

CLINICAL

AzoMaxActive™

SIX MONTH CLINICAL TRIAL RESULTS

EVIDENCE



INTRODUCTION

THE RELATIVE IMPORTANCE OF THE ENVIRONMENT COMPARED TO OTHER SOURCES IN THE TRANSMISSION OF HEALTHCARE ASSOCIATED INFECTION (HCAI) REMAINS UNCLEAR. HOWEVER, IT IS ACCEPTED THAT MAINTAINING HIGH STANDARDS OF HYGIENE IS PIVOTAL IN PREVENTING THE SPREAD OF INFECTION AND TRANSMISSION OF DISEASE.¹

In the summer of 2008 Central Manchester University Hospitals NHS Foundation Trust (CMFT) began a formal, ethically approved, comparative clinical trial of the *AzoMaxActive* range of cleaning products.

The study involved four acute care medical wards that had been identified by the Trust Infection Control team as being at an 'elevated risk' for *C. difficile*.

Current guidance both in the UK² and the USA³ recommends that areas at risk for *C. difficile* and/or those with a high prevalence of *C. difficile* infection should be cleaned using sporicidal chlorine releasing agents (typically hypochlorite based solutions) as these have been previously shown to reduce the incidence of *C. difficile* infection.⁴

STUDY AIM:

The aim of this study was to determine the effectiveness of the *AzoMaxActive* product range by comparing it to the 'gold standard' cleaning regime which uses chlorine releasing agents (hypochlorite). Study outcomes focused on the environmental bioburden and included measurements of total viable count (TVC), MRSA and *C. difficile*.

The study duration was eleven months (forty seven weeks). This summary reports an interim analysis of the data at the six month time point.

These results were presented at the European Congress of Clinical Microbiology and Infectious Diseases annual conference in Helsinki, Finland (16 - 19th May 2009).



METHOD:

This study was carried out across four identical acute medical wards, each consisting of five four bedded bays and eight side rooms. Two wards acted as 'controls' and were cleaned with the standard hospital policy for 'high risk' areas. This cleaning regime consisted of 1,000ppm hypochlorite (Chlor-Clean™) on horizontal surfaces and patient shared equipment and neutral detergent on floors.

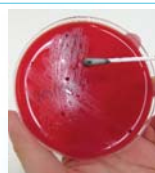
The two experimental wards used *AzoMaxActive* products on all surfaces. On all four study wards only the bays were cleaned as above, all side rooms were cleaned as per routine protocol depending upon the patient occupying the room. Two of the five bays on each ward were bacteriologically sampled throughout the study.

***Sampling points included the following locations:**

- Bed rail
- Nurse call button
- Cabinet
- Chair arm
- Bed control handset
- Table
- Bay tap handle
- Bin lid
- Floor near bed
- Toilet floor
- Toilet assist handles
- Toilet flush
- Bathroom door handle in
- Bathroom door handle out

Each bay was sampled by swabbing twenty pre-determined sampling points within the environment. Two adjacent 25cm² areas were swabbed per sampling point. Therefore each assessment of all four wards required a total of one hundred and sixty individual environmental sites to be sampled with duplicate swabs taken from adjacent areas of each sampling point.*

Prior to commencing the study the designated bays on each ward were sampled four times over a two week period to establish a baseline. Once the study began weekly environmental sampling was undertaken.



SWAB 1

was plated to blood agar (37°C, 48hrs) to obtain a TVC, the swab was then placed into Robertson's cooked meat medium and incubated anaerobically (37°C, 48hrs) before subculture to Brazier's medium (37°C, Anaerobic incubation, 48hrs) to detect *C. difficile*.



SWAB 2

was plated to chromogenic MRSA agar (MRSA Select, BioRad) to quantify levels of MRSA and then into 7% salt broth (37°C, 24hrs) before subculture to MRSA chromogenic medium (37°C, 48hrs).

The number of patients colonised/infected with MRSA identified during their stay on the wards and the number of *C. difficile* toxin (CDT) positive patients were also collected.

For CDT positive patients recurrent positive samples after twenty eight days were counted as new cases.

