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Formalization of Informed Consent. From Ethical to Administrative Use

Ana FRUNZA[1], Antonio SANDU[2]

Abstract: We explore the ethical issues derived from obtaining the Informed consent (IC) in medical practice and research in institutions from North Eastern Romania. We performed a content analysis of 11 IC forms (standardized hospital documents), retrieved from different medical care institutions involved in medical research activities. We also interviewed 10 professionals on how they are using the IC in their medical care practice and medical research. The research started from the presupposition that there is a lack of ethical understanding of inform consent both from the issuer of the IC documents as from the medical staff are using these documents in their relationship with the patients. The analysed IC documents show a formal respect for the legislative framework and for the protection of the doctor and the medical institution towards possible litigations. We conclude that the administrative meaning of the IC overlaps the ethical one, turning the IC from an instrument of ensuring the promotion of patient's autonomy to the institutionalization of the patient's mandatory trust in the medical team.

Keywords: *Informed consent; ethical risks; Romanian medical practice; content analysis.*

Introduction

The paper addresses the issue of obtaining the IC of patients in medical care and medical research institutions with the right to develop research on human subjects from Iasi (NE Romania). One of the paper's objectives is to identify possible ethical risks of using standardized IC documents that exist in those medical institutions.

Secondly, we are interested to identifying if the respect of autonomy and the patient's rights are central principles of the ethical policies regarding the obtaining of IC, adopted in the institutions discussed, as those appear from the IC documents. Otherwise, was the use of IC reduced to an

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Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

administrative formality? Is the promotion of patient autonomy facilitated by standardized IC documents?

We followed to emphasize the ethical reflection on a series of specimen IC documents shown to medical staff from selected institutions.

The research started from the presupposition that there is a lack of ethical understanding of inform consent both from the issuer of the IC documents as from the medical staff are using these documents in their relationship with the patients. We started on the understanding of ethical values of IC obtaining process from the model of Beauchamp and Childress (1994) which we used on the analysis of the documents used as IC, both at the therapeutic level and at the level of medical research, was carried out. This grid from the Beauchamp and Childress (1994) model was used to identify whether the documents are based on a procedural paradigm of obtaining the IC, or on a formalized one, with a pure administrative nature.

Based on this model we compared the documents of IC and the interviewees' opinions with the international standard practice sustained by the model.

Such an analysis could lead to the construction of better ethics policies in medical care institutions. The institutions and the professionals should become aware of the fact that a standardized IC document signed by the patient should not replace the process of obtaining the IC in itself.

We were aware that the scientific literature with a bioethics nature may also indicate other accepted approaches on obtaining the IC, but we considered that the chosen approach can constitute a referential framework of standardizing the international practice in the field of patient rights and the connection between Romanian and international practice.

These analysis grids did not aim to restrict the interpretation of the practice of obtaining IC. The interpretation made within this research, aimed to identify the concerns for respecting the principles of beneficence, non-maleficence, respect for the person and justice.

We noticed from the IC documents a correlation was made between the request of IC for the therapeutic act and the expansion of the requests for consent in using data in future scientific purpose analysis, as well as in the medical education process. Considering these correlations we intend at assessing the legitimacy of using the IC document for therapeutically act as a document entitled for medical research and medical education process.

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

1. Literature Review on Informed Consent

Recent literature defines informed consent as the "aagreement or permission accompanied by full notice about the care, treatment, or service that is the subject of the consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient then either consents to or refuses such a procedure or treatment. (The Joint Commission, 2016).

One of the IC approaches is centred on the autonomy of the individual who consents, and in the deliberate adoption of a decision. The decision once made, will justify the intervention on the deciding person. Another approach centred on the person performing the action refers to the fact that he is determined enough to believe that he acts based on that person's consent (Maclean 2009: 113-114).

Manson and O'Neill (2007) view IC requirements as protective measures against deontological offenses such as assault, deceit, coercion and exploitation. This opinion can be seen as further evidence for the definition of IC as a valuable instrument in thwarting certain acts (Eyal, 2012).

Eyal (2012) synthesised the informed consent from juridical and bioethical point of view as "relevant to medical torts, to distributive and proprietary medical claims, and to ideal doctor-patient relationships".

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

The therapeutic informed consent follows for the patient to give the medical staff permission to perform an intervention relevant to his/her health condition (Maclean 2009). Proper respect for the patient's autonomy requires an ethical approach to the process of gaining the IC, sensitive to the way in which the patient understands the situation and expresses his consent in accordance to what he has understood (Frunză & Sandu, 2017a; 2017b).

In the field of medical research, (Bulger, 2002) defines IC for research as the process in which the participant of the research agrees to participate, after being informed about the procedures, risks, and benefits.

The role of the consent is to create a legal barrier that would control the permission and allow the conversion of an illegitimate act into one that is allowed (Alexander 1996).

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

When obtaining the informed consent, two major issues should be taken into account: it implies a process (Cambon-Thomsen 2004; Sheenan 2011); the information, which is provided to the patient, should also be understood by the receiver, and provision for understanding should be given.

Large difficulties are encountered by the doctors in relationship with their patients related to the patient level of understanding of the IC utility and the lack of time of the medical staff (Matiasek, Wynia, 2008:34).

Obtaining consent implies a process. Beauchamp and Childress (1994), inspiring from previous works (Faden & Beauchamp 1986) set out a series of seven components regarding the process of obtaining informed consent:

The elements of disclosure (preconditions): (1) Competence in understanding and making decisions; (2) Voluntariness (in decision-making);

The elements of information: (3) The disclosure (the material information); (4) The recommendation (of a plan); (5) Understanding (in disclosure and recommendation);

Elements of consent: (6) The decision (in favour of the plan); (7) The authorization (of the chosen plan).

