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The Ethics of the Reuse of Disposable Medical Supplies



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Abstract

The use of single-use items (SUDs) is now ubiquitous in medical practice. Because of the high costs of these items, the practice of reusing them after sterilisation is also widespread especially in resource-poor economies. However, the ethics of reusing disposable items remain unclear. There are several analogous conditions, which could shed light on the ethics of reuse of disposables. These include the use of restored kidney transplantation and the use of generic drugs etc. The ethical issues include the question of patient safety and the possibility of infection. It is also important to understand the role (or otherwise) of informed consent before reuse of disposables. The widespread practice of reuse may bring down high healthcare costs and also reduce the huge amount of hospital waste that is generated. The reuse of disposables can be justified on various grounds including the safety and the cost effectiveness of this practice.

Keywords Disposables reuse · Health inequality · Healthcare cost

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Introduction

Shankarappa is a hypothetical 30-year old typist in a small private firm who suffers from kidney failure. He has a wife to support and two small children. As a result of this condition, he gets tired easily, is too breathless to catch the bus to work and is rapidly going downhill. He is started on haemodialysis on a reuse strategy and improves enough to return to work; His only difficulty is that since the government will not provide the disposables needed for dialysis, he has to spend Rs 1,750 (approx. USD25) per month to stay alive. His wife takes a part-time job to help. Now the hospital has decided to stop reuse of disposables and his bill will come to Rs 8,750 (approx. USD125) per month which he cannot afford. As the doctor in charge, you know that reuse is scientific and safe but if dialysis is stopped, he will die in a few weeks. What is your ethical decision? (Economic and Political Weekly 1996)

The above question was raised by a leading Indian social science journal way back in the mid-1990s. The applications of single-use disposable items are ubiquitous in the practice of modern medicine (Lee et al. 2002). In the 1980s, concerns were raised about the public health implications of using disposable syringes. The concerns raised by the HIV epidemic as well as the fear of hepatitis B transmission led the WHO to promote the use of disposable syringes (Battersby et al. 1999). Subsequently, the use of disposable equipment was vigorously promoted, especially by the equipment manufacturers for many emerging areas of medical intervention, including cardiac catheterisation, cardiac surgery, nephrology and many others.

The last two decades have seen an explosion in the use of disposable equipment which now comprises about 85% of hospital equipment (Souhrada 1988). The price of the equipment is one of the most important components of the cost of many common procedures done in hospitals. In a study done in Indian hospitals, the cost of consumables was about a quarter of the total cost for cardiac surgery, and surprisingly about 30% of the cost of non-cardiac surgery as well (Manjunath et al. 2006; Das 2011). While this may be thought to be a problem of poorer societies, it is now clear that even in rich economies like Japan, the USA and Germany, single-use device (SUD) reuse does happen (Asahi Shimbun 2018; Koh and Kawahara 2005). In resource-poor conditions, this cost burden has led to an impassioned debate about the feasibility of reusing disposables to reduce costs of cardiac and other surgery and thus make the procedures affordable in resource-poor settings as well as to reduce the huge cost of healthcare in richer countries.

Much research has gone into the safety of reusing these devices. Health authorities have also researched the issue and recommendations have been issued (Mansur 2017). One area where there has been much work is in the reuse of cardiac catheters. There is now a considerable body of evidence that suggests that it is scientifically tenable to reuse cardiac catheterisation equipment. However, this has been challenged by other workers who believe that the evidence is not robust enough to recommend the routine reuse of disposable equipment (Ribeiro et al. 2006).

During this debate, there has not been much reflection on the ethical aspects of the reuse of disposables. A scan of the literature reveals that the discussion has been mainly

on the science; the ethics of reuse has not been subjected to much scrutiny though it would be wrong to claim that it has not been addressed at all (Economic and Political Weekly 1996; Collier 2011). In this paper, we intend to look into the ethical issues that arise in the process of reuse of disposable equipment, looking at the issues mainly from the point of view of less affluent societies. We would argue that the reuse of disposables can be justified on various grounds including the safety and the cost effectiveness of this practice and that an examination of the ethical issues involved suggests that there can be no definite ethical objections to it.

