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The outbreak of SARS-CoV-2 causing disease COVID-19 was declared by the World Health Organization as a global pandemic on 11 March 2020[1].

Infection control by healthcare institutions is one of the key factors in limiting the spread of COVID-19, in addition to other nosocomial diseases.

The ophthalmic and optometry sector is particularly at risk of nosocomial transmission.

Scientists expect SARS-CoV-2 may spread via secretions from the eye within tears as previously documented with Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV)[2].

Ophthalmologists are extremely reliant on physical examination during patient consultation. Of particular concern is the proximity between the patient and ophthalmologist during the slit lamp microscope examination. It has been shown that droplets from a cough or sneeze can be propelled for up to 6 metres, a range that definitely encompasses the distance between the patient and ophthalmologist[2].

In addition, the persistence of SARs-COV-2 for up to nine days further on surfaces further exacerbates risk[3].

Patients may remain asymptomatic but infectious for up to 14 days[4] and as a consequence every patient should be treated as high risk.

The information provided below states the standards dictated by law, to guide those within the ophthalmology and optometry sector to ensure compliance and get their disinfectant efficacy to the standard necessary.

The TGA is the Australian Government Department of Health Therapeutic Goods Administration and the regulatory body for disinfectants in Australia.

Disinfectants in Australia and New Zealand are categorised into:

1. Hospital grade or household grade disinfectants (for surfaces)
2. Hospital grade or household grade disinfectants with specific claims (for surfaces)
3. Disinfectants intended to be used on medical devices

[1] https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen
[2] Seah et al., (2020) 'Revisiting the dangers of the coronavirus in the ophthalmology practice', *The Royal College of Ophthalmologists*, https://doi.org/10.1038/s41433-020-0790-7
[3] Kampf et al., (2020) 'Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents' *Journal of Hospital Infection*, https://doi.org/10.1016/j.jhin.2020.01.022
[4] UK Government (2020) 'Coronavirus: latest information and advice' Online: https://www.gov.uk/guidance/wuhan-novel-coronavirus-information-for-the-public?gclid=EAIaIQobChMIoMqRyaLH5wIViLHtCh20XwvVEAAYASAAEgKv_PD_BwE Accessed: 10/02/2020

The first two categories are NOT intended to disinfect medical devices.

The requirements for approval of a disinfectant used on surfaces within healthcare facilities, versus a disinfectant used on instruments or medical devices are different.

Hospital Grade Disinfectants (for Surfaces)

The TGA guidance, TGO104[5] ,stipulates the requirements for Hospital Grade Disinfectants.

Bactericidal efficacy (excluding tuberculocidal) **is the only mandatory requirement** for a hospital grade disinfectant without specific claims.

The requirements of efficacy testing against microorganisms for a Hospital Grade disinfectant are much lower than those of disinfectants used on medical devices. Disinfectants that are intended to be used on medical devices are classified as Class IIb medical devices by the TGA.

Instrument Grade Disinfectants (for use on Medical Devices)

The requirements the TGA set for disinfectant testing of Instrument Grade Disinfectants depend on the classification of the device to be disinfected, either non-critical, semi-critical or critical.

Ophthalmic and optometry devices including:

- Tonometers
- Pachymeters
- Lenses
- Ultrasound probes

Are all classified as semi-critical devices based on:

(a) it makes contact with healthy intact mucous membranes of the human body; and
(b) it does not ordinarily enter normally sterile areas of the body.
(These devices, when disinfected, must be subjected to at least a high level disinfection process with an "instrument grade - high level disinfectant")

All of the ophthalmic equipment listed above, touch the intact mucosal membrane of the eye. Therefore, under Australian Regulatory Law, all of these devices require at least high-level disinfection. (Low level and intermediate disinfectants can be used to disinfectant non-critical devices).

The TGA instructions for disinfectant testing dictate an instrument grade - high level disinfectant must pass suitable bactericidal carrier, sporicidal, fungicidal, tuberculocidal and virucidal tests for high level disinfection; and pass a suitable simulated in use test[5].

[5] Therapeutic Goods Administration (2019) ' Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019' Online: https://www.legislation.gov.au/Details/F2019L00482 Accessed 17/03/2020

A carrier test simulates contamination to a surface. Microorganisms and interfering substance (i.e. clean or dirty conditions) are dried directly on to a carrier, normally a small round stainless steel disk. Disinfectant is then introduced onto the carrier for the specified contact time.

A suspension test does not include a surface. Microorganism, interfering substance and disinfectant are mixed together within a suspension test tube.

