Revista Bioética
ISSN: 1983-8042
ISSN: 1983-8034
Conselho Federal de Medicina

Behrens, Ronaldo
Segurança do paciente e os direitos do usuário
Revista Bioética, vol. 27, no. 2, 2019, April-June, pp. 253-260
Conselho Federal de Medicina

DOI: https://doi.org/10.1590/1983-80422019272307

Available in: https://www.redalyc.org/articulo.oa?id=361570647008

Revista Bioética
Print version ISSN 1983-8042 On-line version ISSN 1983-8034
Rev. Bioét. vol.27 no.2 Brasília Apr./June 2019
Doi: 10.1590/1983-80422019272307

UPDATE

Patient safety approached from the rights of users

Ronaldo Behrens [1]

1. Portugal Vilela Almeida Behrens Advogados, Belo Horizonte/MG, Brasil.

Abstract

Since the publication of the Ministry of Health Ordinance no. 529/2013 that brought the discussion on patient safety, there has been an increase in interest and experience in relation to the topic. The Programa Nacional de Segurança do Paciente (National Program on Patient Safety) – which requires each Brazilian hospital to have a Patient Safety Center responsible for its implementation – there has been an effort to work on the issue of quality of care in Brazil, based on a preventive stance. This article highlights the lack of protection and respect for patients' rights under this program. In order to do so, the following were analized: the theoretical *corpus* that reveal the pertinence of the users' participation as a factor that can boost the results of the Patient Safety Program; some of the rights of the patients that would justify such participation; some possibilities for this participation to become a recurring practice in the health system.
Keywords: Health systems. Patient safety. Patient rights.

Resumo

Segurança do paciente e os direitos do usuário

Desde a publicação da Portaria 529/2013 do Ministério da Saúde, que trouxe a discussão sobre segurança do paciente, têm aumentado o interesse e as experiências relacionadas ao tema. Com o Programa Nacional de Segurança do Paciente, que obriga todo hospital brasileiro a ter Núcleo de Segurança de Paciente, procura-se melhorar a qualidade da assistência no Brasil a partir da postura preventiva. No entanto, este artigo ressalta a ausência de proteção e respeito aos direitos do usuário no âmbito deste programa. Para tanto, foram analisados os seguintes tópicos: manifestações teóricas que revelam a pertinência da participação como propulsora de melhores resultados, os direitos que justificariam essa participação e as possibilidades para torná-la recorrente no sistema de saúde.
Palavras-chave: Sistemas de saúde. Segurança do paciente. Direitos do paciente.

Resumen

Seguridad del paciente a partir de los derechos de los usuarios

Desde la publicación de la Resolución 529/2013 del Ministerio de Salud, que introdujo el debate sobre la seguridad del paciente, han aumentado el interés y las experiencias con relación al tema. Con el Programa Nacional de Seguridad del Paciente, que obliga a todo hospital brasileño a tener un Núcleo de Seguridad del Paciente, se busca mejorar la calidad de la asistencia en Brasil, a partir de una postura preventiva. No obstante, este artículo destaca la falta de protección y respeto a los derechos del usuario en el ámbito de este programa. Para ello, se analizaron los siguientes tópicos: manifestaciones teóricas que revelan la pertinencia de la participación como propulsora de mejores resultados, los derechos que justificarían esa participación y las posibilidades de hacerla recurrente en el sistema de salud.
Palabras clave: Sistemas de salud. Seguridad del paciente. Derechos del paciente.

Declara não haver conflito de interesse.

Attentive to the recommendation of the World Health Organization (WHO) in a resolution approved in the 55th and continued in the 57th World Health Assembly, Brazil instituted the Programa Nacional de Segurança do Paciente - PNSP (National Program of Patient Safety). The program was created by Ordinance 529/2013 [1] of the Ministério da Saúde - MS (Ministry of Health) and put into effect by the Consolidation Ordinance 5/2017, which deals, in Chapter VIII (Articles 157 to 166), *with the consolidation of norms on actions and the health services of the Sistema Único de Saúde – SUS (Unified Health System)* [2]. The overall objective of the initiative was to mitigate the risk of adverse events by *qualifying health care in all health facilities in the national territory* (Article 2) [1].