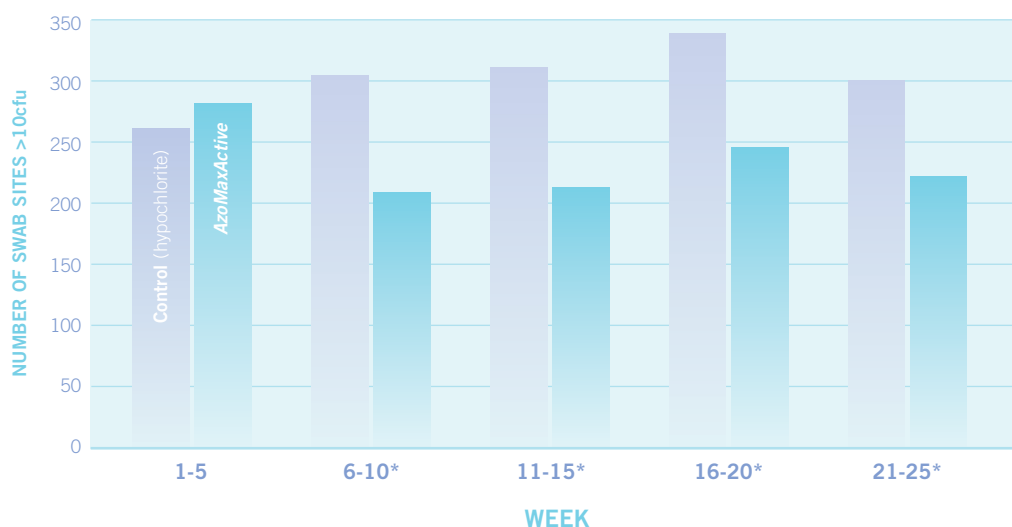
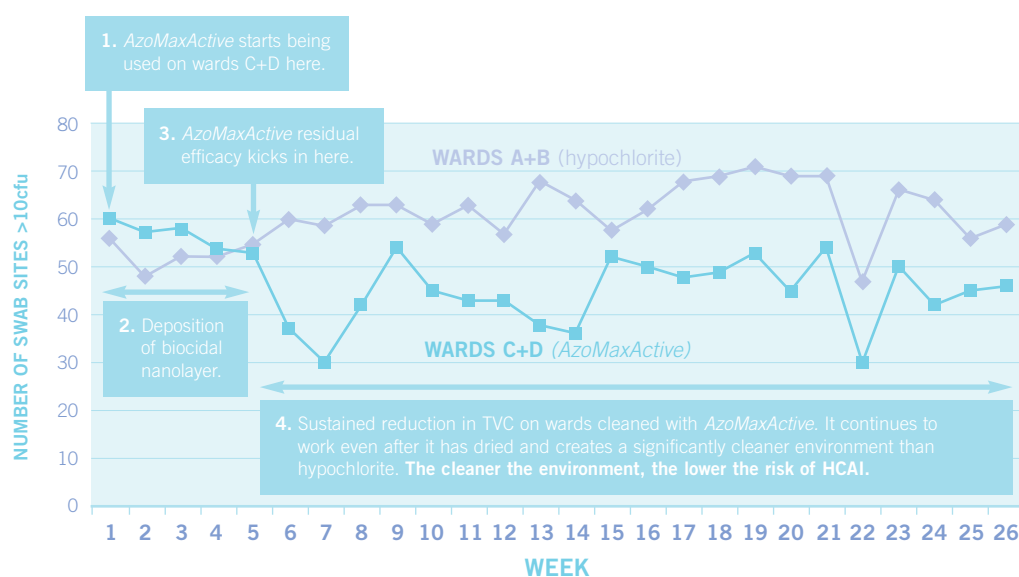
RESULTS:

It is evident from **Table 1** that after twenty six weeks there is a significant difference ($P<0.0001$) in the proportion of sites reporting TVC of either greater than ten colony forming units ($>10\text{cfu}$) or $>100\text{cfu}$. Viewing the data on a weekly basis (**Figure 1**) indicates that the difference in counts was due to a sustained divergence after week five of the study. Analysis of the TVCs by five week groups shows a significant difference in favour of the *AzoMaxActive* area after week six for a TVC $>10\text{cfu}$ (**Figure 2**) and TVC $>100\text{cfu}$ (**Figure 3**).

	<i>AzoMaxActive</i>	Control (hypochlorite)	P-value
Swab sites with TVC $>10\text{cfu}$	1211 (58.2%)	1575 (75.7%)	<0.0001
Swab sites with TVC $>100\text{cfu}$	436 (21.0%)	627 (30.1%)	<0.0001
Direct MRSA +ve swab sites	31 (1.5%)	37 (1.8%)	n/s
Total MRSA +ve swab sites	45 (2.2%)	46 (2.2%)	n/s
<i>C. difficile</i> +ve swab sites	12 (0.6%)	8 (0.4%)	n/s
CDT +ve patients	8	10	n/s

TABLE 1

Summary of key results up to and including week twenty six.



