39 Avoid Reuse of Single-Use Devices

Situation

Single-use medical devices (SUDs) are designed to be discarded after one use and should not be reused under any circumstances. The one-time use of a SUD ensures function and sterility, while preventing cross-contamination and infection. Only SUDs that have gone through appropriate reprocessing, including cleaning, functional testing, repackaging, relabeling, disinfection and sterilization, should ever be reused. However, some healthcare personnel are unaware of, do not understand, or do not adhere to, the guidelines for the appropriate use of SUDs.[1–10]

Inappropriate reuse of SUDs poses a serious health risk to patients, while reuse and reprocessing of SUDs raise legal and ethical questions. The small number of studies that have considered the clinical outcomes associated with the use of reprocessed SUDs are of variable quality and provide insufficient evidence to establish the safety and efficacy of their use. Use of several types of reprocessed SUDs is cost-saving only if it is assumed that there are no adverse effects. However, there is insufficient data to establish the cost-effectiveness of re-using SUDs. Those who fund and use SUDs should consider relevant legal, ethical, and psychosocial issues. In hospital settings in Japan, infection control personnel are employed to conduct surveillance, monitor practices, and provide education and training on appropriate infection control practices. However, specific infection control resources have traditionally been lacking in outpatient settings.[11–16]

Current Policy

In December 2007, the Ministry of Health, Labour and Welfare issued an official notice on the incidence of nosocomial infections related by medical treatment and the importance of a thorough safety management structure.[17] The notice was a follow-up to one issued in 2004, intended to highlight the problem of SUD reuse, and to enhance healthcare facility prevention measures from a medical safety and infection prevention perspective.[18] Since 2001, the Japanese government has directed the drive for the specification of single use in SUD package inserts.

Recommendations

- Enforce compliance with best practice infection control guidelines. National regulations should be developed to ensure that outpatient facilities adhere to standard infection control precautions and aseptic techniques regarding the transmission of infectious disease in healthcare settings.
- Increase oversight of healthcare facilities to ensure implementation of best practices. National standards for oversight should be developed and enforced to enhance inspection and regulation of healthcare facilities.
- Enhance education and training of healthcare workers on infection prevention techniques. In order to address the inconsistencies in adherence to infection control guidelines, infection prevention education and training programs should be developed that include the proper use and handling of SUDs and are targeted to healthcare workers in outpatient settings.
- Encourage adoption of technologies to prevent SUD reuse. Efforts should be made to enhance uptake of existing technologies designed to prevent reuse and support development of new technologies to address this problem.
- Conduct outreach efforts to enhance patient awareness of appropriate use of SUDs. Public outreach initiatives should be developed to educate patients about the appropriate use of needles, syringes, and other-use devices.

References

1. Yamaguchi University Medical Association. 2009. The current state of re-sterilization of single-use equipment in the operating room. Yamaguchi Medical Journal 58(5):224 – 225.
2. 2009 – 10. The risk of re-sterilization and the safe use of disposable products. Yamaguchi Medical Journal 58(5):228 – 230.
3. Japanese Society of Medical Instrumentation. 2004. Survey on the use of re-sterilized single-use equipment. The Japanese Journal of Medical Instrumentation 74(6):324 – 331.
4. 2004. The current state of re-sterilization of single-use medical equipment. The Japanese Journal of Medical Instrumentation 74(4):159.
5. Japan Society of Gynecologic and Obstetric Endoscopy and Minimally Invasive Therapy. 2005. Japanese Journal of Gynecologic and Obstetric Endoscopy 21(1):160.
6. Japanese Association for Operative Medicine. 2004. Journal of Japanese Association for Operating Room Technology 25(2):111 – 114.
7. Japanese Society of Medical Instrumentation. 2002. The issue of reusing single-use equipment. The Japanese Journal of Medical Instrumentation 72(4):154.
8. 2003. The Japanese Journal of Medical Instrumentation 73(4):215.
9. Akita Association of Rural Medicine. 2003. Akita Journal of Rural Medicine 48(2):44.
10. Medtronic Japan Co., Ltd. 2010. Risk of use of worn tool bar for craniotomy.
11. Thompson, N.D., Perz, J.F., Moorman, A.C., Holmberg, S.D. 2009. Nonhospital health care-associated hepatitis B and C virus transmission: United States, 1998 – 2008. Annals of Internal Medicine 150:33 – 39. www.annals.org.
12. U.S. Food and Drug Administration, Center for Devices and Radiological Health. 2000. Guidance for industry and for FDA staff: Enforcement priorities for single-use devices reprocessed by third parties and hospitals. Appendix B: Definition of terms. Rockville, MD: U.S. Food and Drug Administration. www.fda.gov/cdrh/reprocessing/1168.html#_Toc492780057.
13. Miller, M.A., et al. 2001. Canada communicable disease report 27(23):193 – 9.
14. Canadian Healthcare Association. 1996. The reuse of single-use medical devices: Guidelines for healthcare facilities. Ottawa: CHA Press.
15. Ontario Hospital Association. 2004. Executive summary. Reuse of single-use medical devices (Jan 12). www.oha.com/oha/reports.nsf/($Att)/pspr5w8qex/$FILE/ReuseofSingleUse_Medical_Devices_Executive_Summary.pdf.
16. Day, P. 2004. What is the evidence on the safety and effectiveness of the reuse of medical devices labeled as single use only? NZHTA Tech Brief Series 3(2). Christchurch, N.Z.: New Zealand Health Technology Assessment. http://nzhta.chmeds.ac.nz/publications/medical_devices.pdf.
17. Ministry of Health, Labour and Welfare. 2007. Iseishihatsu #1228001 (December 28).
18. 2004. Iseishihatsu #0209003 (February 9).