Reuse of single-use devices: Looking back, looking forward

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ABSTRACT
The reuse of medical devices marked as ‘single use’ by manufacturers has been going on for several decades. The process has been rationalized and legislated in the West as well as in Japan. However, the practice continues in an unregulated manner in India due to a paucity of guidance from the Food and Drug Administration in India. We trace the evolution of reuse policies, look at the prevalent practices in the Indian and international contexts, analyse the available Indian literature and address the ethical and economic implications of reuse. We also suggest some guidelines which may be adopted to formulate policies.


INTRODUCTION
Healthcare in India is prohibitively expensive for a large proportion of the population. In an effort to reduce cost, healthcare providers may resort to practices that may not match international standards and potentially compromise safety. Many hospitals in India have been resterilizing instruments and devices labelled for ‘single use’ by manufacturers. This is especially true of some of the newer devices such as those used in laparoscopic surgery. These procedures involve instruments which are expensive, e.g. harmonic shears, hernia tackers, staplers, etc. Recently, a large hospital in Mumbai decided to discontinue the use of resterilized equipment with the result that the cost of some operative procedures increased substantially. This generated a debate among the staff and stimulated us to look into issues related to sterilization, reprocessing and reuse of single-use devices in India as well as internationally.

LOOKING BACK
The term ‘single use’ on the packaging of medical devices means that the manufacturer intends the device to be used once and then discarded, considers the device unsuitable for use on more than one occasion and has evidence to confirm that reuse would be unsafe.

The practice of reprocessing single-use medical devices (SUDs) for reuse began in the late 1970s. Reprocessing, by definition, is the disassembling, decontamination, cleaning, inspection, testing, packing, relabelling and sterilization of SUD after they have been used on a patient for their intended purpose. This includes SUDs which are opened during cases but not used.

It was around the same time that disposables (mainly plastics) started to gain popularity as products that were consistent in quality, dependably clean and safe. Manufacturers changed labels on certain medical devices from reusable to single use, a shift in labelling that did not require approval from the Food and Drug Administration (FDA). Over a period of time, the terms single use and disposable came to be used interchangeably. Thus, even tongue depressors and adhesive tapes were discarded after one use. The industry aggressively raised concerns regarding the safety and performance of reprocessed instruments labelled as single use by the original manufacturer, including whether the instruments could be adequately cleaned and whether the reprocessed instruments would function as well as new instruments.

Single-use/disposable devices thus became popular in the West where reprocessing instruments was expensive and it was simpler and cheaper to throw away an instrument rather than re-sterilize and use it. This practice got a further boost with the growing problem of HIV infection. As a result, many devices which were initially made of reusable material were now being made of cheap plastic polymers and disposed after one use, to great economic benefit to the manufacturers. Research and development also turned away from reusables to disposables. Soon many hospitals moved to single-use instruments citing fears related to increase in patient infections and the accompanying legal liabilities as justifications for the move.

In June 2000, the United States Government Accountability Office (US GAO, then called the Government Accounting Office) compiled a report entitled Single-use medical devices: Little available evidence of harm from reuse, but oversight warranted. The report revealed that 20% to 30% of hospitals in the USA reused at least one type of SUD. It reported that ‘although [single-use device] reprocessing does pose theoretical health risks, clinical evidence shows that certain devices can be reprocessed safely’. The report also proposed that SUDs be categorized before reprocessing into low-, medium- and high-risk categories depending on the degree of contamination. Thus, devices which breached mucous membranes and sterile vascular systems, e.g. biopsy forceps were considered high risk while those which entered body cavities but did not breach mucous membranes, e.g. laryngoscopes were considered intermediate-risk.

