

Commentary: **A Call to Go Green in Health Care by Reprocessing Medical Equipment**

Gifty Kwakye, MPH, Peter J. Pronovost, MD, PhD, and Martin A. Makary, MD, MPH

Abstract

Health care is one of the largest contributors to waste production in the United States. Given increased awareness of the environmental and financial costs associated with waste disposal and its public health impact, many hospitals are adopting environmentally friendly

practices that reduce waste production and offer equally effective, yet less expensive alternatives. Reprocessing of medical equipment is one such practice that has gained popularity in recent years and has led to major cost savings across several medical disciplines. In this

commentary, we seek to take a closer look at the practice of reprocessing, explore the evidence surrounding its safety, and suggest implications of reprocessing for medical centers.

Acad Med. 2010; 85:398–400.

Bipartisan policy leaders have proposed the adoption of “green” energy and technology as one solution to the widespread economic crisis. Going green on a national level has been projected both to reduce long-term federal spending and to support environmental goals of sustainability. Although many health care providers have been strong proponents for environmentally conscious practices, it is estimated that American health care facilities continue to dispose of over four billion pounds of waste annually in landfills and commercial incinerators, making the health industry the second-largest contributor to landfills after the food industry.¹ Medical schools and teaching hospitals, which make up approximately 22% of U.S. hospitals, also contribute their fair share to health care waste.

One relatively new green practice receiving much attention is the

reprocessing of medical equipment.² Already, more than 25% of U.S. hospitals, including our institution, are using reprocessing as a means of decreasing the tons of disposable waste generated annually.³ We have found it to be a commonsense strategy that uses detailed quality-control standards to recalibrate, clean, sterilize, and remanufacture medical equipment. The result has been a significant waste reduction and cost savings. However, uptake of such green practices by hospitals has continued to be slow because of a misunderstanding of the process and concerns about patient safety. In this commentary, we attempt to address these barriers by explaining what reprocessing is, exploring its history and economic benefits, and reviewing the evidence regarding its safety. Finally, we look at the implications of this green process on academic medical centers (AMCs).

As in all activities, incentives—both economic and noneconomic—drive behavior. Before the introduction of SUDs, most medical devices were manufactured for multiple uses and were reused after cleaning and sterilization by locally trained hospital staff. With increasing concerns regarding safety and rising costs of sterilizing multiple-use devices, health care migrated to SUDs. But as these also became increasingly sophisticated, their costs drove health care organizations to explore other options such as reprocessing which was conducted and monitored by hospitals. However, because of staffing shortages and stricter FDA regulations, there has been a major shift from in-house reprocessing to use of third-party reprocessing companies. These private companies now reprocess more than 100 types of SUDs, including those from our institution and other major hospitals.

What Not to Waste

Three categories of devices currently lend themselves to reprocessing. Class I devices have a relatively low associated risk to patients and include elastic bandages, pressure infuser bags, tourniquet cuffs, and general-use surgical scissors. These are exempt from premarket submission requirements. Approximately 65% to 75% of reprocessed SUDs fall into Class II (medium risk) which requires submission of a premarket notification report providing evidence of equivalence to devices already on the market in terms of safety, effectiveness, and intended use. Class II devices include pulse oximeter sensors, ultrasound catheters, drills,

Ms. Kwakye is a medical student in her final year at Yale University School of Medicine, New Haven, Connecticut.

Dr. Pronovost is professor, Anesthesiology and Critical Care Medicine, Surgery, and Health Policy and Management, and director, Johns Hopkins Quality and Safety Research Group, Johns Hopkins University School of Medicine and Bloomberg School of Public Health, Baltimore, Maryland.

Dr. Makary is Mark Ravitch Chair of Gastrointestinal Surgery and director, Johns Hopkins Center for Green Health, Department of Surgery, Johns Hopkins School of Medicine and Department of Health Policy and Management, Bloomberg School of Public Health, Baltimore, Maryland.

Correspondence should be addressed to Dr. Makary, Johns Hopkins University School of Medicine, CRB II, Ste. 507, 1550 Orleans St., Baltimore, MD 21231; telephone: (410) 502-6845; fax: (410) 502-7050; e-mail: mmakary1@jhmi.edu.

What Is Reprocessing?

The American Society for Healthcare Central Service Professionals describes reprocessing as any process which renders a used, reusable, or single-use device (SUD) to be patient-ready or which allows an unused product that has been opened to be made patient-ready.⁴ According to the U.S. Food and Drug Administration (FDA), a SUD is any device intended for one use or on a single patient, whereas a reprocessed SUD is an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of additional use on a patient.⁵

compression sleeves, and most laparoscopic equipment. The last group, Class III (high risk) devices, requires valid scientific data proving safety and effectiveness, in addition to a satisfactory inspection of the reprocessing facility in order to obtain FDA premarket approval. Devices that fall into this category are balloon angioplasty catheters, percutaneous tissue ablation electrodes, and implanted infusion pumps. Given the high patient risk associated with Class III devices and the strenuous approval process, most health care organizations refrain from reprocessing these items. FDA's postmarket activities involve inspection of reprocessing establishments and reviewing device safety reports, including reports of adverse events. (A complete listing of reprocessed devices is available on the FDA Web site at <http://www.fda.gov/CDRH/reprocessing/510ksearch.html>.)

