Revista Bioética
Print version ISSN 1983-8042 On-line version ISSN 1983-8034
Rev. Bioét. vol.26 no.3 Brasília July/Sept. 2018
Doi: 10.1590/1983-80422018263255

UPDATE

Terms of clarification and accountability in the light of intervention bioethics

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Abstract

In Brazil, access to medicines of the Specialized Pharmaceutical Care Program, within the scope of the Brazilian Unified Health System, depends on filling out and delivering the Clarification and Responsibility Form at specialized pharmacies. These forms are intended to obtain the patient´s informed consent concerning the medication being offered. The study evaluated them in the light of the theoretical reference of intervention bioethics, with emphasis on guaranteeing patient autonomy and protection as a vulnerable entity. Though the forms studied consider patient privacy and provide them with information relevant to their empowerment in dealing with doctors, the term lacks enough protective measures in cases where undesirable effects occur. Therefore, it is a State responsibility to strengthen them to guarantee true autonomy for patients, to identify their vulnerability and to ensure protective measures in cases of adverse event.

Keywords: Bioethics. Informed consent. Consent forms. Personal autonomy. Health vulnerability.

Resumo

Termos de esclarecimento e responsabilidade à luz da bioética de intervenção

No Brasil, o acesso aos medicamentos do Componente Especializado da Assistência Farmacêutica, no âmbito do Sistema Único de Saúde, ocorre mediante preenchimento e entrega do termo de esclarecimento e responsabilidade nas farmácias especializadas. Estes termos visam a obtenção do consentimento informado do paciente no que diz respeito ao tratamento medicamentoso oferecido. O estudo avaliou-os à luz do referencial teórico da bioética de intervenção com ênfase na garantia da autonomia do paciente e na sua proteção como ente vulnerável. Embora haja dispositivos que resguardem sua privacidade e forneçam informações relevantes para seu empoderamento na relação com o médico, os termos carecem de medidas protetivas nos casos em que ocorrem efeitos indesejáveis. Cabe, portanto, ao Estado fortalecê-los para garantir verdadeira autonomia dos pacientes, balizar sua vulnerabilidade e assegurar medidas de proteção em casos de episódios adversos.

Palavras-chave: Bioética. Consentimento livre e esclarecido. Termos de consentimento. Autonomia pessoal. Vulnerabilidade em saúde.

Resumen

Formularios de esclarecimiento y responsabilidad a la luz de la bioética de intervención

En Brasil, el acceso a los medicamentos del Componente Especializado de la Asistencia Farmacéutica, en el ámbito del Sistema Único de Salud, tiene lugar mediante diligenciamiento y entrega del Formulario de Esclarecimiento y Responsabilidad en las farmacias especializadas. Estos documentos procuran la obtención del consentimiento informado del paciente respecto del tratamiento medicamentoso a ser ofrecido. Este estudio los evaluó a la luz del marco teórico de la bioética de intervención con énfasis en la garantía de la autonomía del paciente y en su protección como ente vulnerable. Aunque haya dispositivos que resguarden la privacidad del paciente y proporcionen informaciones relevantes para su empoderamiento en la relación con el médico, los formularios carecen de medidas de protección en los casos de ocurrencia de efectos indeseables. Le compete, por lo tanto, al Estado fortalecerlos para garantizar una verdadera autonomía de los pacientes, demarcar su vulnerabilidad, y asegurar medidas de protección en casos de episodios adversos.

Palabras clave: Bioética. Consentimiento informado. Formularios de consentimiento. Autonomía personal. Vulnerabilidad en salud.

Declaram não haver conflito de interesse.

Actions for comprehensive therapeutic care, including pharmaceutical care, are attributed to the Sistema Único de Saúde – SUS (Unified Health System) in Brazil, as defined by the National Health Policy [1]. Access to certain medicines from the SUS is provided by the Componente Especializado da Assistência Farmacêutica - Ceaf (Specialised Component of Pharmaceutical Assistance) . Its rules of financing and execution were established by the Gabinete do Ministro – GM (Office of the Minister) of the Ministério da Saúde - MS (Ministry of Health) through Ordinance GM / MS 1554 / 2013 [2].

