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A Systematic Airborne Particle Measurement in a GMP Grade C Hospital's Preparation Room

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Abstract : Prior to surgical procedures, a patient is placed in a dedicated preparation room to be gowned and have a peripheral venous catheter near the wrist. Hence, in such facilities, it is imperative that the environment be conducive to minimal risk of contamination with airborne particles. In this study, we examined the effect of the ventilation system and adjacent room cleanliness on the concentration of airborne particulate matter (PM) in a GMP Grade C pre-op room at a local hospital. The preparation room used in this work was equipped with high-efficiency particulate arrestance (HEPA) filters that maintained vertical laminar airflow at all times. All measurements were carried out under at-rest conditions in compliance with ISO 14644-1 guidelines. A Lighthouse 3100+ laser particle counter was used to measure the sum of PM of varying diameters: PM 0.3, PM 0.5, PM 1.0, PM 3.0, PM 5.0 and PM 10.0. Overall, average PM concentrations were found to be in compliance with GMP specifications for Grade C pre-op rooms. Yet, lower PM count was observed in the sampling areas closest to the operating room—a substantially cleaner environment. Based on the findings of this study, having pre-op rooms adjacent to rooms of a controlled environment is advantageous and may contribute to reduced risk of nosocomial infections.

Keywords : Hospital; preparation room; GMP Grade C; particulate matter; field measurement.

1. INTRODUCTION

Hospital pre-op rooms offer a controlled environment to perform mandatory patient preparation procedures prior to surgery. In such rooms, patients awaiting surgery lie down on portable beds as an intravenous (IV) line is set up near the wrist to later allow the introduction of intensive care medications and anaesthetics. Environmental cleanliness in the pre-op room is key as it is located adjacent to the operating room (OR). Contaminated pre-op rooms increase the risk of nosocomial infections, which according to Emmerich et al. [1], are annually responsible for 88,000 treatment-related mortalities and extra hospitalisation costs reaching $3 billion US. Surgical site infection (SSI) is ranked the second and the third most common nosocomial infection in the USA and Brazil, respectively. Nearly 13,000 mortalities occur in hospitals annually due to SSIs; and patients treated for these infections have been shown to collectively endure extra hospital charges of about $1.6 billion US every year [2-4]. Nosocomial infection incidence is strongly correlated with PM concentrations in pre-op and operating rooms [1-3, 5]. Karlatti and Havannavar [6] estimated that in 2016 the probability of developing an SSI was 3.8% and 37.8% under a clean and a contaminated environment, respectively. Therefore, maintaining low PM concentrations in pre-op rooms should reduce the risk of infection significantly.

To maintain low PM concentrations and effective airflow patterns, the ventilation systems in most pre-op rooms worldwide use clean-room technology. A clean-room is defined as a room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner that

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minimises the introduction, generation and retention of particles in the ventilated zone [7]. This is achieved by controlling ambient parameters, such as temperature, humidity and pressure [8]. In a clean room, supply air diffusers are mounted on the ceiling, while the exhaust grilles are located near the floor. This allows unidirectional air to flow from the diffusers, providing superior PM washing effects against contamination sources. According to James et al. [9], this significantly decreases the incidence of infection following surgical procedures. Unidirectional airflow is obtained using high-efficiency particulate arrestance (HEPA) filters, which coincidentally are seemingly capable of trapping PM > 0.3 μm in diameter [2, 10]. Besides the ventilation system, clean-room protocols are also designed to maintain low PM concentrations by mandating proper clothing control [11, 12], surgical helmet systems [12] and approved sterilisation procedures. Besides, a clean room commonly utilises additional mobile laminar air flow (LAF) devices [13].

Healthcare, semiconductor and pharmaceutical clean-room facilities are required to be in compliance with international standards, such as EURO GMP guidelines, ISO 14644-1 and BS 5295. For instance, in Malaysia, pre-op and OR rooms in most hospitals comply with EURO GMP guidelines and ISO 14644-1 standards. These international regulations stipulate a range of clean-room specifications depending on the purpose of the clean room. EURO GMP guidelines recognize four different clean-room grades: Grade A, B, C and D; whereas ISO 14644-1 defines nine different classes of clean rooms: Class 1, 2, 3, 4, 5, 6, 7, 8 and 9. Consequently, requirements concerning the permitted PM concentration vary depending on the room's grade or class. Tables 1 and 2 summarize the particle threshold requirements of EU GMP guidelines and ISO 14644-1, respectively:

