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Consensus Document

Guidance on reuse of cardio-vascular catheters and devices in India: A consensus document

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ABSTRACT

Reuse of medical device is accepted worldwide. Benefits of reuse include not only cost saving but a favorable impact on environment. However, certain requirements should be met for reuse to be safe and effective. The devices, which can be reused, should be clearly defined, a meticulous process for disinfection and sterilization followed and its functionality ascertained before use. Further, an appropriate consent should be obtained where necessary and the cost saving entailed should be directly passed on to the patient.

1. Preamble

Healthcare providers all over the world, particularly in low resource settings are expected to deliver quality patient care in a cost effective manner. Closely monitored and regulated single use device (SUD) reprocessing provides an opportunity to do so along with the potential to have a favorable impact on environmental waste. Devices can be sterilized ***onsite*** (in-hospital) or by ***third-party reprocessing facilities*** which enter into contracts with hospitals. In the west, hospitals often engage with third-party reprocessors who clean, sterilize and re-package SUDs in a manner that the quality and performance are not affected and the SUD remains safe and effective for clinical reuse, eliminating any legal liability on the hospital.

In the developing nations of Africa, Asia, Eastern Europe, Central America, and South America, although reuse is very common, cleaning and sterilization of SUDs is often performed within the hospital, sometimes in an unregulated manner. India has no third-party reprocessors and up-to-date national policies on reuse. Hence an expert writing committee was formed to give its recommendations regarding the need and method of reuse of cardiovascular products, especially coronary and vascular catheters, valvuloplasty balloons, electrophysiology catheters and pacemakers/defibrillators. This document intends to facilitate a dialogue with governmental health agencies and the medical community to frame appropriate guidelines and in the interim help clinicians and hospitals to follow standard operating procedures for reuse.

This document shall cover the following points:

A. What is a single use device?
B. Why reuse catheters/devices in cardiology in India?
C. Need for Government oversight of SUD reprocessing: International and National perspective
D. Potential concerns associated with reuse
E. Ethical and Legal issues related to reuse
F. Informed Consent
G. Reuse in Cardiology in India
H. Protocols recommended for reuse
I. What is further needed in India?

(A) What is a single-use device? A SUD is a medical device that is recommended for use once (i.e. in only one patient for a single procedure). Such devices are not intended by the manufacturers to be disassembled, cleaned, reassembled, and reused, since doing so may jeopardize its physical and/or chemical integrity,

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performance, safety, and effectiveness.[1] The responsibility of designating a device as single use lies solely with the manufacturer and there is no statutory requirement by the manufacturer to provide validation to support its designation as single-use.

(B) Why reuse catheters/devices in cardiology in India? World-over hospitals have been reusing SUDs since 1970s.[2,3] Reprocessing a medical device involves cleaning, disassembly as required, disinfection, reassembling, inspection, function testing, re-packing, sterilization and relabeling to ensure that a medical device can safely be reused. This includes SUDs that have been previously used in a patient and also those that have crossed their expiry date.

Cost saving on medical expenditure is the single most important reason for reprocessing of SUDs. Annual estimates of healthcare industry savings with reprocessing in US have been reported to be approximately $ 1.8 billion per year.[4] A survey conducted across 3000 hospitals using reprocessed SUDs in USA reported savings in excess of $ 150 million every year.[5] Cost estimate studies from Germany report savings of up to 20 million Euros per year from reprocessing balloon angioplasty catheters.[6] Apart from cost savings, reuse can also lead to *reduction in the toxic-biodegradable waste* generated by disposing medical devices thus favorably affecting the environmental footprint of hospitals. Reprocessing is listed as a best practice for its environmental benefits and as a top green purchasing practice.[7]

Cardiovascular products in India have also been reused with the sole consideration of reducing the cost. Broadly the cardiovascular materials that are reused can be categorized to coronary and vascular catheters and guide wires, balloon valvuloplasty catheters, electrophysiology catheters, pacemakers and defibrillators.

Coronary and vascular catheters and guide wires – have been traditionally reused by majority of the hospitals in India. However the overall reduction in the cost of these materials over the past few years and the difficulty is assuring complete disinfection of these luminal catheters have raised the question of the necessity to reuse them in the present day.

