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'Informed Consent' (IC) in Health Literacy (HL). State-of-the-art of an Elaborate Legal-lay Communication Process

Abstract: Informed consent (IC) is a fundamental ethical and practical part of patient care, and a critical component of clinical research: it is a mandatory legal requirement, a fundamental ethical step, and a crucial practical part both of patient care and of clinical research. A linguistic and cross-cultural approach to the study of the IC is especially complex, as it takes place at the intersection of lay (the patients or the research subjects), scientific (the physician or the researchers), and legal (the regulatory framework) discourses. From the Universal Declaration of Human Rights (1948), to the Oviedo Convention (1997-99), up to the 'Carta di Firenze' Document (2005), this contribution is aimed at defining the value of IC in terms of patients' understanding, satisfaction, and anxiety. As the state-of-the-art definition stands at present, IC is an ethical concept, but more work still is needed in the area of 'understanding' health and illness.

Keywords: *Health Communication*, *Health Literacy*, *Informed Consent*, *Legal-Lay Communication*

1. Introduction

Informed consent (IC) has been defined as "the heart and soul of the ethical dimension of science... foundational to research that involves human beings... A cornerstone in the ethics of scientific research".[1] In 2013, the U.S. Presidential Commission for the Study of Bioethical Issues defined it also as "the cornerstone of the conduct of ethical human subject research".[2] In short, IC is a fundamental principle of research ethics. Though being a relatively new concept, its history follows the broader evolution of bioethics and ethical human subject research, up to the very complex issues related to the most recent advances in medicine, technology and biotechnology.

Apart from being an ethical principle, however, IC is a 'contextually embedded practice',[3] made up of texts and conveying information through them. Moreover, it activates a very complicated communication mechanism between the IC principal users, that is, the patients and the doctors. The patient is becoming (and the patients' relatives are themselves becoming) more and more informed on any health issue, both at scientific and at legal levels: what they are all looking for is not only a qualified 'technician' but also a passionate 'supporter' and a

[1] Margaret Thomas and Nicole Pettitt, "Informed Consent in Research on Second Language Acquisition", *Second Language Research*, 33.2 (April 2017), 271-288.
[2] Presidential Commission for the Study of Bioethical Issues, *Informed Consent Background,* (Bioethics Research Library, Presidential Commission for the Study of Bioethical Issues, 2014), *bioethicsarchive.georgetown.edu*.
[3] The expression appears in: Morten Pilegaard and Hann Berg Ravn, "Informed Consent: Towards Improved Lay-friendliness of Patient Information Sheets", *Communication and Medicine*, 10.3 (January 2013), 201-211.

'caretaker'. Moreover, in past centuries, from Gregory to Percival and Hooker,[4] literature on the topic underlined the fact that the doctor, far from being a mere informant and a scientist, must be a good communicator.[5] When dealing with the patient, the doctor must have sensitive specialised knowledge together with a particularly strong psychological background, an in-depth knowledge of the main communicative and relational mechanisms (both verbal and non-verbal, cognitive and emotional) and a holistic vision of illness, along with a deep understanding of the varied signs and expressions of human discomfort and full consciousness of the criticality of information transmission for decision making.[6]

It is in this complicated context that the patient and his/her relatives have to deal with IC, which is a mandatory legal requirement, a fundamental ethical step, and a crucial part both of patient care and of clinical research. The solicitation of IC for medical procedures or research is also a significant form of legal-lay communication.[7] The process of obtaining it – that is guided and structured by requirements stated by the law – can be described as the interaction between the lay participant (patient) and a medical representative (physician): IC is a hybrid concept "which speaks both to physicians' disclosure obligations and patients' willingness to undergo a particular treatment".[8] The communication process in this special Health Literacy (HL) context takes place in the shadow of the law, whose important role is that of prodding physicians to be more attentive to patients' rights regarding decision-making.[9] As understanding the written information supplied in the document can be challenging for patients without appropriate verbal explanation by the health professional/researcher, efforts have been made to seek strategies to improve information delivery and to enhance patient/subject understanding.[10]

Our contribution aims at reviewing progress on this issue, calling attention to evidence that IC has a very long history: some debates about the role of IC in health communication and HL take their roots in ancient times. The final goal will be that of defining the real value and meaning of IC in terms of patients' understanding, satisfaction, and anxiety or other psychological distress.

