Article

Values Grounding the Informed Consent in Medical Practice: Theory and Practice

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Abstract

This research aims to identify the significance of the informed consent (IC) in the medical staff's daily practice. The research does not aim to validate a hypothesis, but it does aim to identify what meaning professionals give to the ethical tools they use. We wish to explore whether or not IC is understood by medical staff as a means of respecting patient's autonomy, or whether it acts as a protective measure for health care staff. To identify the meanings attributed to IC by health professionals in health care institutions, we developed and conducted individual interviews and analyzed the acquired data using a grounded theory (GT) qualitative approach.

Keywords

informed consent process, ethical instrument, Romanian medical practice, medical ethics, ethical values

Introduction and Research Background

Ever since the beginning of bioethics, one of the mandatory actions in medical practice and medical research was the informed consent (IC), as key ethical requirement. When IC was first used, it was oriented toward the professional confidentiality and personal privacy. The paternalistic view of the medical practice has been reduced over the years. The professionals are not seen as experts anymore, the "proper judges of the patients' best interests," in the relationship with their patients, the focus migrating towards the "patients' capacities to make their own decisions" (O'Neill, 2001). The IC became the instrument which turns the patient into the expert of his own health state, able to decide for his own life, based on correct information he or she receives. Oprea, Cojocaru, Sandu, and Bulgaru-Iliescu (2013) starting from the approach of Bodenheimer, Lorig, Holman, and Grumbach (2002) consider that "physicians are experts in diseases, whereas patients are experts in their own lives [. . .]." More than that, the patients should have to define their own therapeutic goals, according to their own social, cultural, and health status and values, and to take the responsibility to achieve them (Bodenheimer et al., 2002; Oprea et al., 2013).

This research aims to identify the significance of the IC in the medical staff's daily practice.

We aim to identify whether the IC is perceived and used as an ethical tool for promoting patient's autonomy, or it rather is an administrative procedure designed to comply with the legal obligations.

Bioethical Perspectives on IC

This section will expose some of the most important perspectives on IC process which are available in the scientific literature in the field.

When obtaining IC, two major issues should be taken into account: IC implies a process (Cambon-Thomsen, 2004; Sheehan, 2011) and the receiver/patient should also understand the information provided, so a provision for understanding should be given. The authors cited above refer to the specificity of IC in research, but we consider that IC for therapeutic practice and research should also consider these aspects.

To obtain consent, there is a process that needs to be fulfilled. Beauchamp and Childress (1994) set out a series of seven components in the process of obtaining IC: the elements of disclosure (preconditions): (a) competence in understanding and making decisions, (b) voluntary participation (in decision making) and the elements of information, (c) disclosure (the material information), (d) recommendation (of a plan), (e) understanding (in disclosure and recommendation) and elements of consent, (f) the decision (in favor of the plan), and (g) authorization (of the chosen plan).

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IC is based on one of the main bioethical principles: the principle of respect for autonomy (Beauchamp & Childress, 2001).

By giving IC to the medical staff, the patient gives them permission to perform an intervention that is relevant to his or her health condition (Maclean, 2009). What gives power to the IC as an instrument is the respect for the patient's autonomy. An ethical approach of the process of obtaining IC should be sensitive to the way in which the patient understands the situation and expresses his or her consent in accordance to what the patient has understood de facto.

IC for research represents the process in which the participant to the research agrees to participate, after being informed about the procedures, risks, and benefits (Bulger, 2002, pp. 117-125). The practice of gaining IC can be interpreted in a formal manner by referring to strict rules of gaining IC and their formalization, turning the IC into an instrument that fulfils the legal obligations of respecting the patients' rights. IC can be approached in a paternalistic manner, the rules being transparent, thus offering the therapist the possibility to manipulate the patient's decision by presenting the risks, benefits, and procedures (Bulger, 2002, pp. 117-125).

In addition to respecting the person's autonomy, fundamental to the practice of IC are also a series of other functions: protection (for the doctor and the patient) against the malpractice accusation, preventing medical abuse (Manson & O'Neill, 2007, p. 75), self-ownership and the right to dispose over one's own body (Archard, 2008, pp. 19-34), and protection of personal integrity.

Legal Perspectives on IC

The Rules of Good Clinical Practice defining the procedure of obtaining the patients' IC were first adopted in 1998. Nowadays, following the Orders 903 and 904 from 2006[1] of the Romanian Ministry of Public Health, Romanian legislation is transposing the Directives of the European Parliament and the European Commission on the approximation of laws, regulations, and administrative provisions of the Member States on the principles and detailed guidelines for good clinical practice into the conduct of clinical trials on medicinal products for human use. The European Parliament and European Commission Directives (2001/20/EC) are the manifestation of the effects of the World Medical Association Declaration of Helsinki.

We identified references to IC in the Romanian legislative framework, which was used in both medical practice and medical research. The Romanian legislation that requires the patient's IC is Law No. 95/2006 on health care reform and Law No. 46/2003 on the patient's rights (updated in 2015).

Chapter 3 of the updated version of Law No. 46, effective January 21, 2003, includes the patient's consent for medical intervention. This chapter refers to the procedure for obtaining IC both for medical intervention and in the context of involving patients in didactic activity and medical research.

The legislation does not expressly require a standard IC form, but the practice makes all medical units use their own IC form, which is given to patients along with the admission forms before the diagnosis. Patients are rarely presented with IC forms during hospitalization, especially when facing complicated medical interventions. The IC form is standardized in some situations, and is available for download on the medical institution's website, with blanks for filling in the patient's identification and/or diagnosis/therapeutic procedures that are recommended or are to be refused. The forms automatically include information on patient's consent, covering the situation in which the information and samples collected in the process of diagnosis and therapy can be used in further research activities.

The European Commission guidelines given by the Directive 2001/20/EC for the implementation of good clinical practice in conducting clinical trials on pharmaceutical products for human use require for the IC form to contain "adequate information to meet the necessary requirements [. . .]." In this case, the principle of "informed and free decision" remains valid for any other kind of research (European Commission).

