Disinfectant standards: what you need to know

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looks at the current European standards on disinfectants and the key considerations for hospitals to ensure the biocidal efficacy of the chemistries they use.

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Effective disinfection of surfaces, instruments and hands is critical to minimise infection risks (bacterial, fungal and viral) in hospitals especially during the current global pandemic. This requires the selection of the most appropriate disinfectants, their correct application, and an assessment of their capability to inactivate or kill microorganisms. There is a wide choice of disinfectant formulations available and it is essential to ensure the most appropriate disinfectants are selected for the use for which they are intended and are then used correctly.

This article examines European Norms (EN) in relation to disinfectants, considers the importance of updates to these standards and offers some practical advice on ensuring that accurate comparisons between different disinfectants can be readily made.

The main function of a disinfectant lies in its ability to kill or inactivate microorganisms. Therefore, a key step in the selection process is ensuring the disinfectant has the required level of biocidal activity. Disinfectant manufacturers provide efficacy data relating to the two key criteria of contact time and required concentration. This data should be based on product testing which is both rigorous and repeatable. In Europe, this means being tested to the European Norms (EN). Even with the UK's departure from the EU, European Norms are likely to continue to provide the 'gold standard' tests for disinfectants in the UK, for the foreseeable future.

According to the EU, 'a Standard (French: norme, German: Norm) is a document that provides rules, guidelines or characteristics for activities or their results, for common and repeated use. Standards are created by bringing together all interested parties including manufacturers, users, consumers and regulators of a particular material, product, process or service.' Each European Standard is identified by a unique reference code which contains the letters 'EN'. All ENs will have been adopted by one of the three recognized European Standardization Organizations (ESOs): CEN, CENELEC or ETSI.

European standards for testing disinfectants are based on test methods orientated towards the practical use of the disinfectant. Theoretically, these standards should allow the direct comparison of disinfectants from different manufacturers, as they should have been tested using the same standard.

The key word is 'should'. These standards are regularly reviewed and updated, but it is not mandatory for a disinfectant manufacturer to test to the latest standards. For example, EN13624:2003 specifies a test method and the minimum requirements for fungicidal or yeasticidal activity of chemical disinfectants in hospitals. The 2003 version has now been superseded by EN13624:2013, which specifies more rigorous efficacy testing. In practice this means that a disinfectant tested to the 2013 EN would need to be used at an increased concentration and / or a longer contact time, than if it were tested to the 2003 standard. If comparing two disinfectants and one was tested to EN13624:2003 and the other to EN13624:2013, it would not be an accurate comparison in terms of concentration or contact times required.

There is no mandatory requirement for an updated standard to be adopted by a manufacturer within a set period of time. As standards become increasingly rigorous, to protect both patients and staff, there appears to be little incentive for disinfectant manufacturers to test to newer, tougher standards, which could mean increased disinfectant concentration times and longer contact times, to ensure microbial efficacy.

There are some manufacturers who will always adopt and test to the latest norms, ▶

to ensure the highest infection prevention standards are maintained, but this may require a little research to ensure disinfectant claims are truly comparable.

Disinfectants have a variety of properties that include spectrum of activity, mode of action, and efficacy. Equally, the actual active chemicals in the disinfectants may be categorised into groups based on their chemical nature, spectrum of activity, or mode of action. Effectiveness is assessed through disinfectant efficacy testing, but a problem faced when selecting a disinfectant, is the array of different standards. This is where the EU standards have a useful role to play, although some understanding of them is required if they are to be used as the basis for disinfection selection.

It is worth noting that the European approach of CEN (European Committee for Standardization) to the evaluation of disinfectants differs from that taken in North America by ASTM (American Society for Testing Materials) standards and the AOAC (Association of Official Analytical Chemists International). This does nothing to alleviate potential confusion about testing and there have been calls for agreed international test standards. However, that is outside the scope of this article.

Disinfectant standards are required for several reasons. Primarily, any company that wishes to market a product in the European Economic Area needs a CE mark which identifies that the product conforms to an accepted standard of quality. The mark stands for Conformité Européenne. By placing the CE marking on a product a manufacturer is declaring conformity with all of the legal requirements to achieve CE marking. It means that the manufacturer has checked that the product complies with all relevant essential requirements, for example health and safety requirements.

Standards for disinfectants aim to prevent manufacturers from claiming activity in a product which is not, in fact a disinfectant. For example, distilled water lyses many bacteria and therefore does have some very limited bactericidal effects, however distilled water could not be described as a disinfectant.[1]

Agreed standards allow for the definition of a minimum requirement for a product to be described as a disinfectant. It also

ensures that manufacturers need to be able to validate claims of bactericidal, virucidal or tuberculocidal activity. Standards give clear guidance on what is required to validate such claims.

