Individualization of orthopedic implants

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According to the Ministry of Health, orthotics, prosthetics and special materials (OPSM) are used in health care and are related to medical, dental, rehabilitation, diagnostic or therapeutic interventions. OPSMs represent high cost in the health field, which triggers the need for more control from the point of view of screening and processing[1].

Among the OPSMs, we can highlight implants, characterized as medical services (MD) that are surgically implanted, temporarily or permanently; its use is given by the need to replace the functionality of a limb or joint in a manner that is close to the physiological one, allowing more longevity and better adjustment to the applied location[2].

According to Specific Resolution n. 2,605, from August 11, 2006, of the Brazilian Health Regulatory Agency (ANVISA), implantable devices cannot be reused, therefore, even if there is an ineffective attempt of implantation, they should be discarded. The mechanical strength attributed to it during this attempt could damage the implant or compromise its structure[3].

In the routine of the Sterile Processing Department (SPD), we receive implants and instruments in cases with large quantities of plates and screws to be processed and used in different procedures. The justification to make implants available in graphic boxes is to facilitate size selection (length, diameter) and the model of the implant that adjusts better to the case of the patient during surgery. This practice has led to many doubts and questions from nurses in the SPD about possible changes in the initial characteristics of products facing the multiple exposures of implants to chemical products used in the cleaning process, the high temperatures used in disinfection and sterilization processes, and the frequent handling by professionals. It is necessary to produce scientific evidence showing if after many reprocessing processes, the mechanical resistance, integrity and biocompatibility of the product remain unchanged; and, based on this evidence, to define the number of times these implants can be reprocessed, thus standardizing the way processing that was already carried out can be registered

The concern about multiple exposures of implantable devices to intraoperative handling, circulation in different health institutions and poor reprocessing practices result in the formation of biofilm on the surface of implants, thus increasing the risks of surgical site infections. Biofilm consists of the aggregation of cells on a surface, which are involved by a matrix of extracellular polymeric substances, which protect micro-organisms against cleaning agents, thus resulting in compromised sterilization[4], and increasing the risks of infection, cost of treatment, implant loosening and, consequently, morbimortality.

The Resolution from Collegiate Board n. 594, from December 28, 2021, of ANVISA, disposes of the requirements to group implantable materials in orthopedics for purposes of registration and other matters[5].

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The practice of individualization of sterilized ready to use implants is already defined and consolidated for some medical applications in Brazil, such as hip and knee prostheses, vascular, heart and dental implants. However, it is possible to observe a large number of implants used in spine surgeries, craniotomies, maxillofacial surgeries, trauma, among others, and these are still provided in sets to be processed in the SPD of the health service without instructions from the manufacturer.

Aiming at answering the doubts of SPD professionals related to the possibility of individualization of implants, the Brazilian Association of Operating Room Nurses, Anesthetic Recovery and Material and Sterilization Center — SOBECC promoted a roundtable discussion during the 13th International Symposium of Sterilization and Infection Control related to Health Care, carried out in São Paulo (SP), Brazil, in 2022, to discuss this important theme. Obviously, the individualization of these MDs has an impact on manufacturing, storage, logistic processes costs and on public and private health systems.

Currently, it is common for the SPD to receive boxes with large quantities of implant, sometimes more than 300 tiny screws, plates and instruments, with little time for them to be processed and made available for use at the time of the procedure.

When the implants get to the SPD, we do not receive information about the route of these products, such as: through which institutions they have gone, circumstances of processing and technological resources that were used, quality of water, standard operational procedure, besides the knowledge and skills of the human resources that handled them. Depending on the adopted practices and the used resources, the quality and safety in processing can be affected. It is a known fact that to meet the work demand in the MSC, important steps of processing can be omitted, since there is no synchronism between time of delivery of OPSM and time of surgery.

All norms, resolutions, national and international guidelines are unanimous to determine that non-sterile MD, both implantable or not, received in the SPD for processing, should be submitted to all stages of processing in a detailed manner, respecting each step and time required to ensure good practices[6-9].

