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Scientific Contribution

Cultural context and consent: An anthropological view

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Abstract. The theme of "consent" is, without question, associated with the origins of bioethics and is one of its most significant paradigms that has remained controversial to the present, as is confirmed by the proposal for its debate during the last World Congress of Bioethics. Seen broadly as a compulsory minimum procedure in the field of biomedical ethics, even today it keeps open the issues that it has raised from the start: whether it is really necessary and whether it can be proven to be effective. My goal will be to attempt to determine the most genuine and relevant meaning of "consent," going back from its present dominant normative meaning and, from there, identifying or simply sketching other possible forms of its expression in the world we live in, so as to justify its pertinence and validity. This objective will involve three stages: (1) " 'Consent' as a privileged paradigm of bioethics (the ethical-juridical sense)," (2) "The symbolic value of 'consent' (the social-cultural sense)," and (3) " 'Consent' as promotion of the human (the humanistic-personal sense)". It is concluded that the common notion of normative "consent" is not the only one, nor does it hold universal validity; that, from a historical-cultural perspective, new expressions of "consent" appear, adapted to different social contexts and to possibly be implemented in developing countries; and, finally, that "consent" is strictly indispensable in situations of extreme dependence, in its symbolic relational character, in as much as it promotes ethical relationships among strangers and ensures that they remain so.

Key words: bioethics, consent, ethical-juridical, person, social-cultural and humanistic-personal perspectives, ethical relations

The theme of "consent" is, without question, associated with the origins of bioethics and is one of its most significant paradigms that has remained controversial to the present, as is confirmed by the proposal for its debate during the last World Congress of Bioethics. Seen broadly as a compulsory minimum procedure in the field of biomedical ethics, even today it keeps open the issues that it has raised from the start: whether it is really necessary and whether it can be proven to be effective (Goldworth, 1996).

My goal will be to attempt to determine the most genuine and relevant meaning of "consent," going back from its present dominant normative meaning and, from there, identifying or simply sketching other possible forms of its expression in the world we live in, so as to justify its pertinence and validity.

"Consent" as a privileged paradigm of bioethics (the ethical-juridical sense)

"Informed consent," in its traditional Anglo-American expression, or "elucidated consent," in an attempt to reformulate the original expression by a Latin Europe (or still other forms of description such as: valid consent, authentic consent, deliberate consent), or merely "consent," leaving aside the controversy over its range, denotes an individual's explicit approval of a proposed biomedical action relative to his/her state of health, acquiring different specifications according to whether it relates to medical research or clinical practice. This act of consent, will be conscious (the individual is competent from the psychic point of view, and also legal, for the necessary, concrete and singular aspect that authorization refers to), elucidated (the individual has properly understood the information given about the procedure itself and its possible side effects) and voluntary (the individual is totally free to give or refuse his/her consent at any moment of the process in question).

The origin of the notion of "consent" in the field which is today called biomedical[1] is, as is known, legal. The event that marks its birth occurred in 1914, in the United States, and refers to the well-known case of *Schloendorff v. Society of New York Hospitals*. Schloendorff complained about a tumour having been

removed without his consent; subsequently the court issued a statement on the "right" that "every human being, adult and of healthy mind, has to decide what will be done with his/her body." However, this is a practically isolated case and no further cases of this kind arose until the 1950s (1957) *Salgo v. Leland Stanford Jr. University Board of Trustees*,[2] (1960) *Natanson v. Kline*,[3] (1972) *Canterbury v. Spence*[4] – each marking new stages in the establishment of the legal procedure of what is now termed "informed consent." Indeed, taking into account the North American system of common law, the decisions taken by judges influence the structure of subsequent legal order, becoming law. Thus "consent" first appears at the level of clinical practice, developing within the context of the structuring of the legal doctrine of medical malpractice and negligence (Jonsen, 1998).

It is, however, at the level of medical research and more specifically of human experimentation, that the need for "consent" is established and becomes international, in fact decisively influencing those developments mentioned at the clinical level. We refer obviously to the "Nuremberg Code," 1947, that, as a result of the heinous arbitrariness committed by Nazi doctors on prisoners, declares that "1. The voluntary consent of the human subject is absolutely essential." Soon after, the "Declaration of Helsinki," 1964, corroborated the need for "consent," now preferentially obtained in writing. It is mostly since then that the need to obtain "consent" has slowly come to be recognised, although the debate around the issue did not intensify until the 1970s and the widespread adoption of the new practice did not immediately ensue. As a matter of fact, as early as 1931, a very important but little known document issued by the German "Council for the Reich's Health" did explicitly establish the need for "consent," both in clinical practice and in human experimentation. However, history has shown that this document had no consequences, unlike the case of the "Nuremberg Code," which remains as the basis for the majority of the regulations for scientific research with human subjects, referred to by some specialists as the birth of the prehistory of bioethics.