The European Commission defines the IC as being

> the decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in the national legislation.[2]

The global acceptance of the definition and utility of IC in medical practice and in medical research can be consulted in the World Health Organization (WHO) ethical standards and procedures for research with human beings. WHO refers to IC as a process that is one of the seven aspects approached by Standard 7: Ethical basis for decision making in research ethics committees.[3]

At the level of Central and Eastern European countries, we found very few references on understanding and implementing the practice of IC. In the Czech Republic, the medical staff gained experience in using IC along with the country's adherence to the European Union, thus adopting important European conventions regulating the area.

In 2007, after a survey on the public trust on physicians and public understanding of IC, 42% of the respondents answered when asked about the IC. According to the mentioned study, "in clinical practice, informed consent is sometimes interpreted as the patient a priori agrees to anything that may occur during the treatment" (Krizova & Simek, 2007, p. 276).

Short Criticism of IC

Bioethicists identified a series of "weaknesses" of the IC procedure. O'Neill (2003) argues on the validity of the IC when referring to the fact that a consent is valid when it is

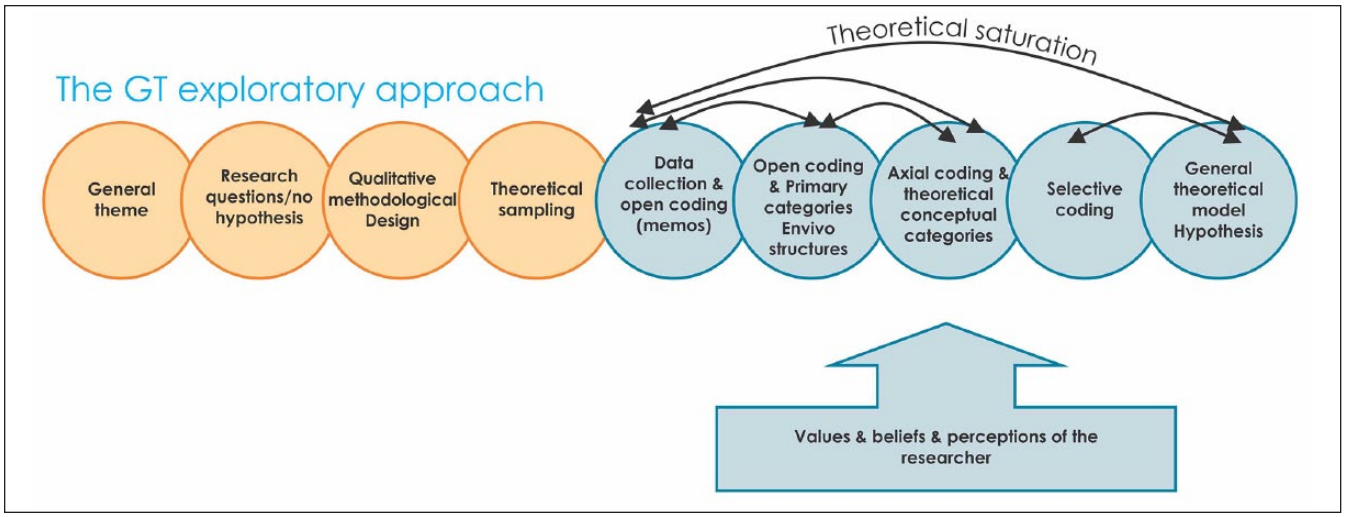

Figure 1. The GT exploratory approach.
Note. GT = grounded theory.

given by a patient who was not deceived or obliged (pp. 4-5). We will underlie some of them, mostly on autonomy paradoxes, to emphasize the contextual value and applicability of the theories on IC.

- "Mandatory" autonomy, which refers to the fact that the practice of obtaining IC forces the patient to express his or her autonomy. Some patients wish not to make any decisions concerning their own health state, preferring to delegate the decision to the doctor (Schneider, 1999).
- The irrationality of the decision on own health—IC is based on the assumption that a better knowledge on the medical situation leads to an informed decision, and implicitly a wider level of autonomy. This is questionable, because many decisions are taken rather emotionally, than rationally (Springs, 2007).
- The state of vulnerability influences the capacity of decision—the patient being in a state of vulnerability—stress, medication, social and financial condition, and pregnancy—may express an altered autonomy. The decision taken in a state of vulnerability may radically differ from the decision that could be taken in a state of emotional or physical comfort (Sheppard, 2016). In the literature, this is called autonomy as authenticity (Sandu, 2013).

Method

For this current analysis, we used a constructionist grounded theory (GT) method for analyzing the collected data and theory development.

We used GT as a research method, comprising the GT steps of data collection destined for theoretical sampling, theoretical model saturation, and so on (Glaser, 2004).

GT aims to pin the social theory in the perceived reality, while being sensitive to the social context. The theory derives from the experiential data, rather than from other previous theories.

The GT approach is based on an overall theme, with implicit hypotheses, without making assumptions in the classical sense (see Figure 1).

The structure of the research underlay the following model that we have developed to describe the specifics of the exploratory research by GT.

General Theme

The understanding of IC.

The Research Questions and Assumptions

How is IC understood by the Romanian medical staff (and medical researchers)? How the is IC used to ensure and promote the patients' autonomy? Is IC used as an ethical or as an administrative tool? We considered the assumption that IC is rather understood as a protective tool for the medical staff to avoid malpractice accusations. We did not go far enough to test this assumption, but we are aware of its influence in our analysis and we minimized it as much as we could.

Qualitative Design

We conducted a series of 10 individual interviews with representatives (doctors, nurses, managers, and chairs of ethics committees [ECs]) of Romanian medical institutions (Iași city) who are allowed to conduct medical research on human subjects.

Table 1. The Saturation of Data Grid.

	Categories								
Interviewees	C1	C2	C3	C4	C5	C6	C7	C8	C9
I01	x	x	x	x	x	x	—	x	—
I02	—	x	x	—	x	x	x	x	x
I03	—	x	x	x	—	—	x	x	x
I04	—	—	x	x	—	x	—	—	x
I05	x	x	—	—	x	—	—	—	x
I06	—	x	x	—	x	—	—	—	x
I07	x	—	x	—	x	—	x	—	x
I08	—	x	x	—	—	—	—	—	—
I09	x	x	—	—	x	—	x	—	x
I10	x	x	x	—	x	x	x	x	—

Data Collection, Open Coding (initial coding), and Memos

The data were collected between March and June 2016. The data collection and the open coding were done simultaneously. We used a semistructured interview guide; during the interviews, the questions addressed to the medical staff were gradually improved. The interviews followed a previous content analysis of a series of IC forms collected from medical institutions from Iași; we used the content analysis framework to construct the initial thematic axes of the interviews.

