INFORMED CONSENT: THE FOUNDATION OF HUMANISTIC MEDICINE

IL CONSENSO INFORMATO: FONDAMENTO DI UNA MEDICINA UMANISTICA

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ABSTRACT

This article analyses the educational perspectives of informed consent, understood as a fundamental ethical tool for medicine based on proximity, responsibility and human dignity. It explores the evolution of the concept from "obligation to inform" to a shared decision-making, essential for building a therapeutic relationship based on trust and mutual respect between doctor and patient. It emphasises the importance of targeted training for future healthcare professionals.

Questo articolo analizza le prospettive educative del consenso informato, inteso come strumento etico fondamentale per una medicina di prossimità, responsabilità e dignità umana. Si esplora l'evoluzione del concetto da "obbligo di informare" a condivisione decisionale, essenziale per costruire una relazione terapeutica basata sulla fiducia e sul rispetto reciproco tra medico e paziente. Si sottolinea l'importanza di una formazione mirata per i futuri professionisti sanitari.

KEYWORDS
Informed Consent, Human Dignity, Responsibility, Training.
Consenso Informato, Dignità Umana, Responsabilità, Formazione.

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Introduction

Informed consent is not simply a bureaucratic formality or a signature on a form. It is the cornerstone of a form of medicine that puts the person at the centre, respecting their autonomy and dignity. This concept, which has evolved over time from a mere “obligation to inform” to a genuine process of shared decision-making, is the litmus test of a healthcare system that aims to be not only technically excellent but also deeply human. Proximity medicine is based on relationships. It is not a fleeting interaction, but a bond of trust that is built over time between doctor and patient. In this context, education on informed consent plays a crucial role. Future doctors must be trained not only to communicate clearly and comprehensibly, avoiding technical jargon, but also to listen. They must learn to understand the patient's doubts, fears and expectations, creating a dialogue between equals. Education must instil a sense of mutual responsibility: the doctor is responsible for providing all the necessary information, while the patient is responsible for actively participating in the decision-making process, aware of the choices and their consequences. This approach avoids medical paternalism and promotes a therapeutic partnership. Informed consent is the ultimate expression of human dignity in the medical field, recognising that every individual has the inalienable right to self-determination regarding their own health. In an age where medical technology offers endless possibilities, it is essential that patients do not become mere objects of care, but remain active subjects. Giving consent means choosing freely and consciously, respecting one's values, beliefs and life plans. Health education, both for professionals and citizens, must therefore aim to strengthen this awareness. Teaching patients to ask questions, seek clarification and not be afraid to express their concerns is an act of civility and a fundamental step towards a more just and equitable healthcare system. The educational prospects for a medicine of proximity, responsibility and human dignity inevitably involve a redefinition of informed consent. No longer seen as a mere legal requirement, but as an opportunity to humanise the care relationship. The training of future healthcare professionals must include specific modules on effective communication, relationship ethics and patient rights. At the same time, promoting a culture of informed consent among the general population will help to create a more transparent, participatory and, ultimately, more respectful healthcare system. In this sense, informed consent is not only a patient's right, but also an ethical duty of the doctor, a bridge that links science to solidarity and effectiveness to compassion. Informed consent and the educational prospects for community-

based and responsible medicine are intertwined on several levels; informed consent is an ethical and communicative process that guarantees the freedom and responsibility of the patient and clinician in sharing therapeutic decisions, while community-based medicine concerns care that is close to the patient, both physically and relationally, with a strong component of social and community responsibility. Informed consent is a communication process that involves the therapeutic proposal, the patient's understanding of the information and their free acceptance, an act of freedom and responsibility that marks the beginning of a course of treatment based on the relationship of trust between doctor and patient. It is an ethical practice that goes beyond legal formality, representing an opportunity for education in individual and collective awareness and responsibility in self-care.[1] Proximity medicine is also a model of care centred on physical proximity to patients and a participatory relationship with the community, going beyond the simple technical provision of services. It involves an educational approach aimed at training professionals who are not only capable of following protocols, but also of listening, reflecting and taking on human and social responsibility, thus building an attentive, empathetic and co-responsible "care community". This model supports a pedagogy of care and relief, placing the dignity and integral well-being of the person at the centre. (Zane, 2024) Responsibility concerns not only the medical act, but also the involvement of civil society, caregivers, institutions and third sector organisations, with a view to circular subsidiarity and the shared construction of responses to health needs. Educating for responsibility means promoting a culture of care that extends from the individual to the community, valuing interdisciplinary dialogue between medicine, pedagogy and other human sciences in order to respect and value the diversity and complexity of the human experience in vulnerability. (Istituto Superiore della Sanità) Ultimately, informed consent and educational perspectives for community-based and responsible medicine are based on an ethical, educational and relational vision of care, which places the patient at the centre, not as a passive subject, but as an active protagonist of their own health, embedded in a care network that also actively involves the community and institutions. Training in community medicine can improve informed consent mainly by strengthening the relationship of trust between doctor and patient, improving communication and understanding of health information, and promoting a person-centred educational approach.