"Informed consent" therefore stems from legal origins and is a legal requirement at research and clinical levels: on the one hand, this requirement must be fulfilled by the researcher/physician, according to the responsibility that they have to the subjects/patients; on the other, the requirement can be claimed by the latter as a means of protection from possible abuse. This legal requirement is justified by the "right to non-interference," by the right to privacy, spread by liberal thinking and subsequently consecrated in national Constitutions.

The legal justification, however, is not in itself enough to serve as the foundation of today's widespread adoption of "consent," since its validity derives from the respective national juridical systems. Wide recognition of the compulsory nature of "consent" can only stem from a field that aspires to universality, the only respective field being that of philosophy.

The relevant philosophical works that started to deal with the issue of "consent" date mainly from the 1970s and draw, as a whole, on the ethical root of the concept: (1969) "Philosophical reflections on experimentation with human subjects" by Hans Jonas, (1970) "The Patient as a Person" by Paul Ramsey, (1973) "Realities of patient consent to medical research" by John Fletcher, (1973) "Reservations about Panel Report on Charge I" by Jay Katz, (1978) "Three theories of informed consent: philosophical foundations and policy implications" by Robert Veatch[5] and the (1978) Belmont Report.[6] These works, in general, already establish the relationship between the individual's capacity for self-determination, inalienable from his/her personal statute, and the need for consent, as the safeguard of that same statute, in which the moral concept of "consent" will effectively be philosophically justified. This decisive step was taken, in our opinion, by Beauchamp and Childress in their famous work *Principles of Biomedical Ethics*, 1979. Here, they recapture the meaning of the previous reflections on "consent" (which, in fact, they helped to build). They develop and consolidate it by integrating it within a coherent and unitary system, in the ethical theory of principles, of which they are the most illustrious representatives: morality consists now in the compliance with stated principles, which include respect for autonomy, which will be fulfilled only if the procedure of "informed consent" is adopted. The principle of respect for autonomy does not merely express the person's capacity for self-determination, in the absence of any external interference (in a negative formulation), but it also demands the effective promotion of those conditions that favour the exercise of autonomy (in a positive formulation). In other words, in the present case, it demands the practice of "informed consent." "Consent" is, therefore, demanded out of respect for individual autonomy universally conceded to any moral agent.

"Consent," according to its ethical root, and also in the realm of research and clinics, stands as a moral demand to be observed by researchers and physicians, derived from the recognition of the other, subject/patient, as a person capable of self-determination. Justified by the principle of respect for autonomy, the moral notion of "consent" evokes a positive right and claims a positive freedom, unlike the case of its legal conceptualization in which it claims a negative right and freedom (no interference).

To sum up, the notion of "consent," which has dominated the short history of bioethics and still prevails, possesses an ethical-legal root and is understood as an ethical demand, actuating mainly at the level of inter-personal relationships, as it imposes respect for the autonomy of the other and, simultaneously, as a legal requirement, particularly important at the level of relationships in society, as an individual right protected by society. This ethical-legal concept is, therefore, principalist in its foundation and legalist in its procedure or, in a single word, of a normativistic nature in the imposition of criteria and procedures.

It is this normative concept of "consent" that constitutes a privileged paradigm of bioethics, in so far as its application establishes the parameters of the specific domain of the latter: at the micro level, it converts the traditional unilateral perspective, dominated by the agent with knowledge and power to act, into a bipolar relationship, in which those who lack that knowledge and wait are able to intervene; or rather, it converts the asymmetrical relationship between the active agent and the subject who places trust in the action of that agent, into a symmetrical relationship in which both acknowledge each other as partners in a common project; at the macro level, it converts an autocratic deontology, the property of a professional group, closed in on itself, that is governed only and exclusively by self-imposed rules, into a democratic ethics in which all moral agents, due to their capacity of decision over what concerns them, can intervene in all domains of human activity. As a bioethical paradigm, consent symbolizes the sharing of power of knowledge and action, as the western democratic spirit extends to the biomedical domain. However, will this normative expression be the only one that "consent" represents?