The sampling was obtained using the snowball method, interviewing only the respondents from institutions selected as subjects for our research.

Data collection through the interview was done considering the model's need for saturation.

To ensure data saturation, we developed a saturation grid (see Table 1), wherein major topics (categories) are listed on the horizontal and interviews to be conducted are listed on the vertical (Brod, Tesler, & Christiansen, 2009; Fusch & Ness, 2015).

If, at any point during the analysis, new information is obtained, as many further interviews would be conducted until the saturation would be reached again, in the niche of the research approached (Brod et al., 2009; Rubin & Rubin, 2012). We repeated the process until no new information was collected.

The respondents were aged between 28 and 60 years; five respondents were male and five were female.

A specific criterion of inclusion was whether the potential respondents had published scientific research results for medical research conducted within the selected institution in the last 5 years. We identified medical staff, other than physicians—for example, nurses, psychologists, and so on—and we included them in the sample. The sample also contained at least two hospital directors.

Open Coding (Primary Coding, In Vivo Structures)

We identified a series of nine initial categories.

The GT design allowed us to understand the collected data. In the process of understanding the answers of the interviewed participants, several themes emerged. These themes were grouped into initial categories as a result of the analysis of the similarities identified in the interviewees' responses.

Each category was defined by the respondents' key phrases. For the analysis of data obtained through the interview process, we used a triangulation of researchers, which involved negotiating the coding processes. In the open coding process, we agreed on representative keywords for the topic of the work and initial categories.

To exemplify the inductive process conducted, spread throughout the whole analysis, we present a table containing keywords noticed in respondents' answers and content structures that resulted in generating categories and the titles of the initial categories.

Axial Coding (Theoretical Categories)

During an inductive process, conceptual categories were created. The categories had an increasingly high level of generality, which helped explain the research topic to both the researcher and the participants (the respondents).

In this particular research, there were two researchers responsible for the data analysis. Data interpretation was therefore a consensus between the perspectives of both researchers on what was the significance of the results.

Selective Coding

At this stage, the categories established on the axial coding stage will be interconnected to get closer to the model we intend to generate based on the process of obtaining IC.

A central category resulted in the analytical process was the "the process of obtaining IC." The other categories are related and subordinated to this.

The Generated Model

The analysis generated the discursive framework of the research and the theoretical corpus, including models with value of hypotheses, to generate further research on the ethical conformity of care practices and the need for ethical training in the field.

Results

This section presents the main results of the analyzed data, according to GT methodology previously described.

Open coding
Category 1: "Operational definition of IC"
Category 2: "IC's role and utility"
Category 3: "The process of obtaining IC"
Category 4: "Voluntary patient participation in medical research"
Category 5: "The need for ethics"

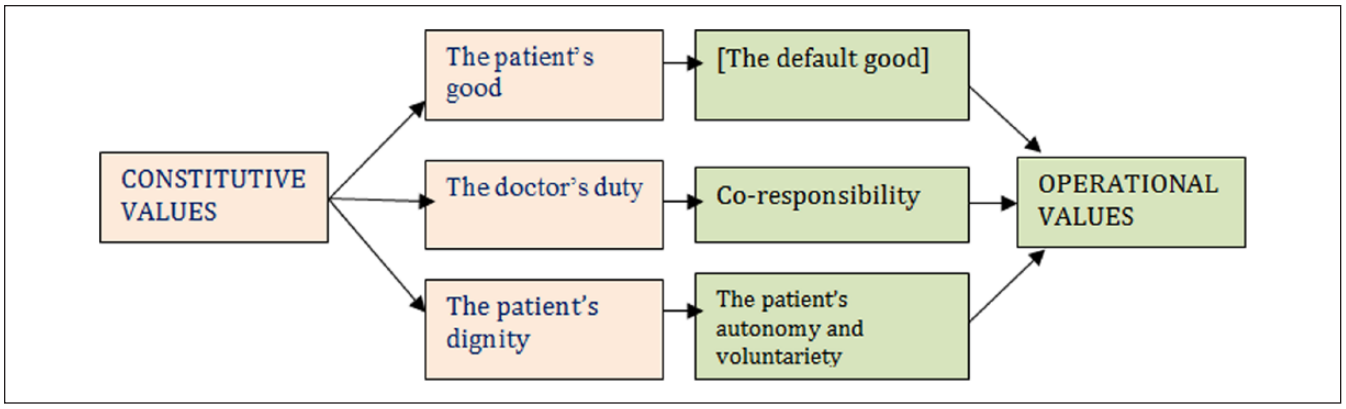

Figure 2. IC-obtaining process—constitutive and operational values.
Note. IC = informed consent.

Category 6: "Coresponsibility in the doctor–patient relationship"
Category 7: "Values in medical practice: The ethical grounding of the profession"
Category 8: "Respect for patient's rights" (see Figure 2).
Category 9: "Specifics and types of IC"

Category 1: "Operational Definition of IC"

The respondents understood IC in terms of *dialogue* and *clarification* on the procedures that will be done, on what will he or she be subject to, and whether the information collected from him or her will be of help to someone else (I01).

The respondent's answer about the IC indicated the agreement with the theoretical perspective on IC that can be found in the literature (Maclean, 2009, pp. 113-114), according to which the respect for patients' autonomy and its development is the key element of the process of obtaining IC, a dialogic process that facilitates the decision. Only based on the patient's decision, facilitated by the doctor–patient dialogue, further therapeutic intervention or research enrollment could be justified. From the perspective of the physician/research investigator, IC is that which entitles him or her to consider what action is warranted, either in terms of therapeutics or research, for the patient as decision maker.

The regulatory practice of obtaining IC transfers the focus from a reflective ethics to a normative one (I05, I10). A reflective ethics would be focused on patients' autonomy, while a normative one would be centered on patients' rights.

