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REFLECTIVE ANALYSIS ARTICLE

REPROCESSING AND REUSE OF SINGLE-USE DEVICES: ETHICAL REFLECTION

REPROCESSAMENTO E REUTILIZAÇÃO DE DISPOSITIVOS DE USO ÚNICO: REFLEXÃO ÉTICA

REPROCESAMIENTO Y REUTILIZACIÓN DE DISPOSITIVOS DE USO ÚNICO: REFLEXIÓN ÉTICA

Maria Dulce Santos Santiago[1], Maria da Conceição Batista Correia[2]

ABSTRACT

***Objective*:** to emphasize the ethical aspects involved in the reprocessing and reuse of single use devices, especially considering the scope of action of nurses in an institutional context. ***Method*:** theoretical study, which from the context of the theme directs the analysis to issues in the field of ethical foundations. ***Results*:** human dignity is stressed, emphasizing the link between the human and the surrounding natural reality, and also the fundamental ethical principle, the source of all principles, values and rights. The result is guidelines for decision making by nurses in the exercise of their professional responsibility, in regard to issues involving the subject. This applies to the question about the very possibility of considering this practice; the population to which the material is intended; and informed consent for its use. ***Conclusion*:** the consideration of ethical issues involved in the issue is a requirement that arises for the nurse, with a view towards a process of responsible decision-making, based on balancing rights and individual interests with the economic and environmental aspects, ensuring that no argument can override the supreme ethical principle of human dignity. ***Descriptors*:** nursing; disposable equipment; equipment reuse; ethics.

RESUMO

***Objectivo*:** salientar aspectos éticos implicados no reprocessamento e reutilização de dispositivos de uso único, considerando sobretudo o âmbito de actuação dos enfermeiros em contexto institucional. ***Metodologia*:** estudo de reflexão teórica, que a partir da contextualização do tema, direciona a análise para questões no domínio dos fundamentos éticos. ***Resultados*:** destaca-se que a dignidade humana, salientando o elo entre o humano e a realidade natural envolvente, é o princípio ético fundamental, fonte de todos os princípios, valores e direitos. Daqui decorrem orientações para a tomada de decisão do enfermeiro no exercício da sua responsabilidade profissional, relativamente às questões em torno do assunto. É o caso da interrogação sobre a própria possibilidade de considerar essa prática; a população a que se destina esse material; ou o consentimento informado relativamente ao seu uso. ***Conclusão*:** a consideração dos aspectos éticos implicados no tema é uma exigência que se coloca ao enfermeiro, com vista a um processo de tomada de decisão responsável, assente no necessário equilíbrio dos direitos e interesses individuais com os aspectos económicos e ambientais, garantindo que nenhum argumento pode sobrepor-se ao princípio ético supremo da dignidade humana. ***Descritores*:** enfermagem; equipamentos descartáveis; reutilização de equipamento; ética.

RESUMEN

***Objectivo*:** destacar los aspectos éticos involucrados en el reprocesamiento y reutilización de los dispositivos de un solo uso, especialmente teniendo en cuenta el ámbito de actuación de las enfermeras en el contexto institucional. ***Método*:** estúdio teórico, que desde el contexto del tema, dirige el análisis de las cuestiones en materia de fundamentos éticos. ***Resultados*:** si pone de manifiesto que la dignidad humana, teniendo en cuenta la relación entre lo humano y la realidad natural circundante, es el principio ético fundamental, la fuente de todos los principios, valores y derechos. Esto plantea las directrices para la toma de decisiones de las enfermeras en el ejercicio de su responsabilidad profesional, sobre las cuestiones en torno al tema. Esto se aplica a la pregunta sobre la posibilidad de considerar esta práctica, la población que se destina este material y el consentimiento informado para el uso. ***Conclusión*:** la consideración de asuntos éticos involucrados en el tema, es un requisito de las enfermeras, hacia un proceso de toma de decisiones responsable, basado en la necesidad de equilibrar los derechos e intereses individuales con los aspectos económicos y ambientales, asegurando que ningún argumento puede anular el principio de ética suprema de la dignidad humana. ***Descriptores*:** enfermeria; equipos desechables; equipo reutilizado; ética.