The symbolic value of "consent" (social-cultural sense)

In fact, the notion of "consent" is not exclusive of or peculiar to bioethics. It has age-old origins, going back to the beginnings of the political domain of human societies.

It first appears without any rigorous specific meaning; it will later acquire this in the field of law. Therefore, besides its technical meaning in law and, later, in bioethics, even today it still does not appear as an "entry" in general works, but only in language dictionaries. It is over the course of time and in the history of social relationships that it acquires specifications of meaning. The very ethical-legal concept of "consent" that we have presented comes precisely in the sequence of the development of a contractualist socio-political thought and of a liberal philosophy of rights. In this very precise political context, consent is derived from the idea that all men are born free and equal, so that any form of government will have to obtain the free agreement of each and every one.

This political meaning of "consent" is a very close and immediate antecedent to the one that dominates bioethics today. One must therefore go back in time, in an attempt to detect the existence of any other meaning of "consent" that may have emerged in public life and been dispersed in the history of western Europe.

Studies carried out in this area (Fletcher, 1983) bring us to the conclusion that, prior to the development of liberalism, "consent " was not understood as an individual prerogative, nor as the expression of the exercise of any power, but rather it evoked a common sense or feeling confirmed by habit or tradition. There is evidence of this fact in both political and religious activity. In other words, "consent" refers to what is in conformity (what agrees) with the habits or traditions of that community, without being requested or granted explicitly or formally (this is only enforced by the legal appropriation of the term). It is instead an implicit, tacit "consent," which denotes the tranquil and serene adhesion of the community to any determination presented as such, to a specific form of action which is perfectly integrated within the customs and habits of that community and is thus legitimated by tradition.

Pre-modern history offers us, then, a concept of "tacit consent," which is not necessarily verbalized, explicit or formalized. In fact, one must add, this meaning still survives in our present-day political and social life when, for instance, in relation to any matter of collective interest, it is stipulated that it can be put into effect only after "hearing out" those social groups more closely implicated in the possible alterations to be implemented. The aforementioned groups are not forced to manifest their agreement. Their consent is obtained whenever they have the possibility to refuse it and they decide to abstain from doing so. Therefore the term "consent" also signifies compliance, tolerance, in other words, some contrariety in the acceptance or in the absence of rejection – that is maintained in its present normative meaning. The concept of "tacit consent" also survives in the clinical field (then frequently termed "implicit consent") in relation to routine medical interventions in which the consent of the patient is assumed, should he/she not express anything to the contrary. The meaning of "tacit consent" has survived, embodied in the saying "silence gives consent".

Evocation of "consent" in this quite broad and proportionally less precise context favours the "pacification" of co-existence, in the absence of opposition,

the "adhesion" of the other through the proposal that is addressed and the "bringing closer" of people through the unison that is established among them, aspects that intersect in a relational symbology characteristic of "tacit consent" and that, curiously, is still present in the early texts of philosophers (H. Jonas) and theologians (P. Ramsey) in their common effort to find a broad foundation for the need for "consent" in bioethics.

The notion of consent also flows out of its normative dimension in the field of medicine itself, as it is exercised, although under a model which is prior to the contemporary biomedical. In fact, medicine has always resorted to various ritualistic forms of bringing physician and patient closer, the former enjoying privileged access to the person, which was denied to others. We refer, mainly, to access to the body, in its nakedness, and to the soul, in the revelation of its secrets. Thus, even in the "Hippocratic Code" we find the explicit prohibition of any sexual contact between physician and patient, whether the latter be free or enslaved, as well as the absolute safeguard of confidentiality.

Furthermore, in Hippocratic medicine "consent" is real and necessary: real, in its tacit rather than formalized expression; necessary, because it was the only means of access to the sick person's privacy. Thus, "consent," in traditional western medicine, is structured not from the principle of autonomy, as in its present model, but instead from the principle of beneficence, following the Hippocratic model.