Among the objectives of the ordinance, set forth in article 3, section II, is *to involve patients and family members in safety actions* [1]. However, this specific point, which will be treated in this article as "patient engagement", was not examined in the text or subsequent regulations. The practice observed in the program, already in the implementation phase, is much more related to physical security issues, including in line with the role set forth in art. 7, item 1 of the same document [1].

There is no intention here to oppose "engagement" and "physical safety". Rather, the idea is to have a glance of the hypothesis that respect for the rights of the patient is part of the points of attention listed by the ordinance. After all, when it defines "adverse event," the document gives an open meaning to the concept of "harm," indicating that it may be "physical, social, or psychological." In this way, disrespect for any basic user right (privacy or autonomy, for example) constitutes a violation and, therefore, must be refuted by the Law [1].

In other words, no judgment should be made a priori. That is, for example, an infection resulting from incorrect hand hygiene is not more or less serious than the violation of some right, such as privacy or autonomy. Of course, this depends exclusively on the patient's own values, and it is not up to the system to establish this hierarchy. Therefore, safety should be prioritized in both cases: both for the patient not to suffer from infections and for not having their rights violated by procedural failures.

This article suggests that violation of the rights of the user should be part of the list of points of attention of the PNSP, in order to foster work that we consider essential for Brazilian hospitals. To do so, it is initially expected that several bibliographic sources and reports of practical experiences start from the premise that user participation contributes to better results in the implementation of programs of this caliber. And there is no possibility of achieving legitimate and full performance without respecting their basic rights.

Then, we will briefly discuss user rights in Brazil, seeking to demonstrate that attention means nothing more than compliance with the precepts of the 1988 Constitution [3]. That is, respect for these rights is a constitutional and legal obligation. Finally, the possibilities of user involvement in the program will be analyzed to demonstrate the conclusions reached.

It should be noted that the term "user right" is used here because "user" is a broader term than "patient". For purposes of this article, the term "patient" is defined as the person who receives the health care directly, and "users", all those who, in addition to the patients themselves, are affected by health services. More than trying to answer the question definitively, the purpose of this article is to stimulate the discussion, contributing to the argument, sharing ideas and, perhaps, helping to change the social reality of the country.

Evidence that patient participation is important

Since the resolution adopted by the WHO, engagement is seen as an important step for safety-related health programs. The WHO itself, in the document "Why Patient Engagement Became a Priority?", Informs that the theme "patients for patient safety" is one of six safety program fields, which should be designed to highlight centrality from the point of view of the user in the essential activities. The text emphasizes *that patients and those who are close to them observe certain things that the health professionals, quite busy, do not observe* [4]. After all, they are not rare the reports of relatives who, for example, perceive with much more celerity and certainty reactions to drugs with great potential for harm to health.

It is necessary not only to encourage the participation of the user in order to remind health professionals of the facts that may go unnoticed but also to create spaces to discuss with the same flaws or errors so that they do not recur. To validate, rather than silence, the manifestation of the users may prevent them as victims from assuming a position of conflict - they must act as a contributor to the

 http://dx.doi.org/10.1590/1983-80422019272307

evolution of the system, which is a great desire of the users themselves.

The paper "Reference document for the National Program of Patient Safety (PNSP)" [5], produced by the MS in partnership with the Fundação Oswaldo Cruz and the Agência Nacional de Vigilância Sanitária - Anvisa (National Agency of Sanitary Surveillance) lists other programs that contribute to the PNSP. Among them, the Política Nacional de Humanização - PNH (National Humanization Policy), which focuses on stimulating the participation of users "on an equal footing" with professionals with regard to health production. Further ahead, the "Reference Document for the PNSP" [5] reads as follows:

According to Lucian Leape, the guiding principle of this approach is that adverse events are not caused by bad people, but by systems that have been poorly designed and produce poor results. This concept is transforming the previous focus on individual error by focusing on system defects. Although the main focus on patient safety has been the implementation of safe practices, it is becoming increasingly evident that achieving a high level of safety in health organizations requires much more. To this end, several currents have emerged. One of these is the recognition of the importance of greater patient engagement in their care. Another one is the need for transparency [6].