Analogous conditions

In order to approach this problem from its ethical standpoint, it is useful to analyse some analogous conditions, which may offer an insight to the problem at hand. There are several medical and social practices that are useful in helping to understand the ethical issues that arise when hospitals and physicians reuse single-use items.

Restored kidney transplantation

Kidney transplantation is a standard procedure worldwide to treat end-stage renal failure. Most transplant programmes have a standard protocol, which is used to determine the suitability of the donated kidney for transplant. However, over the years, the standards have been modified and some conditions, which used to be absolute contraindications for transplant, are now accepted for kidney replacement (Andrews and Burnapp 2018). An example would be restored kidney transplantation.

Even so, it is generally accepted that kidneys, which have been afflicted by a malignant or benign tumour, should not be transplanted in order to prevent malignancies in the recipient. However, in recent times, the problem of a lack of suitable cadaveric donors has led surgeons to utilise even kidneys, which are afflicted with various benign tumours and even with renal cell carcinoma. Patients who had undergone nephrectomy for these conditions were asked for permission to utilise the kidneys, and the tumour was removed on the bench after nephrectomy was done. Subsequently this so-called restored kidney was utilised for renal transplant in carefully selected patients, mainly those who already had a kidney transplant, which had been rejected and had no family members who may act as living donors. This form of surgery was probably first reported by Buell et al. (2005) and also by Nicole in Brisbane as presented to the American Urology Association (Mannami et al. 2008). This is definitely a second-best option for the transplant patient, and this procedure is used because of exigencies that prevent the use of a "new" kidney. Some concerns about the safety and allocation remain.

However, its use has been permitted as a life-saving measure. Obviously, this is a suboptimal procedure that has come into use because of a lack of ideal donors. One must note that this is not absolutely analogous to the present discussion as a SUD would be reused only if scientific evidence backs its safe use. In addition, restored kidney transplantation would be allowed only in case of urgent situations because of its potential risks. Both the use of disposable equipment and restored kidney

transplantation have shared common problems such as safety, efficacy, and just resource allocation.

The use of generic medication

Governments worldwide, the WHO and expert bodies are vigorously promoting the use of generic medication (Choudhry et al. 2016). This has several advantages, most important of which is the decreased cost as compared with using branded versions. However, the compulsory use of generic medications does have some similarities to the use of disposables because its use includes issues of efficacy, cost and safety.

There are concerns that generic medicines may not be as efficacious as the corresponding branded medication, and concerns have been raised about their safety (Howland 2010). However, most authorities have discounted such claims and generic medications are vigorously promoted and indeed in some countries it is illegal to prescribe brand names (Sharma and Nundy 2002). In an order dated 21 April 2017, the Medical Council of India (MCI) has made it mandatory to prescribe generic drugs. If it is true that generic medications have the same effect as branded drugs and are much cheaper, then if reused disposables are shown to be effective and safe there can be no ethical objection to their use. In fact, it may be desirable to do so as it ensures fairness by controlling the cost of medical therapy. One important consideration that must be kept in mind, however, is that while the manufacturers of generic drugs endorse the drugs and guarantee their safety, this is not true for SUDs, which are, according to their manufacturers, for single use only. Still, in ethical terms, when matters of safety and efficacy can be satisfied, and indeed when we can add to the equation a reduction of cost, then the case against both generics and SUDs is greatly diminished.

