

# Reuse of catheters and devices labelled for single use: evidence, recommendations and oversight

Thomas C Crawford, Kim A Eagle

## INTRODUCTION

Cardiovascular disease has become the most common cause of death and morbidity throughout the world, not just the affluent societies. In 2015, there were 422 million prevalent cases of cardiovascular disease worldwide, and it accounted for an estimated 30% of deaths.<sup>1,2</sup> As most people live in low-income and middle-income countries, the burden of cardiovascular disease is the greatest in resource-poor countries. The cardiovascular epidemic has a direct impact on the health of the patients and also on the welfare of the economies in which those patients live and work. Poverty can be both a contributing cause and a consequence of cardiovascular disease. It is in the context of oppressive burden of healthcare spending that the discussion about reusing catheters and devices should be considered.

## Historical context

In the mid-20th century, most medical devices were made of metal, glass or rubber and were generally reusable. Technological developments in the 1960s and 1970s brought out a wave of new polymers, which could be harnessed and which would eventually transition a multiuse medical industry into a single-use paradigm. Many open surgical procedures were gradually replaced by laparoscopic or endovascular procedures. In the 1980s and 1990s, new concerns regarding transmission of bloodborne pathogens such as hepatitis B and C, and HIV coincided with the explosive development of new technologies. Advances in manufacturing techniques, and expectation of improved product performance and predictability deepened interest in single-use devices (SUDs). The confluence of all these factors led to the evolution and dramatic expansion of the SUD concept. Original equipment manufacturers (OEMs) began to submit applications to the United States

Food and Drug Administration (FDA) asking for approval of their products as SUDs. In some instances, the manufacturers changed the labelling from multiuse to single use only without making significant structural changes to the devices.<sup>3</sup> The designation of a product as an SUD is in most cases arbitrary and made by the manufacturer, not the FDA.

Rapidly escalating costs of healthcare in the USA, as well as the growth of medical waste of disposable devices, lead to an interest among hospitals and physicians in reprocessing medical equipment that had been approved for single use. Hospitals recognised that the 'single-use' label was often motivated by economic objectives, rather than patient safety concerns, and they began the reprocessing of select SUDs under the oversight of physicians, nurses, infection control specialists, risk managers and hospital lawyers.<sup>4</sup> In order to assure standardised and safe reprocessing, the FDA issued *Compliance Policy Guide* in 2000, which effectively began FDA oversight over reprocessing SUDs in the USA.<sup>5</sup> The cost of quality assurance, complexity of the devices and concerns about the liability have led to the outsourcing of SUD reprocessing to third-party reproprocessors.

According to the *Compliance Policy Guide*, any reproprocessor, whether it be a hospital or a third party, is treated as the OEM in terms of assuring that the product adheres to initial specifications. Reprocessors are required to file premarket submissions to the FDA, which include validation data regarding cleaning, sterilisation and functional performance. They must show that the reprocessed device will remain 'substantially equivalent' to the original device. With the passage and enactment of the Medical Device User Fee and Modernization Act of 2002, the reprocessing of SUDs became codified and legally supported in USA. In the last 3 years, several national and transnational regulatory agencies began oversight of the reprocessing of SUDs: Canada (2015), Japan (2017) and European Union (2017). WHO issued a position statement recommending regulation of reprocessing in 2016.<sup>6,7</sup>

Despite this changing regulatory environment, in much of the world, particularly in Africa and Asia, reprocessing of SUDs is outside the law.<sup>8</sup> In countries where there is no legal framework on reuse of SUDs, reprocessing occurs in an unregulated manner in hospitals, rather than third-party reproprocessors. Last year in India, the state government of Maharashtra filed complaints against dozens of hospitals for reusing SUDs and charging patients as if the cardiac catheters and guidewires had been new. This unscrupulous practice of a few private hospitals has brought the concept of SUD resterilisation and reuse into focus and criticism. In this article, we argue for creating a legal and regulatory framework to allow the reuse of catheters and other SUDs.

## Appraisal of evidence on SUD reprocessing

There is a fair number of publications suggesting safety and efficacy of interventional angiographic catheters,<sup>9-13</sup> electrophysiology catheters,<sup>14-20</sup> pace-makers<sup>21-26</sup> and implantable cardioverter defibrillators.<sup>27</sup> The literature, however, is of variable methodology and quality. Most of the studies examining the safety and efficacy of the catheters were carried out in the 1980s and 1990s, and some in early 2000s. Because changes in materials likely have an impact on the durability of catheters, one cannot assume that prior safety data are applicable to new catheter designs. Most studies were observational, either prospective or retrospective, included a limited number of catheters and were often survey based. Clinical studies in general do not describe the refurbishing process in much detail. Studies involving patients were usually small and not powered to detect small, but significant increases in risk.

