Informed Consent Procedures Between Autonomy and Trust

Fabio Macioce*

ABSTRACT: Informed consent has been implemented through a set of rules, at both national and international level, which protect individual autonomy as much as possible from paternalism, abuse, inducement, mistreatment, and deception. However, informed consent must not be merely understood as the outcome of a procedure for the transfer of information, however precise and detailed it may be. The article advocates its being rethought within a relational perspective, according to which not only the quantity or the quality of the information provided is at stake, but also the relational context within which this information is developed. The precondition for free and informed consent, besides the information received, is the relationship of trust between the parties involved, and the consistency between their modes of interaction and the need to maintain mutual trust. In that sense, the information is adequate and relevant not in itself, but as a function of the kind of relationship between the parties.

KEYWORDS: Autonomy; relationship of trust; informed consent; communication; decision-making process


1. Introduction

In the literature, significant consideration has been devoted to the relationship between autonomy and trust, and even more to the problem of the relationship between autonomy and informed consent1. However, less consideration has been given to the problem of the relationship between informed consent and trust, and above all to the question of how to model informed consent procedures so that the expression of consent is not a procedural alternative to fiduciary relationships. Rather than being a sort of inevitable surrogate of these relationships, informed consent

---

* Full Professor of Philosophy of Law at Department of Law, Libera Università Maria Ss. Assunta (LUMSA) of Palermo. E-mail: fmacioce@libero.it. The article was subject to a double-blind peer review process.

This essay is developed within the European project “Improving the guidelines for Informed Consent, including vulnerable populations, under a gender perspective” (i-CONSENT), funded by the European Union framework program H2020 (Grant Agreement n. 741856).

procedures should be the regulatory context within which the subject’s autonomy is guaranteed, and the outcome of a relationship that fosters both interpersonal trust (between patient and physician) and systemic trust (towards institutions and health authorities).

For this purpose, it is necessary to rethink both the methods and the content of informed consent procedures, so as to tailor them to the person who is asked to express consent, also considering the specific situation in which such information is to be given. In other words, we need to go beyond the model in which some information is abstractly relevant, and a certain (pre-determined) amount of information is necessary, in order to adopt a perspective in which both the information and the way of giving or explaining it differ from person to person, according to their specific vulnerabilities and needs.

However, although desirable it may be to tailor the procedures of informed consent to the needs of the individuals involved, this objective clashes with a number of difficulties of various kinds. Among them, there is a theoretical difficulty (unrelated to practical, economic or individual factors) deriving from the fact that, for understandable reasons, it is inevitable that informed consent is incorporated (and therefore made evident) in documents with legal value: therefore, in necessarily formal, standardized, and pre-determined documents.

The asymmetry of power and knowledge between the provider (researcher or doctor) and the subject (patient or research participant) requires that both parties involved in the procedure be guaranteed, first of all, from a legal point of view. Renouncing to such guarantees, and simply relying on the trust relationship between patient and doctor, is unrealistic. Notwithstanding this, it is possible to ensure that informed consent is not simply an agreement between the parties for the guarantee of mutual rights, but it is able to implement, and display, the relationship of trust between them.

My concern, and the purpose of this paper, is to argue that informed consent procedures should take the relational character of autonomy into consideration, as well as the link between informed consent, autonomy and trust. In so doing, one might protect the exercise of personal autonomy, rather than its mere possibility, therefore fostering trust between the subjects involved, as well as in the whole health care system. For this purpose, it is necessary to take into consideration the asymmetry of power and information among the subjects involved, and make it the basis of an asymmetrical distribution of burdens: information providers must give evidence that they have taken due account of the specific vulnerabilities and needs of the person expressing consent, through appropriate choices of communication methods and contents.

In order to discuss these aspects, I will briefly highlight the relationship between informed consent and autonomy, with specific regard to the relational dimension of autonomy; then, I will focus on the interplay between autonomy, trust, and consent; finally, I will discuss how the procedures for informed consent should be adapted, so as to be more suited to managing the relational dimension of personal autonomy and fostering trust, at both an interpersonal and intra-personal level.

