

Clean Room Project in Bone Marrow Transplant Unit

Intrusive Aspergillus is the primary life-threatening fungal infection in immunosuppressed patients especially in patients with hematologic malignancy or after bone marrow transplantation. In these patients, pulmonary infections lead to intrusive pulmonary aspergillus (Invasive pulmonary aspergillosis IPA).

Prognosis in these cases is poor, especially in patients after bone marrow transplantation. According to the guidelines of the American Center for Disease Control (CDC) and according to the instructions of the Ministry of Health Hospitalization Rooms Bone marrow transplants should meet the following conditions (ISO-8):

- A. Positive pressure differentials relative to adjacent spaces
- B. HEPA / H-13 air filtration system with filtration level of 99.997%.
- C. Absolute opacity of space.
- D. The total number of air changes in the room (fresh air + returning air) is > 12 air changes per hour.
- E. Closure and separation between construction areas and treatment areas for transplanted patients.

Despite compliance with the above conditions at the Rambam Bone Marrow Transplantation Unit, the proportion of patients diagnosed with invasive aspergillus (IPA) is still high and reaches 20% of all patients.

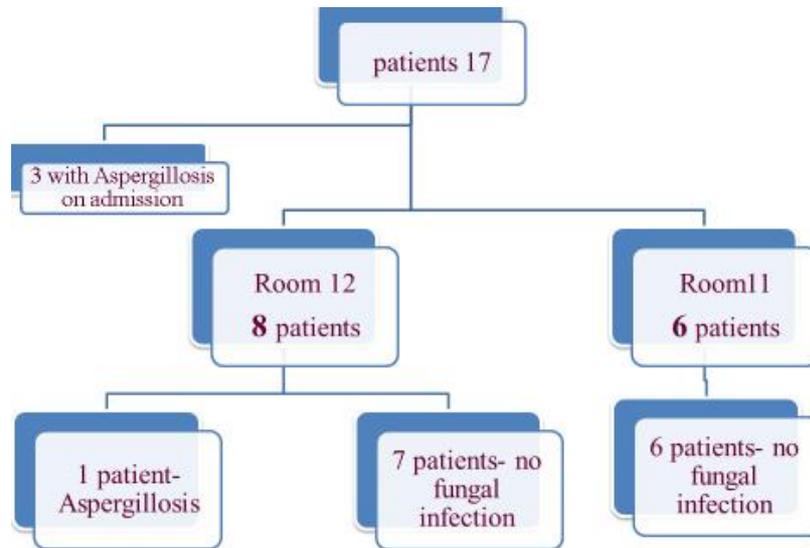
In light of this, it was decided to examine a new system in cooperation with SYS Technologies, which specializes in managing a clean environment.

The "clean room" project in the Bone Marrow Transplantation Unit included the establishment and assimilation of a clean environment system when the user can control, monitor and monitor the level of cleanliness in the system according to his requirements. The uniqueness of the system is that it was designed and developed around the principle of creating a dynamic, yet simultaneous, spinning cycle of the entire air in the system's space, while returning it through a filter system to create a controlled clean environment, all while integrating and interfacing with the existing air conditioning system.