We identified more and more references to the need of a new understanding of the IC obtaining process, that call to better understanding of the ethical value of the IC consent in medical practice and medical research (Bottrell, et al, 2000:26-33, Matiasek, Wynia, 2008:34). The efforts for a better conceptualization of the IC should be based on the simplifying of the IC form. IC form should be used just as an instrument which finalises and synthetises the process of the IC between clinician and patient. Opinions resulted after empirical research on IC obtaining process suggest that a simpler form of IC is rather more useful and better perceived by medical staff and patients than a broad content form (Matiasek, Wynia, 2008:34). We agree with the efforts of simplifying the IC forms, only when these forms are the written resume of an enlarged comprehensive previous discussion between doctor and patient. Otherwise, the form remains avoided of any ethical meaning, by being just an administrative procedure, in the regards of respecting the law.

2. The Romanian background

In the Romanian legislative framework we identified references to IC, which was used both in medical practice and medical research. Rules of

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Good Clinical Practice defining the procedure to obtain IC of patients were first adopted in 1998 and, currently through the Romanian Minister of Public Health's Orders 903 and 904 from 2006, Romanian legislation is transposing the Directives of the EP and the EC on the approximation of the laws, regulations and administrative provisions of Member States on the principles and detailed guidelines for good clinical practice in the conduct of clinical trials on medicinal products for human use. The EP and EC Directives (2001/20/EC) are the manifestation of the effects of the WMA Declaration from Helsinki. The Romanian legislation (Scripcaru, Damian, Sandu, & Ioan, 2014; Damian, Mihai, & Damian, 2008) that requires the IC of the patient is Law No. 95/2006 on healthcare reform and Law no. 46/2003 on the patient's rights (updated in 2015).

3. Methodology

The methodology consisted in two direction qualitative analysis. First we did a content analysis of 11 IC documents collected from different medical institutions with right to develop medical research.

3.1. Collection and analysis of data from IC documents

Based on a list of medical institutions that are allowed to conduct medical research on human subjects, we sent an email requesting the representatives of the institutions to provide us with the IC documents used in medical practice, where such documents were not found on the institution's official website. Following the answers received, we continued to make phone calls to institutions or visits to hospitals in order to ask for the specific IC form.

The process of obtaining the IC form was facilitated by the Romanian legislation on the free access to information of public interest.

The collection the IC forms was conducted between May-June 2016, in Iasi (North-East Romania).

The references to IC forms in this document will follow the following abbreviations:

IC1- chemotherapy; IC2 - surgical intervention; IC3 - IC within the hospitalization forms in the recovery clinic; IC4 - surgery/treatment, in the emergency hospital; IC5 - clinical studies; IC6 - treatment/surgery; IC7 - on the investigations and therapeutic procedures & participation in the medical educational process (Psychiatry); IC8 - performing medical procedures/interventions (Psychiatry); IC9 - hepatitis (Gastroenterology);

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

IC10 - on the methods of diagnosis, therapy, anaesthesia and surgical intervention (emergencies); IC11 - on the investigations, therapeutic procedures & other requirements (emergency hospital).

3.2. Criteria of analysis of the standardized IC documents

The criteria of the analysis were two-folded. First, we considered the grid of analysis starting from Beauchamp and Childress (1994) series of seven components regarding the process of obtaining informed consent*: the disclosure of information* (referring to the patient competence in understanding and making decisions, but also on his/her voluntariness in decision-making); *the information in itself* (the disclosure of the factual information, the recommendation of a therapeutic plan, and the actual understanding of the patient related to the information and the plan recommendation); *the consent in itself* (the decision and the authorization of the chosen plan).

The second grid of the analysis was based on the structural coherence of the documents, following the:

- the structural coherence of the document;
- the implementation of the principles of bioethics (the preponderance of information referring to therapeutic practice towards the research activity; supporting (or not) the patient's real freedom of choice to participate in the research; the existence of elements relative to the concern for the respect of human dignity, welfare, non-injury, from those who have developed the form; the existence of reference to the confidentiality and data anonymization)

Into the IC documents analysis we are making reference to the generic "patient" to whom the IC documents are addressed to. The research is not conducted with patients. We refer to the documents of IC in relation to what the patient in a real intervention should consent to.

3.3. Collection and analysis of data through interviews

Based on the IC documents content analysis results we conducted 10 semi-structured interviews with medical staff from the selected institutions. The interviewees were invited to express their opinion regarding the ethical specific content of the IC forms.

For the qualitative analysis we proceeded with the identification of a minimum 2 representatives of each medical institution for the interview, by using the "snowball" method, starting from contacts obtained by phone or by email. As specific criteria of inclusion we considered whether the potential respondent had published scientific research results from a medical

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

research conducted within the selected institution in the last five years. We identified medical staff other than physicians – for example, nurses, psychologists etc. – and we included them in the sample. We included at least two hospital directors in the sample.

The final sample was of 10 participants, aged between 28- 60 years, male and female.

The participants were medical professionals, affiliated to institutions with the right to perform research; institutions that answered to our request to provide us with the IC forms used in the institution. The medical professionals were doctors and nurses, with or without a management position.

The interview guide consisted of thematic axes, which targeted the meaning of the therapy and the research IC, from the respondent's opinion. In this article, we will analyse only the answers to a series of questions referring explicitly to the IC forms used. Specifically, the subjects were asked to read three specimens IC forms (IC02, IC06, IC5) – as they were collected from the institutions – and to express their point of view on the content. The qualitative analysis of the answers was done starting from the grids already used in the content analysis of the IC forms. For this article we are not focused on the participants' opinion on the IC obtaining process in general, but especially on their understanding on the three selected IC documents shown by the researchers when they conducted the interviews.