2. Informed consent and autonomy: the relational dimension

It has been argued, with compelling reasons, that the pivotal role of informed consent is linked to the overcoming of the paternalistic model of the medical encounter, which for centuries had been un-
understood as necessarily asymmetric. Therefore, informed consent may be understood as having two different meanings, both linked to the concept of autonomy; in a first sense, informed consent is the act whereby an individual with substantial understanding, and in the absence of control by others, intentionally authorizes a medical intervention or participation in research. In a second sense, it is a form of legal authorization, that is, an authorization determined by prevailing social rules, like in the cases of minors or other people not able to give their consent. In both cases, informed consent expresses authorization: in the first case, it is determined by an autonomous chooser, who acts intentionally, with understanding, and without any controlling influence on his/her own behalf; in the second case, the person’s wishes are expressed by others, according to social and legal provisions, due to the person’s lack of understanding and consequent incapacity to give consent.

Over recent years, such a connection between informed consent and autonomy has been the subject of an enormous amount of criticism, aimed at stressing its inability to balance individual and public interests, and its inefficacy in the cases of patients with impaired capacity, psychiatric patients and in end-of-life situations; moreover, its ambiguity has been stressed along with its tendency to conceive the body as property, as well as the shortcomings of such an understanding in specific sectors, such as genetics and the managing of genetic data.

In addition, the focus on personal autonomy has been deemed to be misleading, since it does not take the social, economic and personal factors of vulnerability seriously into consideration. In these cases, and in similar ones, the exclusive reference to the principle of autonomy may be counterproductive, as it entails the risk of increasing people’s vulnerability rather than reducing it. For this reason, a different understanding of autonomy is necessary, one which does not stem from a hyper-individualistic conception.

Such a different model of subjective autonomy is more consistent with the intersubjective dimension of human life. The notion of autonomy is understood not as a subjective predicate (a quality of individuals, due to which we may say that Paul is autonomous and Peter is not), but as an ontological feature whose exercise is facilitated or inhibited by many factors: among these factors, the interpersonal networks available for any person are of paramount importance. In this sense, any person is autonomous, even if some do need the support of others to exercise their autonomy, or a stronger support than others.

---

3 See T.L. BEAUCHAMP, Autonomy and Consent, cit., p. 57.
For these reasons, autonomy largely depends on the resources available for the individual, as well as on institutional facilities and legal instruments that make it possible to exercise it. Among these facilities and instruments, social rights are of primary importance, because they provide the subject with goods and resources, which make autonomy possible: education, healthcare assistance, welfare, the possibility to participate in the cultural and religious life of one’s own community, etc. Moreover, autonomy requires that the subject is inserted in a relational context suitable for the exercise of freedom, which is characterized by positive relations of recognition: “autonomy is a capacity that exists only in the context of social relations that support it, and only in conjunction with the internal sense of being autonomous”8. In other words, autonomous choices, that is choices that can be recognized by the subject as their own and corresponding to their goals, depend on a series of support conditions, which are at the same time normative, institutional, and social (or more generically relational). Such a relational theory of autonomy is based “on recognition of the ways in which, as agents, our practical identities and value commitments are constituted in and by our interpersonal relationships and social environment”10.

Due to this complex interplay between personal capacities, institutional context, and relational resources, autonomy shall be understood as a concept of degree: the social conditions that support autonomy, are at the same time the factors that determine its strengthening or weakening. Personal autonomy depends on a series of attitudes towards oneself and the world — self-esteem, self-respect, and self-confidence — which are, in turn, dependent on relationships of recognition, in both a positive and negative sense. In other words, the relationship that each person has with him/herself is the result of a complex set of social interactions: the normative systems (that recognize the dignity of the person) interact with networks of affective relationships (that shape self-confidence), and with networks of social relationships (that evaluate individual choices and goals)11. If this process is positive, subjective autonomy is strengthened and sustained; if the recognition process is negative (because the subject is placed in a context in which his/her choices are despised and devalued, his/her dignity unprotected or misunderstood, or the bonds are a vehicle of humiliation and degradation), subjective autonomy will be severely limited, or otherwise greatly compromised12.
The relational account of autonomy does not exclude the value of the single individual. On one hand, it is important to protect individual freedom to determine a person’s own goals, values, and desires, without being conditioned by the will of other subjects with greater power, more information, or more resources. On the other hand, the relational context, which is supportive toward the subject’s choices, and in which these choices are recognised and appreciated, must be taken into consideration. For a subject to make autonomous choices, in short, preventing an external will from overcoming that of the individual is not enough: a supportive context is also necessary. Relationships that bolster self-confidence, self-esteem, and respect are in this perspective just as important as the legal recognition of individual autonomy.