Table 1

Clean-room airborne particulate cleanliness requirements per GMP grade

Grade	*At rest*		*In operation*	
	Maximum permitted number of particles/m³			
	0.5 μm	*5.0 μm*	*0.5 μm*	*5.0 μm*
A	3500	1	3500	1
B	3500	1	350000	2000
C	350000	2000	3500000	20000
D	3500000	20000	Not defined	Not defined

Table 2

Clean-room airborne particulate cleanliness requirements per ISO 14644-1 class [7]

Maximum concentration limits (particles/m³) for particles equal to and larger than the considered sizes below						
Cleanliness Class Number	*0.1 μm*	*0.2 μm*	*0.3 μm*	*0.5 μm*	*1.0 μm*	*5.0 μm*
Class 1	10	2	N/A	N/A	N/A	N/A
Class 2	100	24	10	4	N/A	N/A
Class 3	1000	237	102	35	8	N/A
Class 4	10000	2370	1020	352	83	N/A
Class 5	100000	23700	10200	3520	832	29
Class 6	1000000	237000	102000	35200	8320	293
Class 7	N/A	N/A	N/A	352000	83200	2930
Class 8	N/A	N/A	N/A	3520000	832000	29300
Class 9	N/A	N/A	N/A	35200000	8320000	293000

The present study collected field measurements of PM concentrations in a GMP grade C hospital pre-op room following standard quantification procedures. These measurements were later used to validate room compliance with GMP and ISO 14644-1 guidelines, and to investigate the effect of the cleanliness level of adjacent rooms on PM distribution throughout the pre-op room.

2. METHODOLOGY

2.1. Pre-op Room Description

Figure 1 shows a schematic diagram of the pre-op room used in this study. The room was located in one of the private hospitals in Selangor Darul Ehsan, Malaysia, and was categorised as a GMP grade C clean room. The dimensions of the room were as follows: 7 m (W) × 3 m (H) × 4 m (L).

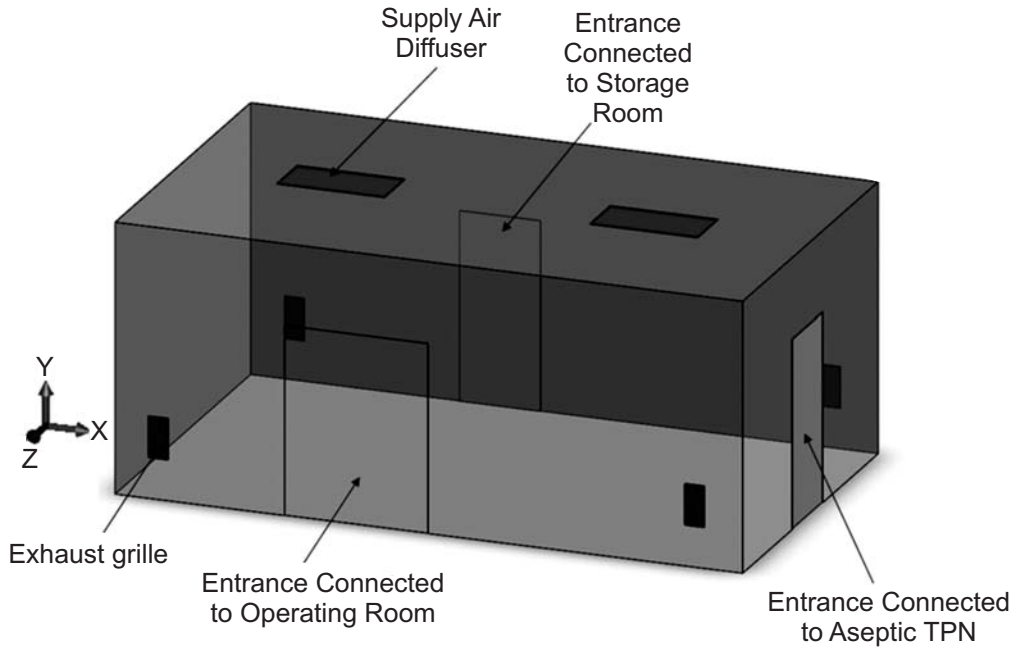

Figure 1: Schematic diagram of an actual surgical preparation room in Selangor, Malaysia

The air was supplied to the room via two supply air diffusers mounted on the ceiling, and exited via four exhaust grilles located 0.4 m above the floor level. The diffusers were equipped with three-stage filters. Stages 1 and 2 filters trapped the large particles, while the last filter, a HEPA filter, served to trap particles larger than 0.3 μm. A detailed description of the room is shown in Table 3.