## Angiographic and interventional catheters

Angiographic and interventional catheters pose a reprocessing challenge given the long narrow lumens, which are difficult to inspect internally without destructive tests. The cleaning of angioplasty catheters requires accurate flushing of the guidewire lumen, and the balloon lumen must be suctioned to eliminate the contrast medium before it crystallises. A standard ethylene oxide process is preferred for sterilisation, and its cytotoxic residuals must be reliably eliminated. Angioplasty catheters must be examined for mechanical integrity of the balloon and the whole pressure system. Atherectomy devices are even more complex and may not be suitable for reuse. Deflated balloons generally

Department of Internal Medicine, Division of Cardiovascular Disease, The University of Michigan, Ann Arbor, Michigan, USA

**Correspondence to** Dr Thomas C Crawford, Department of Internal Medicine Division of Cardiovascular Disease, The University of Michigan, Ann Arbor, MI 48109, USA; thomcraw@umich.edu

do not regain the tight shape of new balloons and may carry organic debris detectable by electron spectroscopy. It has been proposed that interventional catheters are not reused more than three times due to potential loss of mechanical integrity and function.<sup>28</sup>

### Electrophysiology (EP) catheters

Feasibility and safety of EP catheter reuse have been repeatedly demonstrated. A survey of 12 medical centres showed that the incidence of bacteremia within 48-hour use of EP catheters was 0.03% for single-use catheters and 0.002% for reused catheters ( $p=NS$ ).<sup>14</sup> In a prospective study, 178 catheters were used 1576 times during 847 electrophysiological studies and all reused catheters were effective for cardiac pacing and recording. Biological indicators demonstrated adequate sterilisation as did cultures.<sup>18</sup> Functionality testing of deflectable catheters demonstrated reliable deflection and torque as well as the electrical integrity for up to five times.<sup>15</sup> Tessarolo *et al* found no variations in radiofrequency ablation efficiency, electrode conductivity or thermometric sensor's precision and accuracy among catheters reprocessed up to 10 times, although catheters became less lubricious after four reprocessing cycles.<sup>29</sup> Changes in the materials' properties resulting in roughness of the surface appears to increase bacterial persistence after five reuses; however, this number should be determined specifically according to reprocessing protocol and device type.<sup>30</sup> Tests of total organic carbon and protein were reduced >99%, below currently accepted standards.<sup>31</sup> A recent study of a five-cycle reprocessing has demonstrated that reprocessed catheters are functionally equivalent to new catheters and that they meet, or exceed, industry standards and regulatory requirements.<sup>20</sup> Gas plasma sterilisation with vaporised hydrogen peroxide has been suggested as being superior for the elimination of pyrogens during EP catheter reprocessing.<sup>32</sup>

### Pacemakers and implantable cardioverter defibrillators (ICDs)

Pacemakers should only be considered for reuse if they have an adequate remaining life. Acceptable remaining battery longevity may depend on the age of the patient receiving the reconditioned device. We reported on the yield of devices with at least 4 years or at least 75% of the original battery remaining among devices reclaimed from the funeral

industry in the USA.<sup>33</sup> Approximately 21% of donated pacemakers and ICDs and 30% of donated biventricular ICDs had an adequate battery life for potential reuse. The yield of acceptable devices harvested during device upgrades was higher at about 50%.<sup>34</sup> There is evidence that sterilisation of pacemakers and ICDs can be achieved.<sup>35</sup> A set of essential algorithms should also be tested to assure proper function. A meta-analysis of 18 studies involving 2270 patients showed no difference in infection rate between new and reused pacemakers, although the rate of device malfunction rate was sixfold greater with reused pacemakers than new ones.<sup>36</sup> Most of the malfunctions were apparent during implantation and were related to the set screws. With the reported malfunction rate of 0.68%, reconditioned pacemakers displayed a high safety profile, which could still be improved after a systematic evaluation of common malfunction causes. With proper testing and validated protocols for sterilisation, packaging and delivery, we believe that apart from battery life, we can achieve similar efficacy and safety metrics as with new devices.

### Creating a framework for the regulatory environment

As shown in the medical literature and the experience in the USA with selected SUDs, reuse of SUDs may, when properly carried out, be safe and provide effective treatment in cardiovascular disease. In order to assure the public that the use is safe, however, the governmental agencies should provide oversight. The reproprocessors should provide sufficient evidence that the SUD maintains mechanical and functional integrity, is sterile and free of endotoxins. Interventional catheters pose some challenges given their complex design. After reprocessing, SUDs should be encased in validated packaging including double sterility pouches and box and labelled as reused with the date of reprocessing and a use by date, and should be stored under appropriate environmental conditions. The reproprocessor should establish a set of validated protocols, which would stipulate the maximum number of times the devices may be reused. The reproprocessor should track the number of times the device is reused. Hospitals or hospital systems could become the reproprocessors; however, it would potentially be more difficult for them to acquire and maintain competency in the world of ever-changing device re-designing. The burden of updating and validating protocols and

regulatory compliance would likely result in outsourcing of this role to

third-party reproprocessors. Oversight of adherence to the reprocessing protocol could be performed by a governmental or an independent organisation of hospitals, if government fails to lead this effort. The reprocessing standards and protocols should be reviewed and endorsed by relevant professional societies in a transparent manner. Responsible reuse would also include mandatory reporting of catheter and device failures. While this complicated system is not the simplest one could design, it is likely that it would withstand constructive criticism of naysayers and the test of time.

