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Communication and consent in research and clinical practice: a conceptual analysis

Fermin Roland Schramm

Abstract

The devices of communication and consent are important tools in research and clinical practice. They therefore have an important moral dimension in bioethics, as they are structured by the dialectic between the conflict inherent to the *ethos* and attempts to establish convergences within the same. These convergences can appear as modalities of attempts at harmony between the parties involved (as suggested by Maliandi), or, more simply, as a way for moral agents to obtain permission (as suggested by Engelhardt) to use the bodies of moral patients. This article proposes a conceptual analysis of such devices, considering such an analysis a necessary condition to approach the morality of research practices involving human beings and clinical practice, involving moral agents and moral patients.

Keywords: Communication. Informed consent. Conflict of interest.

Resumo

Comunicação e consentimento na pesquisa e na clínica: análise conceitual

Os dispositivos da comunicação e do consentimento fazem parte das ferramentas da prática em pesquisa e da prática clínica, e têm, portanto, importante dimensão moral em bioética. Isso se deve ao fato de serem estruturados pela dialética entre a conflituosidade inerente ao *ethos* e as tentativas de estabelecer convergências nele. Essas convergências podem se apresentar como modalidades de tentativa de harmonia entre as partes (como sugerido por Maliandi), ou, mais simplesmente, como maneira de os agentes morais obterem permissão (como sugerido por Engelhardt) do uso dos corpos dos pacientes morais. O artigo propõe análise conceitual desses dispositivos, por considerá-la condição necessária para abordar a moralidade das práticas de pesquisa envolvendo seres humanos e a prática clínica, que se dão entre agentes e pacientes morais.

Palavras-chave: Comunicação. Consentimento livre e esclarecido. Conflito de interesses.

Resumen

Comunicación y consentimiento en la investigación y la práctica clínica: un análisis conceptual

Los dispositivos de comunicación y consentimiento son parte de las herramientas prácticas en la investigación y la práctica clínica, y tienen, por tanto, una dimensión moral importante en bioética. Esto porque son estructurados por la dialéctica entre la conflictiva inherente al *ethos* y los intentos por establecer convergencias. Tales convergencias pueden ser modalidades de un intento por buscar la armonía entre las partes (como sugiere Maliandi), o, más simplemente, una forma de que los agentes morales obtengan permiso (según lo sugerido por Engelhardt) para usar los cuerpos de los pacientes morales. El artículo propone un análisis conceptual de este tipo de dispositivos, pues se considera que es una condición necesaria para abordar la moralidad de las prácticas de investigación involucrando seres humanos y de las prácticas clínicas que se producen entre los agentes y los pacientes morales.

Palabras clave: Comunicación. Consentimiento informado. Conflicto de intereses.

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Declara não haver conflito de interesse.

Currently, both the undertaking of research that involves human participants, and the clinical practice that aims to cure and/or care for patients, can be viewed as types of interrelationships between social actors that establish themselves thanks to the devices of "communication" and "consent". Moreover, these types of practices involve a set of agents that, in accordance with the jargon that is adopted within the field of bioethics, may be distinct and divisible into two subsets: the "moral agents" (represented *inter alia* by researchers, doctors and other health care professionals) and "moral patients" (represented in this sense by scientific research study participants, and by those that receive care from the agents). The structure that is established between moral *agents* and *patients* leads us to question the:

... meaning behind these acts, the purposes, the circumstances, the consequences (...) *while, at the same time, taking into account the objective, concrete situation, in its singularity and complexity,* (...) [considering that,] *from such a perspective, ethics is required to be constantly an ethics that involves questioning, i.e., the ethics of dialogue and dialectics. Interrogation is required because the situations that arise have never been dealt with, and because the answers to these problems are not clearly evident. Discussion is required because the novel nature and complexity of these issues require, for their resolution, contributions from various fields of study* [1].