3. Relational autonomy and trust

The above-mentioned relevance of the “supportive context” makes the dialectic evident between personal autonomy and trust. Any person may be autonomous (and make autonomous choices) not merely thanks to her inner capacities and resources, but also with regard to certain kinds of relationships, which support both self-trust and trust in other people. If autonomy is not an ideal of independence, referred to people with no ties to others, social relationships and trust are causally necessary for it.

A significant amount of literature has been devoted to the analysis of such an interplay. The basic idea is that conditions necessary for the exercise of personal autonomy (e.g. adequate options, information relevant for the decision) depend on the help of others that are trustworthy. In other words, if autonomy is relational, a certain extent of trust in others is essential. What is at stake is, therefore, when and on what conditions trust is justified. More precisely, for trust to be plausible, the parties (both the trustor and the trustee) must have and display attitudes toward one another that permit trust, and they must be trustworthy. By trusting, we acknowledge the fact that we are vulnerable (at least to betrayal), and we express a kind of optimistic aptitude towards others, particularly with regard to their competence in a certain domain. The central existential question we ask when we trust is, therefore, whether it is reasonable for us to trust, given the information we have and the way things appear to us.

If we move towards a typical medical setting, we can translate this question by asking whether, and on what conditions, the patient may trust the health care provider, and may place his/her trust in the complex of health care institutions, including hospital administrators, and the legal and judicial system. In this perspective, to trust in health care providers does not mean waiving the autonomous agency: when we trust we do not waive our goals, our needs, and our values. As Karen Jones writes,

---

we “hope that the physician takes to constitute acting with integrity and takes to constitute the
interests of her patients will be, at least in part, shaped by the expectations of those patients”17.

As Joffe and Truog explain, in some medical decisions (those about ends, as well as those about
means that necessarily entail choices among ends), physicians function as adviser-fiduciaries to their
patients. In other cases, (when considering decisions about means to settled ends) physicians func-
tion as agent fiduciaries to their patients18. Of course, we are not always guaranteed that a physician
will “allow the expectations of her patients to shape her understanding of what, here and now, good
medical practice consists in”19; for that reason, any autonomous choice of the patient is also in a bal-
ance with the trust she must place in the health care and the legal system.

In other words, the fact that personal autonomy is relational (that is, shaped by and exercised in so-
cial and relational contexts) means that when we affirm that a person is acting autonomously, we are
recognising in her decisions a certain extent of self-governance, of self-authorization, and of self-
determination20, within the interactive dynamic between the people involved. On one hand, these
three axes of autonomy are possible because (and to the extent that) the person is participating in
social relations that afford her this authority21. On the other hand, the person who acts autonomously
also: a) expects a benign behaviour from others (doctors, nurses, health care providers, family
members, etc.); b) attributes a general integrity on the part of these subjects; c) accepts a certain ex-
tent of dependence on these people, as well as the risk and vulnerability connected to this22. The
person may act autonomously also because her autonomous agency is promoted and reinforced by
trust in the other subjects involved, as well as in the complex of relevant institutions and social struc-
tures. The deliberative process within which autonomy takes shape is a collaborative partnership: in
a medical setting, patients give expression to their expectations and wishes about the care, taking
the information received into consideration, and trusting that others will accord to their will a rea-
sonable and respectful consideration23.

At the same time, to be able to do such an intense epistemic work (is it reasonable for me to trust? Is
trust well-grounded? It is justified? How do I evaluate the information I have?) people need, first and
foremost, to trust themselves to do it. Analogously, to choose and act according to their values and
desires, people need some degree of self-trust: people need to understand themselves as beings
whose will and desires will be taken reasonably into account (namely, not underestimated or misrec-
ognised).