Balloon valvuloplasty catheters – These are used to perform percutaneous balloon mitral valvuloplasty (BMV) in rheumatic valvular heart disease, a scourge of millions of socio-economically deprived patients in India. They are also used in congenital heart diseases such as pulmonary and aortic valve stenosis. Balloon Mitral Valvuloplasty is a potentially life-saving procedure that is performed most frequently in the economically weaker sections with rheumatic mitral valve stenosis. It is one of the most commonly performed interventional procedures. Each year about 10,000 patients in India undergo BMV with most of these procedures performed in public hospitals. The cost of BMV varies from *free* to a maximum reimbursement of Rs 60,000 (the approximate cost of BMV in a governmental hospital varies from Rs 15,000 to Rs 30,000). In the state of Maharashtra, the government health scheme sanctions a meager Rs 20,000 for the BMV procedure, thereby presupposing that there would be reuse of SUDs, this is because the cost of the BMV catheter along with its accessories is approximately Rs 1,00,000. Taking into account the other SUDs used in the procedure the total hardware costs for this life-saving procedure would be in excess of Rs 1,20,000. This subsidy in cost is only possible because the valvuloplasty catheter is reused for at least three times. Ethylene oxide sterilization has withstood the test of time as an effective sterilization technique and there have been no adverse events reported in literature (not withstanding the under reporting of such events). A "No reuse policy" for such procedures would be detrimental to vast majority of Indian patients. Majority of the patients will not afford the cost of new balloon valvuloplasty catheter and hence not opt for this life saving treatment. In case the reimbursing agencies were to pay for the new hardware for every individual patient, there will be a three-fold increase in the budget allocation.

Electrophysiology catheters – reprocessing is adopted by many electrophysiology (EP) laboratories in the US with the dual purpose of reducing costs and lessening the environmental impact from discarded bio-waste. Reprocessing EP and imaging catheters have reported savings up to $150,000.[5] Catheters were found to be durable enough to be reused in excess of five times with maintained effectiveness for cardiac pacing and recording of electrical signals.

These catheters are being reused in India as well. The cost of ablation procedure by conventional technique in India varies from Rs 15,000/- in government-aided hospitals to Rs 75,000/- in re-imbursed or private hospitals. However, with a "No reuse policy" the cost of these 'single use' catheters and hardware would be about Rs 1,00,000/- for every procedure. Additionally there would be the cost of the electrophysiology equipment, catheterization laboratory charges, hospital stay and professional fees. The reuse policy in ablation procedures has also helped in shortening the procedure time with the flexibility of using multiple catheters which best suit the need of a given patient.

Pacemakers/defibrillators – The bradycardia pacemakers cost varies from Rs 60,000/- to Rs 1.5 lakhs; the implantable intracardiac defibrillators (ICD) cost from 2 lakhs to 5 lakhs, the bi-ventricular pacemakers from 2.5 to 7 lakhs (COMBO devices) in India. This cost is prohibitive to many Indians and there is no uniform policy of re-imbursement. Thus, these cardiac implantable electronic devices (CIED) are implanted in only 25 per million population in India as opposed to 300 per million implants in the western world.[8,9] To bridge this gap, in India CIEDs have been reused. Saving precious lives with this reuse practice in India has also been acknowledged in Western published literature, which promotes and facilitates this practice.[10]

(C) Need for Government oversight of SUD reprocessing? A device is labeled as single-use only by the manufacturer, as the latter believes that it could not be safely and reliably used more than once, *or because the manufacturer chooses not to conduct the studies needed to demonstrate that the device can be labeled as reusable.*[11] Moreover when a manufacturer seeks approval to market a device as single use, the regulators do not require them to show that reusing it would be inappropriate or hazardous. Since the FDA can only evaluate a device for its intended use by the manufacturer, if a device is approved as SUD, it only implies it can be *used safely and reliably once*. It *does not however imply that it cannot be used safely and reliably more than once, if appropriately reprocessed.* Manufacturers often change labels on medical devices from reusable to single use, sometimes without any significant change in design, performance or material that would preclude safe reuse. Such a shift in labeling surprisingly does not require approval from the FDA; which in fact does not even mandate any device to carry a single use label.[12]

Hence there was a ***growing apprehension*** in the minds of health care personnel that this over-enthusiasm on part of original equipment manufacturers (OEM) to market devices as single-use when they could just as well be reusable was driven by economic incentives. Occasionally, many manufacturers of SUDs themselves offered their own recycling and reprocessing programs, further questioning the relevance of "single use" designation and necessity of complying with it. At the same time, rising cost of medical devices, often forced hospitals to reprocessing so as to bring down expenditure incurred to patients.

FDA oversight of SUD reprocessing in USA: Noting the increasing trend of unregulated reuse, the Food and Drug Administration (FDA) in 1999, sought feedback from healthcare professionals, device manufacturers and reprocessing firms to determine if federal oversight was needed to address the issue of