In this sense, the Política Nacional de Assistência Farmacêutica - Pnaf (National Pharmaceutical Assistance Policy)[3], created in 2004, advocated pharmaceutical assistance as one of the assumptions to guarantee access and equality in health, as well as its provision at different levels of care in the public health network, a proposal that clearly echoes the principle of integrality of the actions assumed by the SUS. The organisation of pharmaceutical assistance was originated by the Ordinance GM/MS 204/2007 [4], which defined that health actions would be executed as financing blocks within the scope of SUS. These, in turn, were constituted by basic, strategic and specialised components [4].

Prior to the creation of the SUS, the acquisition of drugs absent from the Relação Nacional de Medicamentos Essenciais - Rename (National Relation of Essential Medicines), that is, medicines considered exceptional, was conditioned by the severity and specificity of the patient's condition, as well as its justification and special homologation by the service provider. The first list of exceptional medicines was adopted only in 1993, breaking the paradigm of elaboration of a distinct list of medicines other than those considered essential and listed by the Rename [5].

In the years comprised between the Política Nacional de Medicamentos - PNM (National Medicines Policy) [6], 1998, which included guaranteeing the population's access to high-cost drugs for diseases of an individual nature, and the Pnaf, 2004, there were several advances in the policy for exceptional medicines. In 1999, the Ministry of Health began to establish specific financial resources for the acquisition of this type of medicine, conditioned to the annual presentation of physical-financial programming by the managers. Shortly thereafter, it established technical criteria for the selection, inclusion, exclusion and substitution of exceptional pharmaceutical drugs in the SUS table, described in the *Protocolos Clínicos e Diretrizes Terapêuticas - PCDT* (Clinical Protocols and Therapeutic Guidelines) [7].

"Baptised" in 2009 as Ceaf, this group of drugs had its financing and execution rules established by the aforementioned Ordinance GM/MS 1554 / 2013, which defines it in its article 2 *as a strategy for access to medicines within SUS, characterised by the search for guarantee of the integrality of the medical treatment, at an outpatient level, which lines of care are defined in the Protocolos Clínicos e Diretrizes Terapêuticas (Clinical Protocols and Therapeutic Guidelines) published by the Ministry of Health* [2].

The Ceaf's development, therefore, was due to the need to expand access to some high-cost medicines, as well as to incorporate formulas and presentations enshrined in the scientific literature and national and international medical experience, either in the logic of health care, or in expanding the scope of diseases and conditions contemplated [5]. These are formulations intended for the treatment of rare or low-prevalence diseases, as well as for more frequent diseases, such as severe asthma, in case of intolerance or resistance of the patient to first-line drugs available elsewhere in the pharmaceutical care.

PCDTs are therefore part of the instrument adopted in Ceaf's management to make the policy of acquiring medicines technically and economically feasible, characterised by the following attributes: 1) definition of clear criteria for inclusion and exclusion, as well as special cases, with a view to establishing eligibility for treatment; 2) objective description of the condition and the diagnostic criteria; 3) presentation of care procedures for each disease, outlining therapeutic options for all evolutionary phases; 4) detailing the ways of monitoring and controlling the expected results; 5) reporting the scientific evidence used in the preparation of the documents; and 6) presentation of the technical reasons that justify not proposing alternative treatment [8].

The dispensing of drugs that make up the Ceaf catalogue occurs upon submission of the duly completed medical prescription and other documents described in the PCDTs, such as the Laudo para Solicitação, Avaliação e Autorização de Medicamentos do Componente Especializado da Assistência Farmacêutica - LME (Report for the Solicitation, Evaluation and Authorisation of Medicines of the Specialised Component of Pharmaceutical Assistance) and the Termos de Esclarecimento e Responsabilidade - TER (Terms

of Clarification and Accountability). The TERs are part of the documentation required to receive the drugs in 71 of the 83 PCDTs in Brazil. They must be signed by able and autonomous patients or their legal representatives, in the case of patients with reduced autonomy [2].

The terms, which are attached to PCDTs and have a similar language and structure, presuppose compulsory information to the patient or person responsible about the potential risks, benefits and side effects of the drugs recommended by the respective protocols. Similar to the consentimento livre e esclarecido - TCLE (informed consent term), they are presumed to be an essential legal mechanism to prove that there was communication to the patient and to ensure the patient's autonomy, even if the term's goals, as announced in the PCDT, are not clear in this regard.

