

## Article

## Advance care directives: Citizens, patients, doctors, institutions

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## Significance for public health

The impact of such legislation on public health could be significant for various reasons: empowering individuals who are able, precisely, to make decisions “now” to be applied “later”, means fully respecting an individual’s choices irrespective of the reasons: for example, the reasons may be of an entirely personal nature, in some cases driven by the past experience of someone they know, or of a religious nature, with repercussions on the family (such as their children’s health). In this sense, healthcare choices are identified with full acceptance of individual empowerment, which can occur only after the doctor has provided the person/patient with adequate information. Moreover, should the patient refuse treatment, the health resources allocated for their treatment could be re-allocated to another individual who needs them and could benefit in terms of quality and quantity of life.

## Abstract

Italian Law no. 219/2017 established the advance care directives (“Disposizioni anticipate di trattamento” – DAT), a legal document specifying the person’s wishes in relation to health, drawn up in case of the possible future incapacity to make informed decisions. DAT are an important instrument of empowerment for a person who is not necessarily a “patient” and enable the dialogue between healthcare providers and patient to continue when the latter is no longer able to take part consciously. DAT can only be implemented by guaranteeing the fundamental rights of the person, *i.e.* by ensuring the “non-complicated” use of this instrument and easy access to the DAT whenever it may be necessary. Furthermore, on the one hand, the requirement of adequate prior medical information has to contend with the fact that the wishes expressed in the document may have been formed outside of the therapeutic relationship; on the other hand, institutions must ensure that DAT are collected and recorded in such a way as to ensure their availability whenever and wherever necessary.

## Directives

The medicalisation of our existence and the progress of scientific research and technology have highlighted the need to redefine the boundaries of the therapeutic relationship and reaffirm the central importance, in the care pathway, not of the disease but of the patient, considered holistically, which also includes their preferences, personal beliefs, values and their notion of quality of life.

From this perspective, in order to forge a relationship based on consent and guarantee a treatment pathway based on the appropriateness of care, commensurate with the clinical condition and the person, Italian Law no. 219/2017<sup>i</sup> established the advance care

directives (“Disposizioni anticipate di trattamento” – DAT), a legal document containing a person’s wishes in relation to health, drawn up in case of the possible future incapacity to make informed decisions.

The need to value any wishes previously expressed and guarantee they are respected in the event of incapacity of the person concerned can be observed in past judgments ruled by the Italian Courts, in doctrine, in the initiatives of the regional and national legislator and of local institutions.<sup>1</sup> In particular, the institution of the Support Administration (“Amministrazione di sostegno”), introduced in order to ensure adequate support for any person who, due to an illness or physical or mental impairment, is unable, even partially or temporarily, to take care of their own interests, provided space for promoting these advance directives.<sup>ii</sup> The practice of including a document of prior designation of a support administrator, in anticipation of possible future incapacity, with the indication of their preferences regarding care, led to the recognition of this document as the tool through which to convey advance expressions of will, without prejudice to the effective recognition these wishes being subject to legal scrutiny, should the need to protect the individual arise.<sup>2</sup>

For five years now, moreover, these DAT have not challenged the medical Code of Ethics: put simply, once *declarations* they then became *provisions*, perhaps also because the power to instruct can only result from a regulatory intervention that, above all, clarifies simultaneously the limits and the content of the professional obligation of counterbalancing.<sup>3</sup>

The subjective requirements of the DAT are being of legal age and being of full mental capacity, a requirement that raises the question of the procedure for establishing this capacity, in particular in the case of a legal document delivered to the municipal civil registry office or to healthcare facilities. The law does not contain any reference to the legal capacity, nor to the *status civitatis* of the signatory: the Council of State has specified that the national database used to record the DAT may also collect the DAT of persons not registered with the National Health Service,<sup>4</sup> since this entails the constitutionally recognised guarantee of fundamental human rights.

<sup>i</sup> Law of 22 December 2017, n. 219 (Rules on informed consent and advance care directives - “Norme in materia di consenso informato e di disposizioni anticipate di trattamento”), published in the Official Gazette n. 12 of 16 January 2018.

<sup>ii</sup> Law of 9 January 2004, n. 6 (Introduction in the first book, Title XII of the Civil Code of Chapter I, relating to the establishment of the Support Administration and amendment of articles 388, 414, 417, 418, 424, 426, 427 and 429 of the Civil Code in respect of interdiction and incapacitation, as well as the rules of implementation, rules of coordination and final rules – “Introduzione nel libro primo, titolo XII, del codice civile del capo I, relativo all’istituzione dell’amministrazione di sostegno e modifica degli articoli 388, 414, 417, 418, 424, 426, 427 e 429 del codice civile in materia di interdizione e di inabilitazione, nonché relative norme di attuazione, di coordinamento e finali”), published on the Official Gazette n. 14 of 19 January 2004.

