Asking the right questions in hand hygiene

During the pandemic, increased demand for alcohol-based hand rub led to some questionable solutions entering the market. So, what questions should healthcare providers ask suppliers to ensure that their product is suitable and effective for hospital use? **Thomas Oh, Mandy Michie, Pearleen Ho** and **Lars Passvogel** provide an insight.

One of the pivotal tools to facilitate good hand hygiene is alcohol-based hand rub (ABHR). The importance of ABHR became apparent when the world experienced a global stock-out situation, driven by high demand during the height of the COVID-19 pandemic. Today, the supply of ABHR has normalised. However, the increased supply of ABHR raised concerning issues around the risk of some unsuitable products that were found to be contaminated with methanol, insufficient alcohol content and false antimicrobial claims.[1-3] The quality of the ABHR, especially for hospital usage, is something that should not be compromised.

This article aims to address this gap in knowledge, by discussing the type of testing that a credible ABHR should undergo to determine its antimicrobial efficacy – this includes *in vitro* tests against bacteria, yeast, viruses, and the practical tests on the hands of human volunteers. By the end of the article, the reader should have a greater appreciation of the testing that an ABHR should have and, hopefully, that information will facilitate the correct selection of the right product for their hand hygiene endeavor in the respective hospitals.

EN system overview

The antimicrobial efficacy of hand sanitisers can be demonstrated by standardised test methods. One of the internationally accepted standardised test methods to evaluate the antimicrobial efficacies of disinfectants and/or antiseptics is the methodological framework of the European Committee for Standardisation (CEN).[4]

This framework comprises of test methods for products in the field of agriculture, domestic services, food hygiene and other industrial fields, medical and veterinary areas, and test methods for hand sanitisers. Steered by the so-called CEN 'Technical Board', the test methods/standards are prepared by the CEN 'Technical Committees', directing authority over its own application field. In relation to ABHR, it is the technical Committee 'CEN/TC 216' that holds responsibility for the development of new and/or improvement of existing standards in different working groups.

One key characteristic element of CEN standards is the use of standardised test strains defined in the test methods and the recognition of 'surrogates' as a representative to the whole group of organisms, eliminating the need to test each stain individually.

For example, the efficacy of a disinfectant against the recent SARS-CoV-2 and Mpox virus can be determined by EN 14476 test, which uses Modified Vaccinia Virus Ankara (MVA) or the Vaccinia strain Elstree – both surrogate virus for enveloped viruses.