2. Literature Review

[4] John Gregory, *Observations on the Duties and Offices of a Physician and on the Method of Prosecuting Enquiries in Philosophy* (London: Strahan and Cadell, 1770); Thomas Percival, *Medical Ethics: Or, a Code of Institutes and Precepts, Adapted to the Professional Interests of Physicians and Surgeons* (Manchester: Russell, 1803); Worthington Hooker, *Physician and Patient: Or, a Practical View of the Mutual Duties, Relations and Interests of the Medical Profession and the Community* (New York: Baker and Scribner, 1849).

[5] Barbara Stanley et al., "The Elderly Patient and Informed Consent: Empirical Findings", *JAMA,* 252.10 (10 September 1984), 1302-1306.

[6] Dawn Stacey et al., "Shared Decision Making Models to Inform an Interprofessional Perspective on Decision Making: A Theory Analysis", *Patient Education and Counseling*, 80.2 (August 2010), 164-172.

[7] John Conley et al., "The Discourse of DNA: Giving Informed Consent to Genetic Research", in Chris Heffer et al., eds., *Legal-Lay Communication: Textual Travels in the Law* (Oxford & New York: Oxford U.P., 2013), 247-265.

[8] Jay Kats, "Informed Consent: Must it Remain a Fairy Tail?", *Journal of Contemporary Law and Policy*, 10 (Spring 1994), 69-78.

[9] Stacey, "Shared Decision Making Models".

[10] Srikant Sarangi, "Owning Responsible Actions/selves: Role-relational Trajectories in Counselling for Childhood Genetic Testing", in Jan-Ola Östman and Anna Solin, eds., *Discourse and Responsibility in Professional Settings* (Sheffield: Equinox, 2016), 37-62.

Effective doctor-patient communication has a central clinical function. As the history of medicine demonstrates, the doctor must be familiar with the complexity of medical communication.[11]

2.1 *The early origins*

Already at the times of the ancient Greek and Roman civilisation, documents have been found that showed how the doctor's intervention had, in some way, first to be approved by the patient. Plato (Law IV) had already foreseen the problems, the procedure, and the modes of information that are, in synthesis, at the root of the principles of the present formula of IC and correlated the practice of information and consensus with the quality and social position of the patient. The doctor should only guarantee that a fundamental principle of medicine of all times is applied, that is: "in disease, focus on two aims, to improve and not to cause damage".[12]

The Hippocratic physician cared about the patient's suffering; however, s/he was also concerned with her/his own reputation, taking all necessary measures to avoid medical failure or – worse – the death of the patient, even if this meant not taking the suffering of the patient into adequate consideration. The concept of consensus did not exist at that time, although some kind of awareness of the importance of preventive information may be identified. From the early origins, following the Hippocratic tradition, the relationship between doctor and patient was based on two definite criteria, represented by the professional duty of the physician to do what is the best for the patient on the one hand, and on the other by the duty of the patient to accept the physician's decisions and intervention unconditionally and unreservedly. The foundations of this relationship are based in the famous Hippocratic Oath (c. 400 BC), provided below in a translation from Greek by Jones (end of the 19th century):

> I swear by Apollo Physician, by Asclepius, by Health, by Panacea and by all the gods and goddesses, making them my witnesses, that I will carry out, according to my ability and judgment, this oath and this indenture. To hold my teacher in this art equal to my own parents; to make him partner in my livelihood; when he is in need of money to share mine with him; to consider his family as my own brothers, and to teach them this art, if they want to learn it, without fee or indenture; to impart precept, oral instruction, and all other instruction to my own sons, the sons of my teacher, and to indentured pupils who have taken the physician's oath, but to nobody else. *I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong-doing.* Neither will I administer a poison to anybody when asked to do so, nor will I suggest such a course. Similarly I will not give to a woman a pessary to cause abortion. But I will keep pure and holy both my life and my art. I will not use the knife, not even, verily, on sufferers from stone, but I will give place to such as are craftsmen.[13]

[11] Alessandro Porro, "La dimensione psichica della terapia antica", in Carlo Cristini, ed., *Il cambiamento psicoterapeutico* (Milano: FrancoAngeli, 2012), 16-22; Alessandro Porro and Carlo Cristini, "La relazione medico-paziente: storia e attualità", *Ricerche di psicologia*, 4 (2012), 621-638.

[12] Vito Mallardi, "Le origini del consenso informato / The Origin of Informed Consent", *Acta Othorhinolaryngologica Italica,* 25.5 (2005), 312.

