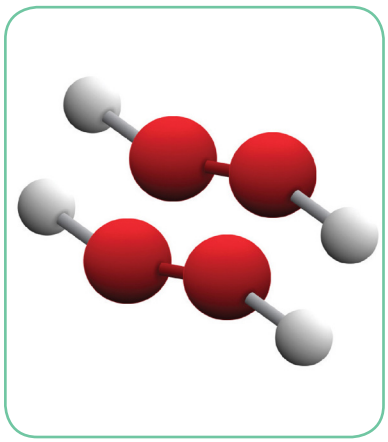

Hydrogen peroxide automated room decontamination: vapour vs. aerosol systems

Hydrogen peroxide automated room decontamination (ARD) systems for hospitals have received increased interest in recent years.[1] Available systems are typically hydrogen peroxide vapour (for example Bioquell HPV), or aerosolised hydrogen peroxide (AHP, such as ASP Glosair, Steris Biogienie or Hygiene Solutions Deprox). There are important differences between Bioquell HPV and AHP systems in terms of their efficacy and potential for clinical impact.[2,3] This white paper examines the evidence supporting Bioquell HPV and AHP systems for ARD in hospitals.

bioquell

Technology description

There are two different types of hydrogen peroxide-based automated room decontamination systems available (Table 1). Some are based on hydrogen peroxide vapour (HPV) and others are based on aerosolised hydrogen peroxide (AHP). Bioquell HPV is created from the flash evaporation (using a hot plate) of 30-35% w/w hydrogen peroxide solution. The flash evaporation ensures an instantaneous phase change from liquid to vapour. Bioquell equipment continues to inject the vapour (ie the HPV) into the room until it reaches saturation – in other words until dewpoint is reached – and approximately 3µm of hydrogen peroxide is laid down on all the surfaces, rapidly killing the pathogens.[1-5] Following the HPV exposure, an active aeration system catalyses the decomposition of the HPV to oxygen and water vapour. In contrast, AHP systems produce an aerosol from a solution containing a lower concentration of hydrogen peroxide solution (typically 5-6%) and other chemicals typically including <50 ppm silver ions.[2,3]
Most AHP systems (including ASP Glosair and Steris Biogienie) use pressure to generate the aerosol. Some AHP systems (including Hygiene Solutions Deprox) use ultrasound to generate the aerosol. Whilst the manufacturer claims that this ultrasound-generated aerosol is a vapour, it is not since the aerosol of fine droplets created by the Deprox AHP system remains in the aqueous phase. In short, an aerosol is not a gas (and not a vapour).[a] In support of this, the Deprox AHP system was described as producing 'droplets of hydrogen peroxide' in a recent study by independent academics,[6] and a regulatory filing from Deprox AHP described their own system as using an 'aerosol delivery system'.[7] Hygiene Solutions have decided to term their technology, incorrectly, as HPV to associate with the superior efficacy of Bioquell HPV, and the volume of peer-reviewed literature that has been published regarding Bioquell HPV.[1,8-10] Since Deprox AHP produces an aerosol from 5% w/w hydrogen peroxide and Bioquell produces a vapour from 30-35% w/w hydrogen peroxide, the systems cannot be considered equivalent.
Whether produced by pressure or ultrasound, the aerosol for AHP systems comprises droplets, typically ranging from 8-12 microns µm in diameter. Following exposure, most AHP systems do not have an active aeration system and rely on passive decomposition of hydrogen peroxide prior to room re-entry.