It is clear that the system and, consequently, hospitals should promote the effective participation of the user in what the PNH formulators call the "health production process". But, as Bronkart points out, *patients are the most underutilized resource of the health system* [7].

The Anvisa document entitled "Safe Care: a theoretical reflection applied to practice" [8] reveals the news that the Projeto de Avaliação de Desempenho de Sistemas de Saúde - Proadess (Project for the Evaluation of the Performance of Health Systems) was created in Brazil *with the objective of proposing a methodology for the evaluation of performance in the country* [9]. In consultation with the website of this program, it can be observed that respect for the rights of the person is considered as one of the dimensions of evaluation of the health system. This respect is conceptualized as *a general parameter of conduct, according to which intervention in the health area must be provided in order to consider the physical needs, emotional state, values, judgments and decisions of each individual regarding their own health condition* [10]. However, despite the overwhelming willingness to work on this performance indicator, no results are found regarding it in the reports of the site.

Chapter 12 of the Anvisa document 8 contains arguments and reports from international experiences that reaffirm the importance of participation in health safety programs. Written by Gonçalves and Kawagoe, the chapter highlights "patient-centered care":

Patient-centered care encompasses the qualities of empathy, compassion, and responsiveness to the needs, values, and preferences expressed by each patient. It applies to patients of all ages and can be practiced in any health care setting. It is based on mutually beneficial partnerships between health professionals, patients, and family members.

The involvement of family members as critical and active partners throughout the caring process is an essential component of patient-centered care. The "family" is represented by those people that the patient chooses to call family, whom he trusts and with whom he has a good relation, and not necessarily that person determined by the health professional [11].

In a very consistent way, one can verify the general understanding that the participation of the users is fundamental for their safety, factor of quality of the health care. In the following, it is tried to demonstrate that, more than convenient, to guarantee this right to the user is effectively constitutional and legal obligation.

Patient rights that justify participation

Unfortunately, Brazil does not have a health code, but it is worth mentioning the initiative of the MS to promulgate the consolidation orders in 2017. The norms referring to the sector are scattered in several legal titles, all evidently influenced and limited by the 1988 Constitution, which enshrines the right to life and its protection, human dignity, autonomy and individual freedom, bases of other rights. In its first article, it states the dignity of the human person as the foundation of the democratic State under the rule of law [3].

Therefore, the Constitution provides for respect for the personal dignity of the individual, considered, according to Moraes, *a spiritual and moral value, inherent in the person, which manifests singularly in the conscious and responsible*

self-determination of life itself and which brings with it the claim to respect by others people, constituting an invulnerable minimum that every legal status must ensure [12]. The same dignity that Minister Barroso, in his work on the subject, seeks to withdraw from the role of autonomous law to consider it legal principle with constitutional status:

Since dignity is regarded as the ultimate foundation of all truly fundamental rights and as a source of part of its essential content, it would be contradictory to consider it as a right in itself, since it is part of different rights. Moreover, if dignity were to be considered as a specific fundamental right, it would necessarily have to be weighed against other fundamental rights, which would put it in a very weak position than it would have if it were used as an external parameter to assess possible solutions in cases of collisions of rights. As a constitutional principle, however, human dignity may need to be weighed against other collective principles or goals. It should be remembered that it should normally prevail, but this is not always the case [13].

Linked to this fundamental precept and materializing this dignity, one sees the principle of self-determination, which enables self-government by endowing the individual with the capacity to decide on their own life, and must obviously take responsibility for their choices. Silva, in dealing with the right to freedom, speaks of a *conscious coordination of the means necessary for the fulfillment of personal happiness* [14].

