failure occurs, then the ventilation parameters, structural integrity of OTs and cleaning procedures undertaken should be re-addressed. The defect should be identified; rectified and microbiological evaluation is repeated to confirm that the parameters are with normal limits. In the present study,

during the commissioning of newly built OTs and CATH lab the microbial load in the CATH lab was not in the acceptable level. It was re-addressed by thorough cleaning and sterilization, re-sampling showed that there was no growth following which all the newly built OTs and CATH lab were commissioned.

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