Even if they are medical treatments offered by the public power, the autonomy and vulnerability of the human person remain inalienable, and the TER can acquire, in this context, an assertive documental character of these attributes, especially when they provide for protective measures to the patient.

The autonomy of the patient and his or her condition as a vulnerable entity in the relationship with the physician and the health service seem, at first glance, contemplated in the TER concept. These are elements that, if not taken care of, can result in moral conflicts that, from our point of view, can be mediated by intervention bioethics (IB).

In the light of the presented scenario, IB is a tool of applied ethics to be used in the analysis of the current TERs to assess the extent to which patients' autonomy and vulnerability are valued, especially when considering the complexity and toxicity of the prescribed drug treatments by Ceaf. These factors tend to increase the vulnerable situation of individuals, and in turn, BI proposes to deal with this issue with intervention measures.

Intervention bioethics

The term "bioethics" was coined in English language in 1971 by the American oncologist Van Rensselaer Potter of the University of Wisconsin, in the book "Bioethics: bridge to the future." Later, André Hellegers of the Center for Bioethics of the Kennedy Institute at Georgetown University used the same term but with a strictly biomedical connotation, unlike the one used by Potter, which was more global and widespread [9].

Bioethics as it is currently known was born in the United States in the 1970s, based on Beauchamp and Childress's principlism [10]. Their four principles - autonomy, beneficence, non-maleficence and justice - would serve as a simplified instrument for the practical analysis of the conflicts found in the biomedical context. Its expansion as a field of study was partly due to reports of inhumane research, such as the study that described the natural evolution of syphilis while depriving patients of treatment, and the establishment of ethical principles in the *Nuremberg Code* [11] and the *Declaration of Helsinki* [12] in order to restrict questionable practices.

From the 1990s, researchers who were concerned with issues that the traditional approaches only tangled theorised the epistemological core of what is conventionally called "hard bioethics", later termed "intervention bioethics (IB)". It is a peripheral and counter-hegemonic proposal of theoretical and practical ethics that considered Latin America and its persistent conflicts for the creation of autochthonous theoretical references with the potential to translate the needs of the populations neglected by the development process and to insert in the ethical agenda the search for the transformation of these realities [13].

Starting from the imminent finitude of natural resources in the face of the predatory frenzy of the capitalist system, intervention bioethics draws attention to the need to establish limits in order to preserve the planet and the need to soften arbitrary and harsh leaderships and stances, especially in the self-proclaimed central countries [13]. It is from this strategy of convergence of human characteristics and needs that bioethics intends to provoke intervention and transformation.

The theoretical and conceptual framework of corporeity admits the body as materialisation of the person, the physical and psychic dimensions concretised in the social relationships and in the relationship with the environment. The physical body is the common structure that sustains societies, the obvious "universal" that justifies the existence of needs related to survival and from which differences and cultures are born. Thus, all the proposed intervention must see the person as *a unique, universal and exclusive requirement for the ownership of rights* [14].

Pain and pleasure appear in this context as extreme indicators of the spectrum of basic needs that move people and take particular meanings in

 http://dx.doi.org/10.1590/1983-80422018263255

the bodily experience of each individual and in his or her relationships with the society and the environment. By establishing pain and pleasure as parameters of quality of life and drawing a parallel between the perception of the individual and the reality that surrounds that individual, IB allows to evaluate social inequality from a subjective point of view, in addition to the objective criteria already consolidated [15].

Uncovering this inequality creates a clear commitment to the most vulnerable, especially through what intervention bioethics calls "4P": "prevention" of possible damage and iatrogenesis, "precaution" in front of what is ahead and is unknown, "prudence", so that technological advances and discoveries do not become ethical problems and "protection" of the most fragile, excluded and unassisted. These actions are intended to address, understand and intervene in issues for which the principlism or hegemonic bioethics is insufficient [16]. Therefore, it makes a valid instrumental from the point of view of vulnerable groups whose dignity must be respected and ensured.

Critical solidarity is an additional foundation of IB and it advocates the commitment of individuals engaged and politicised with the social cause. The action of these actors presupposes the recognition of the other as a human being with the same dignity, in a clear movement which basic indicators (reciprocity and otherness) give space for constant reflection on the practice itself, with the aim of perfecting it and making the practice more efficient for its purposes [17].