Efficacy

The fundamental differences between these technologies in terms of the disinfection solutions and delivery methods result in different microbiological impact. Bioquell HPV achieves a >6-log reduction of nosocomial pathogens *in vitro*,[4,5,10,11] is validated by the inactivation of 6-log *Geobacillus stearothermophilus* biological indicators (BIs),[9,12] and eliminates pathogens from hospital surfaces.[13-16] In contrast, AHP systems are considerably less effective than Bioquell HPV *in vitro*, typically achieving log reductions in the 4-log range,[5,17] are not validated by the use of BIs[18] and do not eliminate pathogens from hospital surfaces.[17,19,20] For example, sampling data from a number of studies of low-concentration AHP systems which convert 5% w/w liquid hydrogen peroxide into an aerosol shows that Bioquell eliminated *C. difficile* from surfaces (100% reduction) whereas AHP systems achieved only an 85-89% reduction in *C. difficile* surface contamination (Figure 1).[6,9,17,19] In one study, 50% of rooms remained contaminated with *C. difficile* spores following AHP exposure.[19]
In particular, AHP systems struggle to inactivate catalase-positive bacteria primarily due to the lower concentration of hydrogen peroxide in the active solution.[5,21,22] For example, in a recent head-to-head study, the ASP Glosair AHP system was poorly effective for the inactivation of *Acinetobacter baumannii* dried on surfaces, with a <2 log reduction achieved at the majority of sites tested (Figure 2).[5] Furthermore, AHP systems are less able to inactivate pathogens in the presence of organic soiling, which may be present in the event of sub-optimal cleaning prior to decontamination (Figure 2).[5]

Distribution

The key differences in the production and delivery of the hydrogen peroxide result in a homogeneous 3-D distribution in the case of Bioquell HPV compared with incomplete distribution for AHP systems. This is illustrated by two recent head-to-head studies comparing the ability of the Bioquell HPV system and one AHP system (ASP Glosair) to inactivate *G. stearothermophilus* biological indicators (BIs) and *A. baumannii* at various test locations in hospital rooms (Figures 2, 3 and 4).[4,5] Particularly poor efficacy was achieved in the bathroom by the AHP system tested in one study (Figures 2 and 3).[5] This is unfortunate given that the bathroom can become heavily contaminated with pathogens associated with gastrointestinal carriage or infection such as *C. difficile* and VRE.

Cycle time

Due to the presence of active catalytic aeration, Bioquell HPV is faster than AHP systems, most of which rely on passive decomposition of hydrogen peroxide. The process time for a single occupancy room is typically 1.5-2 hour for Bioquell HPV[23,24] and 2-3 hours for AHP.[19,25] In a head-to-head study of Bioquell HPV and ASP Glosair, the mean hydrogen peroxide concentration in the room two hours after the cycle started was 2.8±0.8 ppm for ASP, with a maximum reading of 4.5 ppm and no readings <2ppm for the AHP cycles.[5] In contrast, the mean hydrogen peroxide concentration in the room two hours after the cycle started was 1.3±0.4 ppm for Bioquell with none of the readings >2ppm.
Another recent head-to-head study of Bioquell HPV and ASP Glosair found that a single Bioquell HPV unit outperformed two AHP units and confirmed that HPV is faster than AHP. [4] Furthermore, this same study found that multiple cycles were required from the AHP units in an attempt to inactivate the spore BIs (Figure 4).

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a *Definition of terms (all from Dictionary of Science, Penguin Reference, Second Edition): Vapour = 'a term used almost synonymously with 'gas'; strictly, a vapor must be able to be turned into a liquid by compression alone. The term should therefore be used only below the substance's critical temperature.' ('Critical temperature = the temperature above which a gas cannot be liquefied by compression alone.') Gas = 'the state of matter that lacks structure, the particles behaving essentially independently of one another, and expanding to fill any available volume.' Aerosol = 'a dispersion of a solid or liquid in a gas.'*

Despite the use of two units and multiple cycles, 50% of the BIs were not inactivated by AHP, whereas 100% were inactivated by a single cycle from a single Bioquell HPV unit.[4] A previous study also found that multiple cycles of an AHP unit were required to inactivate spores.[25]

