Reusing disposables

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Basis for banning re-use of medical equipment

An evening in May ***1986. I*** was strolling along Juhu beach. Suddenly, out at sea beyond the waves, I spotted a swimmer struggling for his life, his arms flailing above the water and his voice just audible as he screamed for help. I raced to where a little boy was playing with a fully inflated car tube, to take it out to the frantic swimmer. The boy demurred. The tube, he said, had a tiny puncture; it would probably fill, with water instead of helping the swimmer. In this desperate crisis I thought the risk was well worth taking. But while our argument continued, a powerful swimmer went out and made the rescue.

The parallel to the re-use of 'single-use disposable medical equipment' is not altogether real. The little boy had no interest in making me race to his father's tube store to buy a new tube. The drowning man's relatives could not have sued me or the boy had the tube indeed failed while it was trying to bring him to safety. Is the risk of litigation, then, all that supports the case for banning the re-use of such equipment? That looks like an over-simplification, but it is nearly true.

When the controversy over the re-use of disposable items first erupted I naively imagined that someone had started salvaging ordinary disposable syringes for re-use and sale. That impression was dispelled by Dr. P. M. Pai, Dean of Bombay's K. E. M. Hospital, who had been the one to ban re-use. She laid before me an array of forbidding-looking items that I should hate to have pushed into me, most of them with unpronounceable names, the easiest of which was 'catheter'. Each of them 'was packed in a plastic bag that carried a stern warning against re-use. It was clear that manufacturers would accept no liability that might arise should an item fail during 're-use. So the Dean's ban was simply a precaution to save the hospital and the Bombay Municipal Corporation (BMC) from malpractice claims.

Does re-use really cause problems?

How likely are mishaps when such equipment is re-used despite a manufacturer's warning? Most Bombay hospitals keep no systematic history of performance although they regularly re-use equipment, but careful studies have been made abroad and results are available. In a 1987 study at the University of Minnesota, 178 cardiac electrode catheters were used 1526 times (over 8 times on the average) over a five-year period. At the end of this study 28 of them were still ready for further re-use. Half of the remaining 150 catheters had been discarded because they were left inside patients when these patients moved from the theatre to the wards, and, intending re-users could not vouch for careful handling of such catheters in the wards.

To be safely re-usable, catheters employed in heart therapy and neurology must not only be sterile but must also retain sufficient mechanical strength to allow their manipulation inside the body. A 1977 report by researchers at a university in Salt Lake City, Utah, confirmed that despite deliberate exposure to a large concentration of pathogens (they have jaw-breaking names, so I shall leave them anonymous), "complete sterility can be achieved by standard procedures even when the devices are intentionally infected. Survey data indicate no increased incidence of mechanical malfunction when these devices are re-used." But, "four cases of catheter malfunction secondary to mechanical damage were reported. In each case the catheter was a new one. Three cases of guide wire breakage were reported. In two cases the guide wire was new, and in the other it was not possible to determine whether it had been previously used."

In our own country, pacemakers are regularly recovered from dead bodies at the SSKM Hospital in Calcutta and implanted again in patients too poor to pay for new ones. Of 5 121 implants reported between 1967 and 1992, 105 were devices recovered from cadavers. There was no significant difference in the 'incidence of complications between new and reused implants.

Let's leave the heart and descend to the kidneys, for which disposables have been displacing non-disposable dialysers, although they cost six to fourteen times as much as non-disposable equipment. This cost can fall "if the haemodialysers are not discarded after use but rinsed and resterilised for re-use. If they are re-used three times, disposable dialysers are only about twice as expensive as non-disposable equipment, and after seven re-uses they are beginning to be cheaper", according to a European Dialysis and Transplant Association study. "Re-use carries appreciable morbidity but no detectable mortality." The report of an American survey in 1977-81 actually suggested that long-term re-users suffered a lower mortality rate

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than those who did not re-use dialysers. At least one of Bombay's leading hospitals, Jaslok, regularly re-uses dialysers.

Why did K. E. M. ban re-use?

The BMC's (really the K. E. M. Dean's and the Municipal Commissioner's) hypersensitivity to the risks of misuse would inspire less scepticism if our municipal hospitals were immaculate concentrations of sterility and cleanliness. What may be a real threat to safety in regular re-use of equipment is our traditional neglect of strict precautionary protocols. In practice; sterilisation may be less than thorough; inspection of used equipment for mechanical strength may be perfunctory, and if the Dean's primness stems from a fear of such dangers, one cannot blame her. Even in the USA, a 1988 study reported about dialyser reuse, "problems associated with disease transmission and haemodialyser re-use have been almost exclusively due to inadequate reprocessing procedures such as the use of incorrect chemical germicide concentrations." But given careful and determined supervision- and the Dean has a reputation for strict supervision- these defects can well be surmounted. The difference in costs will more than pay for the extra supervisory effort. But for now the BMC has been too ready to let the best be the enemy of the good.