This is particularly true, from the point of view of bioethics, with respect to moral agents and patients, which may be viewed as actors that relate to each other in terms of their *ethos*. This is understood as the *phenomenon of morality* that is to be studied by the field of ethics, which is, in turn, understood as the *thematization of the ethos*, including *every effort to understand it*. This thematizes ethics *in and of itself*, i.e., ethics is integrated into the *ethos*, which enriches and makes the *ethos* itself more intricate [2]. In other words, ethics is structured and restructured as a result of the *set of challenges* that are represented by the *conflicting relationships* that compose the *ethos*, but is also due to the attempts at building convergences.

These convergences may be understood as the *search for a balance between the juxtaposed functions of reason*, and aims to *avoid, resolve or, at least, regulate conflicts*, beginning with the a priori *recognition of the conflict* and of the existence of a *variety of principles* that is understood as a basic element that is capable of *maximizing the harmony between them* [3]. In this sense, communication and consent seem to constitute rational tools that are necessary and appropriate for attempting to deal with the with the conflicts that are being discussed, which may be of interest, but also may represent values and systems of belief that are employed to "avoid", "resolve" or "regulate" the conflict situation.

However, the terms "communication" and "consent" can have various meanings, which makes the debate surrounding these terms quite subjective at times. Moreover, the term "communication" has a denotation that is merely instrumental and quantifiable: that which signifies the *transmission of information* [4], in which "communication" is a synonym for "information". However, this conceptual construct may be viewed as inappropriate, since this association between the two terms may constitute, in reality, a form of subsuming the meaning of "communication" into that of "information", which is a process that, in fact, quantifies and does not incorporate the broader meaning of "communication", in the sense of it representing "social relations".

This broader meaning of the term can be appreciated within at least three types of relationship: 1) a relationship involving the demand or request by a person (or group of people) that requires information from someone else (or from another group of people); 2) a relationship between the transmitter of a message and the receiver of the message (as related to the synonymous nature of the terms "communication" and "information"); and, 3) a relationship of "injunction", which can be viewed as evidence of an *asymmetric relationship in which one of the people* [has] *an active role and the other person a passive role*, i.e., a relationship in which the transmitter, or speaker, of a message supplies the receiver *with an indication that refers to their social relationship* [5]. This relationship may also be viewed, under certain circumstances, as an instrumental relationship (in the case of research), and as a "paternalistic" power relationship (in clinical terms).

To attempt to clarify the two types of devices that are represented by "communication" and "consent", a linguistic analysis of the two concepts will be undertaken below. This analysis is necessary because, as has been established, the concept of communication may be reduced to the mere dissemination of information, considering that, in this case, the device known as "consent" may be viewed as a complicating factor. What actually happened when, in Brazil, the discussions surrounding ethics occurred that resulted in the implementation of the CEP/Conep system for evaluating research procedures

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that involved human participants? In effect, the process that created this system brought to the fore the issue involving the translation of the English term *informed consent*, which, in Portuguese, became "free and informed consent" or, as some prefer, "free and acknowledged consent", in accordance with the traditional French expression *libre et éclairé* [6].

The concepts of communication and consent

The terms "communication" and "consent", which are derived from the Latin words *communicatio* (meaning "being in a relationship with") and *consentire* (meaning "to be in agreement with"), have a logical relationship between one another, since communication may be considered a necessary condition to arrive at consent. However, this relationship also alludes to the common concept of "meaning", considering that, to provide *consent*, one must be familiar with the meaning that is involved and shared, which can be viewed as the result of a "communicative act". According to Habermas, the communicative act should be understood as a necessary precursor to any type of act and is part of a "new critical theory of society". It should also be distinct from the mere "instrumental act", which is understood as a teleological one, albeit whose purposes depend on communication and refer to a possible normative agreement between the protagonists of the act [7].