Structuring this set of principles that guarantee the stance of the State before the individual, limiting the former and giving more power to the latter, it should be noted that the Brazilian Federal Constitution [3] (article 3, IV, article 5, I, VIII, XLI, XLII) refers to protection against all forms of discrimination (race or ethnicity, sexuality or religion, etc.), which clearly reinforces the right to equal access to health services. This is reiterated by Law 8.080/1990 [15] (considered the Organic Law of Health) and by other legislation, such as the Código de Ética Médica - CEM (Code of Medical Ethics) [16] and the Penal Code [17].

The free exercise of the autonomy of the individual, one of the bases of the principle of human dignity, will only exist if the user has access to the information necessary to express their choices. In Brazil, everyone has the right to receive information about their state of health: possible and advisable medical measures, consequences and side effects of treatments, etc.

However, access to such data is only the outermost part of the exercise of that right. What good is this information if the handwriting of the professional is illegible? What does it help to receive them in indecipherable technical terms? What does it mean to have contact with large amounts of data, if the main data can be omitted?

The full exercise of the right to information requires comprehensible communication and loyalty from the physician to the patient. Failure to act in this way distances the patient from the expected protagonism role. Moreover, only after understanding what is happening will it be possible for the patient to manifest their intention, what is called "informed consent".

The right to information imposes a dialogic process aimed at obtaining informed consent. In this process, the patient receives information about their pathology, procedures to be performed and possible normal effects and intercurrences, manifesting their decision only after understanding very well the proposed treatment. In our country, these rights are provided for in Law 8.078/1990 [18] (article 6, III), the CEM [16] and other normative texts.

Of course, the privacy of the patient must be preserved, which imposes on the system the duty to guarantee the secrecy of information. Silva defines, as the object of privacy, *the set of information about the individual that they can decide to keep under their exclusive control, or communicate, deciding to whom, when, where and under what conditions, without it being legally subjected* [19].

And adds: *the doctrine always reminds us that the United States judge Cooly in 1873 identified privacy as the right to be left alone, in peace: the right to be alone. The right to privacy comprehends, as the U.S. Supreme Court decided, the right of every person to make decisions alone in the sphere of their private life* [19]. The patient has the right to their medical records, being the duty of health institutions to keep this document on file (digital or physical); and the information contained therein shall belong exclusively to the patient.

There are many other patient rights in Brazil that will not be covered in this article. The rights discussed here briefly represent the core idea of work: allowing and encouraging user participation is not only convenient but also a legal obligation of the health system and professionals. However, the

 http://dx.doi.org/10.1590/1983-80422019272307

"Reference Document for the PNSP" notes a scenario that, although strange, does not seem unfamiliar:

Most patients are not aware of their rights, and those they know are often not understood by health professionals. Some health professionals react badly when patients ask what type of medication is being given, or when they ask for a second opinion about their diagnosis. Rare are the health facilities that prepare their professionals to inform the patient and their families that an error has been made.

Even practices regulated by the government and recommended by professional councils and class organs are viewed by health professionals as "bureaucracy." Examples are the informed consent term and the obligation that everything related to care should be written on the medical record. The patient's chart is still seen as the "medical record" by health professionals and the studies show a poor quality in its filling [20].

This is the reality with which to live and work, and from which will be suggested ways to encourage user participation in the health process in order to improve the system.

Possibility of user participation

First, it is worth remembering the premises worked up to this point: 1) the formulators of the patient safety program expressly state that the participation of the user is fundamental to achieve better results; 2) this engagement is mainly due to the patient's role, which should be encouraged to contribute to the health process, expressing opinions and choosing paths; and 3) this involvement is a legal duty of the system, since it is an accurate expression of patients' rights: privacy, access to information, secrecy, autonomy, and non-discrimination - all guaranteeing the principle of human dignity.

Nevertheless, in Brazil, the full exercise of this role faces a vice of origin, the lack of information, since many users and health professionals themselves do not understand or are simply unaware of these basic rights. Thus, it is relevant that the matter be present in the daily discussions, being part of the curriculum of schools that train health professionals. Patients' rights should also be exposed in hospitals, as provided for in the MS Ordinance that established the Carta dos Direitos dos Usuários da Saúde (Charter of the Rights of Health Users) [21].