Vertical transmission of AIDS trials

In the last decade of the previous century, there was a raging controversy regarding clinical trials that were conducted in Africa, Asia and the Caribbean which were designed to determine the efficacy of interventions to reduce maternal-foetal transmission of human immunodeficiency virus (HIV). The background of these trials was as follows. In 1994, a landmark trial in the USA suggested that vertical transmission of the HIV virus could be dramatically reduced in patients who received zidovudine (Connor et al. 1994). This rapidly became the standard of care in the USA. However, this regime was far too expensive for the countries worst affected by the HIV epidemic (Dabis et al. 1995). A number of Western funding agencies funded a host of trials conducted over a wide swathe of African, Caribbean and Asian countries, which used a cheaper alternative, but matched it with a placebo instead of the zidovudine regime, which was already established (Shaffer et al. 1999).

This led to a very heated debate on the ethics of such a trial design, and there was much controversy in the research and ethics community. The controversy initially erupted in an article in the New England Journal of Medicine (Lurie and Wolfe 1997). This was preceded by an open letter written by Peter Lurie and Sydney Wolfe of the Public Citizen's Health Research group in Washington to the Director of the US Department of Health and Human Services in which they urged the withdrawal of support for the AZT trials (Wendland 2008). In their article in the NEJM, the two

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ethicists pointed out that of the 16 trials underway in developing countries testing the use of lower doses of AZT, only one (the Thailand trial) was comparing the standard of care, while all the others were comparing with placebos despite the fact that the efficacy of AZT was established. They suggested that the 15 other studies were, in fact, asking a wrong research question and had failed to utilise the data obtained from earlier trials to ask a relevant question. They strongly repudiated the argument that "standard of care" in a poor country was equivalent to "no care."

Subsequently a Working Group was convened by the Elizabeth Glaser Pediatric AIDS Foundation and the Emory/Atlanta Center for AIDS Research at the Rollins School of Public Health in June 1998. This was the "Perinatal HIV Intervention Research in Developing Countries: Public Health, Science, and Ethics" group. They laid down 5 principles of research in developing countries, one of which was that "study participants should be assured the highest standard of care practically attainable in the country in which the trial is being carried out." (Perinatal HIV Intervention Research in Developing Countries Workshop participants 1999). They argued that this implied that the use of placebo was acceptable as the prevailing best practice in the concerned countries was no treatment at all.

They also suggested that the "ethical standards in designing research trials should always be applied so as to reflect the economic, public health, medical, and social realities of the host country." They were of the opinion that in the absence of available retroviral therapy in the countries concerned, and the lack of reasonable expectation that it would be made available, it was imperative to test and identify rapidly a regimen that is more effective than no anti-HIV-1 intervention and more affordable and implementable than the proven ZDV regimens. Most of the participants believed that a no retroviral comparison would be justified under such circumstances.

This position also did not go unchallenged; a lively correspondence in the Lancet ensued. Jackson Omene objected to a statement made that there was no obligation to provide the best standard of care to the study participants and claimed that such a stance was likely to serve as an endorsement to the economic disparity among nations (Omene 1999). African researchers were of the opinion that such an ethical controversy to salve the consciences of developed world researchers who had no idea of the conditions on the ground was a "tortured form of ethical logic." (Gambia Government/Medical Research Council Joint Ethical Committee 1998). Participants in the trial also appeared to be of the opinion that the trial was justified.

This was thought by many ethicists to be unacceptable as such a trial would not have been accepted in any of the developed nations. It was argued that the trials conflicted with the Helsinki declaration especially regarding the standard of care to be given to the patients who were not being treated with the investigated drug(s). However, the trialists argued that using a placebo made it possible to evaluate the efficacy of a cheaper alternative as the use of a placebo would make it possible to discover whether the cheap alternative was better than giving no treatment at all. They argued that the situation on the ground was that these pregnant women were getting no treatment at all; so a placebo was ethical in this circumstance as the zidovudine regime would be unaffordable for the health services in the communities in which they lived.

This argument was generally considered ethically justifiable. For example, the Nuffield Council on Bioethics (2002, 92–93) argues:

there are situations in which it is clear than even if there were an agreed universal standard of care for a disease, it may not be possible for this standard to be provided to the control group in a research project. In some cases the universal standard of care will not be able to be provided because of practical considerations ... even though a universal standard of care cannot be provided to participants, it can be convincingly argued that the research should nevertheless be conducted because it offers the opportunity of developing responses to important healthcare needs in developing countries.

