Let's change paradigm

Christophe Lambert
Editor

After SARS in 2003, MERS in 2012, COVID-19 (coronavirus disease) is the third global epidemic of this 21st century. These zoonotic diseases have in common their unusual transmission route from an animal to man while spreading by means of an intermediate vector. While the bat is the primary reservoir of these betacoronaviruses, the civet cat is thought to have been the vector of SARS-CoV-1, the camel that of MERS and the pangolin, better known as the anteater, that of SARS-CoV-2, unless the latter is the result of a mistake made at the biosafety level 4 laboratory in Wuhan. Whether responsibility for that is proven or not, this pandemic shows our vulnerability and our weaknesses in dealing with it.

Among our weaknesses the inability to provide personal protective equipment (PPE) (masks, protective gowns, etc.) and to supply single-use anaesthesia equipment or anaesthetics confirms our dependence on the manufacturing countries. That scarcity has given rise to initiatives, attempts and experiments aimed at reprocessing single-use medical devices. Just as in a time of war, so too have unavailability and critical need led to price inflation and to the most original and creative alternative remedies. Among them we cite the example of a diving mask that had been designed by one of the leaders of the global sports market and converted into an anaesthesia mask for patients undergoing oxygen therapy.

Many other initiatives have been taken, thanks in particular to 3D printing technology, to offset the shortage of single-use devices. Although in principle single-use reprocessing, still prohibited in France, is permitted by Article 17 of European Regulation 2017/745 for medical devices, this is underscored by the obligation to describe technically and scientifically proven, validated reprocessing procedures. The protocols and recommendations we have seen emerge in this race against time could not of course meet these standards but they also show the researchers' lack of understanding of how hospitals as well as their hygiene and sterilization rules operate. Some of them have even interpreted in a simplified way that an effective reprocessing process just had to guarantee destruction of this new emerging agent. But the key aspects of medical device reprocessing are well established and require more than merely demonstrating the efficacy to destroy a, incidentally quite fragile, virus.

We the medical device reprocessing professionals are perfectly aware that the various steps must be organized in accordance with defined and controlled procedures to assure the safety of the finished product. These steps call for risk-free collection and sorting by the entrusted personnel as well as for cleaning, which is a key and crucial step for the success of the final disinfection or sterilization step. Among the existing methods, dry or humid heat, alcohol, radiation, UV rays, microwaves, vaporized hydrogen peroxide (vH_2O_2) are currently the most commonly investigated methods. And not surprisingly, virtually none of the numerous protocols put forward has succeeded in combining all the reprocessing steps while guaranteeing the functionality of the reprocessed devices. And if that, the very essence of single-use status, meant not being able to accept a reprocessing procedure.

It is our duty to continue our quest for a possible solution to reprocessing these devices which were sorely missing and up to the present day continue to be in short supply for those in greatest need of them. And if the solution to our vulnerability meant a return to procurement from local suppliers and to rational and appropriate use of reusable devices. Healthcare workers have mobilized and shown their willingness to fight this health scourge and must now be given the means to protect themselves and deliver care.