Reuse of SUDs, which was a common practice in many healthcare centres in the USA, decreased from 63% before to 56% after the guidelines were issued. A study by Alfa et al. in 2004...
showed that just 100 items constituting about 2% of all devices labelled as single use were being reprocessed in the USA.6

Since those early days, third-party reprocessing companies have developed detailed guidelines for reprocessing/ remanufacturing, cleaning and sterilizing such instruments. In addition, the US FDA has developed stringent regulations designed to control reprocessing and to assure adequate controlled evaluation and market clearance processes.7,8

Ahuja and Tandon in 2000 did a survey regarding the disinfection of endoscopes and reuse of single-use accessories. Less than 50% of those who were sent a written questionnaire responded and only 38.7% of those who responded carried out disinfection according to specified protocols. Surprisingly, more than 90% of respondents were ready to reuse SUDs, even in developed countries such as Australia.9

The economic recession of 2007–08 forced many large hospitals to turn back to reprocessing as a cost-saving measure. With rising healthcare costs and insurance, companies clamping down on reimbursements, the demand for reuse increased once again. In 2008, the US GAO report said that the available data indicated no additional health risk from reprocessed disposables.10

By the end of 2007, nearly 45% of hospitals in the USA had agreements with third-party reprocessing companies, a number that increased to 70% in 2008 after the economic recession.11 The US FDA currently allows reprocessing of more than 100 different items previously designated as SUDs.3

THE ECONOMIC ARGUMENT

According to the US GAO report, a hospital’s cost for an in-house reprocessed device is less than 10% of a new one and on an average, reprocessed medical devices are 50% cheaper than new devices.5 According to Ascent Healthcare Solutions, a leading reprocessing company in the USA, about US$ 31.5 billion of single-use medical devices are sold annually to US hospitals and surgical centres. John Grotting, Ascent’s chief executive, in an interview with the Wall Street Journal, estimated that about US$ 3.6 billion of SUDs are safe for reprocessing, which could save the US healthcare industry about US$ 1.8 billion a year.12 Of the 14 hospitals that earned Honour Roll status in 2004, a mark of particular distinction from the US News and World Report ratings, 13 used reprocessed devices.13

Most of the catheters used for cardiovascular and nephrology purposes, orthopaedic blades, endoscopic devices, fixation devices, electrophysiology catheters, electro surgical electrodes, endotracheal tubes and ophthalmic knives are now subject to disinfection according to specified protocols. Surprisingly, more than 90% of respondents were ready to reuse SUDs, even in developed countries such as Australia.9

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In May 2010, Practice Greenhealth, a non-profit group in Reston, Virginia, USA, with 1100 hospitals and 80 companies as members, announced an initiative called ‘Greening the operating room (OR)’. This was aimed at reducing operating room waste among other measures to reduce the environmental footprint of healthcare institutions. Some of the sustainable practices suggested in this initiative included recycling of materials used in operations through reprocessing companies that would clean, recalibrate, repackage and resterilize the devices and then sell them back to hospitals and medical suppliers at 40%–69% of the cost of a new device.14

POTENTIAL PITFALLS WITH REPROCESSING

Since the economic recession, developed countries have transformed third-party reprocessing into an important cost-saving sophisticated process. However, in developing countries such as India, China and Brazil the process is prevalent in an unregulated form due to their different economic scenario.15 As reprocessing in developing nations is aimed purely at reducing costs, it could compromise patient safety.

Some risks pertaining to improper reprocessing of medical devices include cross-contamination and hospital-acquired infections, inadequate decontamination and cleaning, non-guaranteed performance, material alterations and residues created from chemical agents during sterilization that could be unsafe.11 A prospective, randomized, single-blinded trial evaluating reprocessed and single-use trocars showed a significant amount of damage along with reduced efficacy of reprocessed instruments.16 Though there was no evidence of bacterial contamination, a radioactive study on the same trocars showed that blood particles still existed in reprocessed instruments. We believe that trocars with a complicated mechanism should not be reused. Metal trocars can be autoclaved and are equally efficacious and should be used instead of disposable trocar-cannulae.

On the other hand, devices such as harmonic shears are far more expensive than trocars, and two studies are available comparing new and reprocessed harmonic shears.17,18 One study showed that a reprocessed harmonic shear works as well as the new one, if proper reprocessing techniques are followed.17 The second study showed a much poorer performance for the reprocessed harmonic shears. However, the second study was sponsored by a company and may have had an inherent bias.18

INFORMED CONSENT

The issue of informed consent from the patients on whom the reprocessed item has to be used has been raised several times. The ethical dimension of reuse of SUDs focuses on the risk of potential complications. While some lobby for patients to provide written informed consent to the use of reprocessed (as opposed to new or single-use) equipment in their care, others argue that since reprocessed devices are as safe as new ones there is no need to disclose that it was reprocessed, and no need to obtain written informed consent from the patients.10,19

Laparoscopic surgery, due to its inherent dependence on instrumentation, is costlier than open surgery but provides lesser pain and faster healing to the patient. Some sophisticated but essential laparoscopic instruments such as the harmonic shear and hernia tacker fall into the category of SUDs as they are constructed of hollow tubes and joints. These instruments breach mucous membranes and are more difficult to clean and sterilize as compared to conventional open surgery instruments.