Thus, a less than perfect treatment was accepted as an alternative to the best possible treatment on cost grounds, which is almost exactly analogous to the situation regarding disposables. In 2008, the US Food and Drug Administration (FDA) relaxed the rules for externally (read "in developing countries") conducted trials overruling the World Medical Association's amendment to the Declaration of Helsinki in 2000 thus giving legal cover to this ethical dilemma. The question of saving life at an affordable cost (failing which most patients in poorer countries would not be treated at all) can be ethically justified as it is instrumental in saving many lives, which would otherwise be lost. In this case, too, fairness is enhanced which is necessary on ethical grounds. Thus, it can be argued that use of less perfect second-best interventions is ethically justifiable when practical constraints such as limited access and unaffordable cost make the best methods impossible to use in some situations.

Ethical issues on SUD reuse and its consideration

Based on the above case analysis, the issues to be considered for reuse of SUD are as follows:

Safety judgment

Is it safe to use single-use equipment more than once?

Several studies testify that the reuse of disposable equipment may be safe. There are two main issues here. One is the durability of the device and second, the possibility of infection. Many studies have concluded that cardiac catheters that are used for many cardiac interventions and diagnostic procedures can be safely reused several times with no loss of function (Ribeiro et al. 2006). Several studies have also concluded that the risk of infection is also not greater than the use of the device only once (Browne et al. 1997; Indian Heart Journal 1997). However, it is also true that some experts have strongly discouraged such use because there are stringent regulations imposed on medical device to obtain performance reliability and requirement for expensive sterilisation validation procedures in the interests of patient safety as well as the possibility and the actual incidents of serious infection due to inadequate resterilisation (Linder 1999).

However, it appears that the balance of the evidence suggests that reuse of disposables may be safe, although we should naturally be careful about the possibility that all adverse events due to the reuse of disposables have not been reported and published. The balance we consider here would include all of safety, efficacy, cost, accessibility, practicality and limited availability of resources in the setting in question. It is preferable that reused disposable have both safety and efficacy, but, in the situation where the alternative is no intervention at all, the balance could favour the efficacy rather than safety because no intervention could result in the loss of life or health.

Such circumstances beg the question why then are these devices marked as single use? Should they not be used several times as normal practice? Why should the patient or the health service provider pay high prices for a non-proven benefit (that of reduced infection and better performance of the device)? Again, it appears to be ethically unjustified to not reuse the disposables if it is safe to do so as this can make medical care much less costly and potentially make it available to many more consumers especially in resource-poor settings. In fact, it may save lives when it makes a previously unaffordable surgery affordable. However, this raises a fresh question. How then can we justify using fresh disposables to those who can afford them and to reuse them in poorer patients who cannot?

Who decides that the equipment is single use?

Traditionally surgical equipment including instruments, syringes, retractors, and drapes were all designed to be reused. Over the past quarter century, many of these have become, sometimes insidiously, single use. In a modern operating room, drapes, surgical gowns, and sometimes even retractors and trocars used for laparoscopic surgery have become disposable. The rationality is that this would reduce infection and thus save money and patient morbidity. However, this has been a subject of debate and the driving force behind the disposable culture might be, we suspect, the commercial interests of the manufacturers of equipment in the era of commercialisation of healthcare.

That is not to deny that a post-surgical infection can have horrendous consequences. However, there is a sense of discomfort when one realises that the principal beneficiaries of this disposable boom have been commercial interests, including the benefits that accrue, unethically, and sometimes illegally, to the physicians who use them. There is a potential conflict of interest here, which raises many ethical questions that need to be answered. The principles of justice demand that the decision to use or not use disposables for a particular procedure or part of it should not be made by physicians who can potentially benefit from the decision. Also, it should definitely not be made by the manufacturers. The principles of ethical conduct demand that careful scientific reasoning must be utilised to lay down guidelines for the use of disposables.