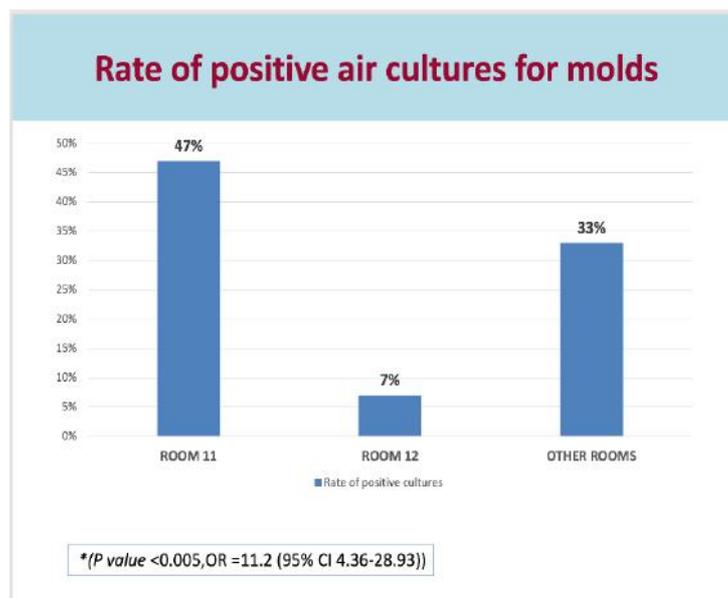
The study included two rooms in the Rambam Bone Marrow Transplant Unit: Room 12, which was the intervention room, and room 11 for control, which has the standard ventilation system in the hospital - ISO Class 14, ISO 14444-1. In addition, monitoring the development of side effects such as pressure sensation in the ears, noise, etc. during room stay was performed by filling out a questionnaire once a week by the patient and the brother / The therapist
The study was approved by the Helsinki Committee of the Hospital and the Ministry of Health.

Results:

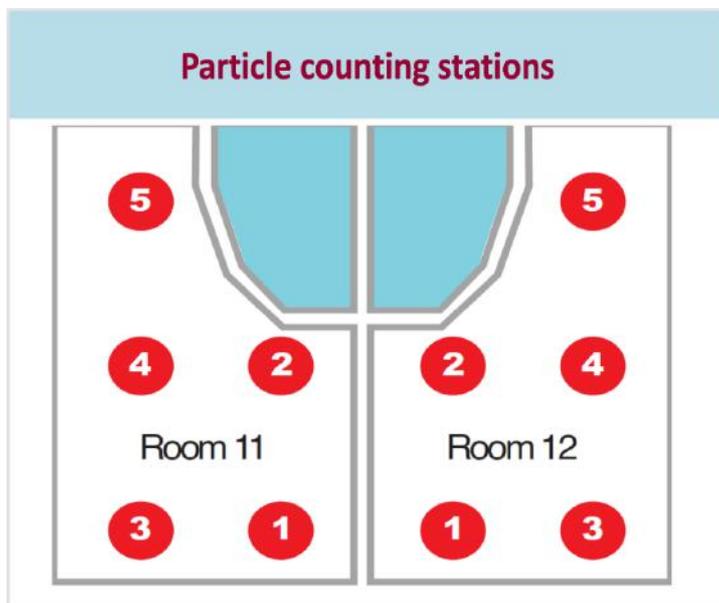
The study was conducted from April to November 2018. During this period 10 patients were hospitalized in the intervention room and 7 patients were in the control room.



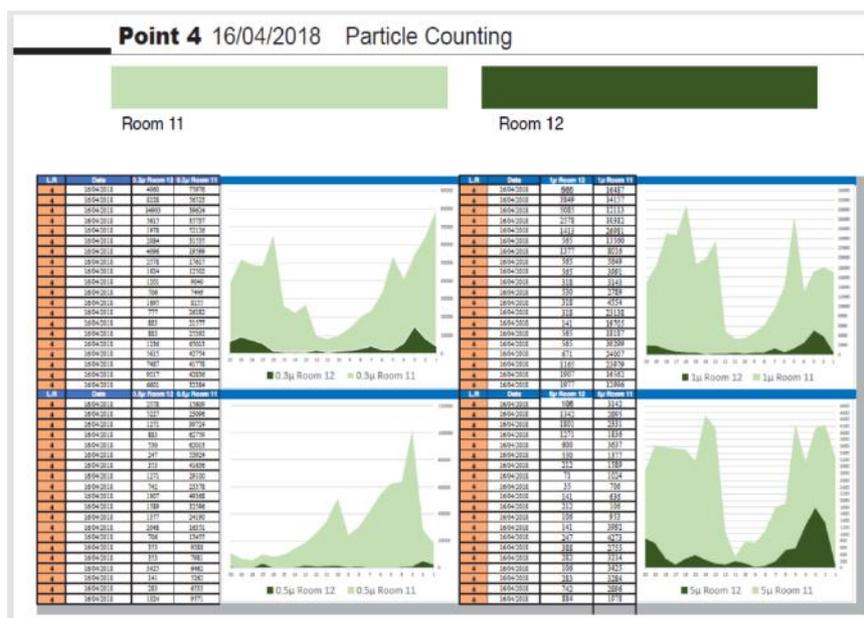
- Over the course of the study period a total of 185 air cultures were taken into molds:
 - In Room 12, 83 cultures were taken.
 - In Room 11, 75 cultures were taken.
 - In addition, 27 cultures were taken from other areas in the department.
- Of the cultures taken from the intervention room, 7% produced embryos compared with 47% of the control room cultures and 33% of the other cells in the department (*P value* <0.005,OR =11.2 (95% CI 4.36-28.93))