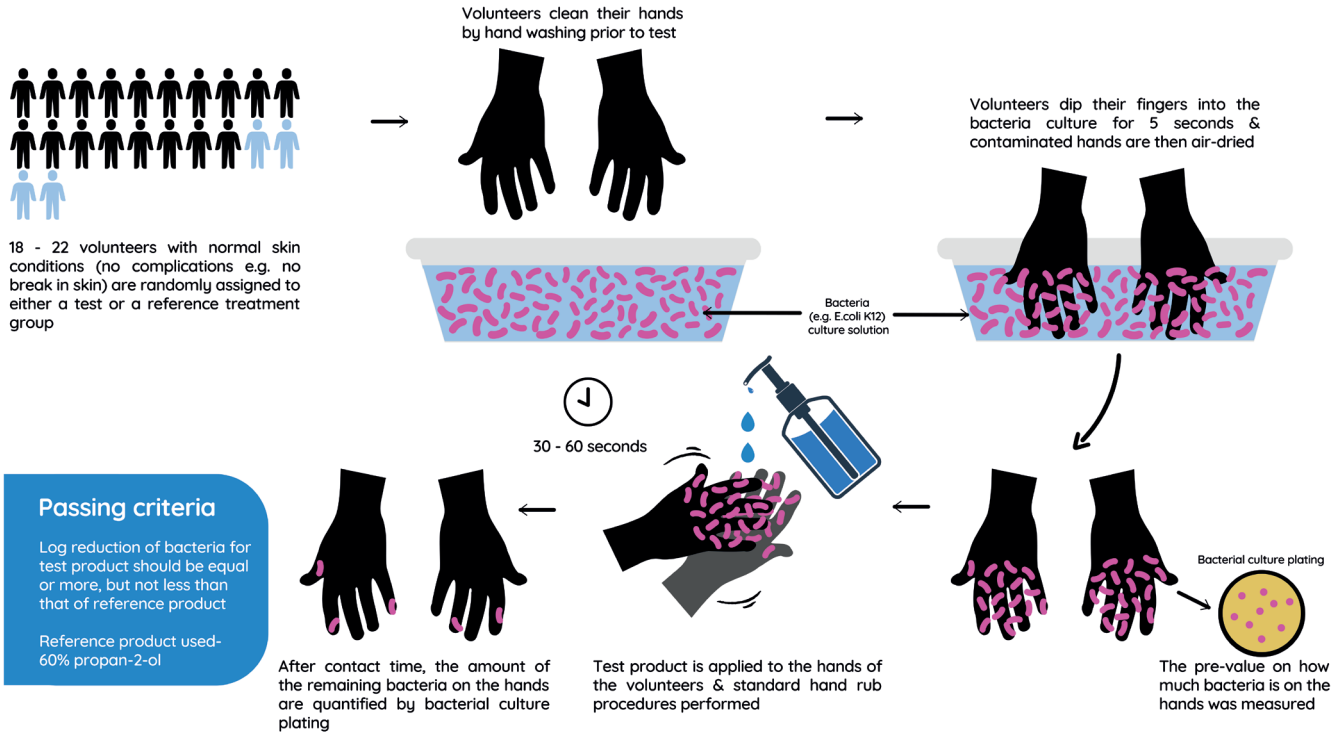

Figure 1. How is EN1500 being carried out?

The surrogate concept is based on the structural similarity between the species within each genus – meaning that an acceptable efficacy against MVA/Vaccinia strain Elstree also applies to SARS-CoV-2 and Mpox as all of them are enveloped viruses.[5] The use of surrogate microorganism(s) alleviates the need to test on the pathogen *per se* which, in the case of highly pathogenic microorganisms (i.e., SARS-CoV-2), is often logistically challenging, due to the non-availability of the strains and the requirement of the test to be conducted in high containment facilities (i.e., BSL-3).

For hand sanitisers, different test methods have to be performed before a product can be deemed CEN-certified, which can be found in the superordinate standard EN 14885. Hence, products must go through the EN testing principles, termed "phases" and "steps", in a numerical increment. Phase 1 tests include quantitative suspension tests, where product and test organisms are tested without any regard to specific application areas or conditions.

Phase 1 tests are only designed for products under development and the resulting data cannot be used for official claims. Instead, phase 2 tests are comprised of a 2 steps approach designed to demonstrate antimicrobial efficacy under test conditions that resemble actual application. In contrast to phase 1 tests, the phase 2/step 1 tests are quantitative *in vitro* suspension tests, except that the test product is tested against representative test microorganism(s) with the inclusion of an organic load – comprising of protein (bovine serum albumin) (i.e., "clean conditions") or a mixture or protein and blood (bovine serum albumin + sheep-erythrocytes) (i.e., "dirty conditions"). The addition of organic load simulates the real-life conditions where soiling is likely to be present.

Depending on the application area of the disinfectants, phase 2/step 2 tests may be required to evaluate the antimicrobial effectiveness of test products against microorganisms under practical conditions that resemble the usage at the customer's site. For example, disinfectants are tested directly on appropriate test surfaces – such as stainless steel or PVC surfaces, or on the hands of volunteers.

Figure 2. How to handrub?

Hand sanitisers intended for hygienic hand disinfection in healthcare institutions must show at least an efficacy against bacteria and yeast according to European standards EN 13727 and EN 13624 (both phase 2/step 1 tests) as well as EN 1500 (phase 2/step 2 test). Additional claims, such as tuberculocidal and virucidal efficacy can be made when acceptable efficacy is shown in the appropriate test methods.