"Consent" thus structured from the imperative of the Hippocratic medical ethics of beneficence relates then, exclusively, to what reverts in favour of the patient's good, according to medical criteria. That is, the physician seeks consent above all for access to information, more than for authorization to act, relative to what is considered absolutely necessary for the well being of the patient and cannot be obtained in another way. In this sense, "telling the truth" to the patient, a demand preceding the obtaining of consent structured on the autonomy principle, is not necessary when consent is structured on beneficence. In this field, as an alternative, the rule of therapeutic privilege comes into action.[7]

There is no violence towards the individual because we refer to a level of development of medicine in which it is performed more as an art than as a science and in which the good in sight is still that of the individual, holistic – the physician cares for the individual's well-being –, and not a circumscribed good, concerning an objectified section of the individual's integral wholeness – in which the physician does cure the patient's disease. This "consent," that we would term "in trust" (paraphrasing Pellegrino and Thomasma in *For the Patient's Good*), establishes a privileged "relationship" between the sick person and the physician, a unique "relationship" in the intimacy and complicity that binds those two people. Its symbolic character is also relational.

The main characteristics of "tacit consent" and of "consent in trust" are, then, similar in the rejection of all formalism or even in the explicit presentation of terms. The difference resides essentially and respectively in the displacement from a community realm to an inter-personal one in which the relationship finds better conditions to be reinforced.

This model of "consent in trust" seems, however, to be definitively outdated due to the evolution of medical practice, whose growing technicality and specialization have objectified and circumscribed medical good, so that it no longer coincides with the good of the individual – the condition for the legitimacy of "consent in trust." Will we be then doomed to the absolutism of "normative consent"? Or can we create a new expression of "consent"? Or, on the contrary, will we conclude that "consent" is no longer a useful term and should be dissolved? Let us consider these questions, recognizing that "consent in trust" is becoming outdated as a process in western societies, – in so far as it is not possible to avoid the explicit expression of individual autonomy –, but not in its symbolic-relational character, which, frequently absent from "normative consent," is still intrinsic to the human person and, therefore, the most consentaneous with its authenticity.

"Consent" as promotion of the human (humanistic-personalistic sense)

We have considered a time sequence – from a far away past to our present – and a diversity of contexts for reflection – ethical-legal and social-cultural – converging paths in the statement of a plurality of expressions that "consent" can assume.

The motto of the VI World Congress of Bioethics "Power and Injustice" that took place in Brasilia, October/November, 2002, already challenges bioethics to conquer new fields and perspectives in its expansion and acceptance all over the world, in which power over the biological raises the question of ethical duty. In developing or under-developed countries, in poor countries, the ethical problems arising from advances in medical research or the processes of clinical attendance should not to be confused with their individual or social control, but appear at the more elementary level of their simple existence and accessibility. Thus one breaks away from the hegemony of a biomedical model of bioethics, which is now challenged, to adopt a "global bioethics" model,

not in a universalizing and homogenizing sense, but in the sense of inclusion of diversity that Potter, to some degree, anticipated.[8] Will this new global bioethics, not demand an equally new expression of "consent," not restrictively normative but laterally broad? Is there a concept of "consent" capable of becoming co-extensive or adaptable to various existing societies?

The answer seems to be necessarily positive, but it raises some significant difficulties that require clarification. Indeed, the recognition, indispensable because it is fair and necessary because it is true, that "consent" adopts a historical-culturally diversified expression, can in the same way lead to a deep ethical relativism. From this perspective, every procedure that was to be presented or interpreted as a cultural variable of "consent" would be legitimate, which would mean that none would be valid.[9] In the absence of any reference pattern or criterion that would identify the very reality in question, there is no ratification possible, which would lead to its dissolution. The threat of dissolution of the need for "consent" forces us to return to the initial questions raised, echoing the core of the long debate that has been developing around "consent": will it be necessary? And will it be effective?

We consider that both within a normative model, paradigmatic of biomedical ethics, or within the broad context of cultural relativism, "consent" remains absolutely necessary. In the first case, it has already been amply justified; in the second – in which the issue appears to be more complex –, we would say that it is really necessary and truly effective if it faithfully preserves its original symbolic-relational character. That is, while "consent" is the expression of proximity, communication and interaction, universal human experience that each society ritualizes differently, it will promote the encounter among people. It is in that encounter, that can be achieved through dialogue or silence, through gesture or glance, or through some cultural ritual, that each person is recognized in itself, in his/her unique originality (subjectivity), and not considered homogeneously and undifferentiated (objectified) among the others. Therefore, "consent," through the respect for the difference that it testifies, is necessary and effective in maintaining the human character of relationships among individuals in extreme situations of deep vulnerability, to guarantee the ethical nature of those relationships, that is, "a non-violent relationship" – in the words of the philosopher Emmanuel Lévinas. This is also our understanding of the concept of "consent" as a means for the promotion of the human. The need for "consent" contributes very decisively to the establishment of favourable conditions, in situations of dependence, for the individual to maintain his/her singular identity as the original and unique fulfilment of the universality of his/her humanity, that is, that he/she remains "person." This is a "personalistic" perspective of "consent".

