Phase 3 testing of an ultra-high level sporicidal disinfectant: the missing link between laboratory based efficacy and clinical performance?

DR. CHRIS WOODALL, CEO, BluTest Laboratories Ltd, Glasgow, UK
RICHARD FORDER, Clinical Affairs Manager, TECcare Antimicrobial Technologies, UK

Improvement Issue and Context

It is broadly accepted by academics and infection prevention specialists that while current European test standards for sporicidal activity (e.g. EN 13704) allow benchmarking of one disinfectant against another, they do not accurately reflect the requirements or performance of sporicidal products used in today's healthcare environments. [1, 2]

Common variables between phase 1 and phase 2 laboratory suspension tests and real world disinfectant use include;

- **Delivery method** – are suspension tests relevant for disinfectants delivered onto surfaces via cloths, mops, wipes, sprays, mists, etc.?
- **Contact time** – are sixty minute wet contact times clinically relevant when disinfectants delivered onto a surface are likely to dry seconds or minutes after application?

The progression from suspension testing to carrier testing to surface testing represents an evolution towards test conditions which more closely resemble actual product usage. Performing surface tests in clinical settings away from the test laboratory adds further credibility to the test results and enables a true assessment of how the disinfectant will perform in a clinical setting.

Controlled field testing or 'phase 3 testing' bridges the gap between in-vitro efficacy and clinical effectiveness. Testing takes place in clinical settings where a known bioburden of a specific organism is dried onto a surface which is then exposed to a disinfectant delivered into the environment in its normal way.

This work used phase 3 testing to determine the efficacy of an ultra-high level disinfectant against validated *Clostridium difficile* spores. The disinfectant on test was TECcare® ULTRA and this was delivered into the room via a specialist misting system – the TECcare® VorTEC™ (see Figure 1).

Figure 1. TECcare® VorTEC™ and TECcare® ULTRA

Methods and Measurement

A 32m³ unfurnished isolation room was used. Prior to disinfection ten plates were placed throughout the room on horizontal and vertical surfaces, including the ceiling, walls and floor (see Figure 2 for location of the ten test plates). The ventilation system, windows and doors were sealed with tape prior to disinfection.

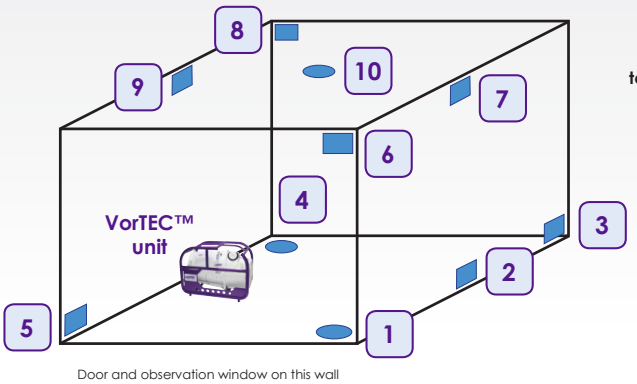

Figure 2. Location of all ten test plates in the isolation room

Each plate contained nine slides. Each slide was inoculated with *Clostridium difficile* spores at concentrations of either 1 x 10^3 or 1 x 10^6. The spores were applied to the slides 20-22 hours prior to testing and desiccation of the inoculated slides took place under sterile air in a class II microbiological safety cabinet.

Room temperature and relative humidity were 20°C ± 1°C and 50% respectively.

TECcare® ULTRA (an ultra-high level sporicidal disinfectant) was dispensed throughout the test room over a seven minute period via the specialist, mains powered VorTEC™ misting system (see Figure 1) which was centrally located on the floor of the isolation room. After forty three minutes dwell-time test plates were collected and processed in the laboratory, by neutralisation and then for *C. diff* viability. Untreated controls (plate 11) were processed in an identical manner.

After neutralising, plating onto Columbia agar and incubating anaerobically at 37°C for three days, microbial growth was reported as total viable counts (TVCs). Results are given in Table 1.

Evidence of Improvement

Table 1. Recovery of *Clostridium difficile* spores after exposure to TECcare® ULTRA.