In other words, for the agent, the instrumental act represents an empirical search for knowledge, which is organized with the aid of techniques and is considered rational as it allows for the attainment of goals due to the techniques that are appropriate for these objectives. Alternatively, the communicative act is a form of social interaction between at least two participants that understand a common language and are involved in an activity that has a normative dimension. In short, the foregoing refers to participants that establish an interpersonal relationship with the aim of attaining reciprocal understanding, which is the objective of communication. In the theory of language, the concept of communication refers to the fact that human beings can speak and try to understand each other, which

...refers directly to the social character of language [which] *characterizes each of the behaviors that involve an exchange of ideas that can be observed within species that are organized within societies ,* [being that]*, in order to explain this phenomenon of communication, one must relinquish the individual plane and pass over to that of society,* [because] *the essential objective of language is to guarantee the communication of ideas, of desires and of emotions within the interior of the group,* [but knowing as well that the group] *can make use of other modes of non-verbal communication* [and that the] *spoken word takes on other roles that do not seem to be directly connected to communication,* [such as] *the role of representation,* [which] *consists of creating substitutes or representatives of the reality that the individual understands, i.e., substitutes whose structure constitutes that which we refer to* [as] *thought* [8].

In fact, the "communicative act" and the "instrumental act" are two types of endeavors that may refer to scientific research as well as to the relationship between the medical professional and the patient (including between any health care professional and the patient that receives his treatment). In such situations, both types of "act" occur together; however, they can become contradictory when the objective of the communicative act is subsumed into the instrumental act. In such circumstances, such practices enter the realm of bioethics, which will analyze them in light of a value paradigm.

This is the case of the Quality of Life Principle, which is primarily espoused by so-called "secular" societies, in which unexplored territories still exist that refer, in particular, to the "use of bodies". This use may be seen as a concept that substitutes the traditional concept of action, since the concept of "use" does not refer to subjects, but to "forms of life", within which "being" and "living" are associated concepts [9]. In particular, the term "use" implies the performance of a procedure that, in principle, may only be undertaken with the consent of those individuals that are involved, whether they be participants in scientific research or patients that receive medical care.

More specifically, "communication" and "consent" are two tools that can be applied to devices that refer to the experiences of any type of scientific research that is undertaken by researchers on human participants that are the object of the study. The same occurs with the type of relationship that is established within clinical procedures, between the doctor and patient (and, in general terms, in health care services, between the health care professional and he that receives care). In other words, both concepts refer to practices that are understood as interrelationships that are built between people or between groups of people or "communities".

However, the two concepts may be distinct in at least two fields that can be viewed as contradictory

due to conflicts of interest and/or divergent opinions that are mutually exclusive between the parties involved. Or, on the contrary, the concepts may be in agreement, sharing meaning, purposes and justifications with respect to a certain endeavor (such as clinical and health research and practice), establishing, as such, some form of "harmony".

Communication, consent and challenges regarding bioethics

From a bioethical standpoint, it can be stated, currently, that the phenomenon of "communication" and "consent" should deal with the problem of the so-called "moral strangers" [10] *because of the seemingly unresolvable conflict that exists between the parties. In fact, according to Engelhardt, the possibility of foreseeing on the horizon a solution for our controversies would no longer exist, considering that the cultural wars that fragment bioethical contemplation into sectarian fields of contention are based on an irreconcilable moral diversity,* [which is due not only to the lack of] *a moral consensus in defense of a common morality which can be a foundation* [for] *a canonic type of bioethics and a health care policy that it defends,* [but also due to] *a desire to negate the challenge of moral diversity to governance and to political stability* [considering that] *no substantive moral consensus can be reached* [11].

Even if one recognizes the enormous challenge of resolving conflicts of interest and of opinion, one cannot forget that - as we have already seen - a state of conflict constitutes part of *ethos* in and of itself. In other words, the conflicts that are analyzed in terms of bioethics refer to the complex interrelationships between agents that are involved in challenging situations. Actors that, as previously mentioned, may be referred to as moral "agents" and "patients", but which may also be viewed as "issuers" and "receivers" of the communicative actions that occur between the participants, and which can be viewed, in particular, as "moral strangers".

However, Engelhardt also cites the existence of "moral friends", which share a common sense of morality - contrary to the "moral strangers" - who are capable of resolving moral controversies through arguments that are congruent and shared via a "moral community", or by referring to some moral authority that is recognized by the parties. As the author himself writes, it is *within certain particular moral communities, and not within large scale societies,* [that] *we live and encounter the true meaning of life and the concrete form of moral orientation;* [communities within which] *we are immersed within a veritable matrix of moral content* [12].