[13] Hippocrates, *The Oath,* in *Hippocrates Collected Works I*, trans. by W. H. S. Jones (Cambridge: Harvard U.P., 1868), *daedalus.umkc.edu/hippocrates*, emphasis mine.

The Hippocratic physician respected a principle of professional responsibility that was more religious and moral than 'legal', in the modern meaning of the word: from a legal point of view, the doctor's formal commitment was very weak inasmuch as it depended upon regulations drafted by human beings. Moreover, over the centuries the certainty that the doctor acted in the interest of the patient's well-being became so consolidated that the physician came to be endowed with moral authority and a kind of legal impunity, conditions that corresponded with the patient's duty of obedience and subjection.[14]

The submissive and passive attitude of the patient towards the physician may find its origins here. The patient's natural tendency to be psychologically subjected to the physician's choices was borne out by traditions thousands of years old. For centuries, sick people have always followed the treatment given by the doctor with an almost spontaneous attitude of respect and gratitude, never asking for any explanation regarding the therapeutic effects of the treatment itself: for his/her part, the 'caretaker' refrained from taking any initiative to inform the patient or the patient's family, unless required.

2.2 *From the 17th to the 19th century*

Two milestones of medical ethics, published in England between the end of the 17th and the beginning of the 18th century, show that the doctor had to be a good communicator and a 'caretaker'.[15] In 1770, John Gregory described communication in medicine like a sort of art:

> I shall endeavour, however, to set this matter in such a light ... that the system of conduct in a physician, which tends most to the advancement of his art, is such as will most effectually maintain the true dignity and honour of the profession, and even promote the private interest of such of its members as are men of real capacity and merit.[16]

Just a few years after Gregory, Percival's writings proposed a relationship between doctor and patient set on a different tone. The themes of value and dignity remained unchanged but the patient was no longer seen as free as it was previously: the patient's freedom was not absolute, and the doctor maintained that informing him/her could be detrimental to the positive outcome of the therapy. In short, it was right that the patient was 'kept in the dark'.

2.3 *The 20th century*

In 1986, Faden and Beauchamp indicated 1957 as the birth date of the IC.[17] In particular, the authors referred to Pernick's and Kats's articles[18] that showed the first usage of the label 'informed consent' in the court decision on 'Salgo vs Leland Stanford Jr. University': the legal

[14] Mallardi, "Le origini del consenso informato", 312-327.
[15] Gregory, *Observations*; Percival, *Medical Ethics*; Hooker, *Physician and Patient*.
[16] Gregory, *Observations*, 9-10.
[17] Ruth R. Faden and Tom L. Beauchamp, *A History and Theory of Informed Consent* (New York and Oxford: Oxford U.P., 1986).
[18] Kats, "Informed Consent", 77; Marc Pernick, "The Patient's Role in Medical Decision-Making: A Social History of Informed Consent in Medical Therapy", in President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Healthcare Decision: Studies on the Foundations of Informed Consent* (Washington: U.S. Government Printing Office, 1982), 1-35.

case[19] involved a patient named Martin Salgo, "who awoke paralyzed after aortography, having never been informed that such a risk existed".[20] The decision held that failure to disclose risks and alternatives was cause for legal action on its own. The concept was further elaborated in 1960, during the 'Natanson vs Kline court case', quoted by Murray,[21] where the court held the medical team responsible for a standard of disclosure of risks that a reasonable practitioner would provide a patient: in this case, the patient, Irma Natanson, suffered severely disabling burns as a result of cobalt irradiation for breast cancer in spite of having been told that there were no risks associated with this treatment. Nevertheless, by no means was this legal resolution accepted carelessly by the public opinion, and by the medical community above all. Following Kats:

> The emerging legal idea that physicians were from now obliged to share decision making authority with their patients shocked the medical community, for it constituted a radical break with the silence that had been the hallmark of physician-patient interactions through the ages.[22]

In other words, the two court decisions formalised the patients' right to make autonomous choices.