The *Universal Declaration on Bioethics and Human Rights* (UDBHR) [18] of the United Nations Educational, Scientific and Cultural Organisation (UNESCO) is in line with the fundamental theoretical frameworks of intervention bioethics and constitutes a special document in relation to its reflection on access to health care by the most vulnerable populations, taking into account different socio-cultural contexts from the perspective of equity, justice and social inclusion [19]. Thus, one of the considerations in its preamble and in Article 14, which deals with social responsibility and health establishes respectively, that *all human beings, without distinction, should benefit from the same high ethical standards in medicine and life science research,* (...) *without distinction of race, religion, political belief, economic or social condition* [18].

In spite of UDBHR's humanised position on consent, in Article 6, informed consent had already been introduced under the principlism approach, as a tool to ensure the autonomy of the research participant and the patient. Engelhardt emphasises that the right not to be treated without consent gains immediate applicability in the wishes of the possible patient. It is enough for that individual to refuse to indicate that the doctor's authority does not apply to that patient [20]. Regarding the priorities that characterise this consent, respect due to dignity and autonomy can be cited [21].

Communication of all information on benefits associated with treatment, risks and viable alternatives must be prior to obtaining consent. It should also consider the profile and the specific circumstances in which the patient is, and, if possible, the patient's subjective perceptions, specific to his or her particular situation. In any case, informed consent must be free from coercion and undue influence, which occurs, for example, when the patient's refusal is followed by reprimand and other harmful constraints [22].

Naturally, the disease brings limitations to the patient's daily life, whose personal meaning of their sickness condition is often tied to the perception of devaluation, with direct implications for their emotional exhaustion and psychic suffering. This patient deals with two issues during the treatment: in the passive pole, he/she is dependent on the family, the health professional and the service; at the other pole, he/she is the active agent of the therapy itself, since the patient is responsible for clarifying the health professional about his/her symptoms and previous clinical history. The patient's inherent vulnerability varies according to their situation and degree of autonomy - hospitalised or unconscious, for example - and the vulnerability can be increased according to specific personal aspects, such as age, ethnicity, gender, education level and social class [22].

Investigating and describing patients' vulnerability after obtaining informed consent for treatment is important for a number of reasons, including the possibility of evidence of circumstances that may invalidate the terms, and elaborate additional measures that would provide more patient protection on the basis of the vulnerabilities identified [23].

Thus IB suggests a reflection on asymmetrical relationships, such as the paternalistic doctor-patient, and stands in favour of respect for the

dignity of vulnerable groups affected by inequality of power. It also proposes patient's protection through mechanisms such as state intervention, in the sense of the application of human rights, critical solidarity and the encouragement of liberation, empowerment and emancipation of the vulnerable, which in this case are patients who depend on specialised drugs for treatment and recovery [24].

Therefore, IB is involved in discussions about the asymmetric relationship between health professionals and patients and on the guarantee of patients' rights, emphasising the need for State intervention in favor of the most vulnerable, protecting them in their vulnerability through protective policies [24].

Method

With the main purpose of analysing, in light of intervention bioethics, selected elements from the TERs, with the conceptual support of principles defined by the UDBHR [18], such as autonomy, consent and vulnerability, we conducted a qualitative analysis of the 71 termos de esclarecimento e responsabilidade - TER (terms of clarification and responsibility), which were obtained in the portal of the Ministry of Health.

Given that all of these terms have similar structure and requirements, the sets of information requested on a recurring manner were identified and ordered, as well as discordant items, that is, items which were present in only part of the terms (Table 1).

Table 1. Main sets of information requested in the TERs (n = 71)

	n	%
Nominal statement of the patient to have been informed of benefits, risks, contraindications and major adverse effects	71	100
Nominal statement of the doctor to have explained and solved all the doubts of the patient	71	100
Description of benefits in accessible terms (by the doctor)	71	100
Description of the risks, contraindications and major adverse effects in accessible terms (by the doctor)	71	100
Express authorisation, ensured anonymity, of use of information related to treatment by the Ministry of Health and Health Secretariats	71	100
Clear guarantee of continuity of care even in case of withdrawal of treatment	71	100
Express guarantee of TER route to the user or legal responsible	67	94
Clear awareness of the use by patient-only	71	100
Manifest commitment of the patient about the return of the medicine in case of withdrawal or interruption of treatment	71	100
Express guidance on the duty to inform the doctor in case of pregnancy and / or breastfeeding	35	49
Information on the risk of fetal malformation	39	55
Declaration of agreement and spontaneous willingness to submit to treatment and responsibility for risks due to possible undesirable effects	10	14
Clear awareness about the possibility of stopping treatment at any time without being constrained by the doctor	5	7
Declaration of understanding and agreement with all TER terms	5	7
Expression of the patient's own free will and joint decision with the doctor	5	7