[1] Informed consent. Proceedings of the Lancisiana Academy Academic Year 2018-2019 Vol. LXIII, No. 1 January-March 2019 I: 77-81

“Informed consent [. . ...] emphasises its function as a synthesis of two fundamental rights of the individual: the right to self-determination and the right to health, since if it is true that every individual has the right to be treated, he or she also has the right to receive the appropriate information [...] which must be as comprehensive as possible, precisely in order to guarantee the patient's free and informed choice and, therefore, his or her personal freedom." [2]

In this judgment read in *Giur. cost*., 2008, p. 4952, the Court deemed Article 3 of Piedmont Regional Law No. 21 of 6 November 2007 (Regulations on the use of psychotropic substances on children and adolescents) to be constitutionally illegitimate on the assumption that “informed consent must be considered a fundamental principle in the field of health protection, the formulation of which is left to state legislation”.

The role of information becomes central in that its suitability to provide the patient with full knowledge of the medical activity to which he or she is to be subjected is a determining factor in assessing the validity of consent itself. (Stanzione, 2003)

1. Training

The teaching of informed consent in Italian universities is not an educational option, but a necessity imposed by a robust regulatory and professional framework. This system of rules, which operates on several levels, ensures that future professionals are fully aware of their legal obligations and ethical duties. In Italy, there has been a regulatory development with the enactment of Law No. 219/2017 of 22 December. This law unequivocally establishes that all medical treatment must be authorised by the person concerned through “free and informed consent”. This fundamental principle is rooted directly in the Italian Constitution, in particular in Article 32, which states that 'no one may be obliged to undergo specific medical treatment except under the provisions of the law'. Further points of contact can be found in Articles 2 and 13 of the Constitution, which recognise the inviolable rights of the individual and personal freedom.

At European level, the law incorporates the principles of the Charter of Fundamental Rights of the European Union, which in Article 3 explicitly states the right to “free and informed consent of the person concerned, in accordance with

[2] Constitutional jurisprudence, 2008, p. 4952

the procedures laid down by law". This law still requires effective implementation, both in the field of public health and in terms of promoting personal freedom. This issue is now also linked to the safety of care and of the person receiving care (Law 24/2017). Training in community medicine emphasises the importance of establishing a therapeutic alliance based on mutual respect and trust between doctor and patient. This is fundamental because informed consent is based precisely on a clear, empathetic and participatory communication process, where the patient feels listened to and understood. The law has significant implications for university training, as it requires curricula to address complex issues that go beyond the mere act of signing in a comprehensive and non-superficial manner. These include the regulation of Advance Treatment Directives (DAT) and shared care planning, which must be updated as the disease progresses. The need to train professionals who are able to navigate these complexities, respecting the patient's wishes even in the event of refusal of treatment or imminent death, is a direct consequence of this legislation. (Law 2017)

The legislative framework is supplemented and reinforced by a set of codes of ethics that define the professional duties of doctors and nurses. These documents are not simple replicas of the law, but provide the ethical compass that guides the professional's daily actions. The Code of Medical Ethics (FNOMCeO) consolidates the principle of consent as a professional obligation. Article 35 specifies that doctors may not undertake or continue diagnostic or therapeutic procedures without "prior informed consent" or in the presence of "informed dissent". Other articles define the doctor's duty to provide comprehensible, complete and exhaustive information (Art. 33) and to respect the patient's wish not to be informed or to delegate the information to third parties (Art. 34). The 2014 Code also explicitly mentions consent in specific contexts, such as the processing of sensitive data (Art. 12) and experimentation (Art. 13). (enpam.it)

At the same time, the Code of Ethics for Nurses (FNOPI) focuses on the "care relationship" as "care time", emphasising the role of nurses in involving and supporting patients to encourage adherence to treatment. Nurses must obtain "free consent" to inform relevant persons and must refrain from any form of discrimination. (fnopi.it)

This coexistence of legal and ethical regulations is not redundant but creates a complementary system of cross-checking. The law establishes the patient's *right* to self-determination, while professional codes establish the professional's *duty* to respect that right. University teaching must therefore cover not only the legal responsibility that arises from breaking the law, but also professional ethics, which provides moral guidance for good clinical practice.

