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INFORMED CONSENT IN THE INFORMATIC ERA

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Abstract: *Developing a web based system related to inform consent is not only a hazard, but is more and more a normal trend in our way of evolution. In this context, understanding the impact of informed consent in medical life, the opportunity of putting together medical doctors, computer science specialists and patients is an opportunity to improve the practices and strategies in ethical fields.*

Key words: *computer science, informed consent, e-communication.*

1. Introduction

Bioethics is defined by John Williams as "the study of morality – careful and systematic reflection on and analysis of moral decisions and behaviour, whether past, present or future. Morality is the value dimension of human decision-making and behaviour." [15]

Bioethics is not a new way of approach to medicine, but in the context of medical progress, a way of developing a lot of industrial interest in the medical field, since it became more and more a necessity.

Developing a clear method of assessment appreciate in the ethical field was a normality in ancient time, but it became a systematical way for proving that there is respect for the human being in our society.

"Bioethicists use a wide range of methods for knowledge development and verification; each method should meet stringent standards of quality" [8].

"The principle of informed consent, aimed at the lawfulness of health assistance, tends to reflect the concept of autonomy and of decisional auto determination of the person requiring and requesting medical and/or surgical interventions" [4].

Bioethics is focused on research by developing a new way of treatment, but is in permanent struggle between benefit and risk, between an individual's rights and society opportunity for a new treatment.

Related with the facilities induced by robotics and Internet, telemedicine was also taking the opportunity to develop other ways to obtain informed consent, in the context of e-Health society.

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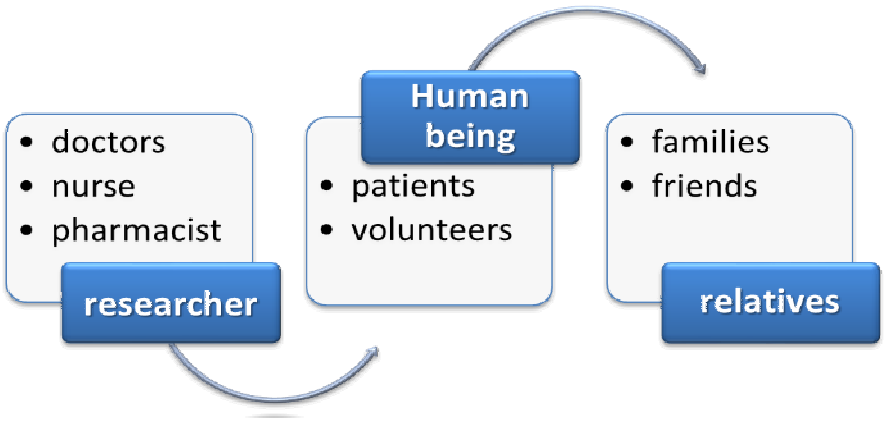

Fig.1. *Partners for developing the e-informed consent*

The main problem of developing a real informed consent through electronic media is to make it accessible to the person who has limited knowledge in using a computer, patient or patient's tutor who could also help the patient with problems of understanding the informed consent's importance and consequences.

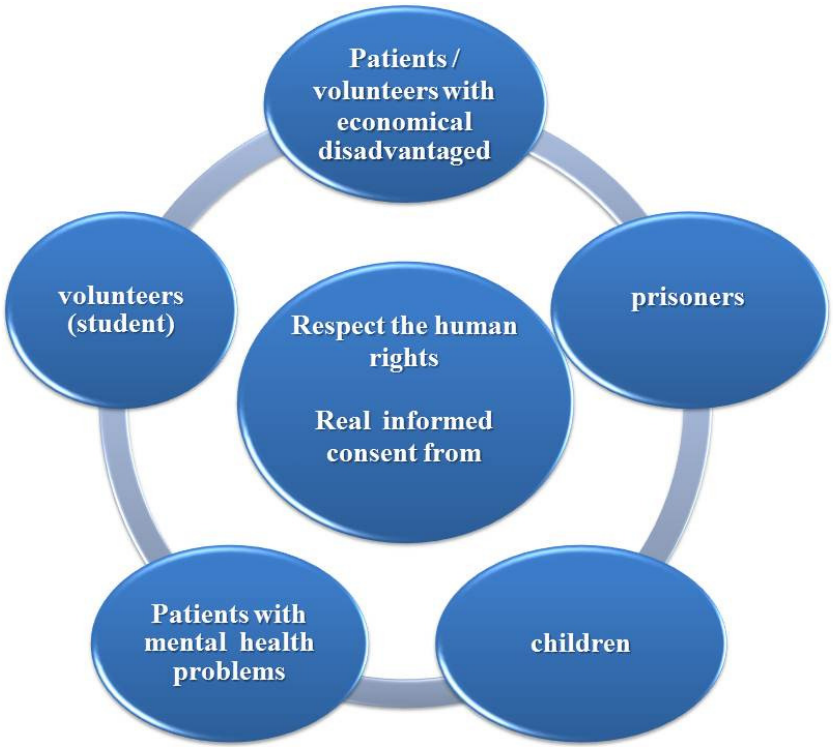

Fig. 2. *Problems in developing real e-informed consent*

Giving proper information in an accessible way, based by legal obligation and awareness of each researcher, is a way of respecting the patients' rights, and in the same time preserving the opportunity to develop sophisticated procedures based on technology.

The moral dimension of our world is, sometimes, in conflict with the development of new technologies or with the classical way of understanding the medical treatment.