### Ethics of reuse

Given the special moral importance of health, meeting health needs at some level is required for a just society. If these essential needs cannot be met due to insufficient resources in the healthcare system, as in purchasing new catheters, pacemakers or ICDs, one should seek another solution which would offer the possibility of equitable healthcare delivery with devices which can reasonably be expected to perform similarly as new devices. If inequalities in access to new devices remain insurmountable due to socioeconomic conditions in the country, safe reuse of medical devices with the goal of improving access of the least advantaged appears to be well justified ethically, as it attempts to create conditions of equality of opportunity, recovery of health and well-being. An argument in favour of reusing medical devices can be made based on the principles of egalitarianism, utilitarianism and justice.<sup>37</sup> In order for the practice of reuse to be justified ethically, it must be transparent, and the benefits of cost savings should be forwarded to the patients. Patients should be able to opt out of reconditioned catheters and implantable devices with proper informed consent.

### CONCLUSION

Improvements in medical science and technological advancements have made it possible to extend longevity and improve the quality of life. This progress comes at a high price and may not be economically sustainable. Many of the available advanced treatments in cardiology are labelled as SUDs, although there is nothing inherently precluding their reconditioning and reuse. It is incumbent on practising physicians and the healthcare regulators to seek solutions to extend the

benefits of these technologies safely to as many patients as possible. This goal may be more achievable with validated reconditioned catheters, pacemakers and ICDs, as part of our armamentarium.

**Contributors** Both coauthors contributed to the manuscript.

**Funding** The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

**Competing interests** None declared.

**Patient consent** Not required.

**Provenance and peer review** Commissioned; internally peer reviewed.

© Author(s) (or their employer(s)) 2018. No commercial re-use. See rights and permissions. Published by BMJ.