Here, criticism must be made of the aesthetics of the Charter of Rights [21], since the visual aspect of the material is difficult to understand for the general population. Adapting it according to each institution and region of the country would be salutary measures to facilitate its understanding. Another important fact is that the Charter is not found in health institutions, public or private, this text should be posted in a visible and easily accessible place, which demonstrates the need to act quickly on the problem, to approach the issue in a more friendly way.

The rights of the user should also be the focus of the PNSP in Brazil, which would oblige public and private health institutions to include respect for these rights in their programs, along with other points such as hand hygiene, safe practices in surgeries, etc. In this way, each nucleus should take care of the theme, as they have already done with the other items of the program, establishing concepts internally, drawing protocols and flows, clarifying and training those involved, measuring nonconformities, setting corrective action plans and divulging improvements achieved.

An ideal starting point would be working with the process to obtain informed consent, privileging dialogue and passing on information in a clear, honest and loyal way, throwing the notion that the act is mere bureaucracy. Thus, respect for the patient's dignity and autonomy would be more plausible.

It is also necessary to train the professionals to fill the medical record in a more complete and understandable way, which would facilitate the understanding of the document and the interaction with the user. This work could be carried out in partnership with the Comissão de Revisão de Prontuários (Medical Records Review Committee), which is mandatory for all Brazilian hospitals in accordance with the Resolution 1638/2002 [22] of the Conselho Federal de Medicina - CFM (Federal Council of Medicine). Still, it is not possible to underestimate the time factor, which greatly hinders this activity of professionals of health, and it is necessary to discuss it more comprehensively in the health sector.

And why not innovate in this sense? Allow, for example, that the patient receive information about their status in the form of infographic when possible, according to the model already widely used in journalism. This effort could be done by trained staff, or by the system itself, which would release health workers, who already have very limited time.

Another idea: why not encourage patients to take notes on their own chart, revealing their perception of the disease that afflicts them and their psychological state? Medical anthropology has demonstrated the importance of this type of interaction, as shown in Uchôa and Vidal's article:

From the anthropological point of view, the sociocultural universe of the patient is no longer seen as a major obstacle to the effectiveness of therapeutic programs and practices, but rather as the context in which the conceptions about diseases, the explanations given and the behaviors before them are rooted. This perspective reorients the perception of aspects related to the effectiveness of health interventions. If we consider that the effectiveness of a health program depends on the extent to which the population accepts, uses, and participates in that program, then that effectiveness appears to be dependent on prior knowledge of the characteristic ways of thinking and acting associated with health in that population and program's ability to integrate this knowledge [23].

Through CFM Resolution 1.821/2007 [24], the use of electronic medical records was regulated, establishing a partnership with the Sociedade Brasileira de Informática em Saúde" - SBIS (Brazilian Society of Health Informatics) in order to certify operating systems for this purpose. It is interesting to note that the certification of electronic medical records of SBIS mentions patients' participation, aiming to *guarantee the right of online and/or off-line access of the subject of care or their legal representative to all information of the Registro Eletrônico de Saúde - RES* [Electronic Health Record] [25], *in addition to allowing the inclusion in the RES of the subjects' information on "self-care", personal point of view on health issues, satisfaction levels, expectations and comments, when* [the patient] *wishes* [26].

This is perhaps the most profound form of what is known as "patient empowerment", which, according to the aforementioned Anvisa document, is *a new concept applied in care in health services, and is related to the safety of the patient* [27]. According to the same text, *the WHO defines empowerment as "a process by which people gain greater control over decisions and actions that affect their health"* [27]. In addition, it is also necessary to pay attention to sensitive information recorded in to reconcile broad access to data and preservation of patient privacy.

It is fundamental to truly respect the rights of users, treating them as a subject rather than an object, and to fulfill the system's ideal of guaranteeing the patient's centrality, achieving better results in terms of safety and quality of care. However, one can dare to go even deeper: why not involve users in the discussion of flaws and mistakes made?