The analysis of the data collected through interviews was combined with the results from the content analysis of the IC documents. The data obtained from interviewed were compared with the researchers interpretation of the IC documents, to infirm or confirm the researchers opinion on the IC understanding.

4. Data Analysis

Grid of analysis of the IC documents internal coherence

The structural coherence of the IC forms

In many of the analysed documents, we observed a relative neglect in writing and structuring the IC document. This led us to a possible approach of obtaining the IC as an administrative obligation – which needs to be fulfilled, but whose deeper purpose was not necessarily deeply understood. There is interplay between the actions for which the patient consents, the plan of the therapeutic intervention and that of harvesting and

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

preserving the biological samples, of processing the patient's data with a medical and personal nature. The documents of IC also combine the consent for therapeutic act and the consent for patient's implicit participation to the educational didactic process conducted in hospitals. This interplay can confuse the patient who is vulnerable, with regard to the object of his consent. Also, about the limits of his possibility to refuse any of the different actions, he is invited to participate in, without limiting his right to treatment adequate to his state of health, but also accepted and consented to by the patient.

The respondents also showed the lack of clarity in the IC forms proposed for analysis:

> *"A common thing in specimen 2 [IC02] and 3 [IC06] is that they are unclear, they are not distinguished on the specifics of the information, treatment, didactic activity, research…. there is no clarity in the paragraphs to be understood by the patients; its form is not friendly; they are far from what these IC documents should be, and I'm not saying it because our institute's document looks better, but because there are a lot of gaps" [I07]*

We do not exclude the fact that a patient could expressly request to eliminate the data referring to his state of health and the biological data collected from the hospital's archives, mentioning this request in the paragraph specific for such situations, which is introduced as: *"I have listed the following procedures, that I don't want to have performed, without any further discussion"*, which offers the possibility of listing the procedures that are unacceptable for the patient. In the manner in which this exclusion request is formulated, it refers to therapeutic procedures; the potential patient is not presented with the possibility of refusal to participate in the teaching and research activity in that hospital.

Another confusing situation refers to the mix of the capacity of exercise [IC10], (the legal right to sign), with the cognitive one (of the patient who is unconscious), with the patient's motor incapacity to sign (who is, however, conscious and capable of informed consent).

The fact that a relative of the patient understood and agreed with the conditions expressed in the form has no connection with the patient's autonomy, which is capable or incapable of consent. Delegated consent cannot be extended legitimately from the patient who lacks judgment, to the one who suffers a debilitating disease.

Regarding the body of forms, the respondents generally showed that an IC form should contain a series of common elements:

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

> *"The diagnosis, risks, and educational purpose are included here in documentation, sequences, and photos; after all there are things that are included. Practically, there are very few differences between these forms." [I02]*

The respondent agrees that the consent for including the patient in education and research activities should be simultaneously expressed through means of the same form, with the agreement for therapy:

> *"[…] the more complete the better." [I02]*

We see this attitude as being justified through the need for a minimum of bureaucracy, especially regarding the vulnerable persons who are suffering. However, there can be reservations about the real promotion of the patient's autonomy by such interrogating formulations of the IC. In the context of certain care actions with a high degree of risk, such as the oncological ones, care for the patient's life and diminishing his suffering can be considered as primordial for the respect for autonomy, but this attitude is, in our opinion, questionable from the perspective of the patient's rights.

Supporting the patient's real freedom of choice

The IC documents abound in expressions that relate to the patient's understanding of his/her therapeutic situation and the risks associated with the therapy. But that also excludes him/her from any decision regarding the therapy itself, except for the situations expressly mentioned by the patient in the content of the IC documents, of excluding certain types of therapeutic procedures.

In some situations, there is the possibility that the patient would exclude a series of procedures that would even be nominated.

> *"[…] I accept to authorize […] and from this consent and authorization I exclude (for example: organ removal, the indication to not resuscitate in case of cardiopulmonary arrest)" [IC4], [IC6]*

Some institutions go beyond that, formulating the therapeutic agreement only for procedures that involve minimum or medium risk, without specifying what happens in the case of high-risk procedures, for example:

> *"I authorize the doctors and the medical staff of the clinic/department to conduct all the necessary investigations and procedures necessary for diagnosis, in the legal context of a fair medical practice, except for the cases in which, I expressly state my disagreement, all usual investigations and treatments, with minimum or medium risk, can be applied." [IC7]*

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

We identified the enunciation of the possibility of general refusal [IC6]: *"I freely give/refuse, knowingly, the consent for the presented surgery/treatment." [IC6],* or partially to the interventions/therapies:

> *"I also know that I have the right to refuse a diagnosis procedure or treatment that I don't agree to." [IC7], [IC11]*

We also saw the documents that did not contain any formulation referring to the possibility of refusal, such as in the case of forms [IC8] and [IC10], that end in formulations such as: *"I confirm that I have read and entirely understood the above-stated text"* [IC10] and make no reference to a refusal, but on the contrary, the patient consents to *"[…] performing the interventions or therapeutic procedures that the doctors consider necessary, including blood transfusions"* [IC10, paragraph 3]. This formulation is, in our opinion, the expression of a paternalist approach, which authorizes the medical institution.

This is the most exhaustive approach regarding the patient's right to decide upon his health condition, who is informed about the nature and purpose of the procedures and the risks, and who is invited to authorize the doctors regarding any therapeutic approach. The patient's autonomy is considered to be minimal and the right to be informed is the only patient's right, which is stated on the document.