Table 3

Pre-op room description

Description of preparation room	
Operating System	*Cleanroom System*
Standard	GMP – Grade C
Air flow supply	Unidirectional
Room dimensions	7m (W) × 3m (H) × 4m (L)
Entrance connected to storage room and aseptic room	0.9m (W) × 2.1m (H)
Entrance connected to operating room	1.3m (W) × 2.1m (H)
Exhaust Grilles	0.22m (W) × 0.46m (H)
Supply air diffusers	1.2m (W) × 0.6m (L)

**W: width; H: height, L: length.

2.2. PM measurement procedure

Field measurements were carried out in July 2015 under at-rest conditions between 8.30 pm and 11.30 pm. According to ISO 14644-1 [7], a clean room is considered at-rest when it is fully furnished and in the original condition with no personnel present. In the present study, the room was purged for at least 12 h before measurements were taken. To achieve a steady-state operating condition, the ventilation system was activated for 30 min before data collection [2]. Supply air velocity, air change rate, temperature and relative humidity were recorded prior to PM measurements. To validate the data obtained, certified clean-room testing was performed according to GMP Guidelines, ISO 14644-1 and NEBB standards.

To measure PM concentration, the pre-op room was divided into six sampling grids according to IEST standards [14]. The minimum numbers of sampling grids was calculated according to Equation (1); and all grid were chosen to be smaller than 30 m^2 [7, 10, 14].

$$N = \sqrt{4} \quad (1)$$

where N : Minimum number of sampling grids

A : Area of the cleanroom in square metres

Figure 2 shows the sampling grids generated to obtain PM measurements in the present work

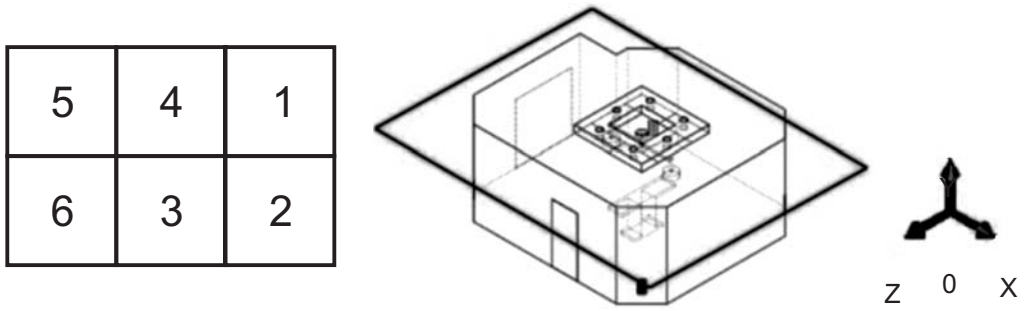

Figure 2: Pre-op room sampling grids

2.3. Instrumental Setup

A Testo 625 digital Thermo-Hygrometer (Testo Inc., Lenzkirch, Germany) was used to obtain measurements of relative humidity and air temperature. Supply air velocity and PM concentrations were evaluated by using an Alnor EBT 721 balometer (ALNOR, Huntingdon Beech, CA, USA) and a Lighthouse 3100++ laser particle counter (Lighthouse Worldwide Solutions, San Jose, CA, USA), respectively. All instruments were calibrated before use. Instrumental specifications are shown in Table 4.

Table 4

Instrumental specifications

Measured Variable	*Instrument*	*Efficiency / Accuracy*
Relative Humidity	Testo 625 Thermo-Hygrometer	+/– 2.5%
Air Temperature	Testo 625 Thermo-Hygrometer	+/– 0.5 °C
Air Velocity	Alnor EBT 721 Balometer	+/– 0.04 m/s
Particulate Matter	Lighthouse 3100 ++ Laser Particle Counter	50% @ PM 0.3 100% @ > PM 0.5

Six PM measurements were collected based on particle diameter: PM 0.3, PM 0.5, PM 1.0, PM 3.0, PM 5.0 and PM 10. The measurements were obtained at 1.1 m above floor level; and the particle counter was placed in the middle of the sampling grid every time. Figure 3 depicts an engineer dressed in a clean-room coverall suit to conduct a PM measurement.