It might also be said that the normative concept of "consent," since it is based on the autonomy of the individual, expresses the same personalistic meaning. However, we do not consider that to be the case in that it neglects the fact that there are not only other expressions of respect for the individual, besides respect for autonomy, but also other forms of recognition of the individual's personal statute. We can and we should respect the person not just in the power he/she stands for but also in the fragility and mortality he/she presents. We can and we should recognize the person, not only through our respect, but also through the care we dedicate.

The broadest personalist perspective of "consent" is based on the person, not on the person as autonomous moral agent, leading to mechanisms of discrimination and exclusion, but just on the person *per se*, unconditionally: the person understood in the universality of his/her singularity. The person, thus defined, constitutes an ethical irreducibility or, in a more updated terminology, an ethical minimum, that is, the widest reality that obtains the maximum consensus. It is also the person considered in the plurality of his/her expressions that prevents ethical relativism and allows flexibility in the process of obtaining "consent," that is, establishes a universal requirement to be fulfilled by "consent" – the promotion of the human –, but admits different expressions of "consent" – from the normative to the personalistic.

At present, a phenomenological-hermeneutical ethics, a narrative ethics, a dialogical ethics, while valuing the power of communication, allows easy access to this personalistic understanding of "consent." It is not, however, our goal to value any bioethics theory over any other, nor to substitute one for another. Neither do we consider the respective validity of each on theoretical grounds. The validity of each of these various forms of "consent" cannot be objectively verified on practical grounds, but only subjectively "attested" (in Ricoeur's terminology),[10] as conviction of its being accomplished, in so far as it promotes the human, that is, in so far as it favours the person's fulfilment in the statement of his/her singular universality. Indeed, our interest is restricted to affirming that the common notion of normative "consent" is not the only one, nor does it have universal validity; that, from a historical-cultural perspective, new expressions of "consent" appear, adapted to different social contexts and to possibly be implemented in developing countries; and, finally, that "consent" is strictly indispensable in situations of extreme dependence, in its

symbolic relational character, in so far as it promotes ethical relationships among strangers and ensures that they remain so.

Notes

1. "Biomedicine" broadly defines the present context of medical practice, referring to its strong scientific and technological nature. "Biomedicine" is considered to be fairly reductionist by medical anthropology.
2. The expression "informed consent" was introduced, for the first time, in the juridical pronunciation relative to this case. *Salgo v. Leland Stanford Jr. University Board of Trustees* refers to the question over whether the injection of sodium urokon during a translumbar aortography could have affected the plaintiff's spinal cord and whether the plaintiff and his immediate family were informed that an aortography was to be performed. The court decided that, due to the nature of the procedure, informed consent should be asked for and that it is authentic only when it presents the risks of the procedure in question as well as its alternatives.
3. The Supreme Court of Kansas establishes the legal obligation of "informed consent" during the trial of *Natanson v. Kline*, a reported case of an allegedly excessive dose of radiation.
4. *Canterbury v. Spence* deals with the amount and type of information that ought to be transmitted. The specific question is to determine whether a 1% chance of paralysis caused by laminectomy was sufficient to require disclosure. Until then, the data transmitted to the patient was exclusively bound by medical criteria: the "reasonable person standard" which was then replaced by the so-called "professional standard".
5. Robert Veatch's "Three theories of informed consent: philosophical foundations and policy implications" is quoted in National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Appendix II, 1–56, p. 26.
6. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* are easily accessible in *Source Book in Bioethics. A Documentary History*.
7. The therapeutic privilege or exception refers to the physician's prerogative of non-disclosure of information to the patient whenever he considers that the information can produce more harm than good. This privilege is an exception to consent.
8. "Global bioethics" is a late expression in Potter's writings. Nevertheless, it comes along with the original meaning of "bioethics." Potter considers that the new "global bioethics" corresponds to a holistic view of today's problems concerning health and the survival of men and other beings.
9. At the same time, every type of behavior that would be consentaneous with the social-cultural tradition of a given community would be tacitly accepted, not permitting openness or the establishment of flexibility to any change.
10. The French philosopher Paul Ricoeur introduces the word "attestation" to refer to a sort of "belief," "certainty" (*assurance*), that a subject acquires about himself, and which is not exactly either epistemic knowledge or an opinion.

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