



DOs AND DON'Ts

REUSE OF SINGLE USE DEVICES - MEDICO-LEGAL IMPLICATIONS

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Let me recount a report of a medico-legal case that took place in USA not too long ago. The outcome of the case is as illustrative as it is instructive for us and has great relevance to the scenario prevailing in our country.

Dr. Kaplan, a urologist from Nevada who performed frequent prostate biopsies, faced a shortage of disposable prostate biopsy needle guides. To cope with this problem, he instructed his assistant to reuse these disposable needles by cleaning them with running water and bristle wires along with Cidex and sterile water to sterilise the plastic guides.

However, the patients were not informed that the needle guides were being reused. In spite of his assistants informing him that they observed that blood and pinkish water left in the guides and brown scratches did not get cleaned during the disinfecting process, he asked them to continue the process. A few months later they reported him to the State Medical Board (like our MMC).

An enquiry was ordered and when asked why the devices were being reused, he answered that he was practising cost-effective medicine.

A criminal case was filed against him and a

Nevada grand jury indicted him for conspiracy to commit adulteration of a drug or device that is "held for sale. He had used a device which could have been contaminated and rendered injurious to health.

In his defence, an expert witness said that the risk to his patients was between one in trillion and one in one hundred trillion. However, the prosecution pointed out that the witness himself had written an article in which he had advised "do not reuse items labelled for single use" and had conducted no study to determine if the plastic guides could be safely reused. After a nine day trial Dr Kaplan was found guilty of conspiring to commit adulteration and that he had acted with intent to defraud or mislead.

The three-judge panel ruled: "A single-use device is meant to be 'consumed' in the course of treating a patient - just like a drug. Once a single-use device is used or consumed, there is nothing left to be done with the device and it has to be disposed Kaplan was convicted under the criminal law.

Members will recall the recent media headline : **FIRs against 37 hospitals for reusing devices, patients to be reimbursed** (*Times of India* -26/07/17)



The FDA sent notices to Fortis hospital-Mulund, Fortis Hiranandani (Vashi) and BSES Hospital-Andheri for violating the Drugs and Cosmetics Act and overcharging patients.

The fact of the matter is that the FDA regulations on this issue are nebulous and there is no clarity about the approved protocol for the reuse of medical devices. The questions that ought to be unambiguously answered are :

- Is reuse of medical devices banned or permitted as per the law?
- If yes, then which devices are permitted and under what conditions.
- What about consent of the patient for the same,
- What about the ethical issues and legal liability.
- Are there any official guidelines for pricing?

What, one may ask has prevented the governmental authorities for laying down clear-cut guidelines?

Going down memory lane, I remember the raging controversy and screaming headlines in the newspapers in March 1996 when the feisty and bold Dean of KEM hospital - Dr. Pragnya Pai ordered a ban on the reuse of disposable items in KEM hospital. Her reasoning was that the Supreme Court by its judgment had brought even public hospitals under the CPA. Dr. Pai stated : The order has been passed to safeguard our doctors who may be hauled up under the CPA for reusing disposables when the manufacturer has stated 'for single use only'.

It will be educative to review the reaction to this by the government, the political class, the media, the public, the consumer activists, some self-appointed NGOs, and the medical profession itself.

Some of the headlines of the newspapers will give you a clue :

Patients affected by new KEM order-cost of treatment increases five-fold

Diktat on disposables hits operations

KEM hospital decision claims first victim

Patients 'denied' treatment in KEM

Patients' safety or cheaper medical care?

To Reuse or Not?

Who decides how many times to re-use?

KEM move hits emergency procedures

This was followed by contradictory comments by all and sundry.

A cardiologist commented : The risk of a patient contracting an infection due to reuse is negligible. A patient would rather bear this miniscule risk than die because he was unable to afford treatment.

KEM hospital doctors reported that intensive care units, cardiology, anaesthesia, neurosurgery and radiology departments were suffering due to the order, the cost of treatment had increased five-fold and poor patients had been hit hard.