**To cite** Crawford TC, Eagle KA. *Heart Asia* 2018;**10**:e011033. doi:10.1136/heartasia-2018-011033



► <https://doi.org/10.1136/heartasia-2018-011034>

*Heart Asia* 2018;**10**:e011033. doi:10.1136/heartasia-2018-011033

## REFERENCES

- World Health Organization. *The global economic burden of non-communicable diseases*. Geneva: World Health Organization.
- Prabhakaran D, Singh K, Roth GA, et al. Cardiovascular diseases in India compared with the United States. *J Am Coll Cardiol* 2018;**72**:79–95.
- Reuse of single-use devices. Hearing before the Subcommittee on Oversight and Investigations of the Committee on Commerce House of Representatives F, 2000. Serial No. 106–89, U.S. Washington: Government Printing Office, 2000.
- Lindsay BD, Kutalek SP, Cannom DS, et al. Reprocessing of electrophysiology catheters: clinical studies, regulations, and recommendations. A report of the NASPE Task Force on reprocessing of electrophysiological catheters. North American Society of Pacing and Electrophysiology. *Pacing Clin Electrophysiol* 2001;**24**(8 Pt 1):1297–305.
- Availability RaRoS-UDRPSaEPFS-UDRbTPaH, A Notice by the Food and Drug Administration on 02/11/2000.
- Association of Medical Device Reprocessors.
- Association of Medical Device Reprocessors. AMDR Summary: International Regulation of "Single-Use" Medical Device Reprocessing.
- Popp W, Rasslan O, Unahalekhaka A, et al. What is the use? An international look at reuse of single-use medical devices. *Int J Hyg Environ Health* 2010;**213**:302–7.
- Browne KF, Maldonado R, Telatnik M, et al. Initial experience with reuse of coronary angioplasty catheters in the United States. *J Am Coll Cardiol* 1997;**30**:1735–40.
- Mak KH, Eisenberg MJ, Plante S, et al. Absence of increased in-hospital complications with reused balloon catheters. *Am J Cardiol* 1996;**78**:717–9.
- Plante S, Strauss BH, Goulet G, et al. Reuse of balloon catheters for coronary angioplasty: a potential cost-saving strategy? *J Am Coll Cardiol* 1994;**24**:1475–81.
- Unverdorben M, Degenhardt R, Erny D, et al. Clinical and angiographic procedural and mid-term outcome with new versus reused balloon catheters in percutaneous coronary interventions. *Indian Heart J* 2005;**57**:114–20.
- Frank U, Herz L, Daschner FD. Infection risk of cardiac catheterization and arterial angiography with single and multiple use disposable catheters. *Clin Cardiol* 1988;**11**:785–7.
- O'Donoghue S, Platia EV. Reuse of pacing catheters: a survey of safety and efficacy. *Pacing Clin Electrophysiol* 1988;**11**:1279–80.
- Avitall B, Khan M, Krum D, et al. Repeated use of ablation catheters: a prospective study. *J Am Coll Cardiol* 1993;**22**:1367–72.
- Ferrell M, Wolf CE, Ellenbogen KA, et al. Ethylene oxide on electrophysiology catheters following resterilization: implications for catheter reuse. *Am J Cardiol* 1997;**80**:1558–61.
- Bathina MN, Mickelsen S, Brooks C, et al. Safety and efficacy of hydrogen peroxide plasma sterilization for repeated use of electrophysiology catheters. *J Am Coll Cardiol* 1998;**32**:1384–8.
- Dunnigan A, Roberts C, McNamara M, et al. Success of re-use of cardiac electrode catheters. *Am J Cardiol* 1987;**60**:807–10.
- Aton EA, Murray P, Fraser V, et al. Safety of reusing cardiac electrophysiology catheters. *Am J Cardiol* 1994;**74**:1173–5.
- Lester BR, Alexander AA, Miller K, et al. Comparison of performance characteristics between new and reprocessed electrophysiology catheters. *J Interv Card Electrophysiol* 2006;**17**:77–83.
- Rosengarten M. Medical devices labelled for single use: the reuse of permanent cardiac pacemakers. *CMAJ* 1989;**140**:1274–6.
- Rosengarten MD, Portnoy D, Chiu RC, et al. Reuse of permanent cardiac pacemakers. *Can Med Assoc J* 1985;**133**:279–83.
- Rosengarten M, Chiu R, Hoffman R. A prospective trial of new versus refurbished cardiac pacemakers: a Canadian experience. *Can J Cardiol* 1989;**5**:155–60.
- Panji BB, Sarkar CN, Kumar S, et al. Reuse of pacemaker. *Indian Heart J* 1996;**48**:677–80.
- Linde CL, Bocray A, Jonsson H, et al. Re-used pacemakers—as safe as new? A retrospective case-control study. *Eur Heart J* 1998;**19**:154–7.
- Nava S, Morales JL, Márquez MF, et al. Reuse of pacemakers: comparison of short and long-term performance. *Circulation* 2013;**127**:1177–83.
- Pavri BB, Lokhandwala Y, Kulkarni GV, et al. Reuse of explanted, resterilized implantable cardioverter-defibrillators: a cohort study. *Ann Intern Med* 2012;**157**:542–8.
- Kapoor A, Vora A, Nataraj G, et al. Guidance on reuse of cardio-vascular catheters and devices in India: a consensus document. *Indian Heart J* 2017;**69**:357–63.
- Tessarolo FF, Ferrari M, Caola P, et al. Reuse of single use devices for interventional cardiology: a HCTA approach. *IFMBE Proceedings* 2004;**6**.
- Tessarolo FC, Fedel I, Caciagli M. Effects of chlorine-releasing compounds on medical devices decontamination. *J Appl Biomater Biomech* 2004;**2**:219.
- Lester BR, Boser NP, Miller K, et al. Reprocessing and sterilization of single-use electrophysiological catheters: removal of organic carbon and protein surface residues. *J AOAC Int* 2009;**92**:1165–73.
- Tessarolo FC, Nollo G. *Critical issues in reprocessing single-use medical devices for interventional cardiology*. Biomedical Engineering, Trends, Research and Technologies, 2011.
- Baman TS, Crawford T, Sovitch P, et al. Feasibility of postmortem device acquisition for potential reuse in underserved nations. *Heart Rhythm* 2012;**9**:211–4.
- Gakenheimer L, Romero J, Baman TS, et al. Cardiac implantable electronic device reutilization: battery life of explanted devices at a tertiary care center. *Pacing Clin Electrophysiol* 2014;**37**:569–75.
- Crawford TC, Allmendinger C, Snell J, et al. Cleaning and sterilization of used cardiac implantable electronic devices with process validation: the next hurdle in device recycling. *JACC Clin Electrophysiol* 2017;**3**:623–31.
- Baman TS, Meier P, Romero J, et al. Safety of pacemaker reuse: a meta-analysis with implications for underserved nations. *Circ Arrhythm Electrophysiol* 2011;**4**:318–23.
- VanArtsdalen J, Goold SD, Kirkpatrick JN, et al. Pacemaker reuse for patients in resource poor countries: is something always better than nothing? *Prog Cardiovasc Dis* 2012;**55**:300–6.