Although suspension and carrier tests provide a reproducible and comparable way to assess efficacy between different disinfectants, they are not wholly representative of clinical use.

Simulated *in use* testing is on a real-life medical device, representative of the worst-case clinical challenge. Without this information, it is not possible to evaluate how a disinfectant will perform on a medical device.

The testing requirement for high-level disinfectants is paramount to assess if a disinfectant can work in real life clinical situations.

The Difference Between Virucidal Testing for a Surface disinfectant and a High-Level Instrument Grade Disinfectant

Hospital Grade Disinfectants (for Surfaces)

For a general virucidal claim (not including blood borne viruses such as HIV, HBV, HCV, Ebola etc)., the disinfectant MUST pass tests, using Poliovirus/Parvovirus and Herpes simplex virus as the test viruses.

If a label claim against HIV, Hepatitis B (HBV), Hepatitis C (HCV) or other specific virus is made, separate data must be provided, in addition to the above.

If virucidal testing is limited to lipid/enveloped viruses, such as Coronavirus, **a label claim for general virucidal activity will not be permitted**. The label must reflect the specific viruses used for the limited testing.

Suspension tests are accepted which are the least representative of clinical use.

It is acceptable for a surface disinfectant not to possess a general or specific virus claim.

Instrument Grade High Level Disinfectant (for use on Semi-critical Medical Devices)

Three mandatory viruses must be tested[5]:

- Poliovirus type 1, 2 or 3 / Parvovirus
- Adenovirus types 1 to 7
- Herpes simplex virus type 1 or 2.

Testing specific viruses without the above mandatory test viruses above is not allowed.

If a label claim against a specific virus is made, separate data must be provided, **in addition to the above**.

Carrier tests must be used.

A high-level disinfectant must be virucidal. It is not acceptable to not have this efficacy.

The Use of Alcohol on Medical Devices within Ophthalmology and Optometry

Alcohol is not suitable for the high-level disinfection of semi-critical devices, such as those used in ophthalmology and optometry.

70% isopropyl alcohol (IPA) is no longer recommended by the Centers for Disease Control and Prevention (CDC) for tonometer disinfection as it is associated with adenovirus epidemic keratoconjunctivitis outbreaks[6].

Alcohol does not meet the high-level disinfectant testing requirements set by the TGA.

Carrier tests against spores, mycobacteria, viruses, fungi, bacteria and a simulated use test against mycobacteria are mandatory.

Microorganism	70% IPA	Suitable as a HLD?	Chlorine dioxide	Suitable as a HLD?
Bacterial spore	Not effective	No	Effective	Yes
Mycobacteria	Not effective		Effective	
Viruses: Poliovirus Adenovirus Herpesvirus	 Not effective[7] Not effective[8] Effective[8]		Effective	
Fungi	Effective		Effective	
Bacteria	Effective		Effective	

Table 1: Efficacy of 70% IPA and chlorine dioxide

To mitigate the risk of low level or intermediate level disinfectants being used incorrectly on semi-critical medical devices, often the labelling of the disinfectant will show the below statement placed on intermediate or low-level disinfectant labels:

"Product xxx is contraindicated for use as a terminal sterilant/high level disinfectant on any surface or instrument that is a) introduced into the body or b) may come into contact with the bloodstream, including broken skin or mucous membranes.

Product xxx can be used to pre-clean or decontaminate medical devices prior to sterilisation or high-level disinfection"

[6] Junk et al., (2017) 'Disinfection of Tonometers' *American Academy of Ophthalmology*, http://dx.doi.org/10.1016/j.ophtha.2017.05.033

[7] Tyler R, Ayliffe GA, Bradley C. (1990) 'Virucidal activity of disinfectants: studies with the poliovirus', *Journal of Hospital Infection*, DOI: 10.1016/0195-6701(90)90090-b

[8] Rutala et al., (2006) 'Efficacy of Hospital Germicides against Adenovirus 8, a Common Cause of Epidemic Keratoconjunctivitis in Health Care Facilities' *Antimicrobial Agents and Chemotherapy* doi:10.1128/AAC.50.4.1419–1424.2006

Medical Device Damage with IPA

As well as efficacy deficiencies, there are also documented compatibility issues:

Damage to tonometer prisms can be caused using 70% isopropyl alcohol.

Tonometer tips are observed to swell and crack by dissolving the glue that holds the hollow tip together.

The tonometer tip cracks can irritate the cornea, harbour microbes and allow disinfectants to enter the interior of the tonometer tip[7].