A consumer activist wrote : The Dean's argument is untenable. In the name of CPA patients are being made to suffer. Dr. Pai has taken a unilateral decision which has



adversely affected the patients who are the end-users of the health care system. The Hospital has not declared the data - based on which the reuse of disposables has been stopped. The CPA has been used as an imaginary bugbear.

One activist asked : How can you reuse medical devices, Doctors must follow the manufacturer's instruction of 'single use'. The so-called informed consent of the patient cannot absolve the medical fraternity and damage caused to the patient as it is not a free consent and is invalid in law. At the same time he insisted that banning reuse of disposables by the dean of KEM was not acceptable as patients were suffering. But he had no solution for the problem.

Re-Using single use devices is indeed a dilemma especially in India where the whole process is unregulated. In the Western countries the process is well-regulated and has an approved protocol. Such reuse is common in many healthcare centres in USA. Cost saving on medical expenditure is the most compelling reason for reprocessing of disposable devices. In the USA the healthcare industry saved 1.8 billion dollars per year due to this factor. Reuse also leads to reduction in toxic biodegradable waste generated by disposing medical devices. Reprocessing is listed as a best practice for environmental benefits.

The Indian Government would do well to crystallise a Policy on reuse of single use devices As suggested by the Hospital Infection Society; Mumbai Forum; the entire process of Reprocessing should be monitored and done with approved norms.

The BMC decided to set up expert committees and refer to their legal department and so on. There were doctors who spoke for the reuse and many who spoke against.

Soon after the issue was driven out of the front pages of the newspapers, all hospitals started reusing disposable devices, at least the costly ones. And every one lived happily after that!

Sporadically, some complication following reuse of a device happened and the doctor was hauled before a consumer court. He was left to deal with it individually and everyone else continued to do the same thing with the hope that it would not be their turn next.

It is quite obvious that there is a lot of double think, double speak and hypocrisy on the part of the concerned authorities.

To Reuse or not? Leave it to the doctors and let them face the music if something goes wrong.

It is very clear that reuse of Single use devices have several advantages in terms of economy, environmental pollution and convenience. However unambiguous norms must be laid down, reprocessing units must be licensed by a regulatory authority. Pricing pattern of re-cycled devices must be laid down. The type of consent should be officially formulated so that well-intentioned effort to do good to a patient by reusing a costly device does not boomerang on the doctor.

Hence, it will be wise to consider all implications before you decide to reuse and single use medical device.



To conclude, I would like to share a letter I wrote to the Editor of Times of India in 1996 especially because the concerns I expressed are as valid today as they were then.

March 1996

To,

The Editor

Times of India

Sir

The ban on the reuse of disposable medical equipment at the KEM hospital and subsequent hardship to patients raises very vital questions which, in fact form the crux of the debate on doctors and the CPA.

While expectations of the people for top-class medical treatment and result-oriented performance from doctors is quite understandable, it must be realised that an aggressive demand for these, without taking into account the economic realities in this country can be self-defeating.

It can only lead to the type of situations of which the present crisis at the KEM is just one example.

Use of disposable items is indeed very costly and if they were to be reused, cost of treatment would definitely come down. In fact, this was and is being practised. However, in the present climate of bias against doctors, why would a doctor want to take risks whose beneficiary is someone else?

The manufacturers of disposables clearly state on the product "Discard after single use". Undoubtedly, re-using these products will be accompanied by some risk, however small. The manufacturer will disclaim any liability whatsoever!

Who is then going to take the responsibility? Even a valid consent is liable to be held untenable in law. Acts resulting in grievous hurt to another person regardless of consent are forbidden within the meaning of Section 320 of the IPC.

It is high time we ended this double-speak. On the one hand we are demanding the highest standards of medical care, on the other hand we start cribbing when we have to spend more money to achieve these. We can't expect zero-error results of medical treatment, threaten to take doctors to consumer courts for every unfavourable result of treatment and then also ask doctors to take risks in the interest of reduced costs. We can't have the cake and eat it too.

Let us not be hypocrites. Let us find solutions to problems within the limitation of our resources and do the best within these. But this will be possible if we reconsider the wisdom of extending a misplaced consumerism to a life and death profession and we stop whipping up an American-type litigation mania. We can disregard this only to the generation of more such KEM-type crises in the future.

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