The concern for respecting human dignity, welfare, non-injury and the patient's beneficence

Most of the IC forms that we analysed did not refer to the value of human dignity, namely the principles of welfare, non-injury, or beneficence. References to the bioethical principles are rare and were mentioned in the context where the patient was asked to accept the total risk of the procedures, delegating the doctor to make the decision:

> *"I accept that the designated doctor would act based on his professional training in consequence, only if these procedures are absolutely justified by medical reasons and only in my personal interest and towards my own good." [IC6]*

The said formulation brings into discussion the principle of beneficence, imposing the doctor to act with professional competence and exclusively in the best interest of the patient.

The existence of references on data privacy and anonymization

The confidentiality of the patient's identity is an object of interest in the analysed documents.

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

Basically, in the formulation of IC7, the patient not only consented to the processing of personal data, but also to its use in scientific purposes, including for detecting infectious or genetic diseases. If, for the infectious diseases, data processing is justified by the interest in public health and epidemiological prevention, we found no justification of genetic data processing for scientific purpose, besides in the direct interest of the patient.

We consider that not even invoking the direct interest of the patient is not sustainable, as long as the patient [IC7] comes from a psychiatric clinic, whose practice does not have the mission to analyse genetic diseases in patients, other than in the particular situations of establishing a diagnosis.

Our opinion that the malicious use of certain paragraphs within role of the affidavit, is that it exceeds the patient's competence.

> *"I certify that I do not suffer from mental diseases that would affect my discernment and that I am aware of the risks and accept them […][IC7]"*

The interviewee sustained that not all of the patients meet in his/her practice agreed to declare that their mental state could reduce their capacity to consent. Also, many patients came in with mental diseases that they did not acknowledge [I08].

The concern regarding confidentiality is expressed only with reference to photographing and filming, but not for other contexts of personal data protection [IC1], [IC2], [IC11].

Conceptual categories developed starting from the model of Beauchamp and Childress (1994) in obtaining of IC

Starting from the model of Beauchamp and Childress, we synthesized a series of conceptual categories aiming to see the way in which they are found in the IC forms used in the medical institutions, which we analysed. Although the model is a dynamic one, referring to the obtaining of the IC as a process, we consider that these steps should be at least partially transposed in the IC document so to prove the persons in charge in ethical and quality policy implementing are aware of the importance of IC ethical values.

(1) Competence in understanding and making decisions

The first analysis component was: *(1) the competence in understanding and decision-making*, which we noticed is based on the patient's affidavit:

The repetition of *"I was informed"* and *"I understand"* from the IC documents [IC01] may lead to the interpretation that the document's main purpose is to exonerate the doctor from any potential medical responsibility

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

and possible liability for malpractice, in the context in which the patient empowers him to make changes in the approach that the doctor himself accomplishes, without consulting the patient. We see this interpretation in the context in which a large part of the IC document refers to the doctor's freedom to decide on changing the procedure:

> *"The doctor will decide how to approach the procedure, but can also decide to change it without consulting me first, when he considers that the situation requires it, and it is in my favour". [IC01]*

This basically means that the entire IC process refers to the risks that are specific to the type of therapeutic intervention and the patient's acceptance, without care of the real understanding of the therapeutic approach as a stage of the intervention which, in accordance with the B&C should be part of the recommendation (of a plan) – that should be explained to the patient in his level of understanding.

We noticed that the IC document had been developed in a paternalist logic, where the doctor's expertise is absolute and the patient acknowledges it and willingly gives full provision to the doctor. Similar formulations, susceptible to analogue interpretations, were identified in most IC documents, which were analysed [IC2] (specific for oncological surgical intervention).

> *"[…] I understand the need for this surgery/treatment that I wish to have, and I acknowledge that I cannot be given a guarantee or an insurance on what the final result might be […]" [IC4]*

The understanding is declared on the patient's affidavit. What is more, in case the patient has discernment but lacks the ability to write, the form provides a special procedure in which a witness confirms that the current document was read to the patient, was filled in in the presence of the witness, and the patient was expressing his/her consent or refusal without any constraints [IC6].

We consider that this formulation can also be interpreted as an excessive care of the issuer to avoid liability for malpractice, which does not necessarily consider the ethical component of obtaining the IC – the patient's right to decide about being truly informed about his/her health condition and evolution.

Regarding the risks, including death, that the patients assume when signing the IC documents, some of the interviewees considered the formulations in the specimens taken for analysis to be insufficient. As long

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

as the limits of the potential risks are not clearly delineated, the consent is characterised by the high level of generality:

> *"They are compelled to give their consent on the risks, complications and death, without having the risks explained; they are absolutely general, since the risk of death ranges, it cannot be that simple;" [I07]*

In most IC forms, there are references to the patient's involvement in medical research, but they do not refer to the institutional care with regard to the patient's understanding that he/she will actually participate in the medical research, but also for which type of research they have consented to have. The formulations are mostly vague and general:

> *"The harvested biological material (blood, tissues or organs) in the purpose of diagnosis can be also examined in the purpose of scientific research, education […]" [IC7], [IC2]*

The doctors interviewed referred to the lack of education of the patients in order to give a real IC:

> *"Our population is not civilized and educated for consent; they sign it because it has to be signed." [I01]*

This lack of competence is generally placed either on the account of the illiteracy, being expressed as a lack of competence to read and understand the IC forms presented to the patient, or as a major difficulty of the patient in understanding his medical condition, the therapy that he/she is about to receive, and the risks and benefits of it. Both situations can be considered as a reference to the administrative nature of the IC.