Safety

In order to ensure the safe delivery of either Bioquell HPV or AHP systems, room re-entry must be led by a hand-held sensor to avoid the risk of exposing patients or staff to hydrogen peroxide levels in excess of recommended safe limits. A recent head-to-head study comparing Bioquell HPV with one AHP system (ASP Glosair) showed that the concentration of hydrogen peroxide measured in the room at the recommended room re-entry time for ASP Glosair was >2ppm, risking exposure to unsafe levels of hydrogen peroxide.[5] Thus, relying on a specified time is not a safe way to re-enter rooms following cycles. In addition, doors and air vents must be sealed to avoid leakage when using either Bioquell HPV or AHP systems.[5]

Repeatability and reliability

The performance of AHP systems varies considerably between repeat cycles. This is illustrated by the variability in inactivation BIs at the same site between cycles (Figure 3 and 4). It also seems from several studies that AHP systems are prone to technical failure and have poor reliability.[5,19,22]

Regulatory position

Bioquell HPV received government accreditation through the UK Rapid Review Panel (RRP) recommendation 1, meaning that 'Basic research and development, validation and recent in use evaluations have shown benefits that should be available to NHS bodies to include as appropriate in their cleaning, hygiene or infection control protocols.' In contrast, one AHP system has been assessed and received a RRP recommendation 3, meaning that the technology is 'A potentially useful new concept but insufficiently validated; more research and development is required before it is ready for evaluation in practice.' Furthermore, Bioquell HPV has been assessed in the Showcase Hospital Programme, which concludes that the regular use of the technology is feasible,[23] which has also been found in a US study.[26] Bioquell HPV-AQ is a US EPA registered sterilant and is sporicidal.[10] The regulatory position for AHP systems with the EPA is currently uncertain. Due to concerns over efficacy, several AHP systems have been withdrawn from the French market by the national disinfectant regulator.[27]

Clinical impact

Currently the only published scientific evidence of clinical impact relates to the Bioquell HPV system. Several studies have suggested that the use of HPV can help to bring outbreaks under control.[13-15,28,29] Three studies have demonstrated that the use of HPV to target the decontamination of rooms and clinical areas used to treat patients with pathogens reduces the incidence of *C. difficile*, VRE and other pathogens.[8,9,30]

Other considerations

Bioquell HPV systems are controlled remotely by a module situated outside the room, whereas most AHP systems currently available have no remote control. This means that if there is an urgent requirement for the room, or in the event of an emergency, there is no way of stopping AHP systems remotely. Bioquell also has considerable experience from decontaminating more than 80,000 hospital rooms world-wide. Finally, there is a potential for the development of reduced susceptibility to hydrogen peroxide or silver due to the selection of mutants through sub-lethal exposure of micro-organisms to AHP systems.

Summary

Bioquell HPV has several key advantages over AHP systems. It is faster, able to repeatedly and reliably eliminate pathogens from hospital surfaces in all parts of a room, can be validated using BIs and there is evidence that the regular use of Bioquell HPV reduces the transmission of hospital pathogens.

Table 1. Comparing the features of Bioquell HPV with AHP systems.

	Bioquell HPV	AHP
Solution	35% H_2O_2 delivered as a vapour.	5% H_2O_2 delivered by an aerosol.
Application	Heat generated vapour.	Pressure or ultrasound generated aerosol.
Efficacy	6-log reduction and elimination of pathogens. Inactivates catalase-positive bacteria.	Does not reliability achieve a 6-log reduction; reduction in contamination but not elimination of pathogens. Problems with catalase-positive bacteria (including MRSA, *Acinetobacter* and CPE).
Distribution	Homogeneous distribution.	Incomplete distribution.
Cycle time	<2 hrs for a single room (active aeration).	>2 hrs for a single room (passive aeration).
Safety	Need to seal doors and air vents.	Need to seal doors and air vents.
Repeatability and reliability	Very little variability between cycles; cycle failures rare.	Variability between cycles; cycle failures reported frequently.
Regulatory position	Rapid review panel (RRP) 1; EPA registered sterilant.	Rapid review panel (RRP) 3; EPA registration uncertain.
Evidence base	Several published studies showing reduced acquisition.	Microbiological impact only; no published controlled studies demonstrating a reduction in acquisition.