Products for use in surgical hand disinfection/washing must be at least bactericidal and yeasticidal (proven by standards EN 13727 and EN 13624) and has to be tested according to EN 12791 (phase 2/step 2 test) to be deemed suitable as a surgical hand disinfectant/wash (please refer to EN 12791 section below for a more detailed description).

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EN 1500

In the European standard EN 1500, hand sanitisers are tested under simulated 'use' conditions by applying the product on the hands of volunteers (Figure 1). Briefly, each volunteer has to contaminate his/her hands first by putting their hands in a test suspension of the bacteria *Escherichia coli*. Directly after that, hands are air-dried, and a "pre-value" is taken by adding contaminated fingertips to culture media in a petri dish. This value is used to determine the logarithmic bacterial reduction and, consequently, the effectiveness of the product.

After this, the test hand sanitiser is applied to the hands according to the volume and contact time defined by the manufacturer. Within the contact time, the defined steps of hand ▶

rubbing, explicitly described in the standard, have to be performed (Figure 2). Fingertips are put in culture media again to determine the bacterial count after product application. Finally, the bacterial count before and after product application is determined and the logarithmic reduction factor is calculated. In parallel with the product testing, a reference product (i.e., 60% (v/v) propan-2-ol) is also tested within a contact time of 60 seconds, following the above-described steps, and respective logarithmic reduction factors are enumerated.

According to CEN requirements, a product only fulfills the criteria of a hand sanitiser if the product is statistically not inferior to the standard solution (meaning that the antimicrobial efficacy of the test product should not be worse than the reference propan-2-ol in order to pass). In addition, all test controls defined in the method, including a valid data set of at least 18 volunteers for the testing and the reference product should be included (Figure 1). Currently, EN 1500 test determines the efficacy of hand sanitiser against (only) bacteria, but further broadening of this phase 2/step 2 test against other microorganisms, such as viruses, can be expected in the future.[6]

EN 12791

The phase 2/step 2 tests according to EN 12791 (surgical hand disinfection) simulates the

application of a hand sanitiser by a surgeon prior to surgery. The EN 12791 test is designed to determine the efficacy against the resident skin flora compared to a transient contamination by artificially introducing microorganisms during EN 1500 testing. The test procedure according to EN 12791 starts with a hand washing step to reduce any transient microorganisms.

In contrast to the test requirement of EN 1500, at least 23 volunteers are needed for EN 12791 to obtain a valid result. Prior to product application, the pre-value (starting bacterial count) is taken as described for the EN 1500 (Figure 3). Then, test product is added and the defined steps of hand disinfection are performed throughout the contact time (Figure 2). Directly after product application, the microbial count is enumerated from one of the volunteer's hands to determine the immediate antimicrobial effect.

The other hand of the volunteer is covered with a sterile surgical glove for 3 hours, after which the microbial counts is enumerated.

The latter step is important to demonstrate the suppression of the skin flora by the hand sanitiser over a longer time period (3 hours post hand sanitising) to mimic the typical duration of a surgical procedure. The ability to exert consistent suppression over this period will aid prevention of surgical site infection (SSI) should there be a glove breach. Also, in EN 12791, the product's efficacy is compared to a reference product, which is 60% (v/v) propan-1-ol tested at a contact time of 3 minutes and 3 hours respectively. To fulfill EN 12791 requirements, the antimicrobial efficacy of the tested hand sanitiser should not be worse than the reference – i.e., propan-1-ol.

The misuse of EN standards

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There are several products found on the market which do not fulfill these requirements

