Advisory Statement A18/06

Requirement for High Level Disinfection of Ultrasound Transducers

Practices should note that TGO54 is no longer in force. The Therapeutic Goods Administration has confirmed that the relevant sections of the Guidelines for the Evaluation of Disinfectants (the TGA Guidelines) are considered equivalent to TGO54 for the purposes of informing practices about the requirements for high level disinfection of semi-critical medical devices. Standard 1.6 of the DIAS Standards was updated from 1 April 2020 to reflect this change.

This Advisory Statement should be read in conjunction with the TGA Guidelines, Advisory Statement A19/02 and the DIAS Standards and User Guide.

Purpose

To remind practices that in accordance with the Diagnostic Imaging Accreditation Scheme (DIAS) requirements of Standard 1.6, Healthcare Associated Infection, ultrasound transducers which come in contact with broken skin, mucous membranes, blood or bodily fluids must undergo high-level disinfection using an instrument grade disinfection method approved by the Therapeutic Goods Administration (TGA), in accordance with the manufacturer's instructions for use.

This Advisory Statement should be read in conjunction with the requirements of Advisory Statement A19/02 and DIAS Standard 1.6 in its entirety.

Issue

Each ultrasound procedure involves contact between the ultrasound transducer and the patient's skin, mucous membranes, or sterile tissues. Many potentially infectious agents may be transmitted by improperly maintained, cleaned and disinfected ultrasound equipment, including transducers. Failing to meet minimum infection control standards, including the proper cleaning and reprocessing of ultrasound equipment and transducers, increases the risk of harming human health by transmitting harmful pathogens.

Effective infection prevention and control is central to providing safe, high quality health care.

Requirements

Prior to 1 April 2020, Standard 1.6 required a practice providing ultrasound services to have a documented infection control policy setting out the requirements for disinfecting ultrasound transducers in accordance with the requirements of either the Therapeutic Goods Order No.54 – Standard for Disinfectants and Sterilants (TGO54) or its equivalent (from 1 April 2019, the TGA Guidelines). Standard 1.6 now requires that where ultrasound services are being provided, the practice has a documented policy for reprocessing ultrasound transducers that is consistent with national standards and guidelines relating to disinfection.

All semi-critical medical devices such as ultrasound transducers which come in contact with broken skin, mucous membranes, blood or bodily fluids, must be reprocessed by cleaning, followed by high-level disinfection using an instrument grade disinfection method approved by the TGA. High level disinfection methods may include:

- liquid, high-level instrument grade chemical disinfectants
- automated, high-level disinfection systems either chemical or light-based
- high-level instrument grade disinfectant wipes.

Approved high-level disinfection methods are listed on the Australian Register of Therapeutic Goods (ARTG). Care should be taken to ensure that the method selected is compatible with the ultrasound equipment being processed.

In relation to ultrasound equipment, the requirements of Standard 1.6, will not be met if a practice using a high-level disinfection method in a way which is not in accordance with the manufacturer's instructions, or is using a disinfection method which cannot provide high-level disinfection. The following do not provide high-level disinfection:

- alcohol wipes
- anti-bacterial tablets, solutions or units specific to infant feeding items
- stain removing powders or solutions.

Under the DIAS, the use of disinfection methods which do not provide high-level disinfection may be grounds for refusal of accreditation, or conditional accreditation, on public health and safety grounds.

In addition to cleaning and disinfection requirements, there are other measures for reducing the incidence and risk of infection, and preventing the transmission of infectious agents which should be included in a practice's Healthcare Associated Infection Control policy and procedures. In relation to ultrasound transducers, this would include information about how infection control is practiced, for example:

- how and where transducers are stored after cleaning and high-level disinfection
- use and disposal of single-use, high quality transducer covers where transvaginal and transrectal procedures are performed.

For more information

See the Australasian Society for Ultrasound in Medicine's Guidelines for Reprocessing Ultrasound Transducers for guidance on methods of high level disinfection.

Practices should also refer to the DIAS User Guide for Practices Applying for Accreditation for clarifying information about the evidentiary requirements for Standard 1.6, and contact their Accreditor for further information and advice.

Practices should also refer to and consider advice in the DIAS Advisory Statement 17/02 regarding the use of light-based disinfection systems for the purposes of high-level disinfection.

Diagnostic Imaging Accreditation Scheme Advisory Statement A18/06

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Information in this statement applies to	DIAS Accreditors Providers of Medicare-funded ultrasound services
Relevant standard	Standard 1.6, Healthcare Associated Infection
Prepared by	Secretariat, Diagnostic Imaging Accreditation Scheme Advisory Committee
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Links to other statements or advisory documents	User Guide for Practices Applying for Accreditation DIAS Advisory Statement 17/02 regarding the use of light-based disinfection systems for the purposes of high-level disinfection.
Notes (if applicable)	N/A