Reprocessing and reuse of single use medical devices: 
Examination of ethical practice

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Abstract
This paper sets out to examine the practice of reprocessing and re-using single use medical devices. It looks at the background of how it became a mainstream practice within our hospitals, the ethics of the process and the risk towards patients’ health and wellbeing. The paper discusses whether or not reprocessing single use devices should continue to be practiced without guidelines or governance and looks towards the future of reprocessing and potential solutions to these problems.

Author keywords
Reprocessing, single use, device, ethics, risk.

Introduction
The reprocessing and reuse of medical devices labelled as ‘single use’ has been common practice since the late 1970’s with the introduction of inexpensive materials and more complex manufacturing methods, which meant equipment could become more disposable. However, with the prevalence of Blood Borne Pathogens such as the HIV/AIDS virus, Hepatitis B and C, it has become more of a contentious issue as to whether reprocessing and reusing equipment is safe for the patient and the clinician and whether it is ethically sound. Several countries including Australia and France have banned the use of reprocessed equipment for fear of safety to the patients and liability should anything go wrong. Conversely there are several large scale health organisations such as the NHS and a majority of hospitals in the U.S (which are under FDA jurisdiction) which still continue to use reprocessed devices. This paper seeks to examine what different healthcare organisations are doing with regards to the reprocessing and use of reprocessed devices and asks whether patients’ safety is being put at risk by re-using equipment labelled as ‘single use’.

History of reprocessing
Plastics, rubber, glass and metal were historically used to manufacture medical equipment, due to the materials’ durability. However, after equipment became more sophisticated, and the development of new, more intricate manufacturing methods introduced things such as narrower lumens and more complex forms, it became less
The development of new plastics in the 1970’s also allowed for a far more disposable approach to medicine. However, this proved costly and in 1987 the FDA allowed for medical devices that were marked as ‘single use’ such as intravenous cannulas and cardiac catheters, to be reprocessed and re-used. ‘Hospitals that reprocess SUDS assume full liability and responsibility for their reprocessing actions and should ensure that the products are adequately cleaned and sterilized and that device safety, effectiveness, and quality are maintained.’ [1]

In the late 1980’s the issue of blood borne pathogens (BBPs) became more prevalent than ever before following the discovery of the AIDS/HIV virus. Blood borne pathogens had previously been a consideration when reprocessing with diseases such as Hepatitis B and C. However, it was even more of a concern with such a serious illness. This brought to light a big ethical issue with hospitals and healthcare organisations as to whether they should be reprocessing single use equipment or not, particularly as there is no way of knowing where the equipment has come from and who used it prior to it being reprocessed and re-used. For countries such as the U.S and a majority of EU countries such as UK, Germany, Spain, Portugal and Italy it was mostly a reliable process. However with countries such as India, where it was estimated that up to 60% of injections that were being carried out were being done with unclean needles, [2] it became apparent that there could be an epidemic of BBPs being spread.

**TYPES OF EQUIPMENT CURRENTLY BEING REPROCESSED IN THE UK**

A majority of single use devices are invasive- even if it is minimally so. This means that they come into contact with bodily fluids when in use which can increase the risk of cross contamination after the reprocessing. The following is a small set of examples of devices that are commonly reprocessed currently in the UK

**Laparoscopic instruments**: An invasive instrument used during ‘keyhole’ surgery. Made from a variety of materials, but primarily metals such as titanium. Risks of reprocessing these devices are mostly from microbial transfer from ineffective cleaning or reprocessing. This can lead to infection in patients.

**Biopsy forceps**: An invasive instrument used during surgery to pick up tissue and vessels. Manufactured from metals such as titanium. Risks of reprocessing come from microbial transfer after ineffective reprocessing leading to possible infection post operatively.

**Angioplasty catheter balloon**: An invasive device used to open blocked blood vessels. Manufactured from polyethylene terephthalate (PET) or Nylon. The risk of reprocessing this device is the balloon may lose elasticity and therefore functionality. This can lead to it malfunctioning/failing in the next procedure. The guide wire is manufactured from plastics which may absorb the chemicals used during the reprocessing
which can consequently leak back into the patient’s blood stream during the procedure.

**Vascular stents:** Invasive device used to hold blood vessels open when they are too weak or blocked. Manufactured from wire mesh, the primary risk of reprocessing this device is microbial transfer from inadequate cleaning and therefore possible infection.

**Intravenous cannula:** A minimally invasive device inserted into the vein to deliver drug therapies. Manufactured from both plastics and metal. The risks of reprocessing this device are both a loss in functionality and also the risk of microbial transfer. The narrow lumen means it is difficult to flush any remaining bodily fluids/dangerous microbes which can lead to infection. The plastics mean that the device can degrade during the reprocessing or it can absorb the chemicals used during the process which can then be leaked into the blood stream causing adverse reactions to the patient.

**How devices are reprocessed**

I- Devices begin the process immediately after initial use. Devices with lumens are flushed and rinsed to ensure no drying of soil can occur as this makes it more difficult to successfully clean at the next stage.