Being able to make autonomous choices is a socially constructed attitude, as well as the ability to
trust others. In both cases, people need self-trust: they need to be able to understand themselves as
trustworthy, people whose decisions, values, and wishes are worthy of consideration. People act au-

18 See S. JOFFE, D. TRUOG, Consent to Medical Care: The Importance of Fiduciary Context, in F.G. Miller, A.
19 K. JONES, “Trust as an Affective Attitude”, cit., p. 10.
20 See C. MACKENZIE, Three Dimensions of Autonomy: A Relational Analysis, in M. PIPER, A. VELTMAN (eds.), Auto-
nomity, Oppression and Gender, New York, 2014.
tonomously only when they trust in their own ability to be worthy of consideration by others. People’s self-conception as marginal, vulnerable, unworthy of consideration, crazy, undermines their sense of self-worth and, hence, their capacity for autonomy. Even if they may be able to reflect and critically understand information, their capacity to form preferences and make decisions are considerably impaired: as Taylor rightly writes, we “define our identity always in dialogue with, sometimes in struggle against, the things our significant others want to see in us”\(^\text{24}\). People’s sense of self-worth stems from social and interpersonal networks: self-trust depends, first and foremost, on relationships of recognition, in both a positive and negative sense. Starting from this attitude towards themselves, people build and shape their attitude toward the world: this is the reason why their capacity for autonomous choices, which is their way of interacting with the world, depends on self-trust, self-respect, and self-confidence.

4. Informed consent and trust

The informed consent is the legal instrument that reminds us of the primacy of human autonomy\(^\text{25}\): it allows the individual to make a decision (either to accept or decline healthcare services) freely, without any form of coercion or constraint. More precisely, it is a process (i.e. not a single event), which allows the patient to make an informed and autonomous choice between the healthcare options available, including the option of refusing the service. However, it has not only been criticised for its tacit individualistic conception of personal autonomy – which I mentioned in the first chapter – but also for being at odds with the strengthening of trust within the medical encounter\(^\text{26}\). Or, at least, for being alternative to it\(^\text{27}\).

I will briefly discuss to what extent informed consent procedures seem to be alternative to the trust between patient and health care provider; then, I will discuss why such a tension between informed consent and trust is unavoidable, and even necessary. Finally, in a subsequent chapter, I will discuss how to rethink informed consent procedures, in order to make them consistent with the need of interpersonal trust.

In a rightly famous book Neil Manson and Onora O’Neill argue that the current model of informed consent is grounded in a notion of information that is quite abstract and scarcely justified. They highlight that informed consent procedures are a kind of abstract transfer of information between doctors and patients, along standardised lines of conduit. In this perspective, to say that relevant and adequate information shall be provided to the patient (as any legal instrument actually does) is to assume that information can be classified, and that such a classification is somewhat objective, being for instance dependent on clinical factors or therapeutic protocols\(^\text{28}\).


\(^{27}\) See F. Macioce, *Between autonomy and vulnerability: rethinking informed consent in a relational perspective*, 2019 (Forthcoming in *Notizie di Politeia*).

Additionally, written consent forms containing information that are given to the person, where signature testifies the terms and the limits of the consent, tend to be mere documents detached from the specific features of the interaction between the subject involved. On the contrary, they argue, both informed consent processes, and their ethical value, cannot be properly reduced to legal agreements. Informed consent procedures have to be understood as discursive practices, which take place in webs of social norms and interpersonal transactions: “This rich normative context (...) is occluded or downplayed when we think of communication merely as the transmission or flow of information from person to person”\(^{29}\).

Human relationships are the framework of autonomous acts and decisions: within these webs of interaction, people express their wishes, make decisions, try to realize their desires and answer to their needs. Thus, the simple fact of exchanging information, which is the premise for these actions, cannot be understood as if it were independent from the action by which the communication is achieved, and from every feature of such a communication. Intentions, behaviours, gestures, and any other act that shape interpersonal communication, are an intrinsic part of the communication itself, rather than being detached (or detachable) from it.