The question of infection

While most studies suggest that infection rates on reusing disposables are within acceptable limits, at least for some indications like cardiac catheterisation and renal dialysis (Chuang et al. 2008; Galvao et al. 2012; Indian Heart Journal 1997; Leichsenring et al. 2018), it is not inconceivable that in the future there may be a presently undiagnosed or unrecognised infection which would create a medical emergency. This misgiving is not really very farfetched. A similar situation arose when the HIV virus first began propagating in humans, and the lack of knowledge about it led to

transmission by blood and blood products (Ammann et al. 1983). It is possible, if not probable, that an analogous infection may lead to disaster before it is recognised. Is it ethically justified to subject patients to this risk?

If the safety of the reuse of SUD can be shown to be equal to that of generic drugs, it can be tolerated without considering effectiveness and necessity because it can be argued that the generic drugs have been widely used without significant health problems in the situation where the affordability and availability of brand drugs and sustainability of fragile healthcare system matter, particularly in resource-poor settings. On the other hand, if there remain some safety concerns, the acceptable balance between effectiveness and necessity must be considered. For HIV mother-to-child transmission prevention study of 2–3, placebo control is considered acceptable in this case, the logic being that "getting even the second best is better than nothing." This could justify the reuse of SUDs.

However, when infectious diseases like HIV or HBV become a problem, it is necessary to consider not only the patient's own interest but also protection of public health. In doing so, it seems necessary to definitely ensure that the risks of infectious diseases are at an acceptable level. We cannot discuss how to manage potential risks caused by currently unknown infections, which could emerge anytime in the future, and we admit that it is difficult to define the acceptable level. However, at least, it can be argued that all we have to do is to keep behaving according to the precautionary principle and that we ought to stop the reuse of SUD as soon as even only one case of the currently unknown infection happens caused by the usage.

Informed consent

Would an informed consent be required in these circumstances? Would the physician concerned be obliged to discuss the reuse of disposables as a specific hazard? If scientific evidence suggests that there is no extra risk, then it should not be necessary to specifically mention that reuse is taking place. After all, in a standard informed consent process, one does not inform the patient that the dissecting forceps or sharp instruments are being reused. However, it would be necessary to guarantee that all the protocols are in place and are being meticulously adhered to. Perhaps the patient can have an opt-out option. However, it must be noted that if the decision to reuse is made by the patient due to economic considerations, it is questionable whether any consent obtained is truly voluntary. The concept of "voluntary" will necessarily differ depending on the patient's access to social security and/or health insurance.

It can also be argued that the patient has a right to try to use cheaper disposables with a higher health risk when he or she has only limited money to pay the price of branded devices. We would claim that it is rational for the patient to choose the cheaper but less safe device where the life or health is at stake. We cannot reject the competent patient's final decision as long as the decision would not cause harms to others or society. Nevertheless, whenever concerns of potential non-voluntariness and exploitation exist, additional protection should be given to the patient in question.

Equity (fair allocation) and pricing policies

The concept of equity is an important ethical principle. In 1992, Whitehead showed clearly that there were wide differences in the health status between European countries

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and within countries, among the different socioeconomic groups and between the rural and urban population (Whitehead 1992). This led to variations, which were iniquitous, as these differences were unnecessary and avoidable and therefore unfair and unjust. An ethics framework has thus developed that suggested that societies have a "positive responsibility to engage in programmes and interventions that seek to lessen societal inequalities, at the very least when those inequalities relate (as essentially all do) to health outcomes." (Kass 2001). While some inequities may be inevitable such as those due to biological or sex differences, others such as those due to inadequate access to health services are unjust and unethical. Especially in developing countries with a poor health expenditure and reduced access to health services, it is very apparent that the principles of distributive justice are not given due priority, time or investment (Prasad and Sengupta 2019).

