Notice to CHICA members re: User Alert Article: CJIC Fall 2006

In the Fall 2006 issue of the CJIC an article was published entitled: User Alert: problems with process monitors for extended steam sterilization cycles (lead author Dr Michelle Alfa, pp122-128: http://www.chica.org/Members/pdf/vol21no3.pdf).

This article was written by Dr Alfa on behalf of the CSA, Sterilization Committee of which all the authors are members. This article highlights what is becoming an increasingly difficult problem in Canadian hospitals; monitoring and assessing all medical devices (and their accompanying instrument sets) used in the facility for safety. The article reviews why some equipment, particularly if manufactured in Europe, now has sterilization recommendations that are different from the standard processes used in Canadian facilities. Several issues arise from this discussion:

1. Infection prevention and control (IPC) should be aware of all devices and equipment used in the facility and should work with sterilization services to ensure that correct manufacturer recommended procedures are used.

2. In facilities where this type of oversight has not been in place it may be prudent for IPC to work with central processing to audit the devices and instruments being used in the facility to ensure that they are being processed appropriately.

3. It is recommended that all facilities, groups of facilities or regions have a committee that includes IPC to review any new equipment and instruments prior to approval for use. Risk management and senior management should also be key players in this committee.

4. The committee should review the manufacturers approved processes for sterilization and ensure that the sterilization equipment available in the facility is appropriate for the process recommended. In some regions committees have rejected equipment that cannot be appropriately processed with the sterilization equipment available in the facility or requested the manufacturer to provide in writing alternate recommended processes that can be carried out by the sterilization equipment available.

In addition, CHICA-Canada has identified this as an issue that requires national advocacy on behalf of IPC programs to ensure manufacturers are aware of the difficulties that non-standard sterilization recommendations cause and the need for biological indicators that are appropriate for the longer processes if they are required.

CHICA-Canada sees this issue as a key risk management issue in infection prevention and control and will formally request that the Therapeutic Products Directorate (Medical Devices) at Health Canada make establishing a common standard for Canada a priority. And in addition that they work to ensure:

a) That all devices approved for use, including devices deemed equivalent to an existing marketed medical device, provide the user with instructions regarding the appropriate sterilization cycles that can be used to sterilize the device safely. This includes devices that were marketed prior to the requirement for manufacturers to provide validated sterilization cycles.

b) That the manufacturer's of the chemical and biological indicators provide validated data to confirm that the BI or CI functions can perform for the specified conditions they are intended to monitor, that these conditions are provided in written format for the users to clearly reference and that the indicators meet CSA standards.

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