If information is not a pre-existing object of the relationship, we should therefore think of information as something that is produced within a specific relationship, due to the characteristics and purposes of the interaction. For this reason, information is deemed adequate or relevant with regard to what the people involved (in the interaction) do, think, expect, deem as important, as well as to the broader context within which the dialogue takes place. This also means that communication (between doctor and patient, for instance) cannot only fail because of the quantity or the quality of the information provided; it can also fail because of the way this information is elaborated within the context of the discourse, because of the interaction between the parties\(^{30}\). Consequently, regardless of the quantity, adequacy, and relevance of the information, the outcome of the communication depends on the relationship and the dialogue between the people involved (doctors, care team, support providers, family members, etc.); this relationship, along with the information received, may indeed bolster interpersonal trust, and guarantee individual autonomy against paternalism and oppression\(^{31}\).

I am sympathetic to the arguments of Manson and O’Neill, and I am convinced that the precondition of free and informed consent, besides the information received, is the relationship of trust between the parties involved. Moreover, the consistency between their modes of interaction and the necessity to keep mutual trust between them must be guaranteed. In this sense, the information is adequate and relevant as a function of the kind of relationship between the parties.

However, as Kukla\(^{32}\) rightly observed, the focus on ethical aspects of discursive interaction, as well as on the trust between the parties, may be misleading. It may lead to overlooking the fact that the process of obtaining informed consent occurs in settings that are shaped by the asymmetrical rela-

\(^{29}\) Ivi, cit., p. 42.

\(^{30}\) See B. FRANZ, J.W. MURPHY, Reconsidering the role of language in medicine, in Philosophy, Ethics, and Humanities in Medicine, 13 (5), 2018, pp. 1-7.


tions of authority and power, even when both parties are well intentioned. Once we consider the context where medical encounters take place, we must notice that such a context is unavoidably asymmetrical: “The institutional and material setting of the clinic affords special social and cognitive authority to the doctor. In the context of the clinic, even a patient who has plenty of authority in other social arenas is inherently at the doctor’s mercy in various ways.”

This is the reason why, as Kukla explains, we talk about patient’s consent, rather than doctor-patient’s agreements, or directives, etc. The term we use displays such a power asymmetry, and the fact that the patient generally accepts one among the different options given by the doctor, or (more frequently) acquiesces to the plan proposed by others. But – more importantly – this is the reason why we need a document with legal force, however formal and rigid it may be. To be more precise, the emphasis we place in the legal force of informed consent, and consequently on the content of the written and signed documents that encapsulate consent, is inherent to the discourse interaction, rather than being separable from it. It is not something that blurs the ethical value of the discourse, or that is alternative and separable from it: rather, it is the necessary framework of such discursive interactions. The fact of signing a document with binding force (however bureaucratic it may appear) does change what both the subjects involved are willing to say, to hear, and to understand: the protection that these documents give to them may counterbalance the potential of manipulation, disrespect, coercion, and misplaced trust that is inherent to such an asymmetrical interaction. In other words, even if signing a document is not sufficient to eliminate the asymmetries, these documents enable the parties (and in particular the patient) to re-negotiate their role within the interaction and manage power relations.

Therefore, on one hand, written documents (with their unavoidable traits of formality, rigidity, and generality) do not ensure that communication has occurred rightly, fairly, and properly. Moreover, they do not ensure that the patient has been informed in the right way, and that the consent is verifiable, autonomous and consistent with the patient’s authentic values and desires. Trust, and trustworthiness, may guarantee the ethical value of consent, by ensuring that the background of understandings and rules about interaction (generally, not made explicit) has been adequately taken into account. In this perspective, Manson and O’Neill are right in saying that “signatures, let alone ticks in boxes, may have legal weight, but they lack ethical weight.”

On the other hand, as we have discussed before, legal documents play a pivotal role in medical encounters, given the asymmetrical structure of these interactions. We cannot simply give these documents up, or reduce them to the legal realm, as if they had no ethical relevance and value. On the contrary, they play a pivotal role in counterbalancing and managing power relations between the parties. What is at stake is therefore how to rethink these (formal, legal, and generic) documents, to make them consistent with the need for trust and trustworthiness between the parties, rather than alternative to it.