Global and Local Savings

In 2002, approximately 25% of U.S. hospitals used at least one type of reprocessed SUD.³ Larger hospitals have been more likely to reprocess equipment, with 45% of large hospitals (>250 beds) participating compared with only 13.3% of small hospitals (<50 beds).³ This disparity, which has been increasing during the past five years, is likely due to a parallel trend toward heightened awareness at universities and teaching hospitals regarding the harmful effects of medical waste disposal in landfills. The resource constraints of these small hospitals may be an additional factor. However, we expect that the number of institutions engaging in reprocessing activities will continue to increase as awareness of the environmental impact of traditional waste disposal techniques spreads.

In addition to the environmental concerns, many hospitals have been struck hard by the current economic crises, with 2008–2009 profit margins at an all-time low. Given these financial concerns, hospitals are increasingly attracted to reprocessing because of its associated 50% reduction of medical device costs compared with purchasing new equipment. In 2008 alone, there was a 20% increase in hospital utilization of reprocessing services offered by one leading reprocessing service, and associated cost savings of \$138,142,000

nationwide.⁶ This represented 4,300,000 pounds (2,150 tons) of medical waste diverted from local landfills.⁶ During the last 20 years of operation, this reprocessor has enabled \$1 billion in savings in supply costs and eliminated 24 million pounds of waste for its 1,700-member health care facilities.⁶

Cost savings differ from one institution to the next depending on types and quantity of devices reprocessed. Across the board, however, hospitals are observing significant savings which are being channeled into badly needed medical infrastructure or services. For instance, Banner Health in Phoenix also reported a total savings of \$1,494,050 across 12 months from reprocessing operating room devices, compression sleeves, catheters, open but unused devices, and pulse oximeters.¹ This should be of particular interest to teaching hospitals, which provide over 40% of charity care in the United States and can divert the net savings from reprocessing to cover costs incurred from providing this unpaid service. Savings could also be used to fund needed research and employee-initiated projects.

Patient Safety

As mentioned earlier, one barrier to the widespread adoption of reprocessing is its potential impact on patient safety. Safety concerns include the possible malfunction of devices, the risk of infectious diseases, and the ethical dilemma about reprocessing presents given the absence of patient consent to use of such devices as part of treatment. Many physicians and politicians have lobbied for legislation requiring written patient consent, documentation of all reprocessed SUDs used during treatment, and stricter systems of tracking SUD failures and injuries, while holding reprocessors fully liable for any adverse events.

The government has responded to these concerns by conducting several investigations and hearings about the reprocessing of SUDs and has introduced stricter regulations at all levels of production. Most notably, the Medical Device User Fee and Modernization Act of 2002 was enacted, requiring that all reprocessed SUDs be labeled and have the identification of the reprocessor. MDUMFA also created more stringent FDA oversight of reprocessed SUDs than

had been present in the past. In January 2008, the U.S. Government Accountability Office (GAO) released a report entitled *Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk*.⁷ In this report, the GAO outlined steps taken by the FDA since 2000 to improve its supervision and regulation of reprocessing, including additional requirements for pre- and postmarket approval and easier and more detailed adverse-effect-reporting mechanisms.⁷ More important, GAO concluded that although available FDA data fail to allow for rigorous in-depth comparisons, reprocessed SUDs do not present an increased health risk when compared with new, nonreprocessed devices.⁷ Of the 434 adverse events reported to the FDA between 2003 and 2006 in which reprocessed SUDs were identified, only 65 actually did involve a reprocessed device, and all adverse events were similar to those reported for new devices.⁷

Implications for AMCs

U.S. medical schools and teaching hospitals have become the center for cutting-edge research, technology development, and highly skilled health professional training. They have spearheaded patient advocacy and safety issues leading to significant changes in health care delivery today. These efforts have also been channeled into promoting green health care practices such as recycling, mercury elimination, and energy conservation in an attempt not only to protect our environment but also to join public health efforts in preventive care.² Today, because of these initiatives, almost all AMCs have extensive recycling projects which have trickled down into the communities they serve. Reprocessing not only provides another arena for promoting green practices but also offers AMCs a chance to proactively reduce the volume of waste stream by safely reusing sterilized, repackaged devices that previously would have been discarded after a single use.

We have discussed both the environmental benefits and cost savings associated with this practice and highlighted how savings could be channeled into other avenues. In addition to this, the relatively new status of reprocessing as a green health care practice makes it an interesting and

needed subject for research. Faculty could create research projects for medical students and resident staff that revolve around issues of acceptance, use, medical device errors, cost-effectiveness, and medical-legal issues that extend over a period of time. Such research will be helpful in augmenting the existing limited literature and will help shape future health care practices especially in the fields of surgery, obstetrics–gynecology, emergency medicine, intensive care, and internal medicine, which all rely significantly on SUDs.