On the other hand, with respect to large-scale societies, which are much broader than moral communities and are taken as being essentially secular in nature, Engelhardt proposes to introduce the *permission principle*. The is because the author considers *it to be the most crucial moral principle with respect to secular bioethics*, since *the act of obtaining permission from people is of fundamental importance for secular bioethics, because no other source exists for obtaining secular moral authority*. In short, in accordance with the author, *in light of an irrefutable moral pluralism* – such as that which exists in the contemporary world – *authority is derived from people themselves* [13]. In fact:

A universal secular bioethical system that is capable of connecting people that do not share a particular moral conception can only extract its authority in situations in which individuals provide their consent. After all, moral controversy takes place between individuals. Such as with moral strangers, who can, through agreements, create domains of common moral authority. [In sum,] *the permission principle will be of central importance not because it is valued, but because the permission of individuals is the only possible source of secular authority*, [considering that] *the bioethics of such a society will prioritize such practices as informed consent, the right to refuse certain treatment, the development of contracts for health care services and the right to decide what will happen to oneself and to authorize others to resolve one's destiny in accordance with the terms of a mutual agreement* [14].

However, it is at this point where the inevitable question arises of whether or not, in the view of secular bioethics, the possibility would exist, between the two universes that are constituted by the moral "friends" and "strangers", of the emergence of a type of relationship that would not involve opposition or mutual exclusion. As previously mentioned, one could argue that *the element of discord, not only in theory but also in the practice of bioethics,* [refers] *to a kind of interrelationship that involves an innumerable quantity of variables that determine the complexity that is so characteristic* [within] *the social realm* [15]. But, it should also be considered that, *in addition to the conflicts, there are also factors of accord that manifest themselves in everything that leans*

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towards a state of order, of organization, of being systematic [and that refers to a state of] "*harmony*" [between] "*conflict*" [and] "*convergence*", [since] *harmony inhibits conflict and vice versa*, [taking into account that] *conflicts establish relationships in the realm of divergence* and *harmony establishes them in the realm of convergence* [15].

We could, therefore, state that a dialectic (or complex relationship) exists between conflicts and convergence. The issue of communication and consent can be viewed particularly as being able to become a device that is capable of creating tools for obtaining such a state of "harmony", provided that a conceptual analysis of these two terms is undertaken. This analysis is a necessary condition in order to deal with conflicts within the relationships between moral agents and patients, which is the case here in the relationship between researcher and participant and in the relationship between the doctor (or healthcare service provider) and the patient or care recipient. In fact, regarding both experiences, the type of endeavors (or "use of bodies"), which can be interpreted as "sharing" and "participating", should be noted.

In other words, it can be considered that, thanks to this conceptual analysis, one can establish a kind of conceptual "bridge" (to use one of Potter's metaphors) that is shared through the experiences that scientific research study participants undergo - which are conducted, in principle, for the well-being of the "studied" humans – and through those experiences that are shared by patients in their relationships with agents that are active in the field of human health care, and which seek, in principle, the well-being of individuals and populations that are the objects of the cures and treatments that they offer.

Communication and consent: from a linguistic analysis to the use of these terms in philosophy

According to their etymologies, the words "communication" and "consent" have the following meanings:

Communication, → from the Latin noun *communicatio* ("the act of communicating, of sharing"), which is derived from the verb communico ("to share, to have relations with") [16];

Consent, → from the Latin verb *consentire* ("to share a certain feeling with", "to have the same opinion, feeling or behavior", "to come to a decision under agreement", "to feel at the same time", "to sympathize with") [17].

Let us analyze each term separately, in greater detail.