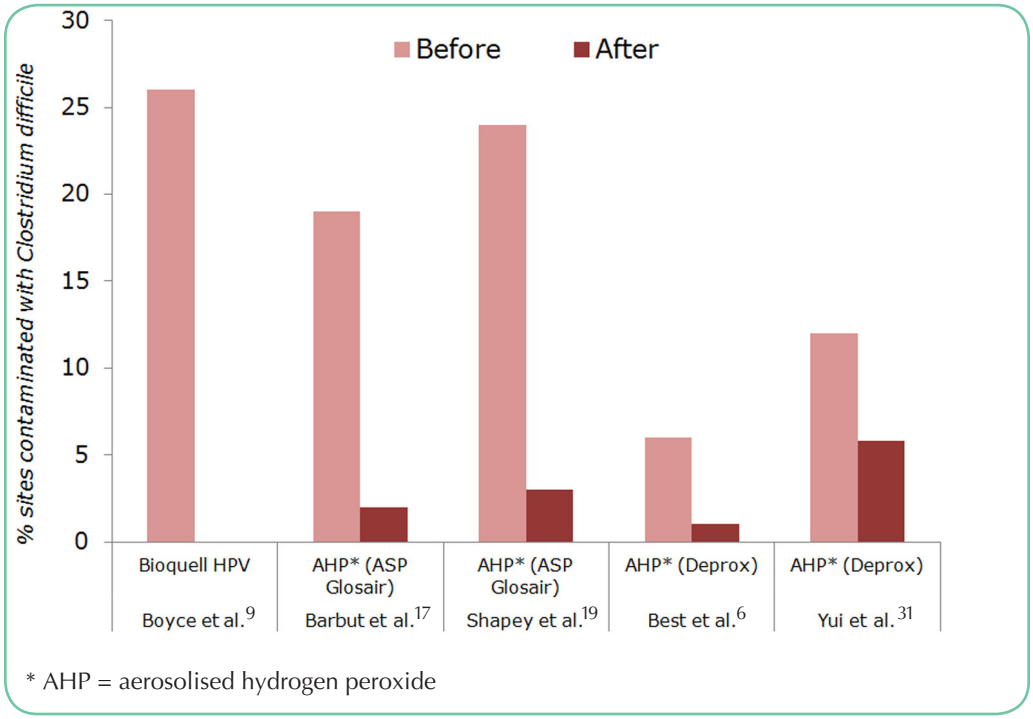

Figure 1. Comparison of studies evaluating the percentage of sites contaminated with *Clostridium difficile* spores before and after exposure to Bioquell HPV[9] or AHP[6,17,19] systems.[31]