IC can be turned into an instrument of regulatory compliance in terms of human rights when the practice of obtaining IC is interpreted in a formalist manner by referring to the strict rules for obtaining IC and their formalization (Maclean, 2009).

The respondents also highlighted the written IC, whose imperative is governed by the national legislation and the European practice. The IC is considered a written document, by which the "patient comes into contact, in detail, with the information on the substance and the benefits of his involvement in that study" (I05), rather than a dialogical process of informing. The process of obtaining IC is also seen as the doctor's obligation to provide the patient with the necessary information about the clinical study or research they will be enrolled in (I09).

Respondents also provided insights on the IC that corroborate the dialogic nature of obtaining the IC against its administrative nature through formalizing the agreement as a written agreement:

> It is a form, but that's not entirely the IC, but you should be aware of your agreement [. . .] It means that the patient understands what will happen with him/her from the moment they accept the investigation and treatment. (I07, I10)

However, some respondents observed a series of inconsistencies between theoretical desire and the practical realities of obtaining effective IC in medical practice:

> In daily practice, the process of obtaining the IC is less elaborate; theoretically, every patient should be asked if he/she wants to be treated by the doctor, which never happens in current practice. (I09)

Category 2: "IC's Role and Utility"

One of the most important functions of IC found in respondents' answers was the *facilitation of awareness of risks and benefits* that the patient/research participant assumes (I01).

The same awareness and active involvement of the patient occurred in other respondents' answers, which diminishes the patients' need for further explanations. We noticed a potential limitation of the dialogic process of obtaining IC, as identified by the respondents. One possible assumption underlined by the answers was that the absence of requests for additional explanations could be "the best way to get the benefits" (I03).

The respondent below drew attention to the inclusion of forms of IC in the observational records of the patient:

> In Romania, every observational sheet of the patient comes together with the informed consent form. Each time the patient signs the informed consent. (I02)

The process of obtaining IC involves several steps, each completed with a form. Although we welcome the declared interest of repeatedly and gradually informing the patients about their condition, we question the ethical issues associated with the process for obtaining IC because multiple forms do not result in multiple dialogues between doctor and patient. We did not identify such repeated procedures except with one of the interviewees. Moreover, in most of the analyzed medical institutions, the IC is signed in the admission process, even before any diagnosis and therapeutical procedures to be discussed with the patient.

The role of the legal regulation of the IC form was identified in the respondents' answers from the perspective of potential disputes in the doctor–patient relationship.

> It has a protective role for the medical staff. Protects all individuals involved in the research. I mean besides the patient, who is informed and assumes the risks of that study, it also protects us from legal perspective. (I03, I05, I10)

Some of the respondents (I05, I08) acknowledged that the right not to be informed should not be confused with any difficulties in signing the IC form; if the first refers to the affirmative will to circumvent the information, a desire that confirms knowledge, then difficulty in signing the form should not be a reason for not informing the patient. Also, signing the IC form should not act as a substitute for information and IC in the therapeutic act or research; patient discernment should not be obstructed by functional illiteracy:

> For many patients, the signing of IC form is a burden. Many of them are illiterate, cannot read, did not know how to sign, and sign with X. (I06)

The role of protection is seen as being ambivalent.

IC was first identified as a protective measure for the doctor in the context of contemporary society's aggression toward the medical practice. The need for protection is seen in the context of what respondents call "a very aggressive world with the medical practice" (I02, I08, I10).

> Yes, it has a protective role for the physician, to prove that he/she was not dealing forcefully with the patient, the patient agreed and shared with the doctor to be hospitalised, had mutually agreed to undergo treatment under the scheme, and so on. (I09)

Subsequently, this protective role for the physician is reduced to a formal one, with protection transferred to the patient (I02).

We identified opinions according to which the IC form helps the doctor save time discussing with the patient.

> For us the IC form is important because that's where we begin the discussion with the patient, when proposing him to participate in the study [. . .] It help us too, for the patient to better understand the specific of the study by reading the IC form at home, because we get rid of a workload. Sitting him/her down to explain what is written there takes too much time. (I06)

The IC's role was identified, in some cases, as being detrimental to the patients, representing grounds for refusing the treatment. Some of the paragraphs from the IC forms' content were identified as inducing fear in the patient—that fear can, in turn, prompt the refusal of treatment (I06). The negative role of IC is correlated with the written form of IC, seen as a liability by the patient.

> [. . .] we were there when the IC forms were conceived, and were given one to read, in its final format [. . .] the word "death" appeared in three places; I do not say that was not supposed to occur, that the patient should be aware that there is a risk to die from the treatment, but when the risk of death is 0.001%, and then to appear three times in the text, I still think that as being excessive. (I06)

Although considered by respondents to have a negative effect on the patient's decision, we consider a patient's refusal of treatment, after reading the form's content, as an expression of patient's autonomy construction.

The ways in which risk is expressed by the physician or the institution via the written IC form modify the patient's decision, which proves that autonomy is ultimately a social construct.

Category 3: "The process of obtaining IC"

Respondents were aware of the nature of the dialogic process of obtaining IC, in addition to being brought into question the necessity of assuming the possible consequences (I01, I04).

The time-consuming nature of the process for obtaining IC was stressed. It was noted that longer lengths of time might lead to the interpretation of the existence of a dialogic process:

> The consent is absolutely necessary, it is time consuming, it requires time and patience, to listen, to explain, then listen and to explain even if you already explained once, and then you realize that you were not understood. (I01, I10)

Other respondents focused on the formal characteristics of obtaining IC, such as the results of legislative constraints and imposed procedures.

The respondent (I02) saw an imposed administrative practice in obtaining IC:

> It is a law that must be respected, meaning that it is compulsory, we are required to comply, we are monitored, and each case must have an IC form. It is also an administrative practice. (I02)

Other respondents admitted the legal coercion used in obtaining IC, but they emphasized the gradual nature of obtaining IC. We see a correlation between the description of the steps to obtaining IC from the perspective of the respondent, and the process described by Beauchamp and Childress (1994).

> The respondents see the process as starting with "a small talk with the patient to assess the level of communication and understanding of the patient," which helps the doctor to adjust his/her way to present the information for them to understand. (I03, I10)

Representatives from certain sectors like medical psychiatry approached the process of obtaining IC all in the manner of a dialogue, even before the legal formalization of the obligation to obtain the IC (I04).

