EDITORIAL

Is there an ethical imperative to reprocess single-use medical devices?

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Is reusing single-use medical devices (SUDs) ethical? This question takes on urgency in a healthcare world facing ever-greater economic pressures and manifest environmental imperatives. What are the ethics, evidence, and debates in this arena? How should urological surgeons in Africa engage with the issue?

In 2017, the South African Health Products Regulatory Authority (SAHPRA) began regulating medical devices for the first time. In 2019, SAHPRA issued a formal directive which states, *"medical devices intended by the original manufacturer for single use may only be used once, may not be reprocessed and must be disposed of after use."*[1]

The SAHPRA directive has put an end to my (JL) decades-long practice of reusing guidewires, Dormia baskets, among other single-use urological devices. My initial response to the ban was like a commentator who said: *"The stipulation that an SUDs never be reused places the healthcare system and society at large in a position of financial hostage to manufacturers."*[2]

The ban led us to try to engage with SAHPRA on the matter. A like-minded group of concerned colleagues has attempted to formally engage with SAHPRA including via a letter to the South African Medical Journal.[3]

SUDs are increasingly the norm in urological practice. In the early 2010s, I (JL) patented a device to aid percutaneous nephrolithotomy (PCNL). A biomedical engineer criticised the device saying that without a disposable part the device's chance of making any money was zero. Not that my device would have (or did) turn any profit, the commercialisation point was well made!

The self-evident medical device industry's imperative for a shift to SUDs needs to be countered by the need for fiscal restraint in health care (especially in the context of our developing economies on the African continent) and by the need for environmental responsibility.

The big (environmental) picture

Reprocessing SUDs is a way to reduce the carbon footprint of health care, which contributes 4.4% of global emissions, equivalent to the annual greenhouse gas emissions from 514 coal-fired power stations.[3]

What contribution does surgery make to global warming? Consider a typical cataract operation. In the UK, it generates 182 kg CO_2, while in India the same operation generates only 6 kg CO_2. This 30-fold reduction is largely accounted for by efficient systems and reuse of equipment.[4]

A robotic prostatectomy contributes 814 kg CO_2 which is equivalent to the emissions produced by driving a petrol-powered car for 3 658 km or the emissions corresponding to a single passenger flying from Cape Town to Johannesburg 3.3 times.[5]

Medical waste is a second environmental problem to consider. Health care can contribute to creating a sustainable future by reducing the substantial amount of waste it produces. According to one study, the US healthcare sector is second only to the food industry in contributing to landfills, disposing of an estimated 1.8 billion kg of medical waste annually.[6] This vast amount of landfill waste becomes explainable when one considers that a simple tonsillectomy can generate over 100 pieces of disposable plastic.[4]

SUDs and healthcare costs

In December 2022, Zimbabwe's main public referral hospital (Parirenyatwa Hospital) ran out of sutures.[7] While this is an extreme (and extremely distressing) example, it does highlight the plight of the developing world to afford health care for their citizens.

It has been estimated that reprocessing SUDs is associated with a 50% reduction of medical device costs compared with purchasing new equipment.[5]

What is reprocessing?

Reprocessing SUDs is an unavoidable practice in low- and middle-income countries (LMIC) where economic constraints are severe.

Yet it's not only the developing world that reuses. Over 8 800 hospitals use reprocessed devices in the US, Canada, Israel, Europe and Japan.[8] Approximately 20–30% of US hospitals report that they reuse at least one type of SUD.[9]

In the US, the Washington-based *Association of Medical Device Reprocessors* (AMDR) represents the private industry that supplies reprocessing services to hospitals.[10]

Currently, the European Union (EU) does not have a single policy regarding the reprocessing of SUDs.[8] Rather, each country has its own regulations.[11] Germany, for example, has a regulatory framework that does not distinguish between the reprocessing of "reusable" and so-called "single-use" medical devices. The guidelines, therefore, allow for SUD reprocessing if conforming to certain standards.[8]

SAHPRA's 2019 blanket ban on reprocessing would thus appear to be out of step with international practices.

Patient safety

Concerns about patient safety (through risk of infection or device malfunction) are likely the main barrier to more widespread adoption of reuse of SUDs. Are these concerns evidence-based? The answer (given the limited literature) appears to be "no".

The US Government Accountability Office (GAO) released a (2008) report entitled *Reprocessed Single-Use Medical Devices.*[12] It concluded that "reprocessed SUDs do not present an increased health risk when compared with new, non-reprocessed devices".

Patient safety can, in our view, be assured if a (US FDA) risk-stratified approach is taken to classes of devices. This implies that costly low- to medium-risk (US FDA Class 1 and 2) SUDs should be targeted first. Regulation and quality control of sterilisation departments and (potentially in the future) private reprocessors are key.

Way forward

Our engagement with SAHPRA aims to evolve the 2019 directive that bans reprocessing to a regulated, guideline-driven environment that permits a risk-stratified approach to devices and ensures quality-control of reprocessing to protect patients, the environment and the national fiscus.

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