For doctors and healthcare professionals, there are specialised training courses that help them develop specific communication skills to explain treatment choices and care implications in an accessible and comprehensive manner. This allows patients to become fully aware of their rights and the options available to them, improving the quality of consent. Training in proximity medicine trains healthcare professionals to see patients as unique individuals with specific needs and particular life contexts. This encourages the active involvement of patients in their care pathway and decision-making process, making informed consent a moment of genuine sharing and empowerment. Educational practices that promote shared responsibility in care are based on cooperation, dialogue and the creation of networks involving professionals, families and communities. Encouraging open discussions, active listening and communication between healthcare professionals, patients and families creates a climate of trust and participation. This helps to develop shared care behaviours, where everyone feels actively involved in the process and responsible for well-being. Involving people in cooperative activities, where mutual help and collaboration are put into practice, allows them to internalise the collective dimension of care. These experiences strengthen the sense of responsibility towards oneself and others, developing interpersonal skills that are essential for supportive care. The creation of alliances between schools, families and educational/health services is crucial to supporting a network of shared responsibility that positively influences the quality of care and education.

This solidarity pact promotes continuity in education and care, respect for individual needs and the active involvement of all members of the community. Mapping, sharing and disseminating good educational and care practices helps to build aware and responsible communities that are capable of caring for their most vulnerable members in an integrated and humane way, promoting a culture of solidarity and attention to overall well-being. In summary, educational practices that promote shared responsibility for care are based on participatory communication, cooperative experiences, alliances between families and services, and the dissemination of a community culture of care and mutual respect. In order to structure shared care programmes between schools and communities, it is important to adopt a participatory and integrated approach that actively involves all actors in the area, enhancing the educational and social network. It is therefore necessary to encourage co-planning between schools, local authorities, social and health services, the third sector, families and other community stakeholders. Participatory planning is achieved through diverse working groups that value each member's skills and work together towards common goals, facilitated by coordinators. This method encourages participation and gives a voice to the educational community, making the programme truly shared and sustainable. The educational alliance between schools and families, extended to social and health

services, is fundamental in building a network of shared responsibility for education and care. This collaboration promotes educational continuity and the well-being of children, supporting their academic and social development through integrated and personalised interventions. (Marcellan et al., 2024) Programmes must promote the formation of educational communities, in which schools, families, services and associations work in synergy to respond consistently to the needs of children and families, overcoming isolation and fragmentation. Memoranda of understanding, shared good practices and continuous training for teachers and operators can be adopted in order to qualify the integrated management of situations towards objectives of inclusion and well-being. (Di Masi, 2017) Schools can be promoted as civic centres, open and shared spaces that encourage the participation and aggregation of the educational community during curricular and extracurricular hours, experimenting with care, learning and socialisation activities that strengthen territorial cohesion. Shared care programmes between schools and communities are structured around participatory co-design, educational alliances, the formation of integrated educational communities, and the enhancement of schools as open and welcoming civic spaces. University training, on the other hand, focuses on empathetic communication and active listening, offering case studies and simulations that place students in realistic doctor-patient interaction contexts, as well as exploring the right to health and self-determination. Ethical and deontological considerations are introduced to help students manage complex and conflictual situations. The use of innovative training methods, such as distance learning, interactive webinars and *role-playing* sessions*,* helps to embed a person-centred approach and a responsible attitude to consent management in students' skills. Training professionals to take a patient-centred approach to the informed consent process not only improves the quality of care but also reduces the risk of legal disputes, promoting a culture of prevention and shared responsibility. It also promotes the humanisation of care, strengthening the therapeutic relationship and the patient's active participation in healthcare decisions. Person-centred university education is an essential frontier for improving the management of informed consent. It requires the integration of legal, communication and ethical skills, with an educational approach that emphasises the centrality of the patient as an active and responsible subject of their own health choices. Best practices for teaching informed consent in university courses are based on a multidimensional approach that integrates regulatory knowledge, communication skills and practical experience. It is essential that students acquire a solid understanding of the laws and medical-legal responsibilities related to informed consent. This provides a solid foundation for understanding the relevance and ethical implications of consent in different professional practices. Teaching must include practical exercises such as role-playing, clinical case simulations, and training in empathic communication and active listening. These methods promote the ability to explain information to

patients in a clear and understandable way, which is essential for truly informed consent. The combination of classroom teaching, e-learning, interactive webinars and multimedia tools improves the effectiveness of learning, making it more accessible and engaging. The adoption of digital technologies also facilitates discussion and critical reflection on ethical situations related to consent. Teaching should guide students to consider the patient as an active and participating subject, respecting their autonomy, values and specific needs.

