Letter to the Editor:

Test parameters for efficacy evaluations of aerial hydrogen peroxide decontamination systems

Dear Editor,

We comment on the difficulties posed when designing test criteria for the assessment of whole-room aerial hydrogen peroxide decontamination systems.

In-use efficacy data of biocides and decontamination systems provides essential information on performance in local hospital conditions, potential advantages and weaknesses that may not be obvious from manufacturer brochure material and commercial test data. Obtaining unbiased data on end-user efficacies is difficult and therefore an independent head-to-head study is useful.

We have previously conducted a study to evaluate the reductions in environmental contamination during in-use operation of two commercially-available hydrogen peroxide whole-room disinfection systems [1].

In the absence of defined, standardised national testing protocols we designed our own testing protocol for our setting. Our assessments involved in-house biological indicators (BIs) using a Gram-positive, Gram-negative and a spore-bearing organism (MRSA, ESBL-producing *Klebsiella pneumoniae* and *C. difficile* 027 spores respectively) to simulate clinically-relevant organisms in the hospital environment and incorporated varying levels of soiling challenges to indicate best and worst-case efficacy outcomes when using either system

Previous trials have employed 6-log Tyvek-pouched *Geobacillus stearothermophilus* BIs, commonly used for sterilisation-validation studies, to gauge potential reductions of contaminating organisms in the environment [2.3]. There are benefits to using such BIs; spore titres are pre-measured and the pouches pose little biological risk to the handler. Also, it is generally accepted that disinfection efficacy against "hardy" spores such as *G. stearothermophilus* and *Bacillus atrophaeus* may be interpreted as valid activity against lesser-tolerant spores and vegetative cells. However these are not pathogens and the end-user (e.g. infection control practitioner) needs validation data against representative organisms of local concern, such as pathogenic organisms responsible for healthcare associated infections, rather than a surrogate organism.

There are potential limitations to using BI pouches. Firstly, they do not incorporate a soil-challenge to simulate the attenuation of a biocide when exposed to dirt, debris and biological materials encountered in the environment. Secondly, due to penetrating limitations of hydrogen peroxide it is not clear whether BI pouches favour the penetration of smaller vapour particles used in vapour-hydrogen peroxide systems over aerosolised hydrogen peroxide.

There are some considerations regarding target reductions of the contaminating organisms. Manufacturers may aim to demonstrate 5-6 $\log_{10}$ reductions in bacteria and spores through a single decontamination cycle, based on targets applied to hard-surface disinfectant solutions. It is not known how these criteria have been derived. Biocidal efficacy criteria for bacteria (EN1276) and spores (EN13704) aim to achieve $5\log_{10}$ and $3\log_{10}$ reductions within 5 and 60 minutes respectively. These bear little resemblance to the mode of delivery during aerial hydrogen peroxide disinfection: the volume of the hydrogen peroxide exposed to the surfaces is significantly less than required in the EN standards, while the time required to achieve the desired aerial concentration will differ between systems and room size. Therefore differences in total exposure duration to hydrogen peroxide will vary between manufacturers and affect final microbial reductions.

Targets aiming for a high level disinfection of a bed area may be challenged with various limitations. Whole-room aerial disinfection systems are intended to eradicate any pathogenic organisms persisting after inadequate cleaning of surfaces or use of suboptimal preparations of disinfectant. Spores of *C. difficile* may remain viable on a surface even when an effective sporicide is used in disinfection [4]. The limited penetration-power of aerosolised and vapour hydrogen peroxide and the presence of organic dirt and debris may attenuate the activity of hydrogen peroxide. Additionally, characteristics of bactericidal activity in hydrogen peroxide decontamination systems may result in pronounced trailing-phases that allow low numbers of organisms to remain on surfaces unless the cycle duration is increased [5].Therefore terminal cleaning and enhanced decontamination (e.g. hydrogen peroxide disinfection) must be complementary and performed to a thorough standard to reduce microorganisms to numbers below transmissible levels.

In an assessment identifying reservoirs of *C. difficile* spores in the clinical environment, levels in the most highly contaminated areas were approximately in the order of $3\log_{10}$ numbers [6]. Thus, applying targets to achieve 5-6log reductions in bacteria and spores in efficacy-testing is arbitrary in practice.

When evaluating hydrogen peroxide decontamination systems, organisms of local concern and relevant soiling challenges should be used to show in-use efficacy. With increasing use of automated whole room disinfection devices a novel testing standard needs to be designed with clinically relevant reduction targets. Comparison of devices between studies may be difficult for readers without a defined standard.

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3. Fu TY, Gent P, Kumar V. Efficacy, efficiency and safety aspects of hydrogen peroxide vapour and aerosolized hydrogen peroxide room disinfection systems. *J hosp Infec* 2012; **80**: 199-205

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