Expressly mentioning the need for reading the IC forms can be interpreted as a lack of a process in factual obtaining of the IC, which would have been expressed by explaining to the patient and making him understand, rather than ask him/her to reading it and further to signing it.

We identified the belief of some of the interviewees in the necessity of a unique IC form, used by all medical institutions, in all situations:

> *"I think there should be a standard IC form that all hospitals should us; not every hospital makes its own document, you also cannot make an IC form for each disease. There should be a clearly stipulated rule of what must be signed specifically." [I09]*

The respondent feels the need for a single procedure that would "de-bureaucratize" the ethical procedures, to which they can appeal in any situation. The ethical reflection that the doctors are facing, through the reform of the health care system and the introduction of the patient's rights,

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

appears to most respondents as an additional pressure of a bureaucratic-administrative type. This pressure seems not strengthening the doctor-patient relationship or minimizing the power disparity between the two parts. This might be considered a weakness of the health-care system.

(2) Voluntariness in decision-making

Voluntariness in decision-making can be associated with the formulations of the patient's request for specific therapeutic intervention. The emphasis of the patient's request for therapeutic intervention can be interpreted as a justification of that practice, with potential to exonerate the doctor's decision.

> *"I mention that the surgical intervention and treatment are done at my request. I authorize the doctors and medical staff of the clinic/ department to conduct it […]" [IC2]*

The formulation leads to the interpretation that the hospital's ethics policy targets the concern for the voluntary character of the subject's participation in the surgery and his/her being informed with regard to the procedures that are about to be made, and the therapeutic practice.

Correlating this information with the repeated support for the patient's acceptance to fully assume that the surgical risk empowers the medical team to perform any other therapeutic action they consider necessary, even if that might lead to a situation of invalidity, mutilation, or risk of death.

> *"I was informed that any surgical action, as trivial as it may seem, has risks, side effects and, in some cases, may have very serious unwanted effects, up to death, even if their conduct was proper" [IC2]*
>
> *"I understand that there is the possibility of reaching surgical interventions that might lead to a high degree of body mutilation […]"[IC2]*

What is more, the potential patient have to fully trust the operating team, in the lack of any insurance offered by it, granting the medical team full freedom.

> *"The change of the surgical tactic, which can be major, is possible intraoperative, so that the surgical intervention can be entirely changed without the consent of the patient or his relatives." [IC2]*

We formulated a series of concerns on the reality of the voluntary nature of the total transfer of the right of decision, from one person by the operating team, given that voluntariness is not only the consequence of understanding the situations that might occur, but also of a minimum

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

guarantee from the surgical teams that the total trust will not be used in bad faith, or with the wilful limitation of the therapeutic efforts.

"The obligation" of trust can be considered to be a direct result of the analysis of this form. According to the IC2 form, the patient is obliged to grant full trust to the doctor, leaving any life or death decision to him. This trust is an institutional and compulsory one, extending to the competence of the entire medical team. The respondents in the interviews supported the idea of fully trust of the patient in the medical team, by showing the formal character of the signed IC:

> *"I'm saying it again, for us it is more of a formality, the signature is all that matters" [I10]*

It is understandable that in certain situations, urgent ones may arise in which a series of intra-operative measures are absolutely necessary for saving the patient's life, but in our opinion, this should be connected to the imminent death or the serious and irreversible degeneration of the health condition in the case of non-intervention, and not transformed into an absolute freedom for 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]*

The fact that "the situation requires it" does not expressly refer to a state of emergency that would justify violating the subject's autonomy.

Almost identical formulations could be found in other IC forms – [IC3], [IC4], [IC6]. The transferred voluntariness is a leitmotif of IC forms, and can mask a policy of not engaging the doctor's responsibility for possible practice abuse. The *diluted voluntariness* questions the very idea of IC. We can translate the previous formulation into the following phrase: "*I consent to be operated on with a laparoscope for the kidney stone, but I give the doctor freedom to remove an organ*".

Voluntariness is also highlighted through formulations such as *"I agree […]"* [IC9], *"I agree to expose myself […] without requiring additional insurances regarding the results"* [IC10]. The formulations lead to the idea of voluntariness towards assuming all therapeutic/ surgical risks and the doctor's exoneration from the responsibility of the results of the intervention. The approach is a utilitarian one that requires the patient to make a risk-benefit analysis in the absence of any knowledge and warranties.

We discussed with the interviewees the possibility of the patient to refuse to participate in the educational and research activity of the hospital.

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

"We must respect the patient's dignity. If we were in the same condition, we would also want to have these principles respected." [I02]

The affirmative attitude is, however, presumed to the patients.

"They are very aware of the fact that most of the time, these things are so. Their life is in danger and they want to live, and this involves the access to the medical situation and the person's didactic presentation." [I02]

The level of therapeutic education of the patient is relevant for the quality of the IC process.

"The more educated they are, the more they are interested, and ask for more details, but the less they are educated, the less they are interested […]" [I01]

The respondent also refers to the general mentality, according to which:

"[…] there is the conception that the doctor is always right and he is superior […]" [I01]

This mentality is contradicted by the need for a partnership between the doctor and the patient, which leads to the replacement of the classic idea of therapeutic compliance with that of adherence to the therapy. The difference lies in the voluntary and conscious nature of the adherence to treatment.

"[…] the current idea is that there is a partnership between the doctor and the patient; the doctor is the one who must explain and offer information; I never perform any procedure on the patient that I don't explain to him, so that he can understand what I'm doing." [I01]

(3) Disclosure of material information

Disclosing information is correlated with the existence of a discussion with the doctor, who should make sure that the information is transmitted to the patient in accordance with the patient's capacity to understand and to answer any of his questions.