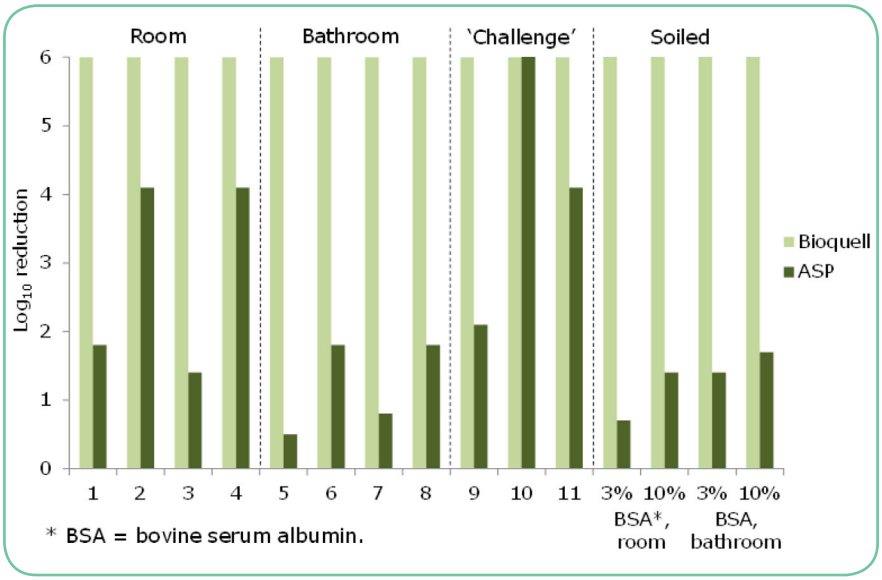

Figure 2. Head-to-head effectiveness of Bioquell HPV and ASP Glosair to inactivate *Acinetobacter baumannii*.[5] The figure compares the median log reduction achieved at 11 test locations in a hospital room and in the presence of increasing levels of organic soiling. See Figure 3 for sample locations.

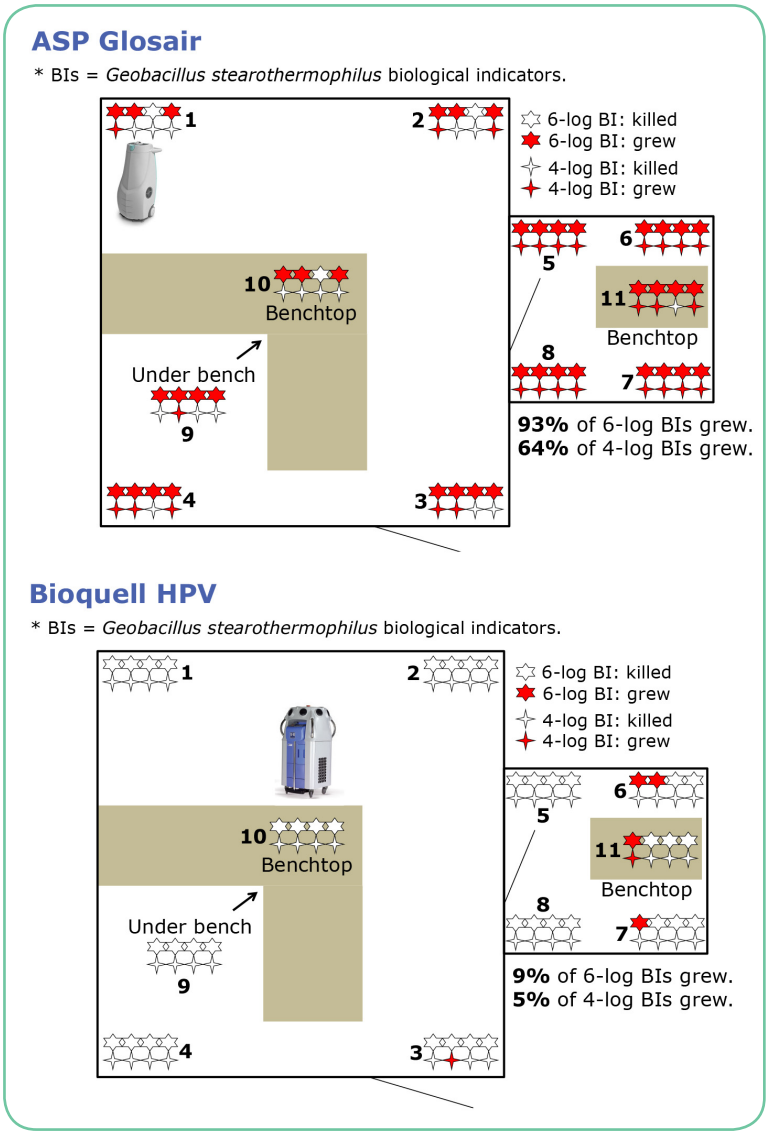

Figure 3. Inactivation of 6-log and 4-log biological indicators by the Bioquell HPV and ASP Glosair systems.[5]