Given the lack of time and need to speed up the entire processing, the method of choice for cleaning is the automated one, through ultrasonic cleaners, because it is faster and for not dislodging the implants from their support. However, not all SPDs have ultrasonic cleaners with capacity for different box sizes. Besides, a proper rinse to remove organic, inorganic and detergent residue is essential to prevent these products from becoming carriers for the bodies of patients during the procedure. Some ultrasonic cleaners do not have the automated rinse system consecutive to cleaning, so professionals rinse the products manually, which can increase the variability of the process and compromise the expected outcome.

Individualized manual cleaning, despite being efficient, is usually unfeasible due to the large number of instruments and implants, but in some institutions, it is the only choice, thus compromising the quality of cleaning.

Besides all difficulties faced by the SPD for processing the OPSM, not all manufactures (national) and distributors (international) provide the use instructions of products so that standard operational procedures can be defined and elaborated according to the guidelines, which can compromise the efficacy of cleaning, and, consequently, patient security.

Another argument in search of the individualization of implants is related to inspection, carried out in a rudimentary manner, to the naked eye, or with magnifying glasses that do not detect the presence of biofilm.

The great problem of circulation of implants in several health services is reported in a study that identified biofilm in explanted materials, which is a warning for late clinical manifestations that can occur up to one year after the procedure. Patients with this type of infection do not present classic symptoms, such as fever. In general, they manifest a chronic inflammatory process, such as pain, low-intensity functional strength, no secretion drainage, no immune response, and no response[9].

In the dental field, implants are individualized, sterilized in double barrier packaging and, through imaging examinations, professionals can estimate the size of implant to be used, with no need to open many of them. Therefore, it is possible to infer that facing the advanced technological resources in diagnostic imaging, it is likely that spine, surgeons, orthopedists, neurosurgeons and maxillofacial surgeons can, through images, estimate the size of implants to be used, thus reducing the risks of opening unnecessary products.

In this context, it is observed that the individualization of implants is not a concern of manufacturers; their attention is mostly addressed to biocompatibility of the materials used in manufacturing and financial viability. The products with higher biocompatibility cost more, which prevents their use both in private and in public health services (Unified Health System – SUS), whose price chart is not updated regularly. With the proposal to individualize implants, there is a reaction

that is more related to the increasing costs of production and the need for readjusting the final price of the products.

Another argument for the non-individualization of implants is the need to increase storage areas in the manufacturers' stocks, as well as in distributors, hospitals and in the logistic process.

Implants are considered as single use products, regardless of packaging. The fact of opening a box with several implants and only handling the product outside the surgical field does not characterize them as multiple use, which enables their reprocessing. However, according to the use instructions of manufacturers and regulation systems, once the individualized and ready to use MD package is opened, its non-use will lead it to being discarded, once the validation of processing of this MD was exclusively carried out by the manufacturer.

Some experts report that the diversity and complexity of surgical procedures, and the different options of sets of implants, are factors that make it difficult to individualize orthopedic implants. In surgeries with primary hip and knee prostheses and in elective procedures, planned in an orderly manner, it is difficult to be flaws in the selection and opening of implants. Due to the high complexity and high risks of spine surgeries, the probability of implant deviation, requiring changes in MD, is more common. Tibial plateau, hand and foot fractures require implants of different sizes, and individualization may make it more difficult to carry out the technique and the surgical procedure itself.

In non-standardized procedures, such as trauma, a high number of screws is replaced during surgery due to flaws in the specific instruments used to prepare the bed where the implants will be inserted, such as: uncalibrated measuring, divergence between sizes of the drills, male threads and screw sizes, so that the implant does not adjust to the prepared orifice. Besides the risks for patients caused by excessive handling, these screws are returned to their place in the graphic box. It is important to mention that the pressure put on the screw during its insertion may lead to loss of function and mechanical resistance of the product; however, when professionals in the SPD are not informed about this attempt, the implant can be used in another patient, which can compromise the expected outcomes of the procedure.