[1]Nurse Specialist in Surgical Nursing. Master in NursingSciences. Doctoral student in Nursing at the Catholic Portuguese University. Adjunct Teacher in the College of Health – Polytechnical Institute of Beja. Beja, Portugal. E-mail: dulcessoares@gmail.com; [2]Nurse Specialist in Surgical Nursing. Master of Sciences in Education in the specialty of Curriculum Development and Evaluation. Doctoral student in Nursing in the University of Lisbon. Adjunct teacher in the College of Health of Beja - Polytechnical Institute of Beja. Beja, Portugal. E-mail: conceicao.correia@ipbeja.pt

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INTRODUCTION

In the field of health care technological advances observed in the last decades have marked the confrontation of professionals who develop their activity in this context, with the proliferation of instruments for diagnosis and treatment, designated as medical devices. The scope of the term more concretely refers to:

> [...] any instrument, device, equipment, software, material or article [...] intended by the manufacturer to be used on human beings for purposes of diagnosis, prevention, control, treatment or attenuation of a disease [...].[1]

Of these devices, a few are considered as single-use, which means that the device should be used only once by only one person.

However, nowadays, the reuse, after reprocessing (disassembly, decontamination, cleaning, inspection, testing, packaging, re-labeling and sterilization) of some single-use devices (SUD) seems to be a very common practice. This is so true that it actually constitutes a real phenomenon on a worldwide scale, which has been assuming increasing importance in health institutions and at the same time is involved in considerable controversy.

The controversy caused can be understood when confronting the very definition of the term and the controversy that arises from it. In fact, if it is considered that by SUD, is meant a disposable device, normally labeled as such by the original manufacturer of the equipment, which is made for single-use and not intended for reprocessing or reuse, it is clearly senseless to think of reprocessing and reuse of such material.

Around this practice, which already presents itself as paradoxical in its own designation, various complex questions arise, which have motivated a few approaches of different types about the subject.[2-5] Thus, if on one hand economic and environmental questions arise, on the other hand, the questions emphasized are related to safety, to the quality and correct working performance of the product, or even to those related to regulatory and ethical aspects.

The controversy established around this issue, the argumentative fluidity of the field in which health professionals who live with this phenomenon work, very often participating in some practices that are not well presented as to the effectiveness and safety obtained, are some of the aspects requiring reflection about the issue, particularly considering the questions that arise from this.

In fact, from the level of personal decisions to the decisions related to the institution and society in general, several problematic areas can be found regarding this issue, where questions are registered in the domain of ethical foundations.

As nurses and teachers, from this widened context, the intention is to approach some ethical issues raised about the reprocessing and reuse of SUD's, mainly considering the context of decisions that nurses make in an institutional context, when involved in the problem, either at the level of concrete practice in sterilization or other services, or at the level of ethics commissions, of infection control commissions, or even management.

It is expected that the course of the developing reflection allows clarification of some points about this issue which is still so nebulous, offering clues to guide nurses in the decision-making process, when, in the context of their own professional field, they happen to face concrete situations related to the subject under discussion.

- **The phenomenon of reprocessing and reuse of single-use devices**

In the early 80's, one could see, in health institutions, the arrival of disposable material, which was conditioned in sterilized packages, easy to use, practical, very convenient and safe. The large acceptance that this type of material received, also marked the diminution of the previous concern with the consequences of multiple use and wear of the instruments used till then, which did not need scientific studies, because daily practice proved this fact. "Use it and throw it away" came to be the dominant mentality and in great extent it followed the proliferation of numberless medical devices that the technological advances brought.

However, the financial pressure that the institutions underwent, on the other hand, highlighted the concern about the costs of health care, where the medical devices used in the various clinic procedures take a very important part. It must especially have been in the context of these concerns that the possibility of reuse of some devices classified as single-use came to be considered.[2]

The truth is that, nowadays, the processing and reuse of SUD's presents itself as a real phenomenon on a worldwide scale, which has been taking increasing importance in health institutions, regardless of the controversy in which it is involved.

It is a contradictory practice, to say the least, which affects a vast range of procedures, considering different situations. Among them one can consider the SUD's that have expired and have never been used by one person, those that have never been used, despite the open package, and those that have been previously used by someone for the intended purpose .[2]

Although it is a very widespread practice, it has been growing silently, and only subsequently did it start to receive some attention from the competent authorities, with the elaboration of certain documents declaring opinions on the issue, including recommendations for the professionals in the health field.[6-7]

Before legislation, regulation or official positions, the controversy around reprocessing and reuse of SUD's has long assumed a peculiar complexity, with strong argumentation related both to support and to opposition to this practice.

At the minimum ambivalence prevails around this issue, which seems to strengthen the idea that men can find or lose themselves altogether in the products of their own technique.