We welcome the consultation offered by caregivers, because the patient's autonomy is in fact relational, as caregivers play a special role in a patient's decision. We identified formulas such as "it [IC] is given at home" which refers to the IC form. The respondent made remarks about a dialogue of clarification with the patient, them being encouraged to ask the doctor subsequent questions if they desire any further information. The doctors embrace the idea of patients reading the IC form with their family and make a decision with the support of the caregivers (I05).

Some respondents excluded the idea of doctor–patient dialogue when obtaining IC, stressing the need for the patient to allocate time to read the IC form, which they considered just a simple form:

> In my opinion, a patient should sit 10-15 minutes to read the IC and not simply sign it. (I08)

> After entering the hospital room, and has already received the observational sheets, it would be normal and correct for him to read it and sign it. Being a very large flow of patients, I do not know if you can cover all the patients the IC obtaining and depends from patient to patient. (I08, I10)

A negative factor that overcame in obtaining a completed and correct IC is the daily practice overloading of the medical staff.

Category 4: "Voluntary Patient Participation in Medical Research"

When discussing voluntary patient participation in research, respondents generally referred to the consent to participate in activities other than those of diagnosis and treatment of patients. They also referred to the presumption of implicit patients' participation in didactic activities, if they will ask for health services provided by university hospitals; this issue even applies the involvement of "hopeless" patients in clinical trials:

> It is presumed that the patient knows the function and specificity of hospital (teaching hospital) and by coming to the hospital, he anticipates the presumption that he/she knows what is going on in that hospital, accepting to participate in hospital-specific actions (therapeutic, teaching, research). (I03)

It is important to specify the doubts found in the respondents' answers about how patients do or do not understand the implications of enrollment in research activities that take place in hospitals.

The attitude of accepting a participant's enrollment has been regarded as being questionable. We consider this attitude as providing a chance to patients who have no therapeutic alternatives, and we find it acceptable only if the patient understands and accepts the risks and benefits of their enrollment. Furthermore, the obtaining of the IC is considered as more appropriate to be accomplished by a professional different from the medical staff—an additional professional in relation with the patient.

> I explained [to the patient that we test drugs with therapeutic role]. And that they may be in the placebo group, which actually take the medicine and has no value. I think many of them do not understand. Many come and hope to be in the responding group. I don't even know if all understand. I personally think that an additional professional should deal with the consent obtaining process. (I01)

The participation in research should not be thought of in terms of personal therapeutic benefit, but should be considered in terms of development of knowledge in the field, and in the progress of medical science. Understanding the purpose of medical research as something other than the contribution to the knowledge development may lead to therapeutic misconceptions. The respondents who were interviewed challenged this approach by indicating that the participation in research is considered a last resort and may have lifesaving potential. From the interviews, we noticed that voluntary participation is presumed.

Category 5: "The Need for Ethics"

Most respondents identified the need for training in ethics, which would help the medical staff reach a compliance with patients' rights.

We identified that a reflection on the need for ethics in medical practice was generated during the interviews themselves. In other words, an interview question about the need for ethics in daily practice generated awareness about its importance:

> I think so [for the counselling of ethics to be necessary]. We do not have time to think about these things. Here everything happens with speed. You have to take a break to stop thinking. (I01)

There are some positions that outsource the ethical practice of obtaining IC by assigning the ethical duties of dialogue

with the patient to an outside medical practice specialist, a facilitator, a psychologist, or a "doctor trained in ethics" (I01).

We especially consider it necessary to emphasize the fact that the medical ethical training, as medical ethics, bioethics and professional deontology, are disciplines that were only included in the curriculum of the faculties of medicine in the last 10 years; the professionals trained before the introduction of such disciplines are less trained in ethics than those who benefited from such disciplines earlier (I10).

The need for ethics is enforced by educating the public about the usefulness of clinical trials and the forum decision of medical institutions, whose involvement made it possible to sustain a current compliance to practices/institutional policies of ethics.

The respondents show interest in increasing the number of people trained in bioethics, starting from the public through the decision-making group in the medical institutions and in the public health system (I02).

The need for ethics training was seen as also covering the need to minimize damages in case of malpractice. There were made references to previous trainings in ethics some respondents benefited of. Within these trainings, the participants were informed about the fact that the IC form offers a very weak protection in case of doctor's malpractice, from the legal point of view (I05).

One of the respondents referred to the importance of being trained in the IC-obtaining practice. There were no references to the importance of ethical training, but to an administrative and legal update of their practice which can further protect them in case of malpractice. We do not argue against physicians' self-protection against malpractice accusations, which can occur even if they perform their practice at the highest standards. Providing the patient with all the specific aspects of the therapeutic relationship helps the physicians to protect themselves. What we disagree with is the excessive formalization of the IC-obtaining process, by asking the patients to sign a form which can give freedom to physicians to act however they consider appropriate.

We present an example picked from a Romanian institutional IC form, which exemplifies the patient's responsibility transferred to the doctor: "The doctor will decide on the surgical approach, but can decide to change it without consulting me first, when he considers that the situation requires it, and is in my favour" (IC2). This type of permission could be considered as normal in emergency situations, and it should be mentioned that its validity should not be general but should be extended to other than life-saving situations.

The need for ethics training was seen as imperative, especially in terms of enrollment in clinical trials:

> It is mandatory to have training in ethics, at least as a researcher who participates in clinical trials [. . .] we must do ethics training every two years. These are based on Good Clinical Practice, on the Declaration of Helsinki. (I06)

Respondents were aware of the need for training in ethics and for their daily practice among physicians:

> Any doctor should take such a test [of ethical knowledge], not just those who are involved in clinical trials. (I06, I07)

Category 6: "Coresponsibility in the Doctor–Patient Relationship"

IC was seen as a form to be filled in, and less as a process based on dialogue and information. The interviewees become aware of the importance of the patient's understanding of information regarding their health condition and therapy. IC was generally regarded as more of an administrative act. It was also seen as shared coresponsibility in the doctor–patient relationship. The respondents acknowledged the patient's own disavowal as expert, transferring the decision to the doctor. We noticed a paternalistic approach in some of the respondents' answers:

> At some point it's an advantage because they do not waste time [when signing without asking questions]. (I01)

There were significant references to the therapeutic adherence as a superior form of respect for the patient, which requires for the patient to become an expert. The respondents invoked the therapeutic alliance between the doctor and the patient (Oprea et al., 2013, pp. 176-189).

