

Examination of the TGA Medical Devices Safety Update

The Victoria Managed Insurance Authority (VMIA) and Therapeutic Goods Administration (TGA) in Australia have highlighted increased risk of damage to plastic surfaces if compatible disinfectants are not used^{1,2}.

The focus of these alerts is primarily on disinfectants and use but the materials used in construction of these surfaces also have a role to play.

On the 1st of May 2017, the TGA issued a Medical Devices Safety Update on the use of Quaternary Ammonium Compound (QAC) based disinfectants on plastic surfaces within the healthcare environment (<http://www.tga.gov.au/publication-issue/medical-devices-safety-update-volume-5-number-3-may-2017#a2>).

A case reported to the TGA described discovery of dried material within the case and internal components, of infusion pumps. Cleaning procedures were investigated and found the products used to clean the pumps contained benzalkonium chloride, a QAC.

Reactivity of Quaternary Ammonium Compounds

QACs were identified as the key component of disinfectants used on items that were showing signs of material incompatibility. Despite the TGA's conclusions that the QAC, benzalkonium chloride, was the causative agent, there was no evidence to support its causative role in the damage seen.

QACs are a popular choice for healthcare disinfectants because of their ability to also act as detergents; this allows manufacturers to formulate products that disinfect and clean in one step – vital for improving staff compliance and ensuring Infection Prevention and Control (IPC) policies are carried out. They have been shown to be relatively unreactive and have good surface compatibility compared with other disinfectants³.

Benzalkonium chloride is commonly used at 0.5% in disinfectants, considered to be safe at concentrations less than 5% by the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) and is used globally as a surfactant/disinfectant. Despite its global use, reports of incompatibility seem to be primarily limited to Australia. This suggests that the material incompatibility observed in the infusion pumps is unlikely to be due to benzalkonium chloride.



The Role of Amines

A material incompatibility test, carried out by ExcelPlas on failed polycarbonate plug sockets, supports the hypothesis that QACs are not the cause of the damage. Data identified the causative agents as three amines deposited by disinfectants on the surface of the plug sockets.

Polycarbonates are easily damaged by amines – this process is so effective that it has been investigated as a potential method for recycling plastics^{4,5}. This issue is not limited to polycarbonate: amines have been found to cause chemical weakening of PET, PVC and rubber⁶.

Amines are hydrocarbon derivatives of ammonia and are sub-classified as primary, secondary and tertiary based on the degree of hydrocarbon substitution. It is this substitution that reacts with plastic surfaces to cause damage.

QACs are amines with four hydrocarbon substituents, are positively charged and exist as 'permanent cations'. This makes QACs morphologically and functionally distinct from primary, secondary and tertiary amines. The reactivity of amines depends on the presence of a free electron pair on the nitrogen; QACs do not have this and therefore do not undergo chemical reactions in the same way.

There is a vast amount of supporting evidence for the wide use of QACs as disinfectants. Incompatibility is unlikely to be caused by QACs but by the reactions that occur with primary, secondary and tertiary amines. The most likely source of amines in a hospital environment is, not from use of QACs but, from chlorine-based disinfectants; reactions between chlorine-based disinfectants and organic matter produce, amongst other things, chloramines⁷. These are highly reactive amines which can be responsible for chemical attack of plastic surfaces.

Compatibility Data

As a disinfectant manufacturer that places great importance on scientific process, GAMA Healthcare has more equipment compatibility data than any other manufacturer. Surface compatibility is a key priority; we work closely with healthcare equipment manufacturers to ensure our products are compatible.

When damaged polycarbonate plug sockets were tested by ExcelPlas, they found that the causative agents were amines. Nuclear Magnetic Resonance (NMR) analysis of Clinell Universal Wipes demonstrated no presence of amines in their eluate. The plug socket manufacturer stated that the polycarbonate can withstand 2% peracetic acid and 30% hydrogen peroxide. Clinell Sporidical Wipes generate considerably more dilute concentrations of these (0.2%-0.3% and 0.6%, respectively). Evidence does not support the hypothesis that Clinell Universal and Sporidical are the causative agents in this case.



How does this impact compatibility?

GAMA supports the TGA in raising awareness of the issue of incompatibility and requesting review of decontamination processes to ensure all products used to clean and decontaminate items in healthcare are compatible with, and used in accordance with, manufacturers' instructions. Caution should be taken in targeting the disinfection process as a predominant issue rather than the need to use compatible products in an approved manner.

Evidence to support these conclusions is vital if they are to justify change in IPC policies towards sub-optimal techniques. It is essential that healthcare equipment is constructed from materials proven robust enough to tolerate regular disinfection. The responsibility lies with both the disinfectant manufacturer and the healthcare equipment/product manufacturer collaborate to ensure compatibility. Selection of wipes is just as important as the healthcare equipment that is chosen. Infection prevention efforts may be compromised if both are not considered in conjunction.

The Medical Device Directive and the Therapeutic Goods Administration (TGA) requirements stipulate that the onus is on the equipment manufacturer to provide a validated cleaning/disinfection program for their reusable surface. Some manufacturers are addressing these issues, however, compatibility data remains lacking. Further studies must be carried out to develop clear standards of material selection and disinfectant formulation.

The best way to prevent material incompatibility is to have a systematic approach to equipment procurement. GAMA has put together a checklist of questions (<http://clinell.com/equipment-manufacturer-checklist>) to discuss with manufacturers to ensure they have provided adequate decontamination instructions. These are important questions for a manufacturer to answer: evidence-based infection prevention practices are vital to ensure patient safety. Environmental cleaning practice should not be compromised because equipment manufacturers have failed to perform compatibility testing.

GAMA Healthcare collaborates with manufacturers of healthcare equipment to test compatibility, produce decontamination procedures, and inform polymer choice for new products; you can find a list of equipment for which GAMA products are approved for use (http://clinell.com/wp-content/uploads/2017/08/Clinell_JBN17415_Aproved_Equipment_DOC34_28-06-17_issue11.pdf).

References

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