Plate Number	Position / Location of plate in isolation room	*C. diff* seeding density	Total Viable Count*
1	Horizontal on floor, right hand corner opposite VorTEC™ unit	1 x 10^3	<1.4 x 10^1
		1 x 10^6	<1.4 x 10^1
2	Vertical to floor, bottom centre of wall directly opposite VorTEC™ unit	1 x 10^3	<1.4 x 10^1
		1 x 10^6	<1.4 x 10^1
3	Vertical to floor, left hand corner opposite VorTEC™ unit	1 x 10^3	<1.4 x 10^1
		1 x 10^6	<1.4 x 10^1
4	Horizontal on floor, left hand corner aligned with VorTEC™ unit	1 x 10^3	<1.4 x 10^1
		1 x 10^6	<1.4 x 10^1
5	Vertical to floor, right hand corner aligned with VorTEC™ unit	1 x 10^3	<1.4 x 10^1
		1 x 10^6	<1.4 x 10^1
6	Vertical to ceiling, top left corner of wall to right of VorTEC™ unit	1 x 10^3	<1.4 x 10^1
		1 x 10^6	<1.4 x 10^1
7	Vertical to ceiling, top centre of wall directly opposite VorTEC™ unit	1 x 10^3	<1.4 x 10^1
		1 x 10^6	<1.4 x 10^1
8	Vertical to ceiling, top left corner of wall to left of VorTEC™ unit	1 x 10^3	<1.4 x 10^1
		1 x 10^6	<1.4 x 10^1
9	Vertical to ceiling, top centre of wall behind VorTEC™ unit	1 x 10^3	<1.4 x 10^1
		1 x 10^6	<1.4 x 10^1
10	Inverted horizontally in the centre of the ceiling	1 x 10^3	<1.4 x 10^1
		1 x 10^6	<1.4 x 10^1
11	Untreated control (plate not exposed to TECcare® ULTRA)	1 x 10^3	5.6 x 10^2
		1 x 10^6	5.6 x 10^5

* Actual TVCs for all slides were 0 (zero) indicating no viable spores were recovered from any of the slides exposed to the TECcare® ULTRA disinfectant delivered into the room via the VorTEC™ system. For protocol reasons it is not possible to report a TVC of 0 and the lowest TVC level recordable is <1.4 x 10^1.

Future Steps

This phase 3 test demonstrates that delivering TECcare® ULTRA into a sealed side room as a mist (generated via the VorTEC™ misting system) is a highly effective method for eliminating *Clostridium difficile* spores dried onto surfaces within clinical settings.

After a seven minute misting cycle followed by a forty three minute dwell time the log reduction of *Clostridium difficile* was greater than 4.6.

The reduction in *Clostridium difficile* spores after exposure to TECcare® ULTRA is a clear indication that both the delivery method and contact time are clinically appropriate for this specific disinfectant. In addition, the time in which this log reduction is achieved (fifty minutes) compares favourably with other room misting or fogging systems which utilise alternative disinfectant technologies.

Phase 3 testing offers manufacturers and customers significant insight into disinfectant performance in the clinical setting and may assist decision makers when adopting new disinfectants into clinical practice as it enables them to see how the product performs when it is delivered onto surfaces in its normal way.

Both Humphreys 2011[1] and Speight et al 2011[2] have raised concerns over the use of suspension tests to quantify sporicidal activity of disinfectants used within healthcare environments. The test process outlined in this poster is one way to overcome the existing shortfalls of current disinfectant suspension tests as it simultaneously addresses both the delivery method and contact time of the product on test.

In the absence of any internationally agreed phase 3 sporicidal test standard the procedure outlined in this poster represents a realistic test methodology which could be used to compare the sporicidal efficacy of disinfectants intended for use in clinical settings.

References

1. Humphreys PN. Testing standards for sporicides. J Hosp Infect. 2011;77(3):193-8.
2. Speight S, Moy A, Macken S, Chitnis R, Hoffman PN, Davies A, Bennett A, Walker JT. Evaluation of the sporicidal activity of different chemical disinfectants used in hospitals against Clostridium difficile. J Hosp Infect. 2011 Sep;79(1):18-22.

Poster produced by TECcare® in association with BluTest. TECcare® have provided the author of this poster with conference sponsorship only. No other funding has been provided.

BluTest
GLOBAL MICROBIOLOGY EXPERTISE