The coresponsibility of the doctor and the patient was brought into the discussion in terms of patient involvement in therapeutic plans: "the therapeutic process not being considered a unilateral process" (I06, I02, I10).

The practice of obtaining IC was, for some respondents, strictly related to the doctor–patient relationship and therapeutic dialogue. Understanding the situation and the active participation of the patient in the therapeutic process assigns the process of obtaining IC a therapeutic role, along with its administrative and ethical role (I02).

There were opinions that supported the limited nature of doctor–patient responsibility, referring to the patient's sense of relieve from the therapeutic decision, transferring these decisions to the doctor.

This, as noticed by one of the respondents, diminishes the value of IC:

> Many of them let us decide on their behalf, because they don't take any therapeutic decision; and then IC loses its value for the patient. (I06)

> [. . .] They do not quite understand, although they are receptive to the idea of signing and do not give any importance. Nor understand all aspects of the consent. (I04, I10)

Category 7: "Values in Medical Practice: The Ethical Grounding of the Profession"

In analyzing the discourse on the values the surveyed practitioners adhere to, we identified both prompt and delayed answers, caused by overlapped reflections on values in clinical practice. The prompt answers may indicate that practitioners

have previously reflected on the topic. We identified a mixture of values, principles, and standards seen from different perspectives—both of the patient and of the doctor:

> [. . .] I know how to do good, I will not ever be able to hurt a patient; I have not thought about it [the values] [. . .] we also have many patients and have not had much time to contemplate on these moral values [. . .] It comes from the heart, I do not know how to explain. (I04)

Medical activity, undertaken either by practitioners or researchers, was described as being "profoundly ethical." Doubts regarding the compliance with the medical ethics are made public by the media, which contributes, in some doctors' opinion, to the distortion of the medical image in the patient's eyes:

> Everything the doctor does is profoundly ethical. Only the TV suspects that doctors are otherwise. (I02)

Associating their practice with a number of ethical values, some respondents have shown that beneficence does not necessarily exclude risk taking, as some treatments such as those in oncology, which involve side effects, occur before any positive outcomes (I02).

Professional ethical operational values such as "transparency" and "information" in terms of a doctor's perspective support constitutive ethical values of medicine as a profession. Terms such as "dignity" and "good" were both found in the respondents' answers:

> Dignity is important. The individual has an assumed dignity, a very strong personal pride. (I03)

> All you have to do is good. (I02)

> Firstly, there should be professionalism; those who practice medicine have to be good professionals; then to be honest; to give the correct information on the steps that a patient goes through in hospital. (I10)

Generally, the identified values can be translated into the meaning of bioethical principles, respect for individual's autonomy, beneficence, nonmaleficence, and justice (I07, I09).

Category 8: "Respect for Patient's Rights"

A special category of operational values is the "patient rights." The rights most frequently mentioned by the respondents were "the right to be informed," "the right to make informed decisions," and the "right to refuse." The refusal is brought into discussion when the doctor refers to the importance of the patient's awareness, when it comes to what a treatment/intervention involves, as additional risk to the patient's health condition (I03, I02).

While some respondents considered the equality between doctor and patient, others adopted a paternalistic nature, accepting the transfer of responsibility from the patient to the physician when making decisions over the treatment:

> I do not know [. . .] there are patients who are interested in what will follow, and they ask questions related to that, but there are some who say "I will do everything you are telling me to do." (I01, I10)

Category 9: "Specifics and Types of IC"

This category exemplifies the specifics of the IC, repeatedly identified in the respondents' answers, of possible similarities and differences between IC for therapeutic activity, teaching, and research/clinical trials.

In an initial discourse analysis, we identified the fact that there were no such differences between IC forms in terms of actual consent, not taking into consideration the fact that the consent itself must have a clearly defined object to start with.

We identified two types of IC for therapeutic intervention and research/clinical trials. The process of obtaining IC is different in both situations, depending on the patients' voluntary involvement, the specific physician–patient dialogue, how much time the care team spends on informing the patient, and so on. Many respondents shared this view (I04, I05, I06, I07):

> In medical practice is easy, because when the patient comes, he is already informed about what treatment options he/she has, and it's clear what he/she wants from the medical staff [. . .] they all come in order to treat themselves, and seek for solutions, therefore the discussion is pretty straightforward; [. . .]. Also, we tell them about benefits, side effects, then we ask them if they agree or not, and further to sign or not the IC form. (I06)

> The research is different because we search for the patient, we propose them to enroll in the study; we explain them that it is a new drug that can address his/her illness [. . .] and then we give the IC form, we give them time to think, to talk to whomever they want; we tell them to write down all the questions they identify while reading the IC form, and then they return to us, and if there is an agreement, he/she will sign the IC, always in two copies, and we enroll them in the study. (I06)

Another administrative approach is that related to the IC for research; however, the focus is on a more complete description of the potential drugs included in the experimental treatment, which could indicate possible transformations in the factsheet drug IC. In this context, IC loses, at least partly, its ethical value, in favor of the administrative, technical, and legal aspects.

> In a clinical trial instead, the standard therapy is associated with the drug study, and things are very clear. For example it is easy to say that there are potential side effects to 2-3 medicines, but when you have 100 on the list, the IC should be 100 pages long. (I06)

> We noticed that the IC is developed either by people who are familiar with the problem and know what to include in the IC, they know a basic structure of the form, either by people who have more of an administrative job. (I03)

> In the respondent's perspective, the administrative liability may involve omitting things that are quite important. This situation occurs especially when there is no face-to-face contact with the patient. (I03)

> Regarding informational content, respondents noticed the deepening of the written information on the forms used in clinical trials, due to the studies' international specifications; they also identified the shallowness of the forms used in clinical practice in hospitals. (I03)

The hospital-specific IC form was described as being general, containing a unitary agreement, validated by a signature generally valid for multiple actions, which actually erases the idea of consent, free choice, and informed decisions:

> The form includes and asks permission for the patient's participation in all activities in the hospital. It sounds like this: "I came willingly and I accept that my doctor will administer any treatment he considers it's correct, I know I have the right to refuse." (I04)

We identified differences between the IC for therapy and the IC for clinical trials in terms of voluntary participation. We believe that such a response may indicate a misunderstanding of the idea of voluntary participation, as long as it is presumed that hospitalization is imposed by an individual's health condition and that the acceptance of hospital conditions must be involved.