In fact, it seems that the first example of a legally recognised IC (conceived of in terms of asking patients' permission before activating any medical procedure) dates back the 18th century. Gallin reports that:

> In an English lawsuit, 'Slater vs Baker & Stapleton', two surgeons were found liable for disuniting a partially healed fracture without the patient's consent. This case set an important precedent described by the court: 'Indeed it is reasonable that a patient should be told what is about to be done to him that he may take courage and put himself in such a situation as to enable him to undergo the operation.[23]

Some forms of IC in medical contexts may be discovered even to about five centuries ago, although no 'medical intervention' was so clear at that time. Nevertheless, we read of an example of that time in a contribution by Selek,[24] who reports the case of a father contracting with the doctor in order to 'remove urinary stones' from his son: he had to agree before a court that he would not sue the doctor if anything went wrong.

Apart from these isolated pieces of evidence of the usage of the IC label in modern and contemporary ages, the concept was fully legitimised in 1947 with "The Nuremberg Code": this document is regarded as the first major code to contain guidelines on the ethics of medical research for the protection of human subjects in experiments. It was introduced after the Nuremberg trials, when Nazi doctors were convicted of the crimes committed during human experiments on concentration camp prisoners. The Code, based on ten points, attempted to give

[19] *Salgo vs Leland Stanford Jr. Univ. Bd. Trustees* (1957), https://caselaw.findlaw.com.
[20] Douglas S.T. Green and C. Ronald MacKenzie, "Nuances of Informed Consent: The Paradigm of Regional Anesthesia", *HSS journal: The Musculoskeletal Journal of Hospital for Special Surgery*, 3.1 (February 2007), 115.
[21] Peter Murray, "The History of Informed Consent", *The Iowa Orthopaedic Journal* (January 1990), 104-109.
[22] Kats, "Informed Consent", 72.
[23] John Gallin, "A Historical Perspective on Clinical Research", in John Gallin and Frederick Ognibene, eds., *Principles and Practices of Clinical Research,* Third Edition (London: Elsevier, 2012), 6.
[24] Salih Selek, "A Written Consent Five Centuries Ago", *Journal of Medical Ethics,* 36.10 (2010), 639.

clear rules about what was legal and what was not when conducting human experiments. The first and most important point states that anyone participating in an experiment must give 'voluntary consent': that is, nobody can be forced to participate in human trials and all participants must understand the potential risks. Moreover, the ninth point declares that:

> During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.[25]

Therefore, central to "The Nuremberg Code", which was the first to target the protection of research subjects, was the concept of subject consent. The Code was mainly enacted to ensure that participants were informed about research and voluntarily consented to participate in.

After 1947, several declarations containing recommendations for doctors followed over the years to monitor human experiments. In 1948, *The Declaration of Geneva* (known as 'Physician's Oath') was adopted by the General Assembly of the World Medical Association at Geneva (later amended in 1968, 1983, 1994 and editorially revised in 2005 and 2006).[26] It was a declaration of a physician's dedication to the humanitarian goals of medicine, intended as a revision of the 'Hippocratic Oath' into a formulation of that oath's moral truths, which could be comprehended and acknowledged in a modern way, where patient's health became doctor's 'first consideration' (article 4).

The drafting of more recent guidelines in documents such as the *Belmont Report*[27] and the *Declaration of Helsinki*,[28] followed by the *International Guidelines for Biomedical Research involving human subjects* by the CIOMS (Council of International Organisations of Medical science) in collaboration with the World Health Organisation (WHO),[29] up to the most recent guidelines designed to help applicants in getting suitable proposals for Horizon 2020 funding[30] have streamlined the guidance on conducting research and specifically on how research subjects should be informed about studies in which they are involved.

All these guidelines refer to the process of obtaining IC as a prerequisite to conducting research. They emphasise different aspects of how IC should be obtained. For example, the *Nuffield Council on Bioethics*[31] stipulates that the consent of a senior family member or community leader may be required in addition to that of an individual taking part; or, the CIOMS prefers that participants give their written consent; or, the *Helsinki Guidelines* explain how to manage in the case of minors or participants that are not able of giving consent alone. The aim of all the guidelines is to protect participants from any form of harm.

[25] "The Nuremberg Code" [1947], in Alexander Mitscherlich and Fred Mielke, eds., *Doctors of Infamy: The Story of the Nazi Medical Crimes* (New York: Schuman, 1949), xxiii-xxv, *www.cirp.org*.
[26] *The Declaration of Geneva* (1948), adopted by the General Assembly of World Medical Association at Geneva Switzerland (September 1948), *www.cirp.org*.
[27] *The Belmont Report*, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Department of Health, Education, and Welfare (April 1979), *www.hhs.gov*.
[28] *The Declaration of Helsinki*, The World Medical Association (1964-2008), *www.wma.net*.
[29] *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, Council for International Organizations of Medical Sciences and World Health Organization (1993), *apps.who.int*.
[30] *Horizon 2020 Programme: Guidance How to Complete Your Ethics Self-assessment*, EUROPEAN COMMISSION Directorate-General for Research & Innovation (4 February 2019), http://ec.europa.eu.
[31] *The Nuffield Council on Bioethics, nuffieldbioethics.org*.

