Bulletin of
Health Policy and Law

Re-used Medical Devices in the Era of Rising Healthcare Costs, Patient Centered Care, and Going Green

Sarah E. Jordan

Abstract: *As healthcare costs continue to rise, there is an increased likelihood that healthcare providers will be inclined to reuse medical devices both as a cost saving and eco-friendly measure. Proper guidance in this arena has become a forefront concern of the Food & Drug Administration (FDA), especially in light of recent reports on hospital-acquired infections.*

Keywords: medical equipment; FDA regulation; reusable equipment; patient safety

Introduction

Medical waste disposal and the purchase of new medical devices can cost healthcare providers over five million dollars annually.[1] In efforts to reduce these costs, healthcare providers have been reusing medical devices for over two decades.[2] With domestic healthcare costs expected to rise to $1.8 trillion over the next decade, healthcare providers are likely to continue cost-effective business practices like reusing medical devices.[3] However, while appropriately reprocessed medical devices can help save money, they can also result in financial losses as well as loss of patient trust when insufficiently cleaned.[4]

Issue: Reprocessed Medical Devices and the Increased Risk of Hospital Acquired Infection

A device is deemed a single use device (SUD) when it "is intended for one use or on a single patient during a single procedure."[5] "A reprocessed SUD is an original device that has been previously used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient."[6] There are three main risk classifications for reprocessed, single use devices: critical (e.g., electrode recording catheter)[7], semicritical (e.g., orthodontic appliances)[8], and noncritical (e.g., blood-pressure cuff).[9] Each instrument is categorized by its intended use, and the type of contact it will have with the patient.

Recently, technological advancements in the medical field have allowed device manufacturers to produce many state of the art, life saving instruments, many of which fall into the categories of critical and semicritical reprocessed SUDs. As these new, life-saving devices enter hospitals, their potential to cause life-threatening infections must be considered, as they can harbor human tissue and debris.[10] Most alarming, perhaps, are the results gleaned from recent research by a risk management clinical engineer at the University of Michigan Health System, who discovered that, "even when technicians followed cleaning instructions, often times the instruments still contain debris."[11] Furthermore, "[i]n a study by CDC and CMS conducted in three states, more than one in four (28 percent) ambulatory surgery centers had infection control deficiencies associated with the device reprocessing."[12] In view of these statistics, the FDA and the Association for the Advancement of Medical Instrumentation (AAMI) members understand there is a need for new cleaning techniques, sterilization procedures, and policies guiding the reprocessing process.[13] With the potential risk of infection arising from using reprocessed medical devices, reprocessing groups like the Association of Medical Device Reprocessors (AMDR) have advocated that patients should go through the informed consent process.[14] With informed consent, patients would know: (1) whether a single-use device will be used during a particular procedure; and (2) "what steps have been taken to ensure [the device] carries no additional risk."[15] Commentators are also arguing for heightened transparency for processed devices, including incident reporting. Currently, "if a dirty medical device finds its

way into an OR [operating room], the FDA does not require hospitals to report it."[16] Critics believe incidents of hospital-acquired infections arising from reused medical devices should be reported.[17]

Because hospitals and healthcare providers are saving money by using reprocessed medical devices, questions also arise as to whether the patient should be reimbursed. For example, in 2010, reprocessing programs resulted in hospitals saving hundreds of millions of dollars.[18] It has not been determined whether this savings should translate into less expensive medical procedures, and thus result in direct patient savings. It is clear, however, that this hundreds of millions of dollars in savings could potentially be reinvested in patient-oriented quality, such as hiring more nurses and purchasing much needed equipment.[19]

Conclusion

Reprocessed medical devices have tremendous potential for savings and can be environmentally friendly. However, patient consent, clinical and technical concerns must be addressed so that these devices are appropriately integrated into the healthcare delivery system.

Competing Interests: None reported

Acknowledgments: None reported

Author(s)

Sarah E. Jordan is a J.D. candidate at California Western School of Law and Executive Lead Articles Editor, California Western International Law Journal. She received her B.A. Psychology and Spanish from Bates College.

References (Bluebook)

[1] *See Trash Talk: Kaiser Permanente Sets Ambitious Target to Reduce Waste*, Kaiser Permanente News Center (Aug. 17, 2011), http://xnet.kp.org/newscenter/aboutkp/green/stories/2011/081711wastereduction.html

[2] *See* Laura Landro, *Hospitals Reuse Medical Devices to Lower Costs*, Wall St. J. (Mar. 19, 2008), http://online.wsj.com/article/SB120588469924246975.html.

[3] *CBO: Federal Health Spending To Double Over The Next Decade*, Kaiser Health News (Feb. 1, 2012), http://www.kaiserhealthnews.org/Daily-Reports/2012/February/01/cbo-budget-report.aspx.

[4] *See* Joe Eaton, *Filthy Surgical Instruments: The Hidden Threat in America's Operating Rooms*, iWatch News (Feb. 22, 2012), http://www.iwatchnews.org/2012/02/22/8207/filthy-surgical-instruments-hidden-threat-americas-operating-rooms (last visited Mar. 3, 2012)); *TODAY Investigates: Dirty Surgical Instruments a Problem in the OR*, MSNBC: Today Show (Feb. 22, 2012) [hereinafter *TODAY Investigates*].

[5] Federal Drug Administration, Medical Devices: Definitions, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121090.htm (last updated June 18, 2009).

[6] *Id.*

[7] *See* Department of Health and Human Services (Food and Drug Administration), Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data, 68 Fed. Reg. 23139, Attachment 1 (Apr. 30, 2003) (effective Apr. 30, 2003)

[8] Department of Health and Human Services (Notices), Medical Devices; Semicritical Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data, 69 Fed. Reg. 19433, 19434 (Apr. 13, 2004) (effective Apr. 13, 2004).

[9] Department of Health and Human Services (Food and Drug Administration), Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data, 68 Fed. Reg. 38071, Attachment 1 (June 26, 2003).

[10] Eaton, *supra* note 4.

[11] *TODAY Investigates*, *supra* note 4, at 3:10-4:00.

[12] Assoc. for the Advancement of Med. Instrumentation (AAMI), Reprocessing (2011 Summit): Priority Issues from the AAMI/FDA Med. Device Reprocessing Summit 8 (2011), http://www.aami.org/reprocessing/Materials/PDF/2011_Reprocessing_Summit_publication.pdf [hereinafter AAMI Med. Device Reprocessing Summit].

[13] *See id.* at 21.

[14] Laura Landro, *supra* note 2.

[15] *Id.*

[16] *TODAY Investigates*, *supra* note 4, at 4:19-4:27.

[17] *See id.*

[18] Lars Thording, *Anti-reprocessing Tactics are Anti-hospital Tactics*, DOTmed Business News (May 2011), http://www.dotmed.com/news/story/15844.

[19] *Id.*

e-ISSN: 2168-6513