The North West London Hospitals NHS
NHS Trust

Northwick Park Hospital
Watford Road
Harrow
Middlesex
HA1 3UJ

Tel: 020 8864 3232
Fax: 020 8869 2009
DDI: 020 8869

Mr J. Burrows B.Sc (Hons) C.Eng
Managing Director
Pathogen Solutions Limited
29 Navigation Drive
Brierley Hill
West Midlands
DY5 1UT

26th June 2007

Dear Mr Burrows

I am pleased to advise that the "Clean Air Project" is now complete and have pleasure in enclosing a brief medical research abstract titled "Ultraviolet Sterilised Bed Room Air Protects Patients Against MRSA" which contains the main findings of the clinical trial.

I would inform you that I have already submitted the attached abstract to the 8th Congress of the International Federation of Infection Control which will take place in Budapest, Hungary during October 2007.

May I also advise that I will also be presenting the project results together with supporting data at the 3rd International Congress of the Asia Pacific Society of infection control Conference in Kuala Lumpur on July 9th.

Please note that the abstract content has been necessarily limited to 250 words to conform with congress requirements.

In conclusion may I formally state that I believe the results of this trial to have been outstanding, conclusively identifying the significance of airborne MRSA cross-contamination. It should become an essential component of any strategy to deliver efficient infection control measures in the modern NHS.

Yours sincerely

Dr Peder Bo Nielsen
MD MRCPath MSc DLSHTM DipHIC
Consultant Microbiologist
Director of Infection Prevention & Control

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250 word Abstract for forthcoming congress on:
Ultraviolet Sterilised Bed Room Air Protects Patients against MRSA

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Peder Bo Nielsen, Jayakeerthi Sadarahalli Rangaiah
Northwick Park Hospital, London, United Kingdom

Ultraviolet Sterilised Bed Room Air Protects Patients against MRSA

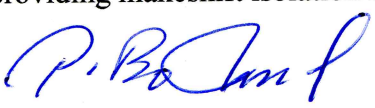
The frequent contamination of hospitals with MRSA is a risk for patients. MRSA becomes easily airborne following normal patient care. Consequently, the patient may be colonised.

Hypothesis: ultraviolet light (Medixair Unit) can control MRSA contamination and cross infection in a clinical setting.

Study design
The case-control study defines "a case" as a single bed-room with one patient and a Medixair Unit - the "UV-room". The "control-room" is similar without UV light. Patient and room environment are screened for MRSA three times a week for eight weeks.

Result
The analysis includes 23 set of patient-environment MRSA screening. In the "UV-room" and "control-room" MRSA was present in the environment in 39% versus 100 %($p < 0.001$), respectively and the patient's screening sets 0% versus 47% ($p = 0.001$), respectively. One control patient developed clinical MRSA infection. After the study the mobile Medixair Unit was moved to the "control-room" and another 17 environmental screening sets were collected. The "UV-room" remained statistically around the same level – 39% versus 23% ($p = 0.33$), while the Medixair Unit reduced MRSA from 100% to 47% ($p < 0.001$).

Discussion and conclusion
This case-control study shows ultraviolet light's effectiveness in protecting patients by removing airborne MRSA. No patients in the "UV-room" were colonised with MRSA. It also showed that the effect on the environment lasted many weeks after the mobile Medixair Unit was removed. It is speculated that Medixair may be used for providing makeshift isolation rooms in case of epidemics.



Dr Peder Bo Nielsen
MD MRCPath MSc DLSHTM DipHIC

The Efficacy of a New Mobile Air Sterilisation Device on the Airborne Spread of Methicillin-Resistant *Staphylococcus aureus*

Abbreviated title:
UVC light and the airborne spread of MRSA

by
Peder Bo Nielsen, MD, MSc, FRCPath, DipHIC, Jayakeerthi S. Rangaiah, MBBS, MD, John Burrows, BSc (Hons), C Eng, MIEE

From the Department of Clinical Microbiology, Northwick Park Hospital, North West London Hospitals NHS Trust, Harrow, Middlesex, United Kingdom (P.B.N., J.S.R.) and Pathogen Solutions Limited, West Midlands, United Kingdom (J.B.)