3. IC in Lay Discourse

The complexity of IC understandability is linked to the complexity of the IC concept in itself, and to its sociolinguistic nature. On the one hand, doctors and researchers treat it as an event; on the other, patients and participants talk about it as a discursive process. In other words, it is:

> A process that unfolds over the course of multiple communicative interactions. Like many such processes ... it is open-ended, unstable, and sometimes unsettling. Patients import, re-contextualize, and reanimate texts from many sources as they talk about consent with the interviewer; recount (and often perform) conversations with friends, families, and even themselves; and describe their exposure to various public discourses.[32]

While talking about their IC or while filling in the IC forms, patients and participants produce constantly new meanings, causing them to challenge their previous understanding. At the end, when they sign the IC, they are supposed to be 'informed' about any health issue they are directly involved in and they 'consent' to the provision of that information in that form. They will sign it, as it is imposed by law, and in doing so they will transform their act into something ordinary.

3.1 *IC understandability*

Two studies on IC understandability factors have recently underlined the fundamental interaction between IC clarity and its ethical role:[33] if the participants do not understand its content, the researcher does not satisfy the ethical requirements to ensure that the patient is making an 'informed' decision to take part in the study, and will, therefore, not be adhering to the principle of respect for the person and for human dignity. In other words, there is at least one very strong ethical and legal implication to consider, that is, participants who do not figure out what IC implies are not providing their IC fully.

In fact, understanding even basic health information seems to be a very common and frequent issue all around the world, both for medical and for research issues. Weak health literacy and the complexity of some scientific/medical written and/or oral texts are among the most common causes of lack of understanding in IC. The 2004 *American Institute of Medicine Report*, released by the Committee on Health Literacy, insisted on the relevance of good HL as a background for IC:

> Many American adults have difficulty understanding and acting upon health information. A great deal of health information, from insurance forms to advertising, contains complex text. Even very literate people may have trouble obtaining, understanding, and using health information: a surgeon

[32] Conley et al., "The Discourse of DNA", 248.

[33] Nikolina Duvall Antonacopoulos and Ralph Serin, "Comprehension of Online Informed Consents: Can it be improved?", *Ethics and Behavior,* 26.3 (2016), 177-193; Nathalie Ilič et al., "Informed Consent Forms in Oncology Research: Linguistic Tools Identify Recurrent Pitfalls", *AJOB Primary Research,* 4.4 (2013), 39-54.

> may have trouble using an insurance form, a science teacher may not understand information about a test of brain function, and an accountant may not know when to get a mammogram.[34]

HL is the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions. However, HL goes beyond the individual. It also depends upon the skills, preferences, and expectations of those health information providers, that is: doctors, nurses, administrators, home health workers, the media, and many others. Health literacy arises from a convergence of education, health services, and social and cultural factors, and brings together research and practice from diverse fields.

Brach et al. have widely demonstrated that:

> adults with limited health literacy ... experience more serious medication errors (Schillinger et al., 2005), higher rates of emergency room visits and hospitalizations (Baker et al., 2002), worse preventive care and health outcomes for their children (Sanders et al., 2009), and increased mortality (Sudore et al., 2006; Bostock and Steptoe, 2012; Yaffe et al., 2006) compared with individuals with adequate health literacy.[35]

Moreover, HL has become recognised as an important component to delivering culturally and linguistically appropriate services. The 2001 final report of the 'National Standards for Culturally and Linguistically Appropriate Services'[36] acknowledges that addressing HL is integral to providing quality health care to diverse populations.