On one hand, at the base of a defense for the reprocessing and reuse of SUD's, from the beginning, lies the consideration of the fragility of the very designation of single-use devices. It can be stated that this denomination does not, in many cases, correspond to the real characteristics and possibilities of the material, but it does correspond to a little-justified option by the manufacturer. This consideration, associated with the high and increasing costs for this type of device, that proliferate vertiginously in a climate of tight institutional budgets, really seems to constitute the starting argument for the defense of reprocessing and reuse of SUD's, which is also strengthened by its association with the reduction of environmental impact.[2]

This defense is, however, far from gathering a consensus, as strong objectors of reprocessing underline the lack of scientific evidence for the safety of the process and the risks associated with this practice, marked by insufficient guarantee of the maintenance of the physical, chemical, and biological characteristics of the devices.

The scientific community itself, in an attempt to bring light to the issue, when searching for scientific evidence about the practice of reprocessing and reuse, hesitates before the evidence that demonstrates either the effectiveness of reuse, or the harmful effects of reprocessing.[3-5,8]

Among so distinctive positions, the truth is that the medical community faces a problematic phenomenon, which on the various continents takes different shapes and also operates in the most distinctive legal frameworks that range from total prohibition through the absence of any position, to the existence of regulation and procedures, with protocols of reprocessing which are correctly validated.[9]

It should therefore be noted that the problem around the issue persists, and it is still on the agenda at several levels. The current situation of the subject is presented to us by the interest of the competent authorities, expressed among others, in the positions of FDA (Food and Drug Administration) in the USA,[10] or in the European Union,[7] about the reprocessing of SUD's. To emphasize, recently the European Commission published on its website the report elaborated by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), about the safety of reprocessing the medical devices placed on the market with the purpose of single-use. Here we can highlight the following:

> Not all the single-use medical devices are capable of being reprocessed, considering their characteristics and complexity. (...) In order to identify and reduce the potential dangers associated with the reprocessing of a certain single-use device,, all the cycle of reprocessing, from the return of the device after its first use to the final sterilization and delivery to the users, including functional performance, needs to be validated and evaluated.[7]

These considerations evidence that many issues really lie unsolved still, having a long way to go themselves, even when referring to the field of an emerging legal framework to guarantee safety and protection of public health. One should state that the debate about this subject emphasizes that even legal positions that strengthen the prohibition of reprocessing SUD's, do not seem to guarantee the elimination of its practice. On the contrary, the proliferation of indiscriminate and incorrect practices of reprocessing lies mainly in the absence of regulation, with increment of risk for the users and everybody involved.

It is most important that this discussion be centered on the facts, and they say that reprocessing and reuse of devices classified by the manufactures as single-use, regardless of the legal context and the scientific evidence, is a practice performed all over the world. Its

implications, either for the users, or for the health professionals, are not to be underestimated and as such it is an issue that deserves special attention, double attention, it could be said, the lack of definition range of and uncertainty that involves it is considered.

● Ethical aspects regarding the reprocessing and reuse of single-use devices

From the considerations presented so far, it seems that the greatest evidence related to reprocessing and reuse of SUD's, is precisely the observation of the controversies and ambiguities that involve this practice.

This fragility determines that the decisions around the issue find particularly problematic zones, where important questions are registered in the field of ethics.

The brief approach that has been developed so far, forces the confrontation of issues related to the reprocessing and reuse of SUD's, inherent not only to the responsibility of any professional group at the level of health institutions, but to the responsibility of several domains of decision that enter into the processes related to health.

However, when considering some issues evoked by reprocessing and reuse of these devices, mainly considering the context of the nurse's action when involved in the problem, either at the level of the concrete practice of sterilization or other services, or at the level of ethics commissions, commissions for infection control, or even of management, the problem does not lose relevance from the ethical point of view.

A reflection that gives perspectives on some ethical aspects imposed in a correctly based process of decision making seems therefore pertinent, because of certain questions with which nurses at the individual or collective level are confronted related to the subject under discussion.

● To reprocess or not to reprocess SUD's

At this level, on a first plan, an apparently simple decision seems to impose itself, seated in the dichotomy of "to reprocess or not to reprocess". An interrogation that rises from the confrontation of these two possibilities of action, in a climate of shadow that does not allow facing with clarity the limits among actions that oppose or promote the welfare of the human being, this being considered within the unavoidable interdependence of the world in which one lives.

The simplicity of the answer fades right away, not only because of the lack of clarity around the issue as has been confirmed, but also because of the complexity it takes. In fact, the widened notions of good do not seem to match the mere dichotomies of yes or no, requiring a more complex approach that integrates with other perspectives.

In the field of reprocessing and reuse of SUD's, the adoption of an ethical attitude about the subject, for the nurses as well as for all the health professionals involved, just implies that they face this possibility from several perspectives, above all clarifying which principles and values will guide their practice.