II- The device is thoroughly cleaned in a dedicated cleaning facility either in the hospital or by a third party. Within the UK, if a third party other than the NHS reprocess the devices, they become liable for any malfunction after this time or until it is next reprocessed.

III- If required, the device is specifically disinfected or sterilized, again either on site or by the third party and is then repackaged as new and sent back into circulation to be used again. [3]
REPROCESSING AS A GLOBAL PRACTICE

Reprocessing single use devices is a widely accepted process globally. However the differing standards and lack of governance and guidance means it is practiced with widely varying success rates. Throughout Europe, a majority of countries practice reprocessing single use devices without quality standards. France is the only European country to ban the reuse of single use devices. Australia has also banned the use of reprocessed devices. A majority of Nordic countries such as Denmark, Finland and Sweden, practice reprocessing to a high standard but it is self-governed and is in need of reviewing. Germany and the UK have vague guidelines set in place which stipulate that a manufacturer does not need to prove that a single use device can withstand reprocessing as this is not the devices primary function. [2] The US are governed by the FDA which stipulates that if reprocessed equipment is to be used then it must be done so to the same standards as a new piece of equipment.

ETHICS AND REPROCESSING

Equipment marked as single use is viable to be reprocessed and reused according to the NHS. [4] However, ethically, there is an argument about whether it should be reprocessed or whether by reprocessing it and then sending it back into circulation ‘as new’ it is misleading the standard of quality to patients and practitioners alike. It takes the choice of treatment options away from a patient who may not want to have reprocessed devices used as part of their treatment. Equipment, while it can be thoroughly cleaned and sterilised, cannot be guaranteed to be free from microbes which can contain blood borne pathogens such as the HIV virus or Hepatitis B or C.

It is argued that the cost of reprocessing the device is much lower than the cost of manufacturing a new device and that the money saved from this can be utilised elsewhere in the healthcare system. This is mostly true (see figure 2); the cost of reprocessed equipment is much lower but this is often reflected in the quality. A Canadian study found that with an angiograph catheter balloon (see figure 3), it broke 8% in the first use, 10.9% in the second use and 26.8% in the third use. [5] due to the fact that the equipment comes back into circulation appearing ‘as new’, it is difficult to identify potentially faulty/low standard equipment unless it is obviously faulty or not fit for purpose. Reprocessing also reduces the amount of landfill taken up by the equipment, such as syringes and angioplasty catheters. This, again, saves money as well as being better for the environment but at risk to the quality of the equipment. It is seen as a greener option because of the reduction in landfill and in the materials. The process is effectively recycling. However, the author questions whether the carbon footprint left by the process of reprocessing actually outweighs that of manufacturing a new set of equipment?
<table>
<thead>
<tr>
<th>Intervention</th>
<th>Device cost</th>
<th>Cleaning cost</th>
<th>Expected cost of adverse events</th>
<th>Total cost of intervention</th>
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<td>Reuse</td>
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<td>$15</td>
<td>$973</td>
<td>$1235**</td>
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</table>

*probability of adverse event is 12.6 per 1000

**probability of adverse event is 445 per 1000

Figure 2
Table indicating values of reprocessing

Figure 3
angiograph catheter balloon
**Patient’s rights and reprocessed equipment**

Ordinarily, patients have to consent to procedures completed in hospitals within the NHS. However, patients are not informed if a piece of reprocessed equipment is used as part of their treatment. If a patient was to request to have new equipment used throughout their treatment, it would be very difficult to differentiate between new equipment and reprocessed, due to the fact that reprocessed equipment comes in looking and packaged ‘as new’. However, a group of manufacturers in Massachusetts, US have attempted to have a bill passed that requires practitioners to inform patients if a piece of reprocessed equipment is part of their treatment, and give them the choice between a new or reprocessed piece of equipment. [6]

The author feels that patients should have the right to refuse reprocessed equipment being used as part of their treatment, or at least be informed that reprocessed equipment is being used. Informed consent is a contentious issue in a lot of medical practices and experiments. The reprocessing of equipment is seen by many as one of the biggest medical experiments in modern times. Yet because there is very little ability to trace a piece of equipment’s history, it is difficult to assign accountability. “There is an unknown risk in using reprocessed devices, their use constitutes a vast medical experiment. Patients are asked to assume the risk… they are put at risk for the financial benefit of the hospital [5]

**Guidelines for reprocessing equipment**

If reprocessing is to remain common practice, the author feels that there should be a set of guidelines or legislations passed in order to give consistent definitive information about what to do with devices and equipment after they have been used, to make them more suitable to be reprocessed. For example ensuring that the device is not left to dry out after the initial use which increases the likelihood of microbes being left on the device after it has been reprocessed. This has been undertaken by the FDA in the US. They have implemented stringent rules regarding what types of instruments can be reprocessed and how this should be undertaken. There is an obligation from the NHS to implement guidelines as to which equipment is not suitable for reprocessing. For example, equipment used on patients with blood borne pathogen contaminates such as the HIV/AIDS virus or hepatitis should not be reprocessed due to the additional risk posed from the contagion. However, under the NHS this is still possible and even likely to happen, as there is nothing that stipulates that devices used on patients with contagions should be discarded and destroyed.