There are a number of European testing standards (EN standards) that are currently available, including both suspension testing methods, which test the ability of a disinfectant to kill microorganisms in a liquid suspension, and surface/carrier testing methods, which test the ability of a disinfectant to kill microorganisms dried onto a surface.

Key considerations when considering which testing standards, a manufacturer has employed include:

- Disinfectant neutralisation. If this is not performed correctly, efficacy will be over-estimated.
- The level of soiling. Various approaches can be taken to replicate soiling, often using proteins. This should reflect in-use conditions as far as is possible.
- Selection of test organisms. For example, only testing against vegetative bacteria is unhelpful if a sporicidal disinfectant is required.
- Contact times. Unrealistically long contact times may well not provide a meaningful assessment of the disinfectant that is being tested.
- Pass criteria. Most EN standards require a greater-than-or-equal-to 5-log reduction, but some standards have a lower pass criteria for practical reasons.

It is also vital that manufacturers have performed disinfectant testing in accredited laboratories, with experience at performing this type of rigorous and specific testing. If disinfectant neutralisation is not performed correctly, the actual contact time required will be longer than the published contact time which means the efficacy of the disinfectant may have been overestimated. Therefore, when reviewing a disinfectant for use in a hospital, it is worth asking:

- Is it biologically plausible that this disinfectant chemistry will have the level and range of biocidal activity that is being claimed? For example, only a relatively few disinfectant chemistries have meaningful sporicidal activity.
- Was an appropriate testing standard used? For example, a suspension test (such as EN 13727:2012) does not provide good evidence that a disinfectant will be active against bacteria dried onto surfaces; instead, a carrier test (such as EN 13697:2015) should be used.
- Were the tests performed in an accredited, experienced laboratory that has produced a report with a sufficient level of detail? If not, biocidal efficacy could be over-estimated.

For hospital and medical use, there are a number of applicable standards which manufacturers of disinfectants may be

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testing against. This depends on how the product is intended to be used. For example, EN 17126:2018 relates to disinfectants claiming sporicidal activity, which might not always be required. Whereas EN 14476:2013+A2:2019 which relates to virucidal activity should always be considered when efficacy against viruses including coronaviruses is of paramount importance.

- EN 13624:2013 "Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1)". This supersedes EN 13624:2003
- EN 13727:2012+A2:2015 "Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity in the medical area. Test method and requirements (phase 2, step 1)". This supersedes EN 13727:2003
- EN 14476:2013+A2:2019 Chemical disinfectants and antiseptics "Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)".
- EN 17126:2018 "Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area. Test method and requirements (phase 2, step 1)."

These European Standards apply to products that are used in the medical area in the fields of hygienic hand rub, hygienic handwash, surgical hand rub, surgical handwash, instrument disinfection by immersion, and surface disinfection by wiping, spraying, flooding or other means. They apply to areas and situations where disinfection or antisepsis is medically indicated.

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The standards outlined above evaluate disinfectants through the suspension test for instrument disinfection by immersion, and surface disinfection by wiping, spraying, flooding or other means. The basic requirement is at least a 5-log reduction of vegetative microbial cells under EN 13624 and EN 13727 and a 4-log reduction for bacterial spores under EN 17126 (which are harder to kill).

The suspension test to evaluate disinfectant efficacy

The disinfectant efficacy validation aims to provide documented evidence that the disinfectant demonstrates the virucidal, bactericidal, fungicidal, and/or sporicidal activity necessary to control microbial contamination in general and to eliminate pathogens of concern.

The purpose of the quantitative suspension test, as set out in the above standards, is to evaluate the activity of a given disinfectant against a range of microorganisms under conditions that closely simulate the practical use of the disinfectant.

The test consists of inoculating a prepared sample of the disinfectant under test in simulated 'clean' and 'dirty' conditions using a challenge suspension of the test microorganism.[2] After a specified contact time an aliquot is removed, and the microbicidal action is immediately neutralised by the addition of a proven neutraliser.

