EAMDR
European Association for Medical Device Reprocessing

Myths and inaccuracies: The centric role of patient safety in Medical Devices Reprocessing

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The medical devices reprocessing industry is a new, dynamic market segment, aspiring to safely reprocess medical devices whilst maintaining the quality of the product in full. In this way it aims to make cost-cuttings possible and reduce environmental waste while guaranteeing patient safety. At European level, this industry sector is represented by the European Association for Medical Device Reprocessing (EAMDR).

Every evolution in the medical world faces, at first, scepticism regarding actual or rumoured risks. This is only logical given the sensitivity of the issue, since good health is the indispensable foundation of quality of life. But what happens when the medical equipment manufacturers, who supply hospital and patients with medical equipment, use this trust relationship to damage the reputation of reprocessing methods as a whole and generalise common fears related to hypothetical potential risks by launching a campaign against them? A very promising, emerging industry is threatened by this.

The medical devices reprocessing sector is, in effect, exposed to an attack by its competitors who are, at the same time, immediate suppliers of hospitals and patients. Having established a close relationship with their clients over the years, manufacturers have a strong influence over the public opinion concerning the alleged damaging potential of medical devices reprocessing.

In its recent press release the manufacturer's association EUCOMED tries to undermine the integrity of the reprocessing industry using the following methods:

- The description of health risks in conjunction with reprocessing, implying an unsubstantiated causal link between the two areas: "(...) In the European Union, there are approximately 3 million healthcare associated infections and 50.000 related deaths per year. In 2003, the WHO estimated that 8.9 million people were infected with Hepatitis C and another 500 000 people with HIV. In many cases, the hospital does not know whether a patient is infected or not. Reusing medical devices that are not designed to be reprocessed increases the risk of cross-contamination";
- Hypothetical statements which are not qualified by the data or justifications necessary to place them in a concrete and therefore understandable context: "[S]afety and functionality (of single use medical devices) can be jeopardized, with potentially severe consequences for the patient. In particular, there is an increased risk of infection, injury, diagnostic errors and ineffective care";
- Generalisations which aim to dispute the validity of reprocessing methods, but which only refer to unproven health risks: "Today, such sophisticated single use instruments and devices are being reprocessed and reused, with the risk of harming the patient. Action to prevent this is urgently required";
- Infection data loosely juxtaposed to a mention of the use of reprocessed devices, without any corresponding data for the latter. This again implies a causality, without offering any supporting information: "The direct and indirect costs of hospital acquired infection have been estimated at over 11 billion /year. It would be interesting to investigate what proportion of these infections are due to the use of reprocessed single use medical devices";

- Vague references to alleged costs that might be incurred - under the assumption that reprocessing is not performed correctly: "[Potential additional costs] include longer procedure time and hence prolonged anaesthesia; patient injury and repeat surgery or intervention; repeated diagnostic tests; hospital acquired infection and subsequent treatment (e.g. increased use of antibiotics); patient incapacity (absence from work, etc); pain and suffering of the patient and relatives; legal proceedings or out-of-court settlements; negative impact on hospital reputation; and handling reprocessed products (administrative, transport, etc)". In this context it is noted that the above-mentioned fictive costs remain uncorroborated.
- Failure to distinguish between validated, monitored and tolerated, or uncontrolled reuse of medical devices, therefore unacceptably equating them to each other: "To guarantee patient safety complete device testing is mandatory on every reprocessing cycle and on every single device, according to the University of Trento. This is clearly not being done"; "However, in countries where reuse of single use medical devices is tolerated, patients are not told that they will be treated with a reprocessed product against the manufacturer's instructions, or informed of the related risks (described above)".

Biased non-representative studies used to support the alleged danger of reprocessing methods: Not only is the majority of those studies completely outdated (most of them dating from 1999, even though the reprocessing industry has achieved major progress over the past years), but also, almost all of them are conducted by manufacturers themselves! And by once again not distinguishing between standard-compliant, high quality reprocessing and uncontrolled, poor quality reprocessing, it is plainly obvious that the manufacturers had the opportunity to focus on isolated incidents of careless reprocessing, and present them as representative of prevalent reprocessing standards.

Effective reprocessing of medical equipment requires a European legal framework to provide legal certainty for high-quality reprocessing services throughout the territory. Such a framework would also therefore greatly reduce the related risks to patient and user safety.

EAMDR is working towards an amendment of the Medical Devices Directive that would

- only allow reprocessing as long as validated procedures are in place,
- establish a quality management system of reprocessing,
- clearly define the terms "single-use", "multiple-use", "refurbishing" and "reprocessing" and, consequently,
- ensure a high level of protection for patients, hospitals and medical personnel.

In order to reach a consensus on technically difficult and socially sensitive issues such as these, an honest dialogue based on best founded arguments instead of popular bias is needed. Prejudging and stigmatising a new industry sector, thus precluding an in depth discussion of the issues at stake, is counterproductive and inadmissible. EAMDR is, therefore, striving for a substantiated dialogue on medical device reprocessing that would dispel prejudice, and enhance both transparency and close monitoring, whilst keeping patients' safety and overall welfare at heart.