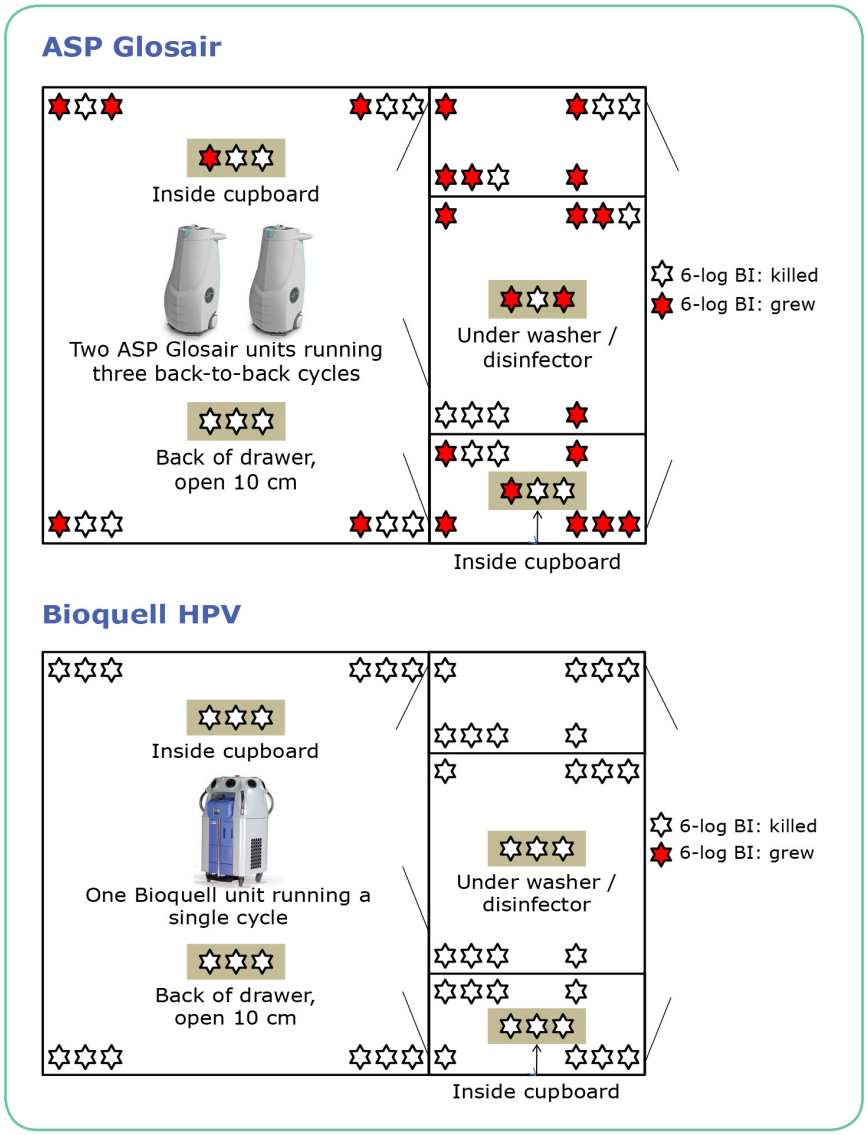

Figure 4. Inactivation of 6-log biological indicators by Bioquell HPV and the ASP Glosair systems.[4]

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E: info@bioquell.com
W: www.bioquell.com

Bioquell UK
T: +44 (0)1264 835 835

Bioquell Ireland
T: +353 (0)61 603 622

Bioquell France
T: +33 (0)1 43 78 15 94

Bioquell USA
T: +1 (215) 682 0225

Bioquell Asia Pacific
T: +65 6592 5145

Bioquell China
T: +86 755 8631 0348