Therefore, when it comes to ethical issues, the approach to this theme cannot continue without making it very present at the start that human dignity is a fundamental ethical principle and that no consideration can be placed above it. Here the value of the person is highlighted, and it should be considered always and simultaneously as a purpose and never just a means. Human dignity is, thus, the real pillar on which all the decisions related to health care should be based, the current subject being no exception.

It will be important to state that in the search for a wider concept of human dignity, one can consider not only the issues of relationships and of respect that every human being deserves, but also the relationship with all the beings in the universe inhabited by the human being. It is in this sense that the concept of human dignity strengthens the tie between humans and all the natural reality that surrounds them. Hence we can infer that contributing the integrity and balance of the world in which we are involve, also means to contribute to the defense of human dignity.

When it comes to the field in which nurses work, the acknowledgement of the person's dignity forms one of the main bases and criteria for all the decisions made by this professional. The respect for the person's rights, in their condition of health or disease, is placed as a guiding principle for the nurse's activity, since the continuation of any practice that has the person's welfare as a goal is a duty that comes from the guarantee and protection of these rights, but also from professional responsibility. Likewise, the defense of the person is understood related to any practice that can affect their welfare as an absolute value.

It therefore becomes clear that the decisions about the practice of reprocessing SUD's cannot in any way be guided exclusively or predominantly by considerations of an economic or utilitarian type that in favoring social benefits could harm even one individual. This when one should say before

"non nocere", recalling the bioethical principle of nonmaleficence.[13] The guarantee of personal safety and the exclusion of additional risk will therefore be determinant criteria for a responsible decision about reprocessing and reusing this type of device.

However, the nurse's responsibility is aimed at the person who exists as part of a whole. In this sense, awareness of the threat that man's intervention with nature causes in himself will influence the process of decision making, which cannot avoid being based also on an ethics directed to the consequences on the environment, that includes respect and preservation of nature itself.[14]

It is worth restating in a more consistent way, that in the field of reprocessing and reuse of SUD's, a responsible practice requires clarification about the principles that guide it, not omitting consideration of the fair balance among the rights and interests of the individual, of the institutions, of the society and the very world of which we are part.

In a broad perspective, this seems to be the background where many criteria are written which can eventually support the practice of reprocessing. Criteria that cannot be considered in an arbitrary way, but should be present in an explicit way in dispositions, properly based, that propose to regulate the reprocess and reuse of this type of devices.

Thus, in the ethical point of view, the practice of reprocessing and reuse of a certain device, whatever device it may be, could not be accepted until it is oriented by protocols elaborated from studies with very well established levels of evidence. Without omitting the economic aspects and environmental impact, this evidence should prove for every SUD the maintenance of its functionality, integrity and sterility, with the guarantee that its use should not result in increased damage for the people who use them, from the point of view of either the user or the professional.

In this context, it really cannot be forgotten to highlight the various occupational risks to which health professionals are subjected, consisting of the services of reprocessing contaminated articles themselves, a particularly critical area, whose risk should not be increased by less safe practices.[15]

Again, centered in the user of health services and having discarded the possibility of a practice of maleficent care in concrete cases, it should be remembered that ethical reflection about the issue started by considering the welfare of the human being, understood in the unavoidable interdependence with the world he inhabits. Despite this broad notion of welfare, it seems that the general benefits of this practice, beyond the exclusion of malfeasance in concrete cases, should also include the consideration of eventual benefits at the same level.

Actually, because some economic and ecologic advantages are documented from the reprocessing of these devices,[4;5] either in global terms, or in institutional terms, it will also be licit to question the benefits at the user's level. One of the questions that can be asked, for example, is whether this practice leads to a reduction in the cost for each person, related to a health procedure that uses the reprocessed material, whether this practice will provide every citizen with a greater possibility of access or of use of this material. It should be asked as well whether the money saved is used for providing qualified services that could not be offered in a different way.

The favorable answer to these and other questions would add the individual benefits to the list of ethical arguments, thus strengthening the position in favor of the practice of reprocessing and reuse of SUD's.

● The SUD'S users

Going deeper, another question that we find associated with reprocessing and that we cannot prevent from including in an ethical discussion, is the question about what type of patients should use the material reprocessed.[2]

In the search for human dignity as a guiding principle in the practice of health care, as already mentioned, the notion of justice can be appealed to so as to help us base the decision making related to this matter. The principle of justice establishes equity in all human beings, in dignity and in rights.[13] Justice guarantees the inalienable rights of all human beings to health care, considering that technological innovations are aimed at all people, with no privilege, nor discrimination.[17] The innovation, which "reprocessing and use of SUD's" is, cannot be considered beyond this principle.