We consider that the patients' beliefs on them being forced by their vulnerability to accept any conditions posed by their doctor may lead to malpractice connected with the incorrect assignment of an ab initio superiority of the doctor over the patient (I04).

> The IC from the hospitalisation sheets is much thinner, it is not the same as in clinical trials, where it is more comprehensive, because clinical trials are more important. (I07)

> Clinical trials have a rather long document. All aspects are very well covered, because the financial interests are most important. For example, there are IC for treatment, a IC for genetic screening, so the patient can enter the study and choose not to be tested genetically, and IC form of withdrawal from the study. (I06, I09)

The issue of consistency in the IC form for therapeutic activity and research was raised by other respondents, revealing the fact that in medical practice, general information is briefly provided, and this mostly urges the patient to read the IC form, while in research, the form emphasizes on the patient's understanding of all the procedures, risks, benefits, and so on (I05).

Other types of IC mentioned were those for *teaching* and *research activities*. The analysis we performed on the IC forms used in the respondents' institutions revealed that all forms—for therapy, educational activities, the use of data and biological samples, and, in some cases, patient involvement in research conducted in the hospital—are merged into a single form (I05).

The patients' possibility of addressing questions was mentioned, but often their absence was presumed. The mere presence of the patient in the medical institution, especially in university clinics, was considered to be implicit adherence to the treatment, thus without opposing to the suggested treatment.

We identified answers that refer to the necessity of separating the IC forms, based on the activity that requires patient consent:

> There should be six, seven, eight different IC forms: one should be on teaching activity, one on the actual information on therapy, one designed for providing information to the media or to other doctors, one of the persons to whom we can provide information. (I05)

Some respondents considered that the patients' participation in research and medical education is compulsory if the patient undergoes treatment at a university hospital. In case of refusal, the patient has the freedom to seek for another type of hospital (I06, I07).

Axial Coding: Analysis of the Inductively Built Categories

Using GT, the categories emerged from the content analysis of the interview transcripts. These categories underwent several changes in the axial coding process. The criterion in axial coding was how frequent is a certain theme/topic in the interviewees' discourse and its discursive centrality.

Following the narrowing of the initially identified categories, we see a strong correlation between three of them: Category 1: "Operational definition of IC," Category 2: "IC's role and utility," and Category 9: "Specifics and types of IC." All these were restructured into a new category—New Category 1: "The operational understanding of the IC instrument." The understanding of IC combines the theoretical knowledge on the IC with practical/technical routine of obtaining the IC. The IC utility contributes to a higher understanding of the instrument in daily practice.

Another reconstruction of the categories is made starting from the relationship between the Category 4: "Voluntary patient participation in medical research," Category 6: "Coresponsibility in the doctor–patient relationship," Category 7: "Values in medical practice: the ethical grounding of the profession," and Category 8: "Respect for patient's rights." These four categories were reconsidered, and structured into one new axial category—New Category 2: "Ethical

Table 2. Transformation of Categories During Analysis.

Categories in open coding	Axial categories
Category 1: "Operational definition of IC"	New Category 1: "The operational understanding of the IC instrument"
Category 2: "IC's role and utility"	
Category 9: "Specifics and types of IC"	
Category 4: "Voluntary patient participation in medical research"	New Category 2: "Ethical values in doctor–patient relationship"
Category 6: "Coresponsibility in the doctor–patient relationship"	
Category 7: "Values in medical practice: The ethical grounding of the profession"	
Category 8: "Respect for patient's rights"	
Category 3: "The process of obtaining IC"	New Category 3: "The process of obtaining IC"
Category 5: "The need for ethics"	New Category 4: "The need for ethics"

values in doctor–patient relationship." Each of the values identified in the four initial categories can be transposed in terms of bioethical principles: respect for autonomy, beneficence, nonmaleficence, and justice.

Category 5: "The need for ethics" suffers no modifications, the same as Category 3: "The process of obtaining IC."

The key category is the "process" of obtaining IC. We will further refer to how the other categories relate with the central one.

To have a better view on the scheme of the newly reconstructed axial categories, we will present them as it follows in Table 2.

Selective Coding

We have identified a fraction of the speech. There is a speech on the desirable practice, centered on ethical values (the ethical dimension), and a speech oriented toward the daily routine of obtaining the IC under the administrative, legal, and time-related pressure (the administrative dimension).

The ethical dimension. Analyzing the ethical dimension of the process of obtaining the IC, we notice that there is a classification of the ethical values relative to practice. These values are focused on the doctor–patient relationship. We identify a category of values that are incorporated in the medical act itself, and which determine the ethical nature of the practice. We consider these incorporated values to be constitutive values for the doctor–patient relationship, and of the process of obtaining the IC. The constitutive values were identified especially in Category 7: "Values in medical practice: the ethical grounding of the profession," which lead to generating the New Category 2: "Ethical values in doctor–patient relationship." Among these values, we mention right, justice, the doctor's duty, and the patient's dignity.

Besides these values, we identified a series of idealized operational values. These values should guide the practice of obtaining the IC. These values were included in the categories: Category 4: "Patient's voluntary participation in the medical research," Category 6: "Coresponsibility in the doctor–patient relationship," and Category 8: "Respect for patient's rights."

The administrative dimension. As far as the discourse on the practice of obtaining IC is concerned, IC remains devoid of ethical content despite this being legally compulsory. IC is rather considered to be an administrative procedure that is sometimes excessively bureaucratic. There is an awareness of the need for coresponsibility.

Medical practice and research on human subjects were regarded as having an implied ethical nature, but were not perceived as being necessarily required to be reflected upon.

IC is not seen as supporting individual autonomy but the beneficence of the individual. The process of obtaining IC was described as being developed in accordance with the international guidelines, but in practice, it was most often translated by the formal signature given by the patient on the IC form.