Analytical process of reading the TERs

TERs usually range from one to four pages and begin with a patient nominated statement to demonstrate that there has been clarification about the benefits, risks, contraindications, and major adverse effects of the drugs listed in the PCDT in question in the treatment of the condition.

The next item explains that all medical terms and doubts have been duly explained by the physician, and is also indicated by name. Composing this core common to all TERs, there are statements which show that there has been clear information on possible improvements that drugs can bring (with the expected recovery described), as well as on contraindications, potential adverse effects, and risks of use, all of which are extensively described.

Other information in the TERs refers to: authorisation to the Ministry of Health and Health

 http://dx.doi.org/10.1590/1983-80422018263255

Secretariats for the use of treatment information, provided that the anonymity of the patient is guaranteed; the awareness about the use of medicines exclusively by the patient to whom they were prescribed; the patient's commitment to the return of medicines in case of non-use or interruption of treatment; and the assured continuity of treatment, even if the patient gives up taking the drugs.

It is important to emphasise that, although careful communication by the doctor about the treatment as part of medical conduct is presumed, there is indeed clarity regarding the terms used in these terms, especially in the case of adverse drug effects, often of words commonly used by the population.

Exceptional elements worth mentioning include predicted completion of the TERs in two copies, one of which must be given to the patient or his / her legal representative (only four TERs do not have this item); the declaration of "agreement and spontaneous will" in submitting to the treatment with responsibility for possible undesirable effects assumed by the patient (present in ten TERs); the expression of the possibility of suspension of treatment at any time without being constrained by the doctor; declaration of understanding and agreement with all terms; and expression of "free will and joint decision with the doctor". These last three are contained in five TERs.

Derived from the concept of informed consent and having points in common with the termos de consentimento livre e esclarecido - TCLE (terms of free and informed consent) used with research participants, TERs merely communicate potential risks, benefits and side effects, having little information on protection and vulnerability of patients.

One way of validating patients self-determination by informed consent instruments is to certify their understanding and, above all, to provide all the information essential to guarantee their autonom [25]. On the other hand, there are no validated universal protocols for assessing patients' vulnerability or which ensure their full autonomy [23].

Some of the elements identified in TREs, especially those related to autonomy, patient consent and vulnerability, were selected for analysis in light of the appropriate theoretical framework of intervention bioethics: 1) patient privacy and confidentiality of information related to the patient; 2) individual responsibility of the patient for possible undesirable effects resulting from the treatment; 3) information about the treatment risk factor for gestation and breastfeeding; and 4) provision for the possibility of discontinuing treatment at any time without being constrained by the physician.

Finally, these selected elements had their basic principles - autonomy, consent and vulnerability - conceptualised according to recognised theoretical references.

Selected elements from TERs in light of IB

Privacy and confidentiality of patients

Regarding the TER item that assures patient anonymity when using information related to treatment by the Health Ministry and Health Secretariats, it is important to emphasise that professional secrecy has always been part of the doctor-patient relationship as a mandatory moral attribute of the professional. More recently, it has been established as a patient's right, based on the citizen's right to privacy, which confers a double nature to the concept of professional secrecy, since it is both the duty of the health professional and the right of the patient [26].

Therefore, confidentiality is based on the notions of privacy and, in the area of health, is understood as the conditions defined by the patient through which information can be transmitted or revealed, based on the concept of privileged communication and responsibility of the health professional. While privacy translates into the right to privacy, confidentiality represents the guarantee of secrecy [27]. The ethical practice of confidentiality is what favours, therefore, a reliable and safe environment for exchanges in the relationship between health professional and patient with a view to the care.