If justice presents itself as an ethical and guiding principle of a dignifying behavior, it is, to a nurse, a guiding value in the exercise of the profession. It can be added also that caring for the person with no discrimination, is also a right that comes from the guarantee and protection of the rights of people, thus strengthening the position to be adopted related to the question proposed.[12]

Besides this, passing over the discussion about the demand of evaluating the quality of the reprocessed material, this issue is otherwise devoid of any meaning, and there is not even space for considering that the most vulnerable, such as people with depressed immune system, the young or the old, could be excluded from its use. This possibility is considered, only in a climate of doubts and uncertainties, when excluding the practice of reprocessing where it is not possible to guarantee the quality of the material used.

• Informed consent

The issue of informed consent is now presented, related to the use of reprocessed material, and this is the last subject for discussion and requires considering the analysis of the theme taking into account the participation of the person in the decisions that have to be made.

Therefore, recalling that one of the rights coming from the dignity of the human being is self-determination, of deciding about themselves and about their life.[11] Informed consent is based on the respect for the right to determination, or in other terms, the respect for the autonomy of the person, who allows or refuses an intervention in the area of health. This suggests, among other aspects, that the person should previously receive from the health professional, the proper information as to the aim and the nature of the intervention, as well as its consequences and risks.

However, in the field of reuse of SUD's, the approach is not reassuring when it is related to a few elements in the process of informed consent, mainly the ones related to information.[2]

On one hand, there is the defense that the process of informed consent requires the information about the procedure itself and not about the instruments used or the technical specificities. In addition, if the institution has evidence that the safety of the material reused is equal to the new material, there are no conflicts in standards of action.[2] If there are no additional risks with SUD's reuse, there is no ethical obligation of informing about that particularity of the procedure.

On the other hand, there is the defense that informed consent is an ethical demand in all situations of reuse, because there is the rule of veracity that prevents the professionals in health from lying, deceiving or interfering in any way with the person's free will.[2] Thus, the person should be informed about the type of material used, regardless of the level of risk involved.

A certain undefined area exists here, which may dissipate, as people pass beyond a traditional passiveness in questions of health, taking and requiring their active participation in the decisions to be made.

Information available about several aspects of health and disease becomes more and more significant. It would not be surprising, therefore, if in a near future, the person himself could question the nature and origin of the material for a certain procedure that may need to be performed. Having as a base the rule of veracity, many indecisions and uncertainties would end this way.

However and when information is reported about nursing care, the duty of attending with responsibility and care to all information or explanation requested by the individual,[11] will still constitute an enormous challenge for the nurse.

In fact, to attend with responsibility and care, much more than following formal rules, is something that requires from the nurse the recourse to such complexity of elements, in the field of ethics and not only allows them to answer in a solid and proper way to the information request made by each individual, always specific and concrete.

This is after all a requirement that is not only related to information or to the informed consent, but related to all the decisions that nurses make in an institutional context, when confronted with the different questions arising around the reprocessing and reuse of SUD's.

CONCLUSION

This approach is concluded by considering that the process of reflection developed has clarified a few aspects of the issue. Certain questions arising around the reprocessing and reuse of SUD's have been emphasized, considering mainly the context of the nurse's action, when implied in the problem. Among them, the interrogation about their own possibility of considering this practice is highlighted; the population to which this material is designated; and finally the question of informed consent, related to the use of reprocessed material.

From these questions, a process of ethical analysis has developed in which human dignity arises as a fundamental ethical principal, source of all principles, values and rights.

This is how a background is set, which, from the ethical point of view, supports the consideration that the practice of reprocessing and reuse of SUD's can only be

accepted if it is correctly guided by protocols based on knowledge with well-established levels of evidence which can above all guarantee the person's welfare. Once this guarantee is considered, the use of these devices will be directed to all people, with no privilege or discrimination, without forgetting to consider that the person's participation in the decisions that are related to them, is also a right that comes from the dignity of the human being.

These are elements that give basis to a process of making a responsible decision, also marked by the necessary balance between the rights and interests of the individual, of the institutions, of the society and of our world itself of which we are all a part.

Finally, it is suggested that consideration of the ethical aspects is a demand that is directed to the nurse, aiming at a process of decision making which is correctly based, when talking about the different questions involving the issue.

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Corresponding Address

Maria Dulce Santos Santiago
Escola Superior de Saúde do Instituto Politécnico de Beja
Rua Dr. José Correia Maltez, 7800-111 – Beja, Portugal