Our model prevails, as one of IC functions is to empower the patient to assume the risks of the chosen therapeutic approach, but also reducing the administrative pressure on doctors.

We consider that the quasi-paternalistic acceptance of the therapeutic approach, including changes without priory consulting the patient, does not exonerate the doctor of malpractice, nor does it promote quality of patient-centered medical services.

Theoretical Model Generation

From the analysis of the identified axial categories and the possibility of the interrelation of discursive structures with the theme concerning ethical reflection on obtaining IC in medical practice and research, we generated the following operational definitions of using IC:

- IC is ambivalent, being either a dialogic process of informing patients about their medical condition and procedures, or a standardized and written document whose signing by the patient is mandatory by legislation.

- The role of IC is mainly administrative, as protection either for the physician and the institution, or for the patient, from a predominantly legal and administrative perspective. The role of obtaining IC in the construction of patient's autonomy is generally neglected; there is a predominant adherence to regulatory standards, without a prior reflection on the ethical perspectives underlying those rules.

We have identified the following possible frameworks of the model:

- Rejection of a patient-centered model of medical practices, a model that could be seen as an alternative to medical paternalism
- The expert–patient relationship is neglected, including the approaches related to self-care management derived from the Chronic Care Model[4]
- IC is seen as an administrative tool rather than as a required ethical reflective tool;
- Patient empowerment is peripheral
- Medical practice is considered as having implicit ethical values; ethical reflection is less necessary and can be undertaken by other experts, but not necessarily by doctors.

Discussions and Limits

The current section develops the potential limitations of the study and discusses about the epistemological background of the research. In a previous analysis of IC forms, we examined institutional ethics policy products which link the institutional frameworks of IC applicability in medical practice and potential in medical research, which provides a higher degree of objectivity.

The research started from the presumption that the IC is used basically in its administrative utility, and its use operates as malpractice protection rather than as an instrument for promoting patient autonomy. This presumption was identified in the construction of the thematic axes, even as we tried to avoid its transformation into a hypothesis to be confirmed or rejected.

In the GT constructionist analysis of data collected from the interviews, we analyzed the opinion of the medical staff on obtaining IC, with reference to the theoretical goals and practical realities. In this interpretation, the level of subjectivity may be higher; the researchers assumed this would occur, and thus chose a constructionist analytical approach.

The methodological triangulation allowed us to simultaneously examine the subjective dimension of discourse about practice, and the relative–objective dimension of signing an IC as institutional practice.

The constructionist GT approach aims at understanding the constructs through which subjects operate and give meaning to their actions; the approach includes elements of deconstruction that are used in language analysis and the identification of metastories, which in turn become the referentials in subjects' practices.

Data are reconstructed by researchers and participants alike, with the researcher playing an active role in affecting discursive elements considered by him or her as significant. We concur with the idea that such analysis could be understood as having a largely subjective interpretative nature.

Some consider this nature as bias when referring to the validity of the results. In this regard, we argue that constructionist sociology is not necessarily oriented toward the validity of results but, rather, the generative potential of the model that can help start future research on the same topic.

The generative nature of the study's methodology aimed at theoretical construction though inductive strategies, which tend to construct a new and more coherent theory.

An IC form was provided to the respondents prior to the beginning of data collection. Before starting the research, we received ethical approval from the LUMEN Research Center (Romania) and IRB Clarkson University (USA). The LUMEN Research Center approved the research protocol on January 29, 2016, through a decision by the President of Research Ethics and the Publication Ethics Committee of LUMEN. The Certificate of Exemption from a full IRB review and approval for research development from Clarkson University was obtained on March 23, 2016 (16-27E).

We obtained the model saturation; therefore, we ceased data collection when we noticed that no new information was obtained from the respondents. We agree with Strauss and Corbin's (1990) suggestion concerning the saturation. They argue that saturation is a "matter of degree"; saturation should be more concerned with reaching the point where collecting new data becomes "counterproductive" than with the fact that "the new" that is discovered does not necessarily add anything to the overall story, model, theory, or framework (Mason, 2010; Strauss & Corbin, 1990, p. 136).

Conclusion

There was a vague reference to the founding and operational values of medical practice; a reflection on the values of the practice was deemed cumbersome and, for some respondents, was only undertaken for the first time during the interview, not from previous experience.

Analysis showed an understanding of IC in terms of its administrative side, as a form signed by the patient. Using IC is not necessarily the result of an ethical reflection on the construction of patient's autonomy. It is rather an interiorization of the legal obligation to obtain IC in writing with the patient's signature because of the risks of malpractice.

There is—at the declarative level—the desire to implement ethical tools such as IC in medical practice and research, but the interviews concerning practice referred to carrying the IC in subsidiary. Where the real process of obtaining IC was mentioned, instead of only the formal process, this was

mainly in reference to clinical trials whose protocol is built by multinational companies and does not reflect the local traditions of practice.

Voluntary participation was attributed mostly to clinical trials; voluntary participation in therapeutic action was invoked, but partially understood. Coresponsibility was identified as the foundation of the doctor–patient relationship but was seen as more desirable than actually practiced in the daily activities.

Even the results come from a research developed in North-Eastern Romania, the idea that there are at least two dimensions of obtaining IC—the ethical one and the administrative one—could be applicable to the United States and also worldwide as the process of the IC has very similar requirements and the challenges/issues could be very similar as well.

Authors' Note

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Notes

1. Available online at http://www.anm.ro/en/html/legislation_minister_orders.html.
2. European Commission Guidelines on informed consent in research, available at http://ec.europa.eu/research/participants/data/ref/fp7/89807/informed-consent_en.pdf.
3. World Health Organization, Standards and Operational Guidance for Ethics Review of Health-Related Research With Human Participants, available online at http://www.who.int/ethics/research/en/.
4. "The Chronic Care Model (CCM) is an evidence-based policy response devoted to improving the quality of chronic care at the level of primary care. It has been implemented in several Western societies to decrease the morbidity and mortality associated with chronic diseases. The initial evaluations have shown that it is efficient and can also mitigate the social gradient in health" (Oprea, Cojocaru, Sandu, & Bulgaru-Iliescu, 2013).

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