Regarding the privacy and confidentiality of information for children and adolescents, it is necessary to highlight the inherent specificities, which, even in the face of the guarantee of confidentiality, impel the health professional to intervene in cases of detection of high level risk or suffering experienced by this type of patient. Special care should be provided, for example, in the care of adolescents, who, because of their greater degree of autonomy and maturity, may express the desire that personal information provided to the health professional is not passed on to their person responsible, at the risk of a breach of trust [28].

The analysis of confidentiality and privacy foreseen in the TER, concepts intrinsically related

to patient's autonomy, consent and vulnerability, shows that such prerogatives are not sufficiently answered by the principlism. We believe that the examination in light of intervention bioethics is more appropriate, since it broadens the discussion and is based on the due use of information that take into account human rights, as established in the UDBHR in its article 9: *The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law* [18].

Obtaining consent therefore results in respect for the patient's privacy and the confidentiality of their information, and must include clear and sufficient information that explains all the procedures to which the patient will be submitted. The process of information and obtention of consent is important in order to prevent potential conflicts between health professionals and patients. Therefore, respecting the autonomous person presupposes the acceptance of the ethical-social pluralism characteristic of our time [29]. Consent avoids major problems that may arise in the course of the therapeutic process, and when properly obtained, with attention to data confidentiality, qualifies and gives value to the human rights of patients.

In this way, the patient's privacy care "echoes" variables defined by the "4 Ps", especially regarding the prevention of possible harm and the protection of the most susceptible [16], in clear commitment to the most vulnerable, in this case, the relation between patients and physicians/ health care teams. The analysis made in this article, centred in the TERs as documents to ensure communication with the patient, found that there is a specific instrument in all of them to protect the patient's decision to allow the use of information regarding treatment by the Ministry of health and health secretariats, as well as the confidentiality of information and anonymity.

Patient responsibility for undesirable effects

It is not only the doctor who has responsibilities. Patients also have several moral responsibilities, both with themselves and with the treatment. As for the patient's right-duty binomial, therefore, it is expected that, by enjoying autonomy and consenting to a certain medical orientation, patients will become co-responsible for their own health [30].

Consent to a given treatment is nothing more than a choice resulting from a successful information process. Communication with the physician naturally includes risk information, which the autonomous patient must weigh and decide whether to accept, thus becoming co-responsible [31].

Thus, the TER also gives support to physicians in possible lawsuits, since the patient, by signing it, declares to agree to the treatment - even in the face of the possibility of undesirable, foreseen and informed effects - and formalises the good faith in the physician, sharing responsibility for the therapy [32].

Although the individual responsibility of the patient for possible undesirable effects of the treatment is expressed in only ten of the analysed TERs, it is assumed that, in signing this type of document, the patient declares to have understood the intervention to which he or she will be subjected and to be aware of the risks associated. This awareness pervades the responsibility of the patient to present all relevant information to the physician, so that it does not harm the physician's performance and the chosen treatment [25].

Therefore, in this case, there is room for the use of intervention bioethics, because it is clear the principlism's over-valuation of autonomy for the patient and the excessive simplification of their condition. There is no doubt that patients are co-responsible for the treatment themselves and for the success or failure of the agreed procedures. However, any damage should not be charged to the patient without explicitly providing for protective measures, such as help and immediate assistance.

Information on risk of treatment during pregnancy and breastfeeding

This issue fits into the concepts of "vulnerability" and "personal integrity" in the literature, and in view of the importance of the UDBHR as a theoretical and normative basis capable of promoting public policies regarding the protection of individuals or groups belonging to contexts of vulnerability , we proceed to analyse the emblematic situation of the pregnant and / or lactating patient and the risks to their individual integrity and that of the foetus and / or infant due to the toxicity of medical treatments offered by the Ceaf.

Ten Have [33] argues that the vulnerability principle present in the UDBHR allows contingent and ontological aspects of vulnerability to be taken into account. In fact, the UDBHR as an international standard adopted by Unesco, can be used as an

 http://dx.doi.org/10.1590/1983-80422018263255

instrument to stimulate public policies and the adoption of laws on the subject of health care for vulnerable people.