Of course, as underlined by Henk A. M. J. Ten Have and Annique Lelie at Nijmegen Catholic University "we all approach the moral dimension of the world from a set of prior understandings" [6] and the rigorous system of values must be developed and respected. [2]

Using electronic communication must be nowadays in compliance with values mentioned in: Magna Charta Libertatum, Habeas Corpus Act, Bills of Rights or Helsinki Declaration, the European Council Documents. [16, 17, 18]

2. Informed consent process

Informed consent is not an easy process and it is necessary to be based on knowledge, understanding and, more difficult, on evaluation – in an independent way based on medical staff value and behaviour background.

E-communication used for informed consent is a good way to understand participation in clinical trials, also to give one of 4 types of opinion: a) positive; b) conditionally positive (including minor objections); 3) postponed (including major objections and additional documentation, explanations); and 4) negative.

It is very important to prove that a person was not only informed, but the relatives or the person responsible for them understood all the consequences of the participation in clinical trial [1, 5, 7].

Informed consent is a process with antagonist values, not only a document that has to be read and signed by the participant.

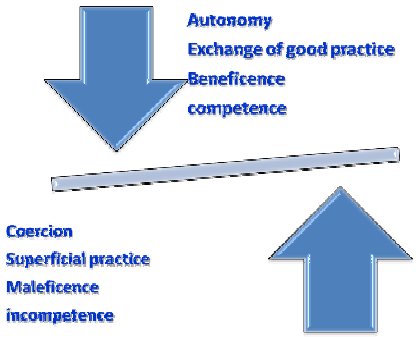

Fig.3. *Informed consent values*

The IC must offer a summary of the clinical trial: "the aims and methods of the research, the expected duration of the subject participation, the benefits that might reasonably be expected". [3]

The informed consent process is correlated with the experience of each person, but also with their education in these fields.

Even if "informed consent is an ongoing, interactive process, rather than a one-time information session" it is very difficult to be sure that all information was understood. [6]

Because the informed consent became more and more complex and difficult to understand, a lot of patients are unable to really understand the whole process and decides after a few minutes that: "My doctor knows best". [9]

Using electronic informed consent could also represent an interactive way of giving information, the possibility to find a way to avoid the lack of time and also involve other specialist in the disclosure of the information, using telemedicine.

E-communication could simplify the informed consent document and is

mandatory for the good of the subjects and for assisting the patients and relatives. [6]

3. E-tools for e-informed consent

The main e-tools which we have used for generating a program was an IT program based on web-based facilities, animation, text and illustration, media presentation.

The IC tools could be used for supplementing the information given on paper by the research team and, even if it is not a way of reducing medical costs it is a method to verify the patient's understanding.

Also, using a tablet PC or a smartphone improves accessibility and mobility, and in time the cost could decrease. Developing a friendly interface, incorporating photography and creating a communication using calm and empathic voice could also increase the impact of e-informed consent. Also, using e-IC is not dependent on the availability of the person who informs the patients.

E-IC is also a way for the researcher to evaluate the problems in the presentation related with the number of seconds necessary for understanding a piece of information.

E-signature and the possibility to print the informed consent are also facilities which must be developed.

The video content could be also included in a specific part of the electronic library. Also it could be possible for the patients to choose the sex of person who discusses informed consent with them (male, female), in order to feel more comfortable.

The question related to understanding the program is connected with the presentation and could automatically evaluate the level of understanding.

Also, the interactive site could be used for training the researcher and current doctor or nurse related with the trial.

Nowadays, even a lot of elderly people have a high rate of satisfaction by using internet and electronic tools, [6] so is important to have the same satisfaction rate in medicine.

4. Ethical aspects and electronic informed consent

An informed choice is based on relevant knowledge, consistent with the decision maker's values, and is behaviourally implemented. [Redman]

Even if the e-IC could standardize the IC in a trial in different countries, it is still difficult to develop a web-site in different languages for the same trial. The next figure presents the main subject which must be achieved in the process of developing the web-site. [10, 11]

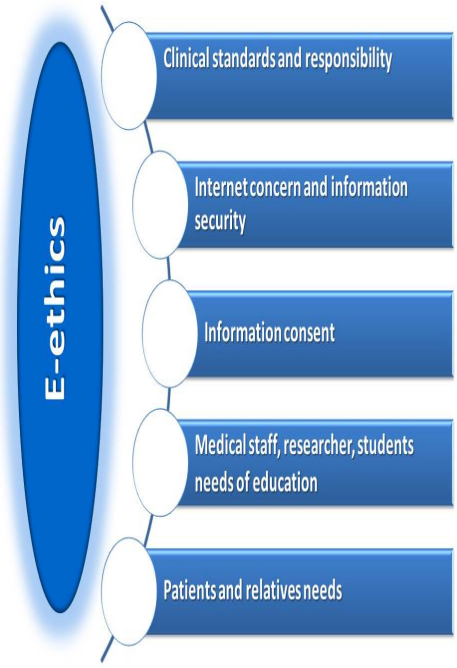

Fig.4. *E-ethics*

5. Conclusions

E-informed consent is a future method of obtaining IC and not only a way to improve the paper IC, but also a possibility to involve children in the process.

It became important to develop standards for e-IC and to increase, in time, the number of electronic tutorials.

This soft, which will be tested in the next month, is based on the experience of different specialist like doctors, computer scientist or teachers in medical fields. [12, 13]

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