It is also recommended by the author that the guidelines give recommendations for how many times it is appropriate to reprocess a device due to the loss of quality assurance with each reprocessing. The guidelines should also stipulate how the devices should be discarded properly at the end of its life cycle to ensure that they cannot re-enter the system and potentially cause harm to a patient. The guidelines
could also show how many times the device has been reprocessed, in a bid to ensure that it maintains a high enough standard of quality to be used without fear of malfunction or breaking causing harm to the patient. This would also help with regards to accountability issues surrounding the process. If a full history of previous usage was available to a clinician they could decide whether or not it was appropriate to re-use the device again. For example, an Immunocompromised patient needs to be particularly careful of catching an infection, therefore a full history of previous usage could help determine whether or not a device was suitable to be used on that patient. The history of the device could include the amount of times it had been used, the type of reprocessing the device had previously undergone and even the previous patient’s health status so that clinicians can see if the patient had a contagion such as Hepatitis.

Debra Dunn, of the Association of perioperative registered nurses, recommends that certain groups of individuals should not receive any reprocessed devices as part of their treatment. These include:

- Immunocompromised patients, such as those with undergoing cancer treatment;
- Patients with mitral valve prolapse or mitral valve replacement, because they are prone to bacterial endocarditis;
- Patients debilitated by chronic health conditions, such as renal failure or diabetes;
- Patients receiving orthopedic implants; and
- Older adult and very young patients.[5]

THE RISKS OF REPROCESSING

Reprocessing is difficult to monitor and govern successfully, due to the fact that there is no way of telling how many times a ‘single use’ device has been reprocessed and reused. As discussed previously, the more times a device is reprocessed it becomes at a higher risk of malfunctioning or becoming faulty. In the US the FDA have implemented rules by which all reprocessed devices are required to undergo the same clinical tests as if it were new. The NHS does not implement any such system.

Patient safety

Although it is a small risk, by using reprocessed devices, there is an elevated risk of cross infection between patients from microbes being left on the device after it has been reprocessed from previous usage or usages. Patient safety is also compromised from toxins being left on the device from the physical cleaning process. These have been documented in a report from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) which claims that the deaths of 16 premature infants was caused due to contamination of a benzyl alcohol solution which is used to flush central venous catheters.

Certain plastics, which are not compatible with the chemicals used in the reprocessing process, will absorb the chemicals which can then be leaked out when it is reused on the next patient.[7]. The physical properties of the devices can
also change. Due to the high temperatures used in certain cleaning methods, it may result in a device changing shape or structure which can result in unfavourable results for the patient. The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) claims that: "Patients with reduced arterial elasticity might react during a procedure carried out using a reprocessed SUD which has changed its physical parameters (e.g. increased stiffness and increased roughness of the surfaces). The higher shear stress in the vasculature could lead to an increased risk of endothelial damage and rupture." [7]

The devices themselves are not designed to withstand reprocessing. The material choices are based upon the device being used and then discarded. The complex forms of the devices and long narrow lumens of some of the catheters are particularly challenging to clean successfully. If a device's physical structure changes due to the reprocessing, it can result in the device malfunctioning during the next procedure after reprocessing. This can result in adverse effects for the patient or even mortality. There was a case reported in an American hospital of the tip of a reprocessed cardiac catheter breaking off during a procedure causing lasting disability to the patient. [7]

It is difficult to prove liability if a device malfunctions or fails as there is no way to trace the devices history. However, the reporting of a device failing is very low as it is almost impossible to prove that it was the reprocessing process that caused the device to fail/malfunction. However, if new guidelines were implemented that required that devices’ history could be traced it would make accountability far easier and therefore would encourage a more responsible attitude towards the reprocessing.

CONCLUSION

Reprocessing is a practice which potentially jeopardises the health and safety of patients. Although it is seen as the cheaper alternative to using new devices, this is often not the case. If properly overseen and governed, it has the potential to be extremely successful and save a lot of money that can be utilised elsewhere in the health care system. The ramifications of the reuse of single use devices has not been fully explored yet, which only increases the irresponsibility of health care systems which operate reprocessing. Until all these issues are addressed, it is not an ideal practice and should be very carefully monitored to ensure patient safety is not jeopardised.
REFERENCES


Figure list

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Figure 2- Hailey. D, Jacobs. PD, Ries. NM, Polisena. J. Reuse of single use medical devices in Canada: Clinical and economic outcomes, legal and ethical issues, and current hospital practice, International Journal of Technology Assessment in Health Care, vol24:4 pg 430-436. [inter library loan]

Fig 3- http://img.tfd.com/vet/thumbs/gr62.jpg