This radically changes the approach to consent, from a simple formal act to a process of dialogue and sharing. Best practices for teaching informed consent include regulatory knowledge, practical communication training, the use of innovative tools and person-centred education, all of which are necessary strategies for preparing competent and ethical professionals. It is essential to understand the characteristics, needs, skills and expectations of each profession involved. This allows for the modulation of language, content and examples, making communication more effective and relevant. Each profession has its own communication methods and styles; for this reason, technical content should be adapted in form and register according to the target audience (e.g., more technical for doctors, more practical for nurses, more educational for social workers). The use of clear terms, avoiding excessive technicality where unnecessary, improves understanding and application. Examples of real or simulated situations specific to each professional field should be included to help contextualise the content and promote concrete and applicable learning. Adapting content also means thinking about inclusivity, for example by using non-discriminatory and accessible language, ensuring that the information is understandable to all users, regardless of their education or background. The use of digital materials that can be modulated or customised according to the professional group allows for greater educational effectiveness and better usability. The guidelines for adapting content to different professions include knowledge of the audience, linguistic and educational customisation, the use of specific examples, inclusivity and the use of flexible tools for effective and targeted communication.

The topic of informed consent is addressed across Italian university courses, with approaches and perspectives varying according to the discipline. This multidisciplinary integration reflects the intrinsic complexity of the subject, which intersects ethics, law, clinical practice and communication. In medical and surgical faculties, informed consent is a central topic in both compulsory and optional courses. It is integrated into courses such as 'Bioethics and the Evolution of Medicine', which places it within a broader debate on complex ethical issues such as euthanasia, organ donation and genetic experimentation. (Lum.it) It is also a fundamental module in courses such as “Legal Medicine, Bioethics and Professional

Responsibility", which is a compulsory training activity in courses such as Healthcare. (Unit.it) Training does not end in the classroom but extends to practical internships, where attendance is often compulsory and monitored by the University. (Unimib.it) This integration of theory and practice is essential for the acquisition of relational and decision-making skills. For professionals who wish to explore the subject in greater depth, there is a wide range of postgraduate courses available, including first-level master's degrees such as the "Master's in Bioethics for Clinical Trials and Ethics Committees" (Univpm.it) and ECM-accredited continuing education courses, such as those offered by professional organisations.

The teaching of informed consent is not exclusive to medical faculties. For example, law faculties address it through emerging disciplines such as "biolaw" and "biolaw", which explore the relationship between law and ethical and biological issues. (Uniroma.it)

An illuminating example is the curriculum of the "Biolaw" course at the University of Udine (Uniud.it), which demonstrates a three-part teaching structure to address the topic comprehensively:

- a Philosophical-Ethical-Legal section: This explores subjective rights, individual autonomy and informed consent from a broader perspective.
- a Legal-Administrative part: Focuses specifically on the civil liability of doctors, with attention to the consequences of compensation.
- A legal-pharmacological section: introduces students to the scientific concepts of biomedical experimentation to help them understand the bioethical implications and legal requirements of consent.

The legal approach is structurally different from the medical one. While the physician focuses on consent as a central element of the "care relationship", the lawyer analyses it as an expression of a fundamental right to self-determination. This divergence of perspectives is crucial and prepares professionals to interact in complex scenarios where legal, ethical and clinical skills must necessarily intersect. Training on informed consent is also extended to degree courses for healthcare professions, as in the case of "Healthcare".

This recognition demonstrates that the responsibility for obtaining valid consent is not the exclusive prerogative of the physician, but a shared duty within the multidisciplinary care team. Communication dynamics, understanding the patient's wishes and documenting consent are skills that all healthcare staff must possess.

The teaching of informed consent does not rely solely on theoretical lessons, but integrates innovative teaching methodologies to ensure that students are able to apply their knowledge in real-life contexts. Lectures and the study of academic textbooks remain the basis of training. University texts explore the intersection

between bioethics and law, commenting on recent regulations and providing a solid conceptual framework. These materials are essential for understanding the legal foundations and ethical principles governing consent. (Libreria universitaria.it)