The formulation *"The doctor […] is the one who informed me on chemotherapy and bears sole responsibility for the medical act."* [IC1] leads to the idea that there was a process of gradual disclosure of information by transmitting the medical information using a vocabulary that was accessible to the patient, and by answering the questions.

"The physician offered me all information regarding the surgery at my level of understanding and I asked questions that clarified the surgery for me, and I agree with it" [IC2]

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

In the form [IC02], it can be identified special care for the patient to declare that he/she was informed about all the situations that might occur during the surgery and he/she has understood all possible risks, which he/she is exposing himself/herself to. This statement is immediately and repeatedly refuted by the imperative of offering full surgical freedom for the physician and his team.

There are formulations, which, through the increased level of ambiguity, may endanger the other steps in obtaining the IC, or may lead to the impression that the patient is informed about a state of fact, that he should accept it as such, without further discussion:

> *"I was informed that the process of medical care is doubled by the educational process." [IC3]*

Even if the above-mentioned formulation is nuanced, by continuing with "I CONSENT to, within the limits of decency and common sense, participate in the educational didactic process, but this mustn't affect the quality of the medical care (…)" [IC3], the joining in of successive phrases, such as: "I was informed" and "I consent" can be interpreted as having a limiting character regarding the possibility of refusal.

The respondents showed that the broad formulation of consent for therapy, which empowers the physician and the medical team to modify the therapeutic approach according to their own professional consciousness, does not exonerate the medical team of malpractice.

> *"However, even if the patient signs, it doesn't mean that if he dies, the doctor is absolved of any guilt […]" [I01]*

The patient's consent is generally assumed, which is why the patients have the IC form included in the hospital admission documents.

> *"Ever since the hospitalization, they consented, since going in the hospital they must sign the IC so they agree to the treatment, only that the IC is taken very quickly. It is considered that the patient came to the hospital to agree to do the treatment, not to be against it." [I01]*

The respondent seems to consider this paternalist approach as being widely enough shared by his colleagues. The above-mentioned paternalist approach is acceptable, while it does not generate violations of a patient's rights, especially when correlated with the empowerment of the medical team to perform treatments that were initially unknown to the patient, and that he might reject, in situations that involve risks for the patient's quality of life or even the possibility of death.

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

(4) Recommendation of a plan

The successive sharing of information in stage (3) is the recommendation (of a plan) (4) component that can be found to a small extent. An example would be the IC for chemotherapy, where it cannot clearly be identified a therapeutic plan to be followed, including all components in such a manner that the patient would understand their logical structure, with an overview of the therapy's management.

In the content of the IC forms analysed, the component designed for recommending a plan is rather implicit; what is more, "the therapeutic plan" is left to the discretion of the doctor, while the patient declares that he will leave the decision on the therapeutic approach almost entirely in the hands of the doctor.

> *"The physician offered me all the information relating to the surgical act using words for my level of understanding and I asked questions that clarified the surgery for me and I agree with it." [IC2], [IC8]*

The fact that there is an intervention plan should be implied from the formulation about offering information on the surgery. In accordance with the IC documents we analysed, we identify a n uncertainty in the document formulation. It might be interpreted that the plan may suffer alterations anytime if this alteration emerges in emergency situations or is a common practice. But the appearance of such alterations is not clearly specified from the document.

In the IC form, the hospital's policy of ethics does not refer to any limitation imposed by the doctor in order to divert from the therapeutic plan in situations in which there is no emergency that would endanger the life or current health state of the patient.

(5) Understanding (in disclosure & recommendation)

This component (5) is left without object, since the stage of recommending the therapeutic plan can also be associated with the understanding of the plan, which is usually left to the concern of the physician, as the patient is considered to be incompetent to consent to a therapeutic plan. There is formal concern for expressing the how patients understand the status, procedures and risks, manifested by using the verb "I understand" of at least five times in the content of the IC form. However, the understanding rather refers to an absolute acceptance of the risks, including that of death and the transfer of responsibility from the medical team towards the patient, simultaneously with the transfer of decisional autonomy from the patient to the doctor.

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

"I understand that I will have the possibility to discuss the details of anaesthesia with an anaesthesiologist before the procedure (it is only explained to the patients that have general or local anaesthesia)." [IC2], [IC1]

"I understand that any surgery can be accompanied by risks and complications, including death […]; […] that might lead to a wide degree of body mutilation, and so that the decision to proceed […]" [IC2]

(6) Decision (in favour of the plan) and (7) authorization (of the chosen plan)

The elements of the consent, according to Beauchamp & Childress can be identified in these stages. The decision (in favour of the plan) can be considered a formal one, given by the completion of the formalities of the administratively necessary forms, played in most documents as a summary of the process of IC through phrases such as: *"I have read (or it was read to me) and I have understood the above-written and agree to it"* [IC1, IC2].

We also found formulations that differed from those mentioned above, which indicate that, besides the possibility of accepting the data submitted in the form and allegedly understood by the patient, there was the possibility of refusal:

"In consequence and in the mentioned conditions, I consent to the presented surgery/treatment." [IC6]

The interview respondents generally referred to the IC forms as being more or less appropriate for respecting the patients' rights from a formal point of view. For example, an interviewee refers to a possible improvement of the IC form by referring to the operating activity form in which it refers to the general possibility of bodily mutilation during surgery.

"I understand that there is the possibility to reach surgical interventions that might lead to a level of bodily mutilation and that the decision to proceed may be taken during the surgery, based on elements observed by the physician" [IC6] .