While reducing costs and providing economical healthcare is also an ethical commitment, it is challenging to explain the pros
and concerns related to sterilization and reprocessing of instruments to patients without scaring them. Maintaining transparency in such situations is difficult but perhaps essential.

Ethical analysis requires a public debate and, in the field of reuse, this discussion has not yet gone beyond healthcare professionals who often take the decision to use reprocessed single-use items without the necessary ethical premises.

INTERNATIONAL SCENARIO BEYOND THE USA

In a national survey on reprocessing and reuse in Canadian acute care hospitals, Polisena et al. reported that larger (>300 beds) and academic hospitals were significantly more likely to reprocess SUDs.4 The survey also discovered that 70% of the hospitals which had ceased to reprocess SUDs had done so between 2002 and 2005.

In Australia too, reuse of SUDs occurs more frequently in larger metropolitan hospitals (in 64% of those with more than 300 beds) than in smaller metropolitan hospitals (in 41% hospitals with fewer than 300 beds) or in private hospitals (32%).20

The National Health Service in the UK does not allow the reuse of devices marked as single use by manufacturers and most European countries have banned the reuse of SUDs.1,2 In the other European Union member states, France has a total ban on reuse of SUDs and classifies reuse as deception of patients, Sweden has a set of essential requirements to be met and patient consent to be received. Only Germany allows refurbishing by third-party companies. The extent of reuse in hospitals is estimated to be 10% in the UK, 30% in Denmark and 100% in Norway.21

Compared to reuse rates in the West, the reprocessing and reuse of SUDs in Japan is still high. Koh and Kawahara conducted two nation-wide surveys in 2000 and 2003 on reuse of SUDs in endoscopic surgeries in Japan and found that although the reuse rate had fallen, it was still at 86.2%.23 They noted that contrary to the West, smaller size and non-public hospitals in Japan were more likely to reuse SUDs rather than university or public hospitals with bed strengths of over 300. This was attributed to stringent regulations for medical insurance in Japan which did not support reimbursement of SUDs and therefore imposed a financial strain on hospitals which followed a single-use policy.

Brazil, a growing third world economy, regularly reuses SUDs. A study by dos Santos et al. in 2008 showed that it is possible to reprocess and redistribute SUDs within the already existing infrastructures using methods recommended by the International Standards Organization (ISO) 14971. This study was an attempt to find a solution to the problem of the growing shortage of SUDs.

THE INDIAN SCENARIO

The hierarchy of medical device regulatory entities in India involves the Ministry of Health and Family Welfare, the Drug Controller General of India (DCGI) and the Central Drugs Standard Control Organisation (CDSCO–Medical Devices Division). In 1998, the Indian government passed the Biomedical Waste Management and Handling Rules, which outlined how hospitals should collect and transport waste, as well as appropriate disposal methods. Despite this legislation, most medical waste in India is dumped in the open and collected with the general waste.25

Before 2005, no regulations existed for medical devices in India. Today there are registration procedures for certain classes of medical devices regulated under the provisions of the Drugs and Cosmetics Rules. Manufacturers of medical devices which require registration can leverage their approvals in the USA, Canada, Europe, Australia or Japan to register their medical devices in India.28

In 1996, the then dean of Seth G.S. Medical College and K.E.M Hospital, Mumbai, temporarily withheld the reuse of devices marked as single use by manufacturers. The reason given was the absence of protection from legal liabilities and litigations for reusing disposable items due to lack of guidelines and norms for sterilization from statutory authorities and policy-makers such as the FDA and Department of Science and Technology (DST). This drew a slew of protests and arguments against the move.27