Although not original, the idea does not even seem to be taken into account by the system. The users yearn for this kind of contribution, as we can see from reading the aforementioned article "Why did patient engagement become a priority?". In the text, patients claim *they have much more to offer than simple testimonials charged with emotions about the avoidable harm of which they have been victims.* (...) *We, patients, and our families have needs and needs as soon as things turn bad. So we need people to tell us that something wrong has happened, and we want these same people who take care of our health to be open and to participate in research that aims to find the root causes of the mistake made* [4].

The willingness and spirit of collaboration are evident. However, the system usually deals arrogantly with victims of error, posture, even if silent, based on the absurd certainty that the user can not collaborate, either to alleviate the problem or prevent it from recurring. In the article "Research and innovation in patient safety", Sousa, Uva, and Serranheira conclude:

According to several authors, patient safety "flaws" can have several implications, among which the following are highlighted: i) loss of confidence on the part of patients in health organizations and their professionals, with consequent degradation of relationships between patients and users; ii) increased social and economic costs, varying in size due to the "damages" caused and their casuistry; and (iii) a reduction in the possibility of achieving the expected/desired outcomes, with direct consequences on the quality of the care provided [28]. (...) *Patient safety is, therefore, in itself, an innovative area of intervention that, to place the patient and their family at the center, obliges to reinvent the health system (and the logic of research itself) in an increasingly based perspective on aspects of citizenship and health gains* [29].

Thus, the current approach, in addition to disrespecting constitutional precept regarding patient rights, does not value patients' safety ideals, placing users in a position of distrust, in a defensive posture, which in no way contributes to the good evolution of the cases. What is expected is to bring users to

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participate in solving the problem, informing them clearly; This is evident from the application of their own methodology and protocols, as is already the case in France, with the Kouchner Law [30], for example.

Final considerations

For some time now it has been defended a more incisive conduct of the health system, and especially of the hospitals, to apply methodologies capable of putting the user in the center of the system, in the condition of a subject, and not of an object. Achieving this ideal would cause a real revolution in the health system, even in relation to costs, since more committed patients - "engaged", so to speak - with the treatment itself would achieve, together with the health team, more effective and lesser results probability of recurrence.

In addition, constructing dialogues with the patient and sharing decisions has a liberating effect for the health professional, who, in theory, is no longer unilaterally accused. In France, the Kouchner Law [30] invests on participation by instituting methodology that privileges the user's collaboration in the process, especially in case of failures or errors.

We had the opportunity to do some kind of internship in the Commission for Relation with Users and the Quality of Care (*Commissions de Relations avec les Usagers et la qualité du Prise en Charge*) of a French hospital (Hôpital Avicenne, in the outskirts of Paris). Although there are many corrections to be made in applying the Kouchner Law, we have experienced successful experiences in this hospital: for example, several meetings between complainant and professional relatives, with the opportunity to re-establish communication between the parties and avoid legal claims.

In Brazil, the PNSP generated positive impacts in recent years. Although its application is still in its initial stages, it is believed that this will be a milestone in terms of the quality of health in the country. The initiative, however, could aggregate even more cases if there was greater clarity about user rights, which unfortunately has not yet occurred. In any case, it is envisaged that this is the "gateway" to ally the quest for quality with respect for the constitutional rights of the patient, still unknown and therefore ill-treated in Brazil.

It is hoped that this article has fulfilled the initially proposed role of, from a brief analysis, arising interest regarding the topic of user rights. The expectation is to help push for changes in the current regulation, with patients safety as the core point of preserving their rights and improving the country's social reality.

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Correspondência
Rua Paraíba, 1.000, 10º andar CEP 30130-145. Belo Horizonte/MG, Brasil.

Ronaldo Behrens – Doutor – r.behrens@portugalvilela.com.br
0000-0002-3519-6184

Recebido: 7. 2.2018
Revisado: 19.11.2018
Aprovado: 14.12.2018