The report on the Principle of Respect for Human Vulnerability and Personal Integrity [36] emphasises the vulnerability and personal integrity proposed by the UDBHR and highlights that 1) There are two fundamental categories of vulnerabilities: a) special (temporary or permanent) disabilities, disease and limitations imposed by the stages of human life; b) social, political and environmental determinants: for example culture, economy, relations of power, natural disasters. 2) they focus their attention on conditions that, more or less directly, impinge upon the capacity to live as a free, autonomous individual 3) Although addressed to States, it is rather necessary to boost awareness of the responsibility that all sectors of society share and to promote … those strategies and means of cooperation that are most likely to effectively address the determinants of "special" vulnerability to which Article 8 refers.

Thus IB postulates a measured expectation about asymmetric relationships, such as the doctor-patient relationship, and favours respect for the dignity of vulnerable groups, as is the case of patients who need specialised drugs for treatment and recovery.

Regarding gestation and breastfeeding specifically, the discussion of potential teratogenic effects of drugs and other substances was driven by the epidemic of malformations that followed the use of thalidomide on large scale by pregnant women in the early 1960s. Until this fateful event, embryonic development in the womb would be relatively protected from embryo toxic effects of external environmental agents. However, the generation of children with malformations due to that drug reversed such a conception, reinforcing the medical practice's attention to the use of drugs during pregnancy, and made it ethically reprehensible to carry out clinical studies with new drugs in pregnant women [35].

Clinical practice, however, sometimes uses the benefit / risk ratio to justify the prescription of medications during gestation and breastfeeding, overemphasising benefits and minimising risks, based on the relative safety of the medicines - until risks are duly proven, which is in clear contradiction with the specificity and vulnerability of this population. Moreover, given the uncertainties regarding the extrapolation of scientific results with pregnant guinea pigs for pregnant women, there is still a conflict between the imprecision of the risks of therapy and the need to treat pregnant women under certain conditions [35].

It is, therefore, an example of vulnerability that TERs intend to circumvent by clarifying and strengthening the autonomy of the pregnant and/or lactating patient. In this case, in addition to adequately informing about risks associated with drug treatment, TERs have an extensive list of undesirable effects, with simpler and direct terms, to avoid possible misunderstandings.

Assuming that the understanding of the terms of the treatment, including its risks, is presupposed for the autonomy of the patient, all the TERs analysed contemplate this requirement. Considering possible ignorance of the patient about undesirable effects of the drug, informing it through an exhaustive list of information, as it is the case, is important to provide the patient with means for immediate action in case of adverse reactions during treatment.

The possibility of suspending treatment without onus

The last element fuses notions of the full and responsible exercise of the autonomy of individuals who may be vulnerable. Contrary to paternalistic relationships, there is a certain consensus among several actors - courts of justice, codes of professional ethics and scholars of bioethics - in favour of the recognition of the adult patient and in normal state of consciousness as being endowed with personality to accept or refuse treatments.

This understanding assigns responsibility to patients for their own health and combines with the ambitions of contemporary ethics, that is, advocates that decisions about the treatment of the patient should be those that aspire to the best results according to the patient's own vision. For this to be achieved, two assumptions are fundamental: the information provided by the physician is true and clear, and the patient's decision is being respected and accepted by the staff and the family [36].

There are even different perceptions about pharmaceutical drugs in the association between doctor and patient: it is evaluated by the first one in terms of effectiveness on the disease, to which the patient adds other attributes, such as convenience, accessibility, physical characteristics and other culturally established meanings, which vary from individual to individual and may influence the patient's subjective decision by adherence or non-adherence [37].

The freedom of decision of the patient for the treatment that best satisfies his or her desires is also curtailed by the organisation of the health system, mainly in the public sphere, which does not grant the patient the means to choose the doctor or the service, appointing to the patient what is available.

Unable to choose, and often subject to costly conditions in care, the patient has limited autonomy, having to agree and submit to what is offered. In this way, the patient becomes vulnerable, just as the physician himself, a professional subject to a health system that does not favor humanised care [38].

The possibility of stopping treatment without any embarrassment on the part of the physician, when foreseen in the TER, is important to support the individual in the role of an autonomous and co-responsible patient. It is information that has the potential to weaken any subjective perceptions of the patient that treatment is unilateral and imposed, giving to the patient the empowerment to take the reins of his or her condition as a primary part of the relationship.