In 1997, The Cardiological Society of India (CSI) established a committee to collect data and formulate guidelines on reuse of disposables meant for single use in the cardiac catheterization laboratory. The survey included 26 centres which were constituents of the Regional PTCA (percutaneous transluminal coronary angioplasty) Registry of India which functions under the auspices of CSI. Twelve of these centres were from the public sector and 14 from the private sector and all had been practising cardiac catheterization by reusing disposables meant for single use for an average of 9.8–13.4 years. The reuse of disposables was sometimes associated with minor problems such as shivering and pyrogen reactions in 10 (38%) centres. Major complications such as infective endocarditis were extremely rare and reported only by 2 (8%) centres. In 23 of 26 centres, a hospital infection control committee was in existence. For sterilization purposes ethylene oxide, glutaraldehyde and gamma irradiation were used in 24 (90%) centres, 19 (73%) centres and 1 (4%) centre, respectively. In a majority of centres (22/26; 85%) no special consent was obtained from the patients for reuse of disposables. The committee published its report in the Indian Heart Journal in 1997 recommending that the practice of reuse of disposables should be allowed to continue with strict adherence to guidelines for sterilization.28 The report separately enumerated the guidelines for cleaning and sterilizing solid and hollow disposable equipments. It also gave supplementary guidelines for sterilization of balloon catheters and pulse generators.

The first randomized study on the safety and efficacy of reused angioplasty balloon catheters was published by the Department of Cardiology, Chest Diseases Hospital and the Department of Community Medicine, Faculty of Medicine, Kuwait University, Kuwait in the Indian Heart Journal in 2001.29 It compared the clinical and angiographic success of reused versus new coronary angioplasty balloon catheters across 377 procedures. The incidence of first balloon failure in the reused catheter arm (12/178 cases, 7%) was similar to that in the new catheter arm (10/199 cases, 5%). The angiographic success rate was also similar in both arms—98.9% and 98.5%, respectively. The number of balloon catheters used per lesion, amount of contrast injected and procedural and fluoroscopy time were similar in the two arms. At 30 days, the incidence of major adverse events was similar in both arms; 8 cases (4.5%) in the reused catheter arm and 10 cases (5%) in the new catheter arm. The study concluded that in a wide variety of patients, the results of reused balloon catheters were similar to those of new catheters with more cost-saving per procedure, if reused balloon catheters were used.29

The New Delhi-based Voluntary Organization in Interest of Consumer Education (VOICE) conducted a sample survey of 16 hospitals in Mumbai and Delhi from August to October 2005 as part of its ‘Patient First’ educational campaign. The survey found that gastroenterologists in all hospitals reused the single-use biopsy forceps. VOICE suggested that besides the safety angle, profiteering was rampant with reuse of SUDs when patients were charged for a fresh device each time. The study was extensively reported and quoted by the Indian press.30–33

In March 2006, an order from the commissioner of the FDA
Maharashtra stated that it would be improper to reuse devices marked as single use. However, due to the high cost involved, a committee was convened to look into the matter of reuse of SUDs. The committee, in December 2006, unanimously recommended that the practice of reuse, when done appropriately, benefits many patients without affecting their safety. It recommended that the guidelines drafted by the Hospital Infection Society–Mumbai Forum on reuse policies for SUDs be used as a reference for the same. The draft gave detailed descriptions on setting up a reprocessing unit, sterilization procedures to be followed and monitoring of the entire process. The committee also suggested that since scientific evidence was lacking from India on adverse events resulting from reuse of SUDs, such evidence should be gathered prospectively, once the policy for reuse was accepted, through pilot studies initiated in major public and private hospitals. The committee also proposed that the facilities which reprocess SUDs should be licensed by a regulatory authority (FDA) and the licence should be reviewed periodically or whenever there is a change in policy. To date, to our knowledge, there has been no action by the Government of India on the matter. Hence, most hospitals follow their own in-house policies, which are often unregulated, in this regard.

A search for Indian third-party reprocessors only showed a few private agencies importing reprocessed endoscopes and renal dialysers.

Table I shows the maximum retail price of some SUDs used in laparoscopic, conventional open gastrointestinal and interventional cardiology and radiology procedures and the approximate cost to the patients as levied by most hospitals when the devices are sterilized and reused on more than one patient. The number of times the devices are reused is an estimated figure, drawn on the basis of usage by experienced surgeons, cardiologists and interventional radiologists who have been reusing these devices for more than 10 years.