---

33 Ivi, p. 47.
34 Ibidem.
35 See N.C. MANSON, O. O’NEILL, Rethinking Informed Consent in Bioethics, cit., p. 192.
5. Rethinking informed consent: some remarks

Consent should be rethought as the outcome of a dialogue, rather than as a provision of a certain amount of information. The decision-making process must primarily guarantee that such information is intelligible and correctly understood by the person; in addition, far from being ethically neutral, the relationship should be based on specific values: it must be reliable, truthful, non-manipulative, not misleading, free from prejudice, oriented to mutual understanding. Moreover, it must be grounded in the recognition of the other person as the partner of a dialogue, that is, as a person whose reasons and needs must always be taken into consideration.

To be more explicit, I argue that informed consent procedures must ensure (and give proof) of an effective dialogue between the parties, with specific consideration of three basic aspects: language, time, and specific vulnerabilities and needs of the person. By giving relevance to these aspects, informed consent procedures can bolster interpersonal trust between the parties, beyond the mere transfer of a certain amount of information. Informed consent documents may be the outcome of a dialogical relationship, only by allowing the parties sufficient time for communication, ensuring a common understanding of the situation, and taking the specific needs of the patient into account.

a) Sharing a common language

First, power asymmetries arise from the use of an overcomplicated or overspecialised language by the healthcare provider. This is the reason why main international instruments concerning informed consent require the use of a plain, lay language, that is a language accessible to the person concerned (for instance, Regulation EU No 536/2014, whereas n. 30: “the potential subject should receive information in a prior interview in a language which is easily understood by him or her”). Health literacy, understood as the capacity of the person to obtain and understand information about health and services, is a key factor that must be taken into consideration. It also encompasses the knowledge of the healthcare system, of its mechanisms, its costs, and its interfaces with secondary care and social services.

By saying that information must be given in a language accessible to the person I do not simply mean that the words used by healthcare providers must belong to the daily language (which may certainly be a wise option). Moreover, to say it by using Habermas’ categories, informed consent procedures must rely on the patient’s lifeworld, rather than on the system perspective. A common knowledge about the objective world (in medical interactions: knowledge about physical data, tests, examinations, treatments, symptoms, but also life habits, workload, place of residence, etc.), about the social world (the way people relate to others, the social norms they consider binding, values they respect, etc.), and about the subjective world (intentions, thoughts, and wishes; what the patient perceives as good and desirable) must be reached. Long before the provision of the relevant information, it will be necessary that the participants in the interaction define a common horizon for communication, made of cognitive premises and common beliefs within which the communication takes place: oth-

erwise, however relevant the information may be from an objective point of view, its subjective relevance will be very limited. Therefore, not only a plain language must be used, but evidence must be given that participants in the dialogue addressed each other as equals, and that their values and choices have been met with respect. Evidence must be given that people’s point of view and their opinions have been taken into account, explanations have been provided for what is said, and patients have been permitted to ask and raise questions, no matter how relevant they might be.

b) Finding adequate time

The second factor that must be taken into account is time: trust and trustworthiness are related to the time available for dialogue and communication. Time constraints are at odds with communicative decision-making, and facilitate strategic action or systematically distorted communication. On the contrary, “trust is generally earned through repeated encounters (...), and it can easily be lost through a perception, even a misinterpreted one, that the other party lacks interest, commitment or skill”. Therefore, adequate time must be given for the medical encounter, and for the informed consent procedure that is an essential part of it.

Allocating adequate time may appear a sort of wishful thinking due to the time constraints resulting from the recurrent cost-cutting policies (in Italy, but not only there); however, I argue that it could be fostered by law. For instance, the Italian legislator seems to be aware of the need for such a requirement: in a provision (which is as unnoticed as it is important) of the new regulation concerning informed consent (art. 1 para. 8 of Italian Act No. 219/2017) it states that “the time of communication between patient and doctor is considered treatment time”. By asking to place this process within a dialogical context, this rule imposes much more than a mere informative burden on professionals. It calls for the specific condition of every person to be taken into account, and to adapt the informative process to the needs of the patient. In other words, the time dedicated to communicate with the patient is the pivotal part of the process of informed consent: patients’ needs and their existential situation (values, desires, fears, vulnerabilities, situations of dependency, resources, relational bonds, and any other circumstance that might influence the decision) may become known thanks to it. Moreover, the time devoted to talk to patients, to explain to and motivate them, to listen to their needs and doubts, is as important as the time devoted to therapy or diagnostic workup: that is, it is not a waste of time, but a pivotal part of what doctors and members of care teams are expected to do. The time dedicated to building and consolidating a rela-