To bridge the gap between theoretical knowledge and practical competence, universities are investing in experiential learning methodologies. Clinical simulations provide a risk-free environment in which students can practise complex procedures, hone decision-making skills and improve teamwork. (Anginproject) Role-playing has proven to be a particularly effective tool for teaching medical ethics, communicating difficult news, and obtaining informed consent. This methodology allows students to experience the perspectives of both the patient and the physician, building empathy and trust in a protected environment. However, the effectiveness of this approach depends on its correct implementation, as issues related to embarrassment or lack of realism can limit its benefits. (Bharti, 2023)

The study of complex cases and guided debates are central to bioethics programmes. Analysing situations such as a minor's refusal of treatment or the debate on end-of-life care allows students to apply normative and ethical principles to non-linear scenarios, preparing them to deal with the dilemmas they will encounter in their professional careers. The concept of informed consent is moving beyond the strictly medical sphere to become a broader principle of social and educational self-determination. The example of the Valditara Bill and Bill C. 2423, which introduce “informed consent” for extracurricular activities at school, demonstrates this evolution. This phenomenon is extremely significant, as it highlights how the concept is not static but constantly changing. Faculties of law, education and other disciplines will inevitably have to integrate this new interpretation of consent into their curricula, analysing its legal and social implications. (Camera.it)

The increasing digitisation of healthcare, through telemedicine and electronic health records, presents new challenges for obtaining consent. Although patient consent can also be obtained using IT tools, university education must prepare professionals to document consent in a secure and valid manner in the digital context, ensuring data protection and full understanding by the patient. (Informed consent, Enpam.it)

Conclusions

Informed consent is the cornerstone of the modern healthcare relationship, going beyond its role as a mere bureaucratic formality to establish itself as an ethical and legal principle that protects the autonomy, dignity and self-determination of the individual. Historically, the relationship between doctor and patient has undergone a profound transformation, evolving from a purely paternalistic model, in which decisions were made unilaterally by the professional for the presumed "good" of the patient, to a relational and shared approach. In this new paradigm, the patient is no longer a passive subject but an active partner in the decision-making process concerning their own health. This cultural and legal change has made the teaching of informed consent a central and unavoidable component of contemporary university education, particularly for the health and legal professions.

In the past, the doctor-patient relationship was often based on a paternalistic model, where the doctor held the knowledge and made decisions for the good of the patient, who was expected to trust blindly. Today, this model is outdated. Informed consent is based on genuine dialogue, a communication process that requires time, empathy and listening skills on the part of the healthcare professional. It is not a matter of "getting someone to sign" a form, but of establishing a true therapeutic alliance, in which the patient is an active and informed participant.

Despite progress, training on informed consent still presents challenges that will require careful consideration by academic institutions. The fact that informed consent is taught in different faculties (Medicine, Law, Health Sciences) carries a risk of "silo training", in which each professional learns about the subject exclusively from their own disciplinary perspective. This approach can lead to a lack of mutual understanding between professionals who will need to collaborate closely in the future. A future perspective will necessarily have to promote joint teaching and interdisciplinary projects, to reflect the reality of the healthcare team and to train professionals capable of navigating the complexities that arise at the intersection of legal, ethical and clinical skills. University education on informed consent in Italy is based on a solid regulatory and ethical framework, which requires professionals to act with respect for patient autonomy. Academic curricula, despite different approaches between medicine and law, demonstrate a clear desire to integrate the topic. The use of practical teaching methods, such as simulations and case studies, is a fundamental step in ensuring not only theoretical but also practical training.

Despite its central importance, the teaching of informed consent in medical and healthcare degree courses still has some gaps. It is often reduced to a few theoretical lessons, which address the legal aspects and pay little attention to the ethical, communicative and relational aspects. The ability to communicate complex information in an understandable way, to respond to doubts and to understand the patient's fears cannot be learned from books. It requires a teaching approach that integrates theory with practice through simulations, role-playing and the analysis of clinical cases.

There is a clear need to overcome disciplinary fragmentation by implementing more integrated and interdisciplinary courses of study. In addition, universities will need to remain agile in updating their programmes to reflect the growing relevance of informed consent in non-strictly clinical settings and to address the challenges posed by the digitalisation of healthcare. The training of mature and aware professionals will require a constant commitment to promoting dialogue between ethics, law and clinical practice. University education has a responsibility to overcome the reductive view of informed consent as a mere bureaucratic formality. It must train healthcare professionals who know how to build a relationship of trust and who are capable of active listening and effective communication. This approach not only respects the dignity of the patient, but also contributes to improving the effectiveness of care, as an informed and involved patient is more motivated and adherent to the treatment plan. Santorosso and Mori's reflections remind us that informed consent is an act of civility, a bridge between science and the individual, which must be at the heart of healthcare education and practice.

Author contributions

The authors contributed equally to the article.

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