Communication

The "science of language", known as linguistics, may be understood via the psycholinguistic approach, which places this science within the theoretical interactive realm proposed by the epistemology of Piaget. According to this theory, all of knowledge, including linguistics, is constructed by the *permanent dialogue between the subject and the object*, which implies the *bestowing of a certain status to the subject, but also to the objects and the setting, or environment* [18]. Using this approach as a springboard, every linguistic operation may be viewed as being composed of at least four parameters or notions:

- the *objective reality*, which constitutes the *content* and the *situational reference point of what is being communicated*, which could be represented herein by the investigative measures that are implemented and by the clinic;
- the *speaker*, having his or her *implements of knowledge*, which is represented herein by the researcher and by the physician;
- the *linguistic model (i.e., the language that is being used by that social group);* herein, the forms of language that are used by the speakers, which are represented here by the researcher and the accompanying physician;
- *statements*, that the speaker *must process*, i.e., *produce, understand, memorize etc.* [19].

Communication is, therefore, a cognitive activity that can be included, arguably, in the field of psycholinguistics, which, as a field of inquiry, studies communication as a device that has aspects that are, in principle, and concomitantly, of a cognitive and affective nature, or - if one prefers - symbolic and imaginary. However, in fact, in the era of virtual reality and the pervasive nature of IT, communication as a device seems to be increasingly reduced (or subsumed) into stored information. In other words, communication is currently viewed merely as an activity in which meaning is transmitted, which can, in principle, be quantified (for example, into *bits*) and which can also, therefore, "circulate" from one place to another, however in only one direction, bereft of any reciprocity between the "speaker" and the "receiver".

Such a reduction, generally speaking, does not occur in the case of the communication device, within which there always exists reciprocity between the poles and between the actors that are involved. In short, if the information-bearing device is, in principle, unidirectional - which makes it easily quantifiable - the communication device is at least bidirectional, because it implies the constant existence of *reception* and *response*, which may result in the fostering of a *negotiation* between conflicting parties. Particularly, this communication may result in the request for permission (as suggested by Engelhardt, although he only applies it to communities and not to society as a whole), in which the shared production of meaning can arise. Or, it can also be viewed as an instance in which communicative asymmetries can emerge, and where the participants give new meaning to their content in accordance with their interests and values.

In the field of philosophy, but also in sociology (as we saw within Habermas's philosophical-social proposal involving the communicative act), the term "communication" is employed to indicate *the specific character of human relations* understood as *relationships of reciprocal participation or understanding* [20]. And, specifically, *a synonym of "coherence" or of "life with others"*, which designates *the set of specific modes in which human coexistence can have an impact* and *within which a certain possibility of participation and of understanding can be preserved* [20].

In fact, according to the philosopher Abbagnano, humans form communities because *therein they can participate reciprocally within their manners of being*, considering that "communication", which is understood as a *specific characteristic of human relations*, would circumscribe the sphere of these relations within which a *certain degree of liberty may exist* [21].

In sum, the relevance of the form of communication that is characterized within contemporary philosophy is due to: 1) *the recognition that the relationships between humans imply a condition of alterity between the same*; and 2) *the recognition that such relations are not later incorporated into the reality that has already been consolidated among those people, but become part of its constitution* [21].

Consent

The term "consent" originates from the verb *to consent*, which is derived from the Latin verb *consentire* (which means "*to be in agreement with*" [22]). According to Lalande, the term would indicate an *act of will*, from which one decides to *not be opposed to a certain action that was initiated by a third party* [23]. The meaning of the term is less forceful than that of "approval", a word whose positive meaning involving the *favorable judgment of appreciation* makes it a term that would have an inevitable ethical connotation, whereas the term *"consent" is notable for incorporating a nuance of restraint when referring to a thought that has an element of action* [23]. In particular, the term "consent" - when used with reference to the patient (or recipient) and to the subject, which is a collaborator and the object of the scientific research study - indicates the

act by which the physician may proceed with a treatment that he previously discussed with the patient, [considering that], *for the patient to give his authorization for the undertaking of a medical treatment implies having prior knowledge of the cause, making the choice between, on the one hand, accepting the completion of this particular treatment (principle of Free Will), and, on the other hand, authorizing the completion of this treatment on his own body (the principle of respect for one's physical integrity)*, [and considering that] *this treatment may be of a therapeutic or experimental nature* [24].