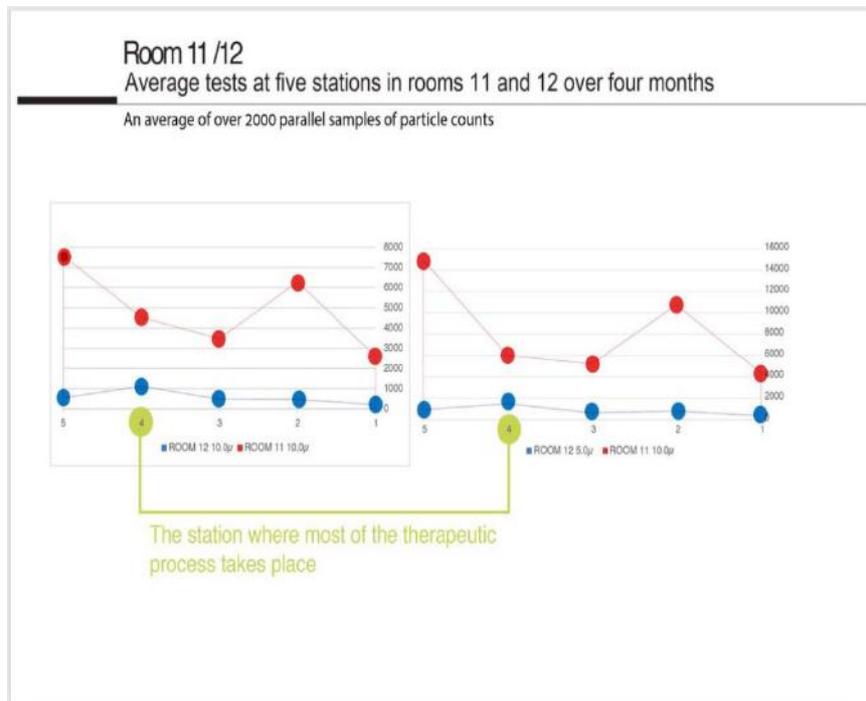


- The rooms were divided into 5 different testing areas according to the test protocol definitions found in the clean room inspection regulations.

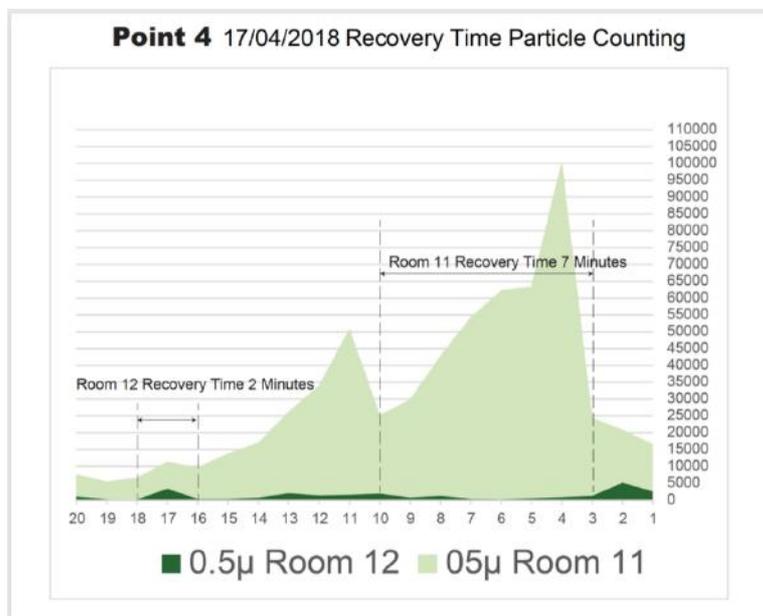


- Throughout the period we performed a particle count over a period of about 20 minutes at each station to examine particle movement and size within the chamber during hospitalization including the patient, the attending staff, and the guests.