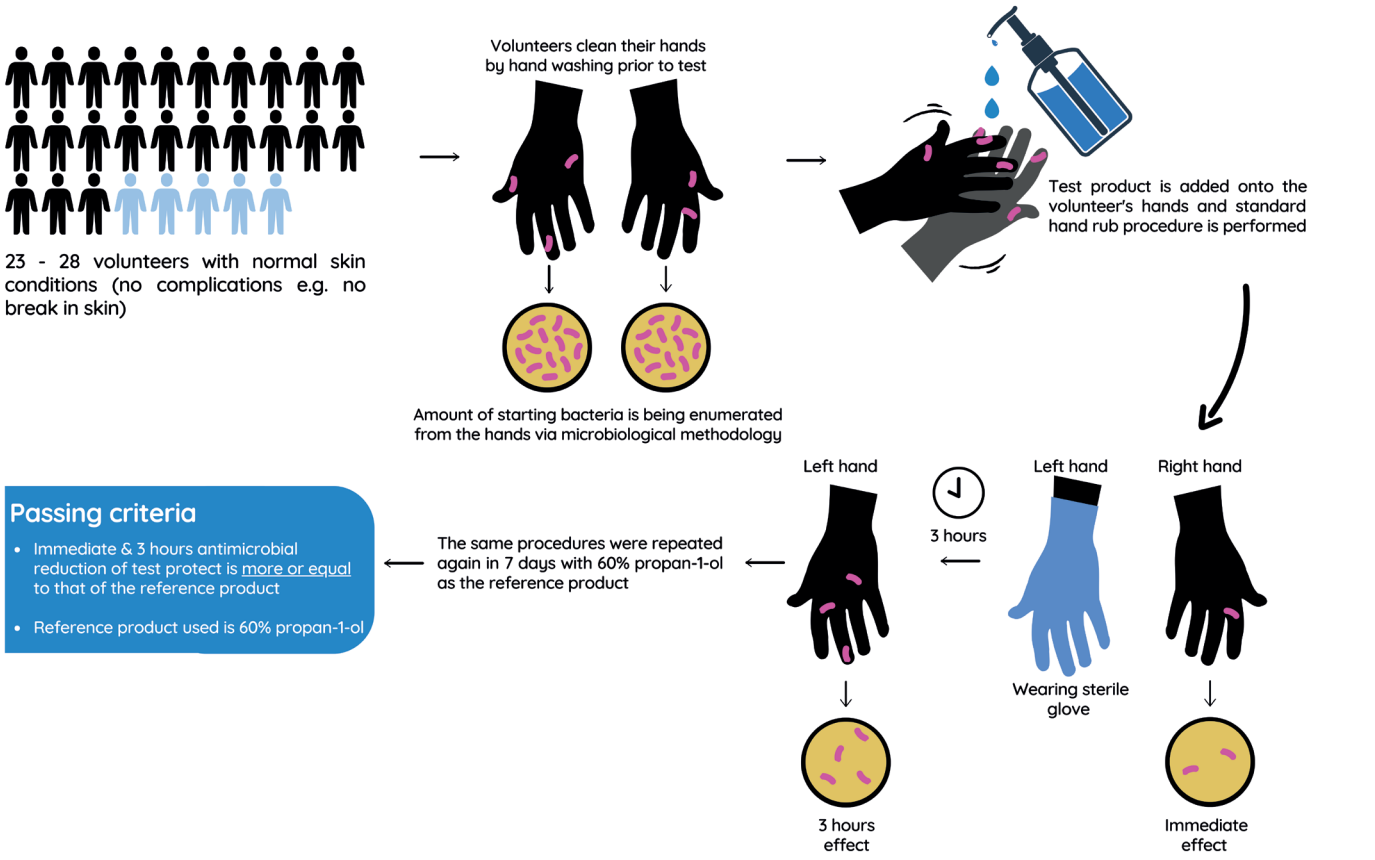

Figure 3. How is EN 12791 being carried out?

and can theoretically compromise infection prevention control. Apart from ABHR, products with alternative active ingredients – such as sodium chloride/ sodium hypochlorite and hypochlorous acid – have been offered by several manufacturers as an alcohol-free alternative with the aim to circumvent alcohol usage for those who are either allergic or unable to use alcohol-based products.