40 Ivi, p. 1178.

tionship of trust is functional in the decision-making process, and an essential part (even from a legal point of view) of the medical practice.\textsuperscript{42}

c) Taking vulnerabilities and needs into consideration

The third main feature of informed consent procedures should be the consideration of the specific needs and possible vulnerabilities of the person, in order to tailor the information to the individual. Informed consent documents should therefore provide evidence that these vulnerabilities and needs have been taken seriously into account, and that the information has been given in a way that is appropriate for the person.

Different kinds of vulnerability may become relevant, and different needs should be taken into account. To give some examples, the age of minority, or pregnancy, or breastfeeding, are not in themselves conditions of vulnerability, but they may be in specific situations (e.g. a clinical trial), owing to the specific type of risks and burdens they expose the person to. Similarly, the belonging to a group is not in itself a sufficient reason for being a person considered vulnerable, but it may be the case due to the particular group the person belongs to (a discriminated minority, or people deprived of their liberty)\textsuperscript{43}. In a different perspective, being subject to the authority of others, being undervalued by society at large, being deprived of important goods and services, being under sedation, and lacking the necessary linguistic or cultural competences, may be regarded as conditions of vulnerability\textsuperscript{44}. Some of these conditions are well known, and expressly mentioned by national and international legal instruments; others are situations of vulnerability that are the outcome of contingent factors, which for instance produce a fear of negative consequences, or other stressful conditions\textsuperscript{45}. What is at stake, however, is not to elaborate a definite list of conditions of vulnerability, but to recognise the necessity of tailoring the information to the needs of the person, so as to counterbalance (rather than to increase) the power asymmetries among the parties of the medical encounter.

By asking that healthcare providers provide evidence of the actions they have undertaken, in order to address the specific vulnerabilities of the person who receives the information, I am placing an additional burden on them. They have not only to tailor the information to the specific needs of the person, but they also have to provide evidence of how the informed consent procedure has been tailored (by describing the specific vulnerability they noticed, and the way they have adapted the informed consent in order to take it into account).


Such a burden of proof is a way (consistent with the characteristics of legally binding documents) to counterbalance the power asymmetries between the parties involved in a medical encounter. Therefore, it is a feasible strategy to underpin trust (or, at least, to settle the conditions that make the relationship of trust possible): acknowledging the asymmetrical starting point of the relationship between patient and provider, it assumes that the perspective of the subject who is in a position of powerlessness, or of vulnerability, deserves a privileged consideration. The interests, needs, and arguments of the parties are not on a par with each other: and even if a mutual understanding must be the expected outcome for both, providers have additional burdens, which counterbalance (as much as possible) their different starting point and their position within the dialogue.

6. Conclusion

Informed consent procedures are the context within which the subject's autonomy is guaranteed, as well as the outcome of a relationship that fosters interpersonal trust. Rather than being written documents with mere legal value and no ethical value, they could become a powerful instrument to foster interpersonal trust between the parties (for instance, a doctor and a patient, or a researcher and a person enrolled in a trial).

For this purpose, informed consent procedures must be rethought, by taking the relational character of autonomy into consideration. The idea that information can be classified and transferred as a thing must be abandoned: information that is to be given should be tailored to the person who is required to express consent, also considering the specific situation in which such information is to be given.

Moreover, documents certifying informed consent must also guarantee that the entire process is a dialogue, where power asymmetries are (as far as possible) reduced. Furthermore, it must be reliable, truthful, non-manipulative, not misleading, free from prejudice, and oriented to mutual understanding. It must also ensure (and provide evidence) that three basic aspects have been taken into consideration: the language has to be as lay and shared as possible; the time for the dialogue has to be adequate; attention has to be given to the specific vulnerabilities and needs of the person.

By giving relevance to these aspects, informed consent procedures can bolster interpersonal trust between the parties, beyond the mere transfer of a certain amount of information. Informed consent documents may become the outcome (and the proof) of a dialogical relationship, and of interpersonal trust between the parties.