Centers interested in reprocessing should consider internal education of employees and students before initiation to maximize use and benefits. We have found that U.S. reprocessors have a strong environmental mission and operate transparently. They offer random factory site visits, conduct exhaustive testing of reprocessed devices, are registered with the FDA, and have adequate liability insurance coverage. It is important that similar high standards of service and production are upheld by any potential reprocessing organization that a hospital is interested in using. Though no regulatory oversight is perfect, our experience is that the reprocessing of SUDs currently has strong oversight to

help ensure high quality standards and patient safety.

Conclusion

Health care can contribute to creating a livable planet by reducing the substantial amount of medical waste it produces. Reprocessing is one strategy to accomplish this. The practice has a reliable safety record of excellence identical to that of new equipment, while being friendlier to the environment. Reprocessing offers health care institutions a solution to reduce waste and to reduce costs; as such, it should be explored.

Acknowledgments: The authors wish to thank Hugh Waters (Johns Hopkins Center for Green Healthcare) and Gary Cohen (Healthcare Without Harm) for their guidance and support of this research.

Funding/Support: Funding was provided by an unrestricted research gift from Mr. and Mrs. Chad and Nissa Richison.

Other disclosures: None.

Ethical approval: Not applicable.

References

1 Diconsiglio J. Reprocessing SUDs reduces waste, costs. *Mater Manag Health Care*. 2008; 17:40–42.

2 Kwakye G, Brat G, Makary M. Green practices for surgical healthcare. *Arch Surg*. In press.

3 United States Department of Health and Human Services. Food and Drug Administration. Center for Devices and Radiological Health. Executive Summary: Survey on the Reuse and Reprocessing of Single-Use Devices (SUDs) in U.S. Hospitals. Available at: <http://www.fda.gov/cdrh/reprocessing/survey-execsum.html>. Accessed January 14, 2009.

4 Selvey D. Medical device reprocessing: Is it good for your organization? *Infect Control Today*. January 1, 2001. Available at: <http://www.infectioncontrolday.com/articles/111feat1.html>. Accessed January 12, 2009.

5 United States Department of Health and Human Services. Food and Drug Administration. Center for Devices and Radiological Health. Reprocessing of Single Used Devices: Definitions. Available at: <http://www.fda.gov/Cdrh/reprocessing/definitions.html>. Accessed January 13, 2009.

6 Ascent Healthcare Solutions. Hospitals benefit from sustainability initiatives with more than \$138 million in savings in 2008 [press release]. January 12, 2009. Available at: http://www.ascenths.com/docs/press/2008_year-end_011209.pdf. Accessed January 14, 2009.

7 United States Government Accountability Office. Report to the Committee on Oversight and Government Reform, House of Representatives. Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk. Washington, DC: United States Government Accountability Office. January 31, 2008.

A Call to Go Green in Health Care by Reprocessing Medical Equipment
Academic Medicine, Vol. 85 No. 3/ March 2010

About the Authors:

Martin A. Makary M.D., M.P.H.

Dr. Makary is the Mark Ravitch Chair of Gastrointestinal Surgery and Director of the Johns Hopkins Center for Surgical Outcomes Research. He specializes in advanced laparoscopy, pancreas surgery, gastro-intestinal tumors, and special issues of elderly patients.

Dr. Makary is an active surgeon and researcher, serving jointly on the faculty of the Johns Hopkins School of Medicine and School of Public Health. Dr. Makary serves in leadership roles for the United Nations World Health Organization (WHO), and the International Union of Risk Management. He is the author of several books on public health and surgery, patient safety, quality of care, and health policy.

His current research interests focus on the delivery of quality care, the science of medical errors and patient safety, international health, and health policy. He has several ongoing studies including the clinical and public health implications new technologies in surgery. Dr. Makary also serves as Co-Director of the Johns Hopkins Quality and Safety Research Group at Fells Point.

Peter J. Pronovost MD, PhD

Dr. Pronovost is Medical Director for the Center for Innovation in Quality Patient Care, which supports quality and safety efforts at the Johns Hopkins Hospitals. In 2003 Dr. Pronovost established the Quality and Safety Research Group to advance the science of safety. Dr. Pronovost and his research team are dedicated to improving healthcare through methods that are scientifically rigorous, but feasible at the bedside.

Dr. Pronovost chairs the JCAHO ICU Advisory Panel for Quality Measures, the ICU Physician Staffing Committee for the Leapfrog Group, and serves on the Quality Measures Work Group of the National Quality Forum. He also serves in an advisory capacity to the World Health Organizations World Alliance for Patient Safety, and is leading WHO efforts to improve patient safety measurement, evaluation, and leadership capacity globally.

Dr. Pronovost was Chosen by Time Magazine as one of their 100 most influential people in the World for 2008.

Source: Johns Hopkins website: www.hopkinsmedicine.org