However, the efficacy of some products may be questionable. The inferiority of products containing sodium hypochlorite or sodium hypochlorite and hypochlorous acid was reported by Suchomel *et al* (2023).[3] In the study, it was clearly shown that sodium hypochlorite-containing products are inferior to the reference procedure defined in EN 1500 – compared to the reference logarithmic reduction factors (lgR) of 4.78, the products comprising of sodium chloride/ sodium hypochlorite and hypochlorous acid showed a lower value of $\log^{10}$ 1.68 and 1.89 respectively. Due to the failure in fulfilling the EN 1500 requirements, the authors advised not to consider sodium hypochlorite-containing hand sanitiser, containing 0.05–0.06% of this active ingredient.

There are also products that claimed relevance for hospital usage by referencing irrelevant EN tests, such as EN 1040 or EN 1276. As mentioned previously, EN 1040 (phase 1/ step 1 test) is only meant for products under development and resulting data cannot be used for official claims.

As for EN 1276, it is a phase 2/step 1 test to evaluate bactericidal activity of disinfectants used in food, industrial, domestic and institutional areas, not hospitals. It is prudent to know that according to EN standards, you need to pass EN 13727, EN 13624 and EN 1500 before a hand sanitiser can be deemed appropriate for use in the hospital. These examples clearly show that the selection of an appropriate hand sanitiser should be carried out based on valid efficacy claims in order to ensure patient safety.

Healthcare institutions (in certain regions) have resorted to using different hand hygiene products within the hospital – EN 1500 tested ABHR products are used in higher risk areas, such as the wards and an untested (and supposedly cheaper) ABHR are used in the public and/or general areas. The latter raised serious concerns as pathogenic microorganisms are not only restricted to wards but also on high-touch surfaces in public areas, such as the elevator buttons, staircase railings, escalator, information counter etc.[7,8] Therefore, the prioritisation of EN 1500-tested ABHR only for specific areas will undermine the effectiveness of hand hygiene within the multimodal approach towards lowering infections in the respective institutions.

Simple checklist

With wider acceptance of ABHR as the gold standard of care for hand hygiene practice in healthcare settings, product selection has become even more critical to improving hand hygiene compliance and providing safe care.[9] There are key considerations that can guide clinicians during the evaluation and selection process of hand sanitisers. These involve not one, but several factors that contribute to the successful implementation and effective use of such products. The top consideration is antimicrobial efficacy, with an understanding of the importance and relevance of EN 1500 testing for hand sanitiser products in healthcare, as explained in this article.

Secondly, it is important to consider the formulations of different ABHR solutions, with products comprising of different types of alcohol, emollients, consistency and scent. The decision process leading to the selection of an ideal hand sanitiser can be complex and requires a full understanding of what is required of the product and the various tests surrounding it. The following checklist will help to direct healthcare workers towards a more informed product selection:

Minimum requirements

1. At least a minimum of 60% alcohol content (ethanol and/or iso-propanol).
2. Relevant certifications include EN 13727, EN 13624 and EN 1500.

Optional requirements

1. Additional certifications, such as EN 12791 if the product is to be used for surgical hand disinfection; EN 14476 virucidal certification if the product is to be used in specific areas i.e., norovirus in neonatal ward.
2. Dermatologically tested.
3. Scented or non-scented depending on the local preferences and regulatory requirements.
4. Practical consideration (dispensing/ bracketing options, liquid or gel format, round or square bottles etc).

Importantly, healthcare workers need to use hand sanitisers correctly according to the manufacturer's instructions for use. The required contact time is typically 30 seconds for hygienic hand disinfection and 90 seconds for surgical hand disinfection with good coverage and technique to ensure the most effective outcome of hand hygiene.

Conclusion

Hand hygiene continues to be the cornerstone of infection control. Given the plethora of products that flooded the market following the pandemic, the need for a robust verification mechanism for hand sanitiser has become increasingly important. Among them, the EN standards provide the necessary framework to govern the antimicrobial standards of hand sanitisers for use in critical areas, such as the hospital. The continuous sharing of EN standards, and the relevant tests to look out for, must be a priority as part of educational endeavors for World Hand Hygiene Day for 2023. With continuous education, healthcare workers will become more accustomed to the knowledge and, in time, translate this know-how into better decision-making processes when it comes to the selection of hand sanitiser for their healthcare institutions. **CSJ**

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