MAXIMUM RETAIL PRICE

The environmental protection laws in India are rather fragile or non-existent and the large amount of toxic medical waste of disposed medical devices will further endanger an already over-burdened ecosystem. While a government decision in this matter may take a while to materialize, hospitals have to evolve their individual stands in this regard. These decisions will have far-reaching implications for hospitals aggressively pursuing medical tourism and for those institutes hoping to get National Accreditation Board for Hospitals (NABH) and Joint Commission International (JCI) accreditation.

It is our view that SUDs should be thoroughly, mechanically cleansed and resterilized by ethylene oxide, steam or plasma sterilization. SUDs should be reused for a fixed number of times and stopped before instrument fatigue (e.g. a harmonic shear should be reused a maximum of five to six times). Reprocessing units will finally need to be set up which can handle several hospitals at a time. A regular audit should be conducted once in 3 months or at set intervals to report any suspected cross-infection, instrument faults, etc. Random microbiology check cultures could also be added to ensure adequate sterilization.

CONCLUSION

Our aim is to revisit an important debate with the Indian healthcare sector in mind. Every product whether disposable or reusable has a functional life which cannot be determined precisely. If a product can be economically reprocessed with validated protocols and deemed to be functional, there is no reason to discard it after one use. If working models of safe sterilization and reprocessing can be achieved, it will be of use to both the patient and the environment. This practice should ideally be adopted by hospitals that are interested in controlling costs of expensive medical instruments and reducing environmental waste. It is our view that we will have to formulate our own policies based on local financial implications and environmental concerns. Unlike the West where most (if not all) healthcare is borne by third-party

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Single-use device MRP (₹)</th>
<th>Cost per patient when used multiple times (₹)</th>
<th>Additional cartridge cost (₹)</th>
<th>Saving per patient in multiple use (₹)</th>
<th>Procedure where device used (₹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harmonic shear</td>
<td>40 000–50 000</td>
<td>7000–10 000 approximately</td>
<td>nil</td>
<td>30 000</td>
<td>Advanced and routine laparoscopic surgery</td>
</tr>
<tr>
<td>Hernia tack</td>
<td>22 000</td>
<td>750 per tack</td>
<td>nil</td>
<td>7000–10 000 depending on the procedure</td>
<td>Laparoscopic hernia repair</td>
</tr>
<tr>
<td>Endoscopic linear cutters</td>
<td>22 000–36 000</td>
<td>5000 approximately</td>
<td>6000–8000</td>
<td>11 000–18 000</td>
<td>Advanced laparoscopic gastrointestinal surgery</td>
</tr>
<tr>
<td>Open surgery linear cutter</td>
<td>21 000–28 000</td>
<td>4000–5000 approximately</td>
<td>4000–6000 approximately</td>
<td>12 000–18 000</td>
<td>Open major abdominal surgery</td>
</tr>
<tr>
<td>Multiload clip applicator</td>
<td>19 700</td>
<td>2000 per clip applied</td>
<td>nil</td>
<td>8000 if an average of 6 clips used</td>
<td>Clipping of blood vessels, cystic duct</td>
</tr>
<tr>
<td>Skin stapler</td>
<td>734</td>
<td>183</td>
<td>nil</td>
<td>500</td>
<td>Skin incision approximation</td>
</tr>
<tr>
<td>Diagnostic guidewire</td>
<td>1000</td>
<td>250</td>
<td>nil</td>
<td>750</td>
<td>Interventional cardiology and radiology imaging</td>
</tr>
<tr>
<td>Angioplasty balloon catheter</td>
<td>10 000–12 000</td>
<td>4000–5000 approximately</td>
<td>nil</td>
<td>5000–6000 approximately</td>
<td>Interventional cardiology and radiology procedures</td>
</tr>
</tbody>
</table>
payers, the patient (and occasionally his insurance company) foots the medical bill in India. Almost 80% of healthcare in India is provided by the private sector. Thus, the financial burden of using single-use devices only once will need to be borne by the patient while reuse will reduce the financial burden substantially. Although there are many issues impacting the cost of healthcare in India, a national policy on reuse without compromising on the safety of patients could make its own small contribution to reducing the economic burden.

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