Address reprint requests to Dr Peder Bo Nielsen, Department of Clinical Microbiology, Northwick Park Hospital, Watford Road, Harrow, Middlesex HA1 3UJ, United Kingdom (peder.nielsen@nwlh.nhs.uk)
Phone +44 20 8869 5066
Fax +44 20 8869 2970

Presented in part: 8th Congress of the International Federation of Infection Control; Budapest, Hungary; October 18 – 21, 2007 (Abstract P46).

Summary

A controlled, sequential clinical trial assessed the efficacy of a new mobile air sterilisation device (Medixair®) using ultraviolet light for sterilising the air in a single bed room of a busy general medical ward. The study measured the effect on MRSA colonisation of patients and MRSA contamination of the bed room environment. The intervention room was fitted with a continuously operating UVC light air sterilisation device. The other single bed room served as a control room. Microbiology samples from patients and environment were collect and the MRSA burden of the two rooms was compared. At the start of the study neither the environment of the UVC nor the control room were contaminated by MRSA. The use of a UVC light air sterilisation unit demonstrated a significantly reduced level of environmental MRSA (100% vs. 39%, $p < 0.001$). The environment of the control room was at no stage free from MRSA. No patients were colonised or infected with MRSA when they entered the study. In the UVC room no patient swabs tested positive for MRSA in contrast to 47% positive ($p < 0.001$) from the control room. As a cross-over extension of the study the UVC device was relocated to the persistently and heavily contaminated control room that resulted in a significant reduction of environmental MRSA (100% vs. 47%, $p < 0.001$).
It is concluded that the installation of a mobile UVC light air sterilisation device in a single bed room reduces the amount of environmental MRSA and protects patients against MRSA colonisation.

The most significant mode of transmission of Methicillin-Resistant *Staphylococcus aureus* (MRSA) is assumed to be the hands of health care workers,[1] and consequently,

the most important intervention is hand washing.[2] However, using hand washing as the sole intervention may not be successful, as other risk factors may contribute decisively to cross-infections.[3] Hospital cleanliness and contaminated environments have recently attracted the attention of professionals as well as the public. Some papers have reported widespread MRSA contamination of clinical areas,[4] and Boyce[5] and French et al.[6] have shown how ineffective routine cleaning is in eradicating MRSA. It is conceivable that floors, furniture and medical equipment are reservoirs for the spreading of MRSA to the hands of health care workers.[7-11]

Little attention is given to other modes of transmission pertinent to MRSA, in spite of older literature that has documented the significance of airborne transmission of Methicillin Sensitive *Staphylococcus aureus*.[12-15]

Staphylococci will normally be carried on desquamated cells that quickly settle on bed linen, clothes and inanimate surfaces, but become airborne when disturbed by normal nursing care and cleaning activities.[14,16] Some of the staphylococci are respirable as they are carried on particles < 4 μm. This poses a risk for patients and staff for contracting pulmonary MRSA infection.[14]

In the reported study that took place in a busy general medical ward we treated the air using a newly developed UV C (UVC) light air sterilisation device (Medixair®). Its protective effects on MRSA colonisation of patients and contamination of environments were evaluated.

METHODS

Design

We conducted a non-randomised, sequential clinical trial.[17,18] The design was a case-control study, where we compare paired data sets from two single bed rooms; one being provided with a UVC air sterilisation device, the other was without.

Case definition: A case is a dedicated side room with one single bed and one patient in a general medical ward. The room is fitted with two mobile UVC air sterilisation units.

Control definition: A similar room with one patient in the same ward without UVC air sterilisation units.

The clinical team allocated patients for the case or control room purely on the basis of bed availability.

The study has approval from the Ethics Committee (06/Q0408/55) and the Research & Development Department of the hospital.

UVC Device

Medixair® from Pathogen Solutions Ltd, UK is a newly developed mobile air sterilisation device employing germicidal UVC light at a wavelength of 253.7 nm. The UVC light is produced by four UVC tubes. The optimal efficacy of the device was established through analytical determination of the 3D intensity field.[19] The modelling included lamp parameters, irradiation vs. distance - based on the inverse square relationship, internal reflectivity (70%), and air flow (0.3 m sec^{-1}) through the device. The 3D power distribution of the intensity field is given in figure 1.

The device is completely encapsulated, ensuring protection against UV leakage for patients and staff. Furthermore, the tubes utilise a glass envelope which incorporates a filter to restrict the emission of ozone forming wavelengths between 160 nm and 220 nm. The air flow of 25 m^3 per hour produces less than 33 dB noise.