Figure 3: PM measurement conducted in the pre-op room

A 95% upper confidence limit (UCL) was adopted for higher confidence levels relevant to the measured PM concentrations. UCL was calculated according to Equation (2) [7, 10].

$$95\%\ \text{UCL} = \overline{C} + F_{UCL} \times \frac{\sigma_c}{\sqrt{N}} \quad (2)$$

where

UCL : Upper confidence limit

$\overline{C}$: Mean particle concentration (particles/m^3)

F_{UCL} : Factor of UCL

N : Number of samples

σ_c : Standard deviation of particle concentration (particles/m^3).

3. RESULTS AND DISCUSSION

Prior to PM measurement, to fulfil clean-room performance testing (CPT) criteria, supply air velocity, air change rate, air temperature and relative humidity were recorded and found to be 0.43 ± 0.02 m/s, 26 ± 1/h, 19.5 ± 0.5 °C and 58.5 ± 0.5%, respectively. The measured parameters were in compliance with ISO requirements.

Table 5

PM readings per particle diameter

	Concentration (particles / m^3)					
	PM 0.3	*PM 0.5*	*PM 1.0*	*PM 3.0*	*PM 5.0*	*PM 10.0*
Minimum	54985	25039	14267	1625	707	565
Maximum	133242	47216	34714	4485	1837	1236
Average	80482	33938	21377	2507	1195	854
Std. Deviation	29893	7967	7913	1083	428	250
Standard Error	12204	3253	3231	442	175	102
UCL Factor	2	2	2	2	2	2
95% UCL	104890	40443	27838	3391	1545	1058

Table 5 details the minimum concentration, maximum concentration, average concentration, standard deviation, standard error and 95% UCL values of the measured PM concentrations. Small standard deviation values indicated minor variations between the data collected and the mean [15]. On the other hand, a low standard error signified that the sample mean was not far off from the population mean [15]. A factor of 2 was adopted when reporting 95% UCL values. Selection of the factor was based on the quantity of sampling points. For a measurement of more than nine sampling points, 95% UCL calculation was not required.

In a GMP Grade C pre-op room, PM 0.5 and PM 5.0 concentrations may not exceed 350,000 and 2,000 particles/m^3, respectively under at-rest conditions, or 3,500,000 and 20,000 particles/m^3, respectively under in-operation conditions. The corresponding measurements obtained in the present work are shown in Figure 4. The distribution of PM 0.5 and PM 5.0 was found to be uneven throughout the room; and the maximum fluctuations recorded were of 22177 particles/m^3 and 1130 particles/m^3, respectively. Overall, the results suggested that PM 0.5 and PM 5.0 levels were well below the thresholds prescribed in GMP guidelines.