DAT must be drawn up after having acquired adequate medical information about the consequences of personal choices. Legislation does not specify the source and procedure for acquiring such information by a person who is not necessarily a “patient”: while a qualified professional would guarantee the requirement of adequacy, especially with respect to “DIY” searches, recourse to DAT, a typical instrument for exercising a fundamental individual right, must be prevented from being too expensive or difficult precisely in terms of acquiring this adequate information.<sup>5</sup> DAT are an instrument of empowerment, and they can only be implemented by guaranteeing the fundamental rights of the person, *i.e.* by ensuring the “non-complicated” use of this instrument; on the other hand, although DAT are an ideal tool for continuation of the dialogue when a patient is no longer able to make an informed contribution,<sup>6</sup> the requirement of adequate prior medical information has to contend with the fact that the wishes expressed in the document could also have been formed outside of the therapeutic relationship.

The Council of State observes,<sup>4</sup> including in relation to the possible liability of the doctor who adheres to the DAT, considering them to be valid, that there is a clear need for certainty regarding the “adequacy” of the medical information acquired by the person concerned and regarding the consequences of their choices and states that although this cannot be identified in terms of the validity of the legal document, it seems definitely appropriate to certify this circumstance.

According to the National Council of Notaries it is desirable that the document proves the provision of the medical information necessary to formulate the provisions,<sup>7</sup> with the added option, when drafting, of referring to or attaching medical documents or providing the name of the physician with which the signatory had contact, as the opening part of the document.

DAT may include instructions relating to specific health treatments, but may also cover a wider scope of expressions of wishes in the medical field, in relation to a broader and more complex universe of principles and personal values that help shape a person’s attitude towards choices in this field.<sup>8</sup>

In this context, the so-called “fiduciario” can play a central role, as the trusted person indicated by the signatory – and who has accepted the appointment – with the task of acting on his/her behalf and representing him/her in relations with the doctor and with the healthcare facilities or guaranteeing his/her wishes are respected, including by updating such wishes: the need for a prior agreement between the doctor and the proxy, who knows the biographical identity as well as the most intimate intentions of the patient, would significantly reduce the risk of deviation from the instructions departed.<sup>9</sup> The figure of the proxy restores the relationship of care and trust with the doctor and the healthcare team in view of the decisions to be taken, on the basis of an appointment founded on the choices made by the patient-signatory,<sup>10</sup> promoting the individual autonomy and allowing the “dual” configuration of the relationship, despite the incapacity of the person concerned.

DAT must only be disregarded for medical and health reasons:<sup>8</sup> evident inconsistency or non-correspondence to the actual clinical condition of the patient or the existence of treatment that was unforeseeable at the time of signing and that offers the real possibility of improving the standard of life.

DAT can take the form of public deed or authenticated private writing or private writing delivered personally by the signatory to the civil registry office of the municipality of residence or to the healthcare facilities, where legally permitted, without prejudice to the option of using video recording or communication devices for people with disabilities.

The provision of such formal requirements, much more rigor-

ous than that required for informed consent to health treatment,<sup>iii</sup> raises the question of the binding nature of all those statements that, although documented and/or documentable, are not expressed in the forms established by special rules or delivered to the offices of the public administration indicated,<sup>9</sup> such as indications expressed on social media or by computer or telephone or in writing. Considering these other expressions of personal wishes could also help to reconstruct the wishes of the person concerned, within the framework of a legal system that puts the person “at the centre”, even when they are incapable of making their own decisions, acting in the best interests of the patient will become central among the requirements for certainty of the form – to protect the content and the origin of a document that is still, broadly speaking a living will – and attention to the substance emerging from the declaration – in view of fulfilling the intimate wishes of the person – in any circumstance, mode or form expressed, provided that it is documentable.<sup>9</sup> It is here, therefore, that the legislator confirms and strengthens the jurisprudential approaches, under a seal that will now be very difficult to break in court.<sup>11</sup> And, above all, it will no longer be necessary to go to court: firstly, and quite simply because the proxy, unlike a support administrator, does not require a decree of appointment by the judge supervising the guardianship, but merely the drafting of a public record, an authenticated private agreement or a private agreement delivered to the civil registry