Hysterical reaction to the Consumer Protection Act (CPA)

The K. E. M. ban on the re-use of single use equipment was clearly a panic reaction to a Supreme Court ruling that brought hospital services under the CPA if these hospitals levied any charges for treatment. The panic arose out of a mistaken belief that hospitals' liability for malpractice had suddenly blown up unimaginably. In fact, the Court's order had added practically nothing to the tort liability provided under the ordinary law before the CPA got on to the statute book. Victims of medical malpractice have always been able to sue wrongdoers, only poor patients could never afford the cost of litigation; besides, with the congestion in our courts, there was hardly a chance that such suitors would survive the cases they might file. All that the Supreme Court has given such people is a chance of inexpensive justice before they die. To react hysterically to the ruling is really a cynical admission that you did not earlier bother about malpractice because justice was beyond your victims' reach, particularly if they happened to be poor. And apart from that, it is an unacceptable paradox to let the application of the CPA hurt the very consumers for whom it was enacted.

Patients who undergo surgery in our hospitals are usually asked for a declaration indemnifying the surgeon and the hospital against mishaps. Legal pundits would have to tell us how safe a protection that is for a careless or negligent surgeon or an unsterile operation theatre. But patients on whom a single-use device is re-used could be asked for a similar declaration after careful explanation to them of the manufacturer's injunction against re-use. After such a declaration, the hospital and its medicos could expect at least the same measure of safety in re-use as in their regular treatment of patients.

Hasty bans such as those imposed at the K. E. M. hurt only poor patients. The affluent can always find money to pay for new catheters/pacemakers/dialysers. To extract from a poor man as much as five to eight times what multiple re-use would cost - and that too only to protect the wealthiest municipality in south Asia from a remote threat of tort liability - is a display of callousness of which I know the present K. E. M. Dean is not capable, once the implications are clear to her. Nor would she relish the notion that her policy was vigorously promoting the interests of equipment manufacturers, whose sales would soar if re-use were widely banned.

The risk she might in fact anticipate, and properly so, is the danger of imperfect sterilisation and inspection of used devices before re-use. As I have written above, that risk is hardly real in an institution run as tightly as the K. E. M. is run by its present Dean. Elsewhere I would not be so sure, but if sterilisation and inspection protocols are carefully prescribed, risks and damage will be negligible.

Denying the poor

Still another issue lies latent in this controversy. Can equipment - new devices, if you prohibit re-use - acquired out of public funds be denied to patients who cannot afford to pay for their use, but who, like the rest of us, pay their taxes? Can a government introduce* a specific charge for police services, for example, such that our cops can refuse to investigate a murder (always costly to probe) reported by a poor man? If not, can poor patients be turned away from treatment at a public hospital that is priced beyond their means?

On an international flight last year a passenger suddenly took ill. On a request from the stewardess, two doctors came forward from among the passengers. They determined that the patient would quickly die unless immediate chest surgery were performed on her. With astonishing courage, the doctors used a coat hanger as a probe, and then, with a Swiss knife and the cutlery available on the plane, they cut the woman open and drained her lungs, which had been filling with liquid. She survived. On a later TV programme she expressed her appreciation of the two doctors and their ingenious improvisation. Would the BMC medical authorities have wanted that case to be handled

with courage, as it was, or would they have preferred safety from possible litigation and let the patient die?

Response from the Dean, K. E. M. Hospital, Bombay

1. The word 'banned' has been misused as the minutes [of a meeting held by the Additional Commissioner] clearly state - temporary stoppage of usage until a policy decision is made. The-intention has been to protect our doctors from avoidable litigation by regularising the practice, as legal opinion is against reuse.

2. There is no over-reaction to CPA because if you violate the manufacturer's directives, will the consumer forum uphold the action and accept all the justifications which are being given in the name of poor patients?

3. Protection from reusing the disposable items has to come from a statutory authority like Food and Drugs Administration (FDA), Department of Science and Technology (DST), Drugs Controller of India (DCI), who need to lay the guidelines and norms for sterilisation.

4. Individual opinions, even if they are voiced loudly either at personal level or through the press, may not be acceptable, hence there is need for the statutory bodies to lay down policy.

5. Policy makers (presumably the FDA, DST, DCI) are unfortunately silent on this subject in spite of reminders.

P.M. **Pai**

"If you want layman's terms, my colleague, Dr Hand, will translate at $5 per word."