Miscommunication negatively affects patient care and outcomes in lots of daily situations. Misunderstandings occur not only in clinical situations, such as when treatment options and medicine instructions are discussed, but also when receptionists ask for a signature on a form and billing staff discuss covered services and financial responsibilities. Moreover, even individuals who ordinarily have adequate HL may have difficulty processing and using information when they are sick, frightened, or otherwise impaired. Systems should therefore be redesigned to accommodate the unpredictability of limited health literacy skills.[37] In other words, literacy, language, and culture are intertwined and improve the organisation's linguistic and cultural competence.[38] Finally, independently from the commitment of health organisations all around the world, participants may still have poor IC comprehension, due to careless reading, low-grade reading level, sentence length, or absence of pictures and headings. In

[34] *Health Literacy: A Prescription to End Confusion* (National Academies of Sciences, Engineering, and Medicine, Health and Medicine Division [HMD] division, April 2004), *www.nationalacademies.or*.

[35] Cindy Brach et al., *Ten Attributes of Health Literate Health Care Organizations: NAM Perspectives. Discussion Paper* (Washington DC: National Academy of Medicine, 2012), https://nam.edu.

[36] *National Standards for Culturally and Linguistically Appropriate Services in Health Care: Final Report*, U.S. Department of Health and Human Services, Office of Minority Health, (2001), 1, http://bit.ly/national-standards-report.

[37] Rima E. Rudd, "Improving Americans' health literacy", *New England Journal of Medicine*, 363.24 (December 2010), 2283-2285.

[38] Dennis Andrulis and Cindy Brach, "Integrating Literacy, Culture, and Language to Improve Health Care Quality for Diverse Populations", *American Journal of Health Behaviour*, 31.1 (September-October 2007), 122-133; Rebecca Sudore et al., "Unraveling the Relationship between Literacy, Language Proficiency, and Patient-Physician Communication", *Patient Education and Counseling*, 75.3 (June 2009), 398-402.

principle, limited health literacy has been associated with less primary intervention[39] and poor health outcomes.[40] The existing literature points to a strong relationship between patients' literacy skills and how much they know about their disease: there is a clear connection between the ability to obtain information and the need to turn that information into knowledge.

4. IC in Scientific Discourse

From a clinical perspective, the care and treatment of patients come before anything else; the research setting, by contrast, is focused on experiments or clinical trials. In the first case, doctors are concerned with seeking permission to treat patients that, by consenting, will accept risks related to treatment; in the second case, researchers look for patients' consent in order to test their study. In both cases, however, the peculiarity of IC consists in the process of informing the patients (or participants) about the planned procedure and seeking their 'voluntary' acceptance of the procedure itself.

As a result, understanding and voluntarism seem to be two fundamental prerequisites to IC, on the side of the patient. On the one hand, IC requires that the patient fully understands the information given and its relationship with his/her own personal situation. On the other, the patient must be free from "coercion and from unfair persuasions and inducements".[41] In principle, in any medical treatment as well as in research, communication between patient and doctor (or, participant and researcher), doctor's understanding of the patient's illness and fears, and patient's adherence to the doctor's recommendations are essential for correct and effective IC. In order to guarantee the process, the patient must be also given the information needed to understand a procedure by means of simple explanations: in this way, he/she will be able to make healthcare decisions and authorise the doctor to make the proposed treatment.

These considerations take us to the next step, which is related to the importance of IC legal issues.

5. IC in Legal Discourse

'Information' is strictly joined to 'consent' in the text of the 'Oviedo Convention' (dated 1997-1999),[42] signed by most of the European states, which underlines the principle according to which a person has to give the necessary consent for treatment expressly, in advance, except in emergencies, and can freely withdraw such consent at any time. The Convention stipulates that all patients have a right to be informed about their health, including the results of predictive

[39] Tracy Scott et al., "Health Literacy and Preventive Health Care Use Among Medicare Enrollees in a Managed Care Organization", *Medical Care*, 40.5 (May 2002), 395-404.
[40] Darren A. DeWalt et al., "Literacy and Health Outcomes: A Systematic Review of the Literature", *Journal of General Internal Medicine*, 19.12 (December 2004), 1228-1239.
[41] Alan Meisel et al., "Toward a Model of the Legal Doctrine of Informed Consent", *The American Journal of Psychiatry*, 143.3 (March 1977), 287.
[42] *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (Oviedo: European Treaty Series, 4 April 1997), *www.coe.int*.

genetic tests, and also recognises the patient's right not to know. Chapter 2, Article 5, declares that:

> An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.
>
> This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.
>
> The person concerned may freely withdraw consent at any time.