It should be assumed that, although the conversation with the prescribing physician clarifies the possibility of suspension of the treatment by the patient without any penalties related to the care provided, there may be little understanding about this matter, given the patient's historic position as vulnerable in this relationship with the professional and as a user of the public health service. For this reason it is interesting that this instrument is explicit in all TERs.

Final considerations

The Australian philosopher and professor Peter Singer[39], in arguing that ethics should not be restricted to discussions within the academic sphere, emphasises that there are objects for ethical evaluation in all actions and omissions of everyday life, and therefore ethics can be applied to any situation [41]. In fact, bioethicists deal with questions of multiple and diverse origins, which heterogeneous dimensions and complexities require differentiated proposals and decisions based on theoretical and methodological tools provided by bioethics in order to mediate conflicts and support the weaker side of relationships [13].

As a tool applicable in debates on health systems, intervention bioethics considers as morally justifiable in the public and collective field, under the philosophical foundation of consequentialist utilitarianism, to prioritise decision-making and actions that favor the greatest number of people for the longest possible period of time, aiming at collective well-being. In the private and individual field, it defends the search for viable and practical solutions to conflicts in different contexts [40].

In this sense, the dimension that should be attributed not only to the doctor-patient relationship, but also to the field of research with human beings should not be restricted only to biomedical matters but also to guide the understanding and solution of these problems through social participation, politicisation and respect for human dignity.

Thus, as a transformative proposal, intervention bioethics encourages empowerment, liberation and emancipation as fundamental principles of intervention. The protection in light of the "4Ps" and critical solidarity cooperate as solid foundations in regaining awareness of the factors that provoke inequality and exclusion, in order to undermine sources of vulnerability and reestablish the exercise of autonomy.

Selected as a result of their overlap with the concepts of autonomy and vulnerability of the patient, the four elements analysed in light of intervention bioethics contemplate, to varying degrees, requirements that grant the patient conditions for true consent, understood here as the one whose authenticity and validity depend on relevant information provided by the physician and patient understanding.

All TERs analysed have a device that preserves the privacy of patients and the confidentiality of their information, which contributes to strengthening bonds and trust between the parties. There is also an express mention in all TERs, where appropriate, of the potential risks of treatment for gestation and breastfeeding, in clear compliance with the specific condition of pregnant women, foetuses and infants as vulnerable populations in this context.

Finally, although the treatment decision is shared between the parties, as well as its results, the TERs have little information on the patient's vulnerability in case of undesirable effects of the drug and do not envisage measures to guarantee protection.

The reflections presented here seek to call the attention of the State as Ceaf 's manager body and creator of the TERs for the institution of measures based on the respect to the vulnerable condition of the patient before the institution of treatments that are often associated with the occurrence of negative effects.

 http://dx.doi.org/10.1590/1983-80422018263255

It is important to emphasise the central role of information in the process of informed consent, and to highlight how the patient-doctor relationship has evolved over the history of care practice, which is no longer paternalistic (according to the Hippocratic tradition) and becomes based on the quality of the information provided.

It should be noted, however, that this article restricted its analysis to documents that substantiate informed consent in the case of the drugs contemplated by the Ceaf, and it is not possible to extrapolate the considerations outlined here to the conversation between doctors and patients, although it is important to add that quality and the lack of this channel of communication, as well as the magnitude of the interaction that occurs with the professional, are interesting points for investigation.

Considering the analysis described, considering the selected elements and in accordance with the tools offered by intervention bioethics used here, it is understood that all the TERs analysed partially meet the requirements that qualify the real consideration of the patients' autonomy and vulnerability. If on the one hand there is qualified information about the potential risks of treatment, including the risks for pregnant woman and the foetus, the TERs still fail when they do not inform about a structure, flow or protocol that would shelter the patient in the eventual occurrence of harm.

This article is the result of a research project held in 2016 and developed under the XVIII Lato Sensu Specialisation Course of the Unesco Chair of Bioethics of the University of Brasília (UnB).

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Eduardo David Gomes Sousa participated in the initial planning, the systematization of the TER, the analysis in the light of the theoretical reference, and the final revision and formatting of the article. António Hélder Francisco and Edson Alfredo were responsible for the theoretical basis and final revision of the article. Camilo Manchola collaborated with the entire process as a research leader.

Recebido: 23.4.2017
Revisado: 5.2.2018
Aprovado: 13.2.2018