While there is no consensus on what exactly needs to be equal, it is widely agreed that the definition is pluralist (Culyer 2001). It is also agreed that healthcare is one service where right distribution must be ensured. This implies equal access to health services and is probably best interpreted in terms of the costs, financial and others, to patients of using healthcare services. The principles of justice demand that everyone should have access to medical treatment of an adequate level or higher than that. What constitutes the acceptable level of quality will necessarily differ depending on the level of economic development of the country in which the patient resides. If the risk of reuse is at an acceptable level, reuse should be promoted as it can have a salutary effect on costs and access to the healthcare system in resource-poor settings.

We would argue that in the situations where healthcare resources are seriously limited, whether and when and how it is ever ethically acceptable to include reuse of disposables as part of health services depends on the considerations concerning all of these: safety, efficacy, cost, patient autonomy, accessibility, affordability, availability of alternatives, and sustainability of healthcare system in given societies; and we believe that both safety and cost (affordability) matter very much. However, as Linder claimed, the requirement for expensive sterilisation validation procedures towards SUDs in the interests of patient safety could be costly (Linder 1999), and the cost could be higher than using scarce resources in other ways. The authors acknowledge this limitation of our ethical framework, and when the total cost of reuse of SUDs turns out to be higher than the use of new branded devices, we would argue, our conclusions should be revised. However, we believe that the reuse of SUDs is cheaper and justifiably safe as healthcare device, especially in resource-poor countries when the life of the patients is at stake.

What should be the price of the disposable material? Will it be correct to price the new and the reused instrument the same? One possible way of resolving this dilemma is to decide beforehand how many times a, say, cardiac catheter is to be reused and to split the price between the users equally. This also can pose some issues because how is one to decide who is to get the new device and who is to be given a sterilised one? Is it fair to make an arbitrary distinction? Or would it be a randomised selection? Is this even feasible in a busy clinical context? Further ethical questions also need to be considered, such as whether any particular groups of patients can justifiably benefit from new devices over reused ones, such as children or persons with compromised immune systems. This could, however, be a factor to be included in any risk-benefit analysis.

Another solution would be to charge only the first user and to give it free to the rest other than an amount to cover the sterilisation and repacking charges. Even so, there are ethical issues regarding who would be the "first user". Probably a random selection would be the most ethical method. However, it may not be unethical for rich individuals to choose to pay more to "opt out" by paying more to obtain a sense of security.

Persad et al. (Persad et al. 2009) have suggested some principles for the allocation of scare resources. It may be instructive to review these principles. They reviewed eight allocation principles that are commonly used for scarce medical resources. These include using a lottery system or a first come first served approach, which treat all users equally. A second approach is to prioritise the patient in which case a youngest first, or sickest first principle has been used. Another alternative is to use a utilitarian approach by calculating which allocation would save the most lives or by calculating the prognosis or life years. Finally, it may be possible to promote and reward social usefulness by rewarding individuals for past sacrifices or where the individual's future usefulness is likely to benefit society.

These considerations have given rise to several systematic approaches like the United Network for Organ Sharing (UNOS) system and the Quality or Disability adjusted life years. There are several objections and benefits to these approaches but it may be possible to utilise these approaches to develop an equitable method of allocating first use of the SUD. If there are residual safety issues, which, however, are considered to be within acceptable limits, further ethical questions arise. In the case of vertical transmission of AIDS trials (2.3), the entire population was desperately poor and none was in a position to access expensive medical technology (drugs). In this case, the use of placebo could be justified. However, as for reuse of SUDs, difference in accessibility to healthcare exists between the rich and the poor in the same region. Here is also the knotty issue of how to justify using fresh disposables to those who can afford them and to reuse them in poorer patients.