The implantation of a screw that has been tested in a patient is an inconformity, but still a common practice, despite the nurses' efforts to prevent the situation.

We understand there is a big challenge in the individualization of tiny implants used in maxillofacial and skull closure surgeries. In boxes measuring 20 x 30 cm, which accommodate approximately 250 screws and 100 plates, we could put a total of 350 individual packages containing 1.2 mm screws, which would be safer for patients.

An extremely serious problem that led these products not to be individual until this day is the case of open and not used screws. This could create an unpayable bill due to the health system model in the country, only as a consequence of screw disposal.

Until we reach a point of balance, it is important, after every discussion, to reflect and answer the following questions: Are manufacturers, the economy, health systems, the world, ready for the individualization of implants? In case that happens, how long will it take to adjust the entire process? Is there risk of collapse in the health system due to lack of MD or high cost? Who will pay the bill for this individualization?

Even though costs are important for the survival of health systems, they cannot overlap patient security. From the economic point of view, the lack of good practices in the processing of MD interferes in care quality and leads to increasing risk of hospital infections, which impacts the costs of treatments and damages the integrity, the life and productivity of individuals. The understanding and discussion of the logic of others are the best way and shortest path towards the conciliation of several parties.

The risk exists, and it is necessary to assess if this risk sensitizes the sectors that are more concerned about the economic factor than lack of patient security.

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CONFLICT OF INTERESTS

The authors declare there is no conflict of interest.

AUTHORS' CONTRIBUTIONS

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REFERENCES

1. Fernandes HMLG, Cavassin LGT, Miranda LL, orgs. Boas práticas na gestão de órteses, próteses e materiais especiais (OPME). São Paulo: SOBECC; 2023.

2. Relvas C, Reis J, Potes JAC, Fonseca FMF, Simões JAO. Sistema de fabrico rápido de implantes ortopédicos. Rev Bras Ortop. 2009;44(3):260-5. https://doi.org/10.1590/S0102-36162009000300013

3. Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. Resolução – RE Nº 2.605, de 11 de agosto de 2006. Estabelece a lista de produtos médicos enquadrados como de uso único proibidos de ser reprocessados. Brasília: Diário Oficial da União; 2006.

4. Pereira LA, Lopes LKO, Costa DM, Santos MA, Boff IMQ, Leão-Vasconcelos LSNO, et al. Biofilme em parafusos ortopédicos prontos para uso adquiridos por meio de sistema de consignação/comodato. Acta Paul Enferm. 2023;36:eAPE00811. https://doi.org/10.37689/acta-ape/2023AO00811

5. Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. Diretoria Colegiada. Resolução – RDC Nº 594, de 22 de dezembro de 2021. Dispõe sobre os requisitos para o agrupamento de materiais implantáveis em ortopedia para fins de registro e dá outras providências. Brasília: Diário Oficial da União, Edição 245, Seção 1, pág. 184.

6. Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. Resolução RDC Nº 15, de 15 de março de 2012. Dispõe sobre os requisitos de boas práticas para o processamento de produtos para saúde e dá outras providências. Brasília: Diário Oficial da União; 2012.

7. Association for the Advanced of Medical Instrumentation. ANSI/AAMI ST79:2017: comprenhensive guide to steam sterilization and sterility assurance in health care facilities. Arlington: American National Standard; 2017.

8. Associação Brasileira de Enfermeiros de Centro Cirúrgico, Recuperação Anestésica e Centro de Material e Esterilização. Diretrizes de práticas em enfermagem perioperatória e processamento de produtos para saúde. 8ª ed. São Paulo: SOBECC; 2021.

9. Vickery K, Hu H, Jacombs AS, Bradshaw DA, Deva AK. A review of bacterial biofilms and their role in device-associated infection. Healthc Infect. 2013;18(2):61-6. https://doi.org/10.1071/HI12059