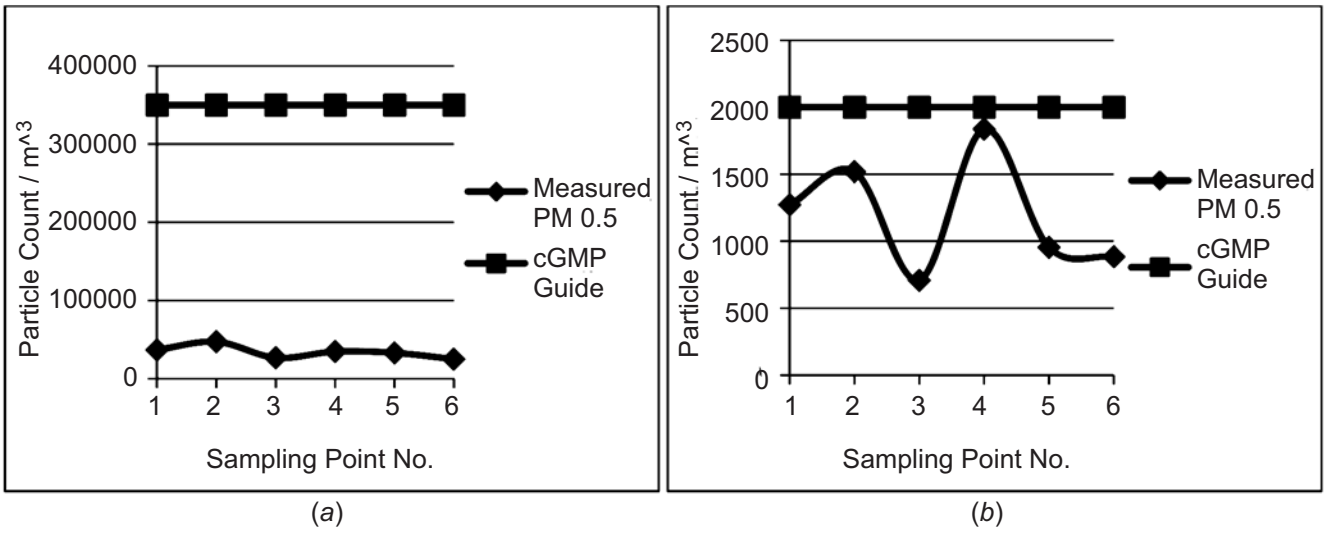

Figure 4: GMP Grade C pre-op room requirements vs. (*a*) Measured concentration of PM 0.5 and (*b*) Measured concentration of PM 5.0

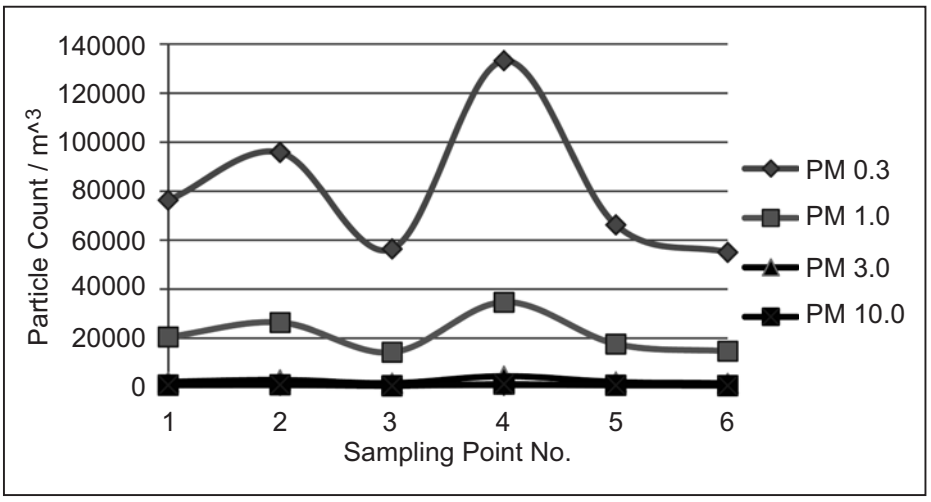

Figure 5: Pre-op room concentrations of PM 0.3, PM 1.0, PM 3.0 and PM 10.0

Additional measurements were conducted to ascertain the concentrations of PM 0.3, PM 1.0, PM 3.0 and PM 10.0. As shown in Figure 5, particle distribution variations were observed throughout the room. Interestingly, the highest particle concentrations were detected at sampling point 4. This indicated that PM flowed into the pre-op room from the adjacent room via the door gap. A schematic layout showed that the

door at sampling point 4 lead to the storage room, in which the environment was uncontrolled. Sampling points 3 and 6, however, had the lowest particle concentrations in the room. It is noteworthy that these sampling points were located nearest to the hospital's ISO Class 7 operating room, which had much lower PM concentrations.

4. CONCLUSION

Field PM measurements were conducted in a GMP grade C pre-op room at a local hospital. PM concentrations in the room were found to be strongly affected by the cleanliness level of the adjacent rooms. When the adjacent room was cleaner than the pre-op room, lower PM concentrations were detectable and *vice versa*. Hence, findings from the present work may suggest that to promote the cleanliness of hospital pre-op rooms, it would be recommended to maintain a highly controlled environment in the adjacent rooms. Moreover, considering that at-rest PM 0.5 and PM 5.0 concentrations were found to be below the thresholds stipulated in GMP Grade C guidelines, this report also served to validate the effectiveness of the ventilation setup in play as it was capable of controlling PM concentrations efficiently.

5. ACKNOWLEDGEMENT

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