For the IC form presented to the subject - here it must be defined what this "level of bodily mutilation" means - we should discover if it has a functional or aesthetic nature." [I03]

The distinction between aesthetic and the functional mutilation brings the idea of an awareness of the need for a dialogue with the patient in the process of obtaining the IC and not only of signing the form. We are entitled to believe that in fact, the practice of obtaining the IC is generally dialogic, but the dialogue refers to the health condition and the therapeutic

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

approach being integrated in the medical practice itself. There is a diffuse awareness of the relationship between the doctor-patient dialogue and the obtaining of the IC, which is somewhat confused with the patient signing the appropriate forms. The signing of the form as an administrative action is *somehow separate* from the doctor-patient dialogue, the first one belonging to the medical bureaucracy, while the dialogue belongs to the therapeutic act.

There are also radical views, among the interviewees, on the inexistence of the IC as a process, as part of the doctor-patient relationship:

> *"I am telling you what happens concretely, not in theory; in theory it would be good to have a discussion with the doctor, not with the nurse, because the doctor diagnoses the patient and prescribes the treatment, he is the one the patient should talk to for questions and clarifications; […] more precisely there is no IC process, let's be serious; or it is done randomly, for some patients yes, for some no […]" [I10]*

We considered that such answers were due to the separation between the doctor-patient dialogue as part of the therapeutic act and the obtaining of the IC as an ethical reflection and the awareness of the patient's rights. The separation of the signing of the IC form, which is sometimes the responsibility of the nurse, makes it unclear for both the patient and the medical staff on the interpenetration of the two IC components: the doctor-patient dialogue, as an informational process in order to obtain the IC, and the signing of the IC form in itself.

The ethical reflection as theoretical action is less significant in the respondents' opinion, which focuses on ethics as an act, on the ethical action and the ethical value of the medical practice in itself.

> *"This (IC) is unclear; it is not very fair to the patient. The fact that he signs in only one place on the form, which contains so many requests, is not fair also" [I05]*

There is among the interviewees the contrary opinion referring to the need for separate IC forms, both as forms and as process of obtaining the IC. This opinion appears although it was previously mentioned the need to cumulate in the IC form the patient's agreement to participate in the medical research and the use of his/her data, including the tissues collected and other biological samples in further research activities.

The closest adaptation of the process determined by Beauchamp and Childress model we identified in the content of the IC documents [IC7], [IC9] and [IC11].

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

We have identified the IC forms that show a real attention for the process of obtaining the IC and the actual understanding of the patient's own health condition.

> *"I have been informed, through sufficient explanations, in clear, respectful and understandable language, of the following: the diagnosis and way of establishing the diagnosis; the purpose, methods and duration of the proposed treatment, as well as the benefits brought by this treatment; possible inconveniences, risks or side effects of the treatment; other possible ways of treatment; risks and consequences of refusing or interrupting the treatment without medical advice." [IC7], [IC11]*

The forms [IC7] and [IC11] mention the dialogic nature of the process of gaining the IC, a process which clearly describes the stages: informing, sufficient explanations, informing on the diagnosis and the way of establishing it, information regarding the therapeutic procedures – in terms of purpose, methods and treatment duration, alternatives to it, risk and benefits, but also consequences of interrupting the treatment. This information clearly exposed the patient's understanding, permitting the development of mutual trust, by eliminating, as much as possible, and the disparity of power. The doctor becomes the manager of the medical expertise and the patient is empowered to the condition of patient expert – knowing his own interests towards his health condition and its limitations. In such conditions, we may invoke the patient's responsibility towards his own condition as a fundamental of the IC, expressed autonomously. The patient-expert can be placed in the centre of the therapeutic action, while care becomes effective by self-care and therapeutic adherence.

Another approach, where the institution makes sure the process of IC is real, including the doctor-patient dialogue, was identified in [IC9].

5. Local micro-model of Obtaining IC

We examined IC forms as institutional ethics policy products.

The way in which the majority of the IC forms are developed shows a formal respect for the legislative framework and the protection of the doctors and the medical facilities towards potential litigation, rather than focussing on the centrality of the patient's interests. The issue of obtaining the IC from the patient is approached from a strictly administrative perspective; the ethical reflection refers to the meaning of the IC in the construction of the patient's autonomy being often reduced to mostly formal

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

aspects. The documents we analysed require the patient to have absolute trust in the professionalism of the medical team. At the same time, granting almost full freedom in choosing the therapy and the necessary intervention may permit to the medical team to go beyond the IC given by the patient.

The content abounds in repetitions of the verbs that express understanding, confirmation, obtaining information, expressed graphically by using bold characters. This aspect contrasts with the exclusion of the patient from the decision, in regards to the therapeutic approach [IC1], [IC2].

This transforms the IC as an insurance against the processes of medical malpractice, by the absolute transfer of all risks towards the patient. The ethical risks identified are mainly connected to the patient's vulnerability, as a paternalist practice of the physician as sole specialist in the doctor-patient relationship. This approach transpires in the institutionalized policy of ethics and is formalized through the IC documents.

We can conclude on a hijacking of the ethical meaning of the IC, from an instrument of ensuring the promotion of the patient's autonomy towards the institutionalization of mandatory trust in the medical team. The practice of obtaining the IC during admission, prior to any diagnosis process or treatment, questions the veracity of obtaining the IC as a process, based on the doctor-patient dialogue.

The IC should be associated with the doctor-patient dialogue, in order to clarify the diagnosis and the treatment. Although this stage exists and is supported by most respondents, it is not acknowledged as being the very process of obtaining the IC, the consent as document being dissociated by the very process of obtaining it. The IC approach as a written form, being administrative, with a high bureaucratic content, is justified through the normative obligation. This approach removes the IC of its moral content, but also of its therapeutic value of being the main instrument of building confidence in the doctor-patient relationship.