This might be seen as a matter of consent: how acceptable is it that those who can consent (and pay) for new devices should be allowed to do so, when limited resources mean that poorer patients can only have access to re-used devices. This is part of a bigger debate about economic and epistemic injustice, but for this article the basis for deciding comes down to balance of evidence of safety and efficacy, and a realist view of what is possible with limited resources. If market economics mean some can afford a new device, then public services must concentrate on the ethics of reuse. This is not a matter of consent in such cases; it is about protection of patients and robust ethics to justify reuse.

Some other considerations (five issues)

Firstly, there is accumulating evidence that the drive towards the use of more and more disposables was initiated by the companies who made the devices in the first place (Medicare Payment Advisory Commission 2017). They incentivised doctors (to use a polite term) to recommend the use of disposables even if they were not really indicated technically and often held up the use of disposables a standard practice, labeling reusable material as "unsafe" and detrimental to patient outcomes. If indeed the use of disposables is necessary, there should be definite scientific evidence to back it up.

Secondly, it has been pointed out that the vast amounts of disposables add to the environmental problem of disposal of plastic material. It has been estimated that in the USA alone the medical industry contributes to four billion pounds of waste annually.

This is second only to the food industry (Macpherson 2010). Is it ethical to add this burden to the environment if it can be prevented by reuse? Would it be better, as it has been suggested, to do away with disposables altogether? (Collier 2011).

Thirdly, one of the important considerations proposed by the stewardship model of public health is to aim to reduce unfair health inequalities. The principal reason that health inequalities occur and are perpetuated is the cost factor. Some interventions cost so much that it is impossible for poorer people to afford and impossible for many health systems to fund even with the best of intentions. Reuse of disposables may be a single intervention that would make many interventions especially common ones like dialysis and cardiac intervention much cheaper and therefore much more available to the common man.

Fourthly, it has been earlier argued that it may not be necessary to insist that everybody should get exactly the same healthcare. It is ethically permissible to ensure as Frankfurt (2015) has argued that each should have enough. The reuse of disposables would make it possible for even resource-poor societies to give "enough" healthcare as it would be instrumental in making common and lifesaving interventions in kidney failure and heart disease available to many more individuals thus decreasing the healthcare inequalities that now exist.

Finally, if we are to reuse disposables or to roll back the tide of disposable use, some specific requirements must be met. The first would be to set up protocols for resterilisation which would be as failsafe as possible. This would not be difficult as, even a few decades ago, most instrumentation was done with reused and re-sterilised material and protocols did exist. Even so, in today's litigious climate, it may be necessary to do new studies to definitively establish that adequate sterilisation is achieved and demonstrate the safety of these protocols in randomised controlled trials.

It is important that new data on reuse from these studies is publicly available, and we have to realise the situation where evidence studies do not need to be repeated again and again once the evidence exists. It must also be noted that who pays for the costs of these trials for assessing safety and efficacy remains unsolved and it would be very hard to reach consensus. All of public fund, health insurance, hospital, and patients themselves have to cooperate with one another.

Conclusions

The cost of healthcare is a recurrent problem and has bedevilled all societies both in the developing as well as the developed world. Particularly in the case of interventions, one of the chief cost centres is the use of disposables. These are expensive and questions have arisen whether it is really necessary to use disposables as frequently as is the case today. Significant cost savings are possible if the disposables are reused after proper sterilisation. Moreover, significant cost savings enable more people to have access to medical care. In order that healthcare costs do not overwhelm societies, it is suggested that reuse of disposables should be routine.

There is scientific evidence to back up the reuse of plastics and no definite ethical objection as well. Even though unknown risks remain, it is not unfair to claim that the benefits of the reuse could outweigh the risks based on currently available scientific evidence regarding safety, especially in resource-poor economies. It may be possible to

extend health benefits to many more numbers of patients if this practice was widely adopted.

Finally, we would argue that ethical deliberation concerning whether and when and how it is ever ethically acceptable to include reuse of disposables as part of health services in limited resource situations would require us to carefully balance evidence on safety and efficacy, appreciate that the ethical question of justice is about some possible benefit from reuse as opposed to no intervention at all, and make the evidence base public to reduce costs for all.

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