In the specific case of the doctor-patient relationship, the ethical aspect *that underlies the issue of consent lies within the tension that arises between the principle of the patient's free will and the physician's principle of beneficence* [25]. This alludes to the debate regarding the paternalist behavior within the relationship that has traditionally been established between the doctor and his patient, thanks to his know-how as a health care professional, but has, however, become the target of severe criticism within the field of bioethics (at least within its "secular" subdivision). As such, *the ethical rule that involves consent is open to a new dynamic concerning the doctor-patient relationship which favors the free will of the patient and his participation in the medical decision making process* [26].

On the other hand, regarding research and experimentation that makes use of human participants, we should remember the cases involving excesses (or criminal acts) that brought forth the *Nuremberg Code* [27] of 1947. These occurrences brought about the need for obtaining consent from research study participants in order to avoid such "excesses" and their deleterious effects on said participants. However, we should also remember that, in this case, the ethical

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problem could be seen as being different from that which exists between the doctor and his patient. This is so because, in experimenting with human beings, *the ethical dilemma that underlies the issue of consent lies in the discord between the principle of free will of the participant and the principle of the applicability of the research study* [28].

Specifically, the principal of applicability, or utility, which was initially formulated by J. S. Mill, cited by Blackburn, refers to the belief that *the conception of life, which is implicit in the majority of modern political and economic planning, insofar as it presupposes that happiness can be measured in economic terms* [29], would imply the prioritization of the greater good for the greatest number of people, which is not necessarily the case regarding the doctor-patient relationship. According to Blackburn, in the words of Mill, *such actions are correct in proportion to their tendency to promote happiness, and are improper if they tend to promote what is contrary to the fostering of happiness* [29].

In sum, *the rule of consent, either with respect to therapy or with respect to experimentation, is based on the principle of Free Will*, considering that, in both cases, patients and research study participants may *exercise their capacities to judge and choose* [30]. However, it is necessary to keep in mind that *the application of the rule of consent is not always easy, considering the variety of clinical situations that are encountered*, including those that arise in the field of research involving the participation of human subjects [30].

The issue of the "use of bodies"

With respect to both research procedures involving the use of human participants, and clinical procedures, relationships arise that do, in fact, involve sensations, feelings, thoughts and judgments that have to do with the field of bioethics. We can understand this concept here as applied ethics, which, in addition, addresses the *modes of living*, within which, in some manner, the matter of how *bodies are used* is addressed. The term "use" - in accordance with Giorgio Agamben's proposal - is understood as a *fundamental political category*, which substitutes, currently, that of "action" [31]. However, the expression *use of bodies* may refer to the possible reduction of the life expectancy of a human being that is the recipient of treatment or participates in research, as a mere means to other ends (that do not involve those of the study). This places the *use of the body* [within] *a zone of indifference between* (...) *one's own body and the body of a third party* [and] *between the artificial instrument and the live body*, engendering a situation *in which the use of the body lies on the unspeakable threshold between zoe and bios* [and] *between nomos and physis* [32].

In fact, the "use" of someone else's body, not only in research but also in the doctor-patient relationship, can be viewed as a specific form of the subject-object relationship, *which has left an indelible mark on the modern concept of the utilization of something by someone* [33]. In this concept, *the subject is not differentiated from the action, and is, in and of himself, the place where he happens*, [becoming a "medium" that] *is situated* [within] *a zone of indetermination between subject and object (the agent is somehow also the object, a place where the action occurs) and between the active and the passive (the agent is pleasantly affected by his own action)*. [This dialectic determines, as such,] *a singular threshold between the subject and object and between the agent and the patient*, [since] *the process does not move from an active subject to an object that is separated from its action, but involves the subject within itself, insofar as it is connected to the object and 'gives itself over' to it* [34].

In short, the "use of bodies" implies a space of "indetermination" that affects moral agents and patients, bringing about not only the "use of oneself", but also the "use of another", which may be viewed as a field of study in which a dialectic functions between subjugation and liberation. *Mutatis mutandis*, the "use" of bodies also concerns public health, wherein populations represent the object to which the tools of biopolitics, consisting of healthcare policies, are applied.

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