Without an effective neutralising agent, the disinfectant may continue to have an inhibitory effect on the test samples during recovery testing, leading to inaccurate results. Selection of the appropriate neutralising agent is dependent upon the nature of the disinfectant. Following this neutralisation step, the number of surviving microorganisms in each sample is determined through the counting of agar plates and the reduction in viable microorganisms is calculated.[3]

Suspension tests require the disinfectant to be of a certain concentration and to be evaluated for a controlled period of time. This assesses how the disinfectant is presented in practice and for how long it needs to be applied. In addition, the disinfectant is made up in the 'worst case' condition by using 'water of standard hardness' (which contains ions like magnesium and calcium, as well as other salts). A further condition is the simulation of 'soiling' (the 'dirty' conditions mentioned above), which is achieved by the addition of bovine serum albumin (at 0.03%, representing 'clean' conditions and at 0.3% representing 'dirty' conditions.[4]

To demonstrate the effectiveness of a disinfectant, the product must be challenged using a panel of microorganisms that are reflective of the clinical setting. The appropriate organisms are set out in the standards, although with the EN 17126:2018 test, the biocidal activity of the disinfectant should be taken into account when selecting the panel of organisms (in the clinical setting, *Clostridium difficile* is an appropriate bacterium to select). This means the EN 17126: 2018 is only applied to disinfectants labelled as sporicidal.

When it comes to the selected disinfectant, ▶

the two key variables to assess under the suspension test are the disinfectant concentration and the contact time.

Disinfectant concentration

Disinfectant concentration affects the microbicidal efficacy achieved[5] The setting of this concentration range depends on factors such as contact time, material compatibility and biocidal activity.

The higher a disinfectant's concentration exponent (the relationship between dilution and biocidal activity), the longer it will take to kill cells. Concentrations that are lower than the label-use have been shown to not be as effective.

For example, if a disinfectant with a set concentration exponent was diluted by a factor of two, the time taken for it to kill cells comparatively may double. The mode of action of disinfectants can vary with concentration and, for example, bactericidal (kills bacteria) disinfectants can become bacteriostatic (inhibits growth of bacteria) if overdiluted, potentially allowing pathogens to survive and increase in numbers.

Contact times

Each chemical disinfectant requires a period of time during which it needs to be in contact with the microorganism to inactivate or kill it. This is known as the 'contact time'.[6]

Contact times are related to the concentration of the disinfectant and are expressed for each disinfectant at its optimal concentration range. The killing effect for a constant concentration of a disinfectant increases over time until the optimal contact time is established. This needs to take place before the disinfecting solution dries and before patients or staff are likely to retouch the surface.[6]

It is important that contact times have been correctly assessed and are adhered to, since reduced contact times are less effective against microorganisms, which may lead to a high proportion of pathogens surviving.[7]

Contact times can also be influenced by the nature of soiling. Although disinfectants are evaluated under 'dirty' conditions, the presence of dirt can significantly reduce their efficacy.[8] Therefore a pre-cleaning step before disinfection should always be undertaken. This helps to physically remove soiling like visible dirt and protein residues. Pre-cleaning removes any barriers to the disinfectant contacting the microbial cell wall.[9]

Changes to disinfectant test standards and why these matter

As mentioned previously, two key standards applicable to hospital disinfection have been updated. EN 13624:2003 has been superseded by EN 13624:2013 and EN 13727:2003 superseded by EN 13727:2012+A2:2015.

The updated ENs contain important modifications which have a major impact on how the concentration and contact times are evaluated. To meet these new standards, three disinfectant concentrations are required to be assessed during the suspension tests. This is to cover the active and non-active range of the product. It aims to provide some control on the test method and ensure that the final product will work effectively. The non-active concentration would be expected to fail the test.

This relationship matters because the relationship between concentration and efficacy of disinfectants is exponential, meaning that changes in concentration (or dilution) affect the cell death rate. Disinfectants have different concentration exponents and relatively small changes in concentration could be significant in terms of how effective the disinfectant is.

To give an example of how this works in practice, the old standards required an evaluation of a 1.5% concentration of a particular disinfectant together with a 5-minutes contact time in order to achieve a 'pass'. Whereas testing exactly the same disinfectant to the updated standard requires the use of a 2% concentration with a 15-minutes contact time or a 4% concentration at 5-minutes contact time to achieve the minimum log-reduction of the microbial challenge.

The updated standards are more scientifically accurate. They demonstrate the actual contact time and concentration required to kill a known population of pathogens. There can be significant differences between various disinfectant concentrations and contact times in terms of efficacy. Therefore, before selecting any disinfectant for use in a healthcare environment, the first step should always be to check that the chosen product(s) have been tested to the most up to date standards - EN 13624:2013, EN 13727:2012+A2:2015, EN 14476:2013+A2:2019 and EN 17126:2018.

Selecting disinfectants tested to the older (and now out of date) standards may mean that concentrations are too weak and/or contact times are too short to ensure that pathogens have been eradicated or inactivated to the degree they no longer pose a threat to health.

In the current climate of the COVID-19 pandemic, risks cannot afford to be taken when it comes to the choice of disinfectants (such as viricidal properties) and how effectively they are used. CSJ

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