Bacteria passing through the UVC device will be exposed for 1.5 sec to a minimum energy of 22,500 µW sec cm^{-2}. The bactericidal power needed for 1 log_{10} reduction of *Staphylococcus aureus* is 662 µW sec cm^{-2} and bactericidal effect is achieved by 1,987 µW sec cm^{-2}.[20]

The kill rate for one passage through the UVC device can be determined by using the equation[20]:

$$\frac{C_t}{C_0} = e^{-kEt}$$

where:

C_t	=	Contaminant concentration at time t (cfu / m^3)	
C_o	=	Contaminant concentration at time t = 0 (cfu / m^3)	
k	=	0.003476 cm^2 / µW sec	UV susceptibility constant for *Staphylococcus aureus* in air
E	=	15,000 µW cm^{-2}	Intensity of UV irradiance
t	=	1.5 sec	Duration of exposure to irradiation

The surviving fraction of the initial bacterial population is:

$$\frac{C_t}{C_0} = e^{-kEt} = 1.081 \times 10^{-34}$$

Demonstrating a germicidal efficacy many orders greater than that required to kill MRSA.

Microbiology

Patients and environments were simultaneously screened for MRSA on Mondays, Wednesdays and Fridays.

Patients were swabbed from the following sites: nose, axilla and groins.

Environmental microbiological swabs were – as in French et al.[6] - collected simultaneously from 5 x 5 cm areas of the following predetermined sites: bed frame, floor around the bed, locker, light above the bed, ledge at rear of the bed, TV line, and curtain.

Swabs were cultured using Robert's Cooked Meat Medium Enrichment Broth, and MRSA was identified according to standard microbiology procedures.

The cleaning regimes were similar for the two trial rooms.

Statistical Analysis

A count of MRSA positive swabs would decide which one of the paired sets contained most MRSA – the UVC room or the Control Room. The study was monitored and analysed by using a "sequential analysis chart" with $2\alpha = 0.10$.

A sequential trial will typically require a smaller sample size than studies with fixed sample size.[17,18]. McNemar's test was used for paired data and Fischer's exact test for proportions.

RESULTS

The initial study samples showed that the environment of the UVC bed room and the control bed room were contaminated with MRSA; eight and four patients were admitted to the UVC and control room, respectively. The average length of stay per patient in the project room were 9 days. None of the patients were, on admission to the bed rooms, colonised or infected with MRSA.

The number of MRSA positive swabs from each of the two paired sets are given in figure 2. Twenty sets from the control room had a greater number of MRSA positive swabs compared to only two sets (number 4 and 18) from the UVC room ($p < 0.001$). No 17 was a tied pair. Thus, the result over 23 paired data sets had only two sets against the UVC room. It is also seen that MRSA is on several occasions introduced into the UVC room; however, it was unable to establish itself as a permanent contamination.

While Figure 2 says how *many* swabs were positive for MRSA, table 1 gives, as a binary function, how *often* a room is contaminated and a patient is colonised with MRSA.

It is evident that the environment is more frequently contaminated than patients are colonised and the environment of the control room was at no time free from MRSA. The UVC room was sporadically contaminated with MRSA, however, none of the patient swabs tested positive for MRSA.

The control room was persistently and heavily contaminated. Therefore, as an extension to the study, the UVC air sterilisation device was relocated to the control room in order to investigate the "cross over" effect. Another 17 paired data sets were collected from the environment. The UVC device produced a similar reduction of MRSA – 39% vs. 47% ($p = 0.75$) - as previously achieved in the "UVC-Room" (Table 2).

The distribution and occurrence of MRSA on inanimate surfaces for both rooms are provided in Figure 3.

DISCUSSION

The present study is the first sequential clinical trial testing the effect of ultraviolet light against MRSA in a clinical setting. The study demonstrated Medixair®'s effectiveness in reducing MRSA contamination from the environment and also its ability to protect patients - even when MRSA was present in the immediate vicinity.

There are sufficient numbers of clinical studies that unanimously show the protective benefit of ultraviolet light especially against TB.[21,22] UVC light with wave length of $\lambda = 253.7$ nm has a strong killing effect on viruses and bacteria.[23] Riley[24] has shown that efficient installation of UV light is equivalent to 20 air changes per hour and "upper air irradiation" provides more protection against airborne infections than duct irradiation.[22]

In spite of documented efficacy, UVC is seldom or never used in clinical settings. It is obviously important to realise that upper air irradiation is only working on "no touch areas" *viz.* the ceiling, walls and air above the installed UV units.