The micro-model generated – valid at least at Iasi (North Eastern Romania) area context – is at the interference between of two contradictory ethical paradigms. The first paradigm is centred on the autonomous individual. Its moral agency prevails precisely because it has the status of client of the health system. The second paradigm is based on the centrality of the system itself, and is placing the patient in a position of peripheral centrality (Cojocaru, 2008) towards the interests of the health system.

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

This interference generates a social practice that lacks ethical consistency, since the constitutive ethical values of the model proposed by Beauchamp and Childress – whose influences can be found in the national standards – are only partially convergent with the ethical values of the local model.

The values that are convergent with the two paradigms refer to the avoidance of malpractice. But the interpretation of such values differs from the two models, if in a liberal model, avoiding malpractice is done through valuing the expert patient and the full agreement with the information understood – being in fact a contractualist model, negotiated step by step. The model identified locally seems an authoritarian one – paternalistic, who avoids malpractice through an approach of "rely on the doctor". In this model prevails the presumed incompetence of the patient, who should be solved through the total transfer of responsibility towards the medical team? IC has the role to guarantee this transfer and offer liberty to the doctor to disavow from the potential further requests of information from the patient. By signature, the patient takes on to himself the responsibility of the doctor's practice, by simply investing the compulsory trust in him.

6. Validity and Discussions

Using a qualitative methodology, tributary to the social constructionist paradigm, we proceeded to a content analysis, using thematic axes. The specifics of the social constructionist analysis is given by the accented subjective nature of the interpretation, which sometimes could be considered a bias when referring to the validity of the results, which was the reason why we turned to the triangulation of the researchers, but also to the data sources in the whole research. In this case, along with the analysis of the documents, we proceeded to conduct individual interviews.

The analysis targeted the specifics of the IC forms at the time of their collection (May-June 2016), showing that there was the possibility of them changing in time, based on the current normative requirements.

The IC forms, which were collected, were extracted from the forms used by the medical staff specifically for each clinic/ward, in the stage of hospitalization in the medical institution.

The analysis covered a number of interpretative frameworks that are clarified in literature of bioethics by Beauchamp and Childress's approach that are internationally accepted ethical frameworks and supporting the development of legislation on patients' rights. This framework can be

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

considered as a universal system of guidelines that can guide local practice. The interpretative community will assimilate these frameworks passing them through the filter of local specificity: mentalities, cultural specific - peculiarities of traditional doctor –patient relationship, the administrative burden of the health system on practitioners, their response to the pressures of medical emergencies, and prioritization of medical interventions under time pressure.

We analysed the IC forms as a result of assimilation of global ethics by the administration of the analysed health system institutions that use the discussed forms, interpreted through the grid of regional peculiarities mentioned. This deconstruction of principlism as ethical metamodel should generate a micro-model of ethics in practice.

This application of ethics may be of interest to the sphere of bioethics, contributing to understanding ethical ways of aggregating regional patterns to normative ethics universal interface.

All the research ethics requirements were considered and ensured, by obtaining the ethical approval of the LUMEN Research Center (Romania) on 29 January 2016, and IRB of Clarkson University (USA) on 23 March 2016 (16-27E).

Conclusions

The analysis of the data obtained through document content analysis and interviews with medical staff allowed us to frame a model of local understanding of the IC utility, ethical meaning and limits.

Our interest in identifying the particularities of the IC obtaining process in terms of its ethical understanding by the professionals and institutions converged in the following understanding:

There exists a partial ethical understanding of the IC obtaining process, which is combined with a predominant administrative meaning.

Our presupposition according to which "there is a lack of ethical understanding of informs consent both from the issuer of the IC documents as from the medical staff are using these documents in their relationship with the patients" is partially valid.

There is a partial compliance between the understanding identified in practice and documents from the selected institutions and the model of Beauchamp and Childress (1994) which we used on the analysis of the documents used as IC, both at the therapeutic level and at the level of medical research, was carried out.

Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

We identified the following possible ethical risks of using standardized IC documents that exist in those medical institutions:

- The IC is becoming hollowed because of its formal using as an administrative written instrument rather than as a dialogic process;
- By using the IC as mainly administrative instrument could lead the violation of the bioethical principle of respect for patient autonomy or the violation of patient's right;

To overlap those risks a higher attention on the ethical practice of the medical institution should be given, by allowing medical professionals attending training of ethics or a counsellor of ethics to give special ethical consultancy to medical staff.

- The administrative us of the IC as document are inconsistent by not mentioning the patient's right to refuse any treatment/intervention;

To overlap this risk the institutional policy makers should be ethically trained on the importance of the IC in respecting the patient autonomy.

- A broad informed consent form may bring the potential patient into confusion and violate his/her rights, as long as in hospital admission he/she is required to sign a general consent for therapeutic interventions, further participation in medical research, medical education process etc.

The incorrect using of IC forms could be overlap or diminished by separate the forms for each specific action, so the participation in medical research not to be associated to the therapeutic interventions or their quality.

As final conclusion, the analysed IC documents show a formal respect for the legislative framework and for the protection of the doctor and the medical institution towards possible litigations. We conclude that the administrative meaning of the IC overlaps the ethical one, turning the IC from an instrument of ensuring the promotion of patient's autonomy to the institutionalization of the patient's mandatory trust in the medical team.

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Frunza, A., & Sandu, A. (2017). Formalization of Informed Consent. From Ethical to Administrative Use. Postmodern Openings, 8(3), 69-95. Doi: https://doi.org/10.18662/po/2017.0803.07

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