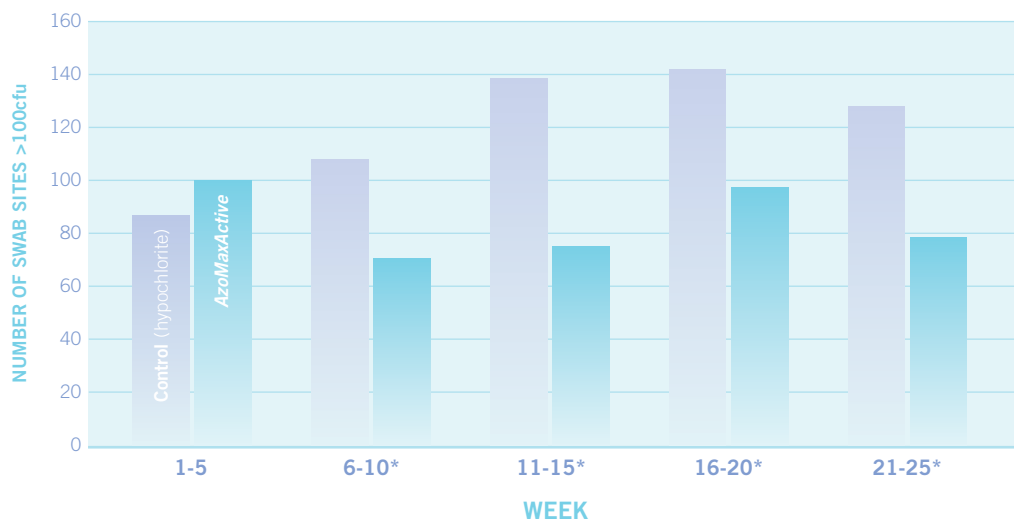


FIGURE 3

Total number of swab sites with a TVC greater than 100cfu in five week periods.



Significant differences ($P < 0.05$, two tailed chi squared test) between AzoMaxActive and hypochlorite areas are shown with an asterisk.

The cumulative counts for environmental MRSA and *C. difficile* were minimal with no significant differences reported between control and experimental wards (**Table 1**). After twenty six weeks, ten patients with CDT +ve diarrhoea had been identified on the hypochlorite wards compared to eight on the AzoMaxActive wards. A total of sixteen patients were identified as MRSA positive, eight in each area.

CONCLUSIONS:

OVER A SIX MONTH PERIOD WITHIN A 'HIGH RISK' CLINICAL SETTING AZOMAXACTIVE SIGNIFICANTLY OUTPERFORMS HYPOCHLORITE BY CREATING AND MAINTAINING THE CLEANEST POSSIBLE CLINICAL ENVIRONMENT. AZOMAXACTIVE REDUCES THE RISK OF HCAI BY REDUCING THE ENVIRONMENTAL BIOBURDEN TO ITS LOWEST POSSIBLE LEVELS.

Clinical areas cleaned with AzoMaxActive will contain significantly fewer micro-organisms than clinical areas cleaned with chlorine releasing agents (or neutral detergents). Reducing the environmental bacterial load reduces the HCAI risk to patients by reducing the opportunity for patients to come into contact with potentially pathogenic micro-organisms.

Up to week five all study wards were similar in terms of TVCs. From week six onwards AzoMaxActive wards demonstrate a significant and sustained reduction in TVCs (**Figure 1**). This divergence in TVC trend lines reflects the build-up of a biocidal nano-layer which continues working even after the product has dried and is a key feature of AzoMaxActive.

The low numbers of environmental MRSA and *C. difficile* detected within the study environment preclude any firm conclusions being drawn from the data at this point. At six months the incidence of *C. difficile* or MRSA infection is equivalent on all wards.

Based on the six month data analysis AzoMaxActive is clinically proven to significantly outperform chlorine releasing agents in terms of TVCs and it appears to be at least as effective as chlorine releasing agents in terms of reducing environmental levels of MRSA and *C. difficile*.

The cleaner the clinical environment the lower the HCAI risk to the patient. In terms of cleaning the clinical environment; AzoMaxActive outperforms hypochlorite which outperforms neutral detergent. Therefore AzoMaxActive offers the greatest HCAI risk reduction in clinical areas that are currently cleaned with neutral detergent. Areas cleaned with neutral detergent are likely to report higher levels of environmental bioburden and therefore have the most to gain by switching to an AzoMaxActive cleaning regime.

AzoMaxActive (containing Byotrol™ technology) is non-toxic, non-hazardous, safe to use, requires no specialist equipment or training and offers healthcare staff the opportunity to practice 'evidence based' healthcare disinfection to reduce the HCAI risk to their patients.



OUR WORK PROTECTS YOUR WORLD™

1. Department of Health. Clean, safe care: Reducing infections and saving lives. 2008;[cited 2008 Jun 24]. Available from: <http://www.dh.gov.uk/publications>
2. Clostridium difficile infection: how to deal with the problem - a board to ward approach. A report to the Department of Health from the Steering Group on Healthcare Associated Infection. HPA Consultation document. 2008; [cited 2008 Dec 1]. Available from: http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1204186175140
3. Wilcox MH, Fawley WN, Wigglesworth N, Parnell P, Verity P, Freeman J. Comparison of the effect of detergent versus hypochlorite cleaning on environmental contamination and incidence of Clostridium difficile infection. J Hosp Infect. 2003;54(2):109-14.
4. Dubberke ER, et al. Strategies to Prevent Clostridium difficile Infections in Acute Care Hospitals. Infect Control Hosp Epidemiol 2008;29:S81-S92.



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