The UVC device used in this study circulated 25 m^3 air per hour and the space of a single bed room is 33 m^3. The bed rooms had no artificial ventilation; therefore, in theory, the room air is sterilised 18.2 times per 24 hours. In addition, the UVC units were placed by the bed, in order to exercise maximum effect on the patient, the bed and the immediate vicinity. During nights and quiet hours this is comparable to recirculation through UVC equipped air ducts.

Some may think that a study with "only" 23 paired sets of samples is a small study with low power. However, McNemar's test statistics show that 2 against 20 is significant at a high level ($p < 0.001$). As the number of positive swabs are given in figure 2, it is possible to apply the two-tailed paired sample t-test for calculating the power of the significant test. The calculated probability that *it is a correct decision to reject the null hypothesis* is 1.0 or 100%. Consequently, the power of the study result cannot be increased further by augmenting the sample size.

The significance of the study results to other hospitals will depend on local MRSA endemicity, case mix and physical infra-structure. However, the settings of the study are believed to be similar to many UK hospitals, where the environment is permanently contaminated with MRSA; sometimes to the extent that the area around every single bed of a ward is contaminated (data not given). Future studies may refine the application of UVC devices.

The UVC device has only one function: namely to deliver clean sterilised air. In this study it has resulted in a remarkable reduction in MRSA contamination and colonisation which can only be explained by interruption of the airborne transmission of MRSA.

In other words, this study confirms the conclusion of previous studies that the airborne route of transmission plays a important role in the spread of MRSA.[14,15] Williams has in his review rendered probable that the aerial conveyance of staphylococci may be as much as 50 to 70 ft and may be suspended in the air for more than 15 minutes. This is supported by Shiomori et al. that found a 25-fold increase in airborne MRSA during bed making,[14] and also that the numbers of MRSA in the air correlated with those on floor and bed. Equally, it is *the* only plausible explanation for the positive effect of upper-air-irradiation.

"The most effective place to stop airborne transmission is at the source, the infected patient".[22] It may be achieved by using a face mask, thus interrupting respiratory droplet transmission. However, if a patient is heavily colonised on the skin, a face mask will be of little use. To our knowledge no air cleaning equipment is in use that continuously interrupts the transmission of infection between patient and staff. A purpose built isolation ward will always treat the air *outside* the room, either by providing "clean air" to the room or by rinsing the air after it has left the room. In principle, ventilation produces a draught through the room, diluting the number of pathogens in the air, but without providing any active air treatment *within* the room. The efficacy will depend on air dilution *viz*. the number of air change per hour. Consequently, if the source of pathogens is *within* the bedroom, *e.g.* from a patient or from staff, there will be no mechanism for interrupting the airborne transmission between patient and staff - apart from personal protective equipment.

Unfortunately, UVC light has a harmful effect if irradiated directly towards patients or staff it can cause skin erythema and keratoconjunctivitis.[25-27] NIOSH recommends that the exposure should not exceed 0.2 $\mu W\ cm^{-2}$ over an 8 hour period.[28] Upper air irradiation is nowadays hardly ever used, because staff and patients may be exposed to the irradiation. This is highlighted by Talbot et al. who reported eye and skin irritation after exposure to high intensity, bare-bulb UV light.[27]

The Medixair® design in which the UVc is enclosed within a metal chamber has a built-in safety factor which does not compromise its killing effect.

The protection of staff is of great concern in the case of outbreaks or epidemics of Flu, avian Flu, SARS, MDR TB etc. It is known that staff caring for contagious patients have a high risk of contracting the infection themselves - as seen during the SARS

outbreak.[29] In some epidemics 30 – 50% of the staff became ill. Surveys predict that only 50% of healthcare workers will report to work in case of avian influenza pandemics. Staff are uncertain about "what measures would be in place to keep them safe".[30] The use of UVC air sterilisation devices may yield confidence in the much sought-after safety of staff.

The UVC device in the trial is mobile and is "ready-to-go" after being connected to an electric socket. The ease of installation makes it feasible to transform ordinary bed rooms and bays into "instant isolation rooms" and in this way to meet the changing needs and priorities of a clinical ward during nosocomial outbreaks, seasonal flu epidemics or pandemics.[31]

Increases in the number of available "instant isolation rooms" might make it possible to isolate many more patients *on suspicion* in the early phase of an epidemic; *i.e.* it will allow the pervasive use of isolation that may be successful in controlling a cluster and thereby preventing a epidemic.

ACKNOWLEDGMENT

Potential conflict of interest. The study is sponsored by North West London Hospitals NHS Trust. It is conducted in collaboration with Pathogen Solutions Ltd., UK. John Burrows. reports that he is employed by Pathogen Solutions Ltd., UK. All other authors report no conflicts of interest relevant to this article.

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Table I

	UVC - Room	Control room	Number of data sets	p - value
Patient sets	0 (0%)	9 (47%)	19	$p < 0.001$
Bed - room sets	9 (39%)	23 (100%)	23	$p < 0.001$

Table I shows that the UVC device significantly reduces the occurrence of environmental MRSA, and furthermore protects patients against colonisation.

Table II

	Before Cross-over	After Cross-over	P - value
UVC-room	9(39%) With UVC	4(23%) Without UVC	P = 0.33
Control room	23(100%) Without UVC	8(47%) With UVC	P < 0.001

Table II compares the data before and after the UVC device has been relocated from the original UVC room to the control room. Subsequently, the control room achieved a low level of MRSA contamination, similar to the level of MRSA contamination in the original UVC room.

FIGURE 1

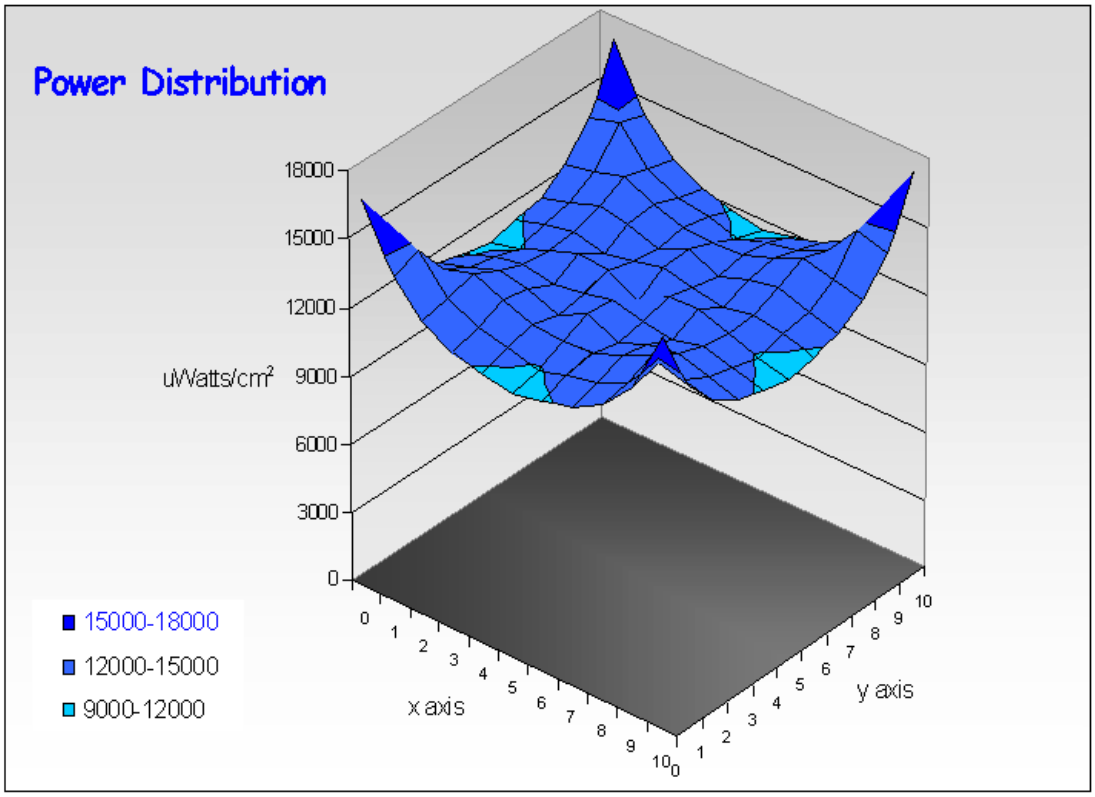


FIGURE 2

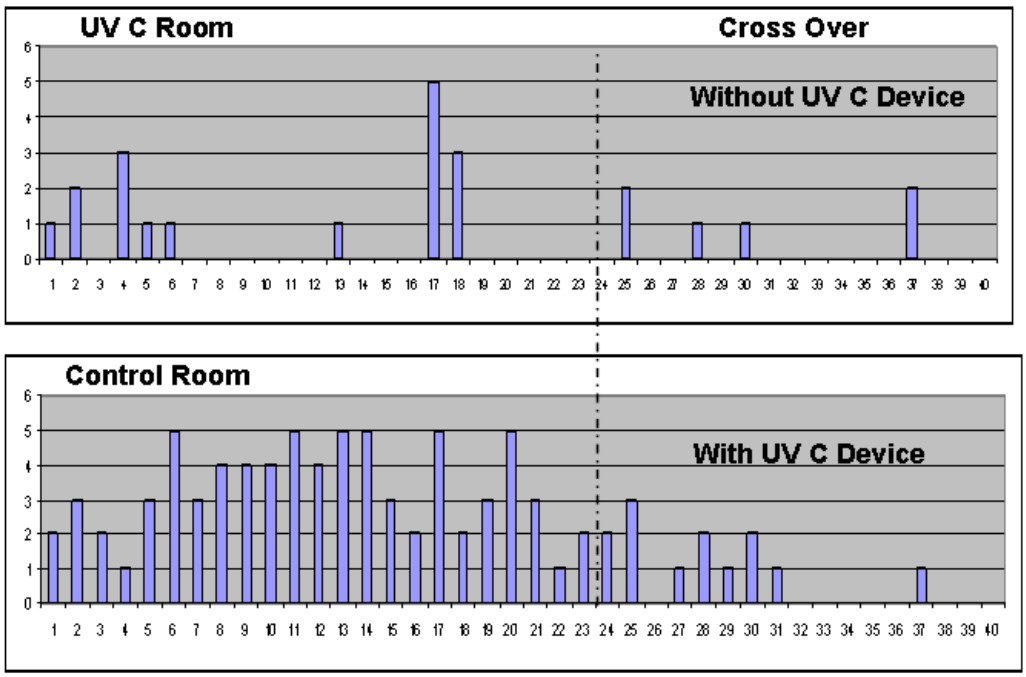
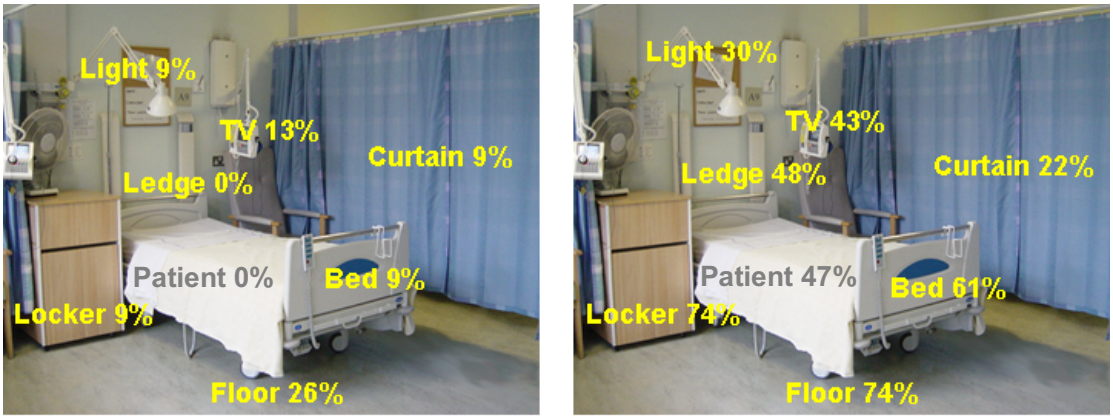


FIGURE 3



UV C Room **Control Room**

Figure legends

Figure 1. Distribution of the Medixair® energy intensity field.

Figure 2. Compares the number of MRSA positive swabs from the UVC bed room with those taken from the control bed room. When the trial was completed, after the 23rd sample, the UVC device was relocated into the control room in order to test the cross-over effect. It was evident after a short period that MRSA was also eradicated from the "control bed room".

Figure 3. The in-situ room distribution of MRSA isolates from 23 paired environmental sample sets are compared in the above two pictures.