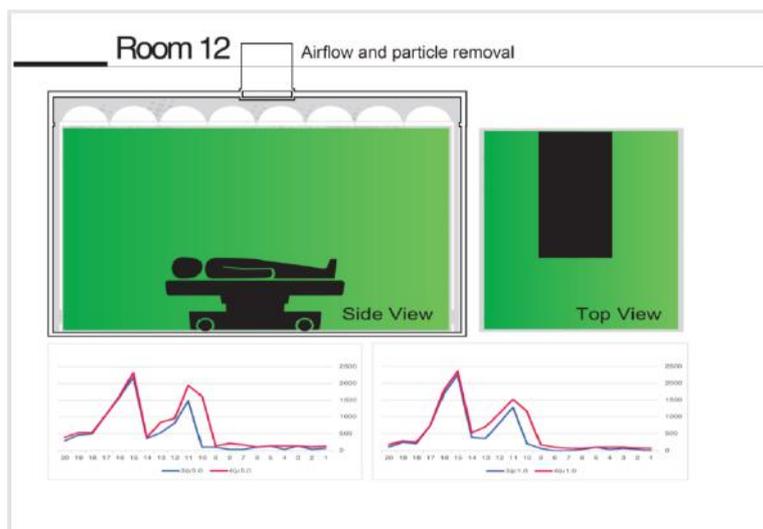
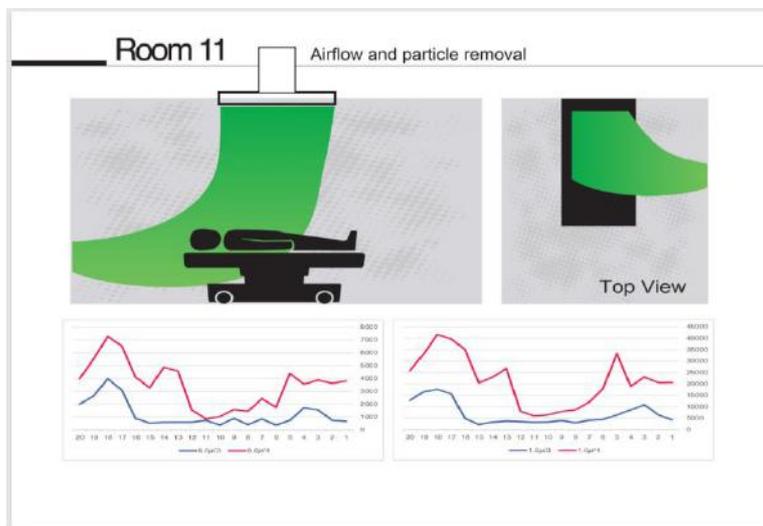




- Approximately 5000 tests of particle count in the air were performed in varying conditions that showed a significantly lower level in room 12.



- Even a comparison of "room reconstruction" time from movement to rest (decrease in the number of particles) had an advantage from my name to the intervention room.



- The uniformity of cleanliness in the room was compared in the entire space, and there were differences between different areas of the room in terms of particle counting, suggesting that there may be voids without the ability to remove pollutants.
- With regard to the side effects, there was no difference in reporting the feeling of pressure in the ears, but 57% of patients in the intervention room reported noise mainly in the morning and evening while the system activity was raised for 10 minutes to clean the room.
- The team reported mainly noise when opening the door and entering the room but the noise stopped after closing the door. In addition, 21% of them reported feeling pressure in their ears while they were in room 12.