More recently, the 'Carta di Firenze' document, published in 2005, reinforced the same concept by stating the following ten rules:

1. The relationship between the healthcare professional and the patient must guarantee the autonomy of the person's choices.
2. The relationship is equal; it must not, therefore, be influenced by any difference in knowledge (the healthcare professional dictates the rules, the patient obeys), but marked by shared responsibilities and freedom of criticism.
3. The diagnostic/therapeutic alliance is based on the recognition of the respective competences and is based on mutual loyalty, honest information and respect for the values of the person.
4. Correct information helps to guarantee this relationship, ensure its continuity and it is an indispensable element for the autonomy of the patient's choices.
5. Time devoted to information, communication and relationship is time devoted to health.
6. Correct information requires clear and shared language. It must also be accessible, understandable, reliable, accurate, complete, evidence-based, credible and useful (decision-oriented). It should not be discriminated on the basis of the patient's age, gender, ethnic group, religion, in accordance with the patient's preferences.
7. Clear understanding of the benefits and risks (negative effects) is essential for the patient's choices, both for the prescription of drugs or other therapies in clinical practice, and for his or her entry into a trial.
8. Any declaration of any commercial or organisational conflict of interest should be part of the information process.
9. Information on therapeutic alternatives, inequality of service provision and the best diagnostic and therapeutic opportunities is essential and promotes, as far as possible, free patient's choices.
10. The doctor shall communicate the diagnosis and prognosis with humanity in a comprehensive way, respecting the patient's wishes, values and preferences.[43]

IC tends to reflect the concept of autonomy and free decision of the person requiring medical intervention. Seeking and obtaining IC, however, involves different disciplines at the same time, namely medicine, law, and moral philosophy: in fact, IC in medicine is rooted in case law, whereas in research it has its basis in ethical codes and statutes.[44] In other words, IC is a hybrid and multi-faceted text, which has gained over the years – and is still gaining – more and more importance in juridical interpretations, influencing at the same time the daily routine of medical professions.

[43] *La Carta di Firenze / The Chart of Florence* (Florence: Società Italiana di Farmacologia, 2005), *www.pharmtox.org*, translation mine.

[44] Marcela Del Carmen and Steven Joffe, "Informed Consent for Medical Treatment and Research: A Review", *The Oncologist*, 10.8 (September 2005), 636-641.

6. Conclusion

From a linguistic point of view, the IC expression 'informed consent' sounds like a hendiadys, which was born, was brought up and proliferated in a professionally and technically bound context, namely in the medical one. In spite of its strong technical foundation, however, IC boundaries have become wider and wider during the centuries, as the hendiadys was adopted everywhere, for consistent interpretative reasons. As our research has shown, defining it in all its implications and connotations is not possible unless the item is studied both diachronically and synchronically: in this second case in particular, any effort in understanding its meanings and implications must come out at the intersection of lay, scientific, and legal discourse. Therefore, a new interdisciplinary approach to the definition of the concept should be created from scratch: legal, medical and linguistic competences should find here a common ground of interest and join as a result, with the common goal of improving comprehensibility and communication in popularising scientific discourse.

As for communicative effectiveness, one of the most challenging aspects of the IC process is that of ensuring that the information provided to potential participants is both comprehensive and clear enough for the reader to understand fully. In other words, researchers must be mindful both of the ethical imperative of IC, and of the applicable regulations and laws that enforce the ethical requirements. Additionally, different research protocols and populations of research participants can necessitate alternate processes and the inclusion of additional information. For example:

> content might need to be translated into another language or written for a lower-literacy audience. Forms might need to include in-depth information about obtaining tissue samples, risky procedures, or specifically include information pertaining to alternative treatments. The informed consent process must provide enough information for research participants to understand the proposed study and its risks and potential benefits without overwhelming them with cumbersome or overly technical information.[45]

To be effective, IC must strike a balance between too much and too little information. In fact, both the quantity and the quality of IC information would deserve critical and significant scrutiny on the side of linguistic and communication experts, in order to improve participant's understanding of the required information, to document that the participant was fully informed, and to establish the participant's voluntary (and autonomous) decision to take part into any medical treatment and/or research. Linguistic support to the writing of any IC document should therefore be taken into consideration seriously for the future, in order to protect either the interests of vulnerable groups from harmful research carried out by powerful organisations or the study of powerful agencies from scrutiny by independent researchers. But this is food for further interdisciplinary research.

[45] Presidential Commission for the Study of Bioethical Issues, *Informed Consent Background,* Bioethics Research Library, Presidential Commission for the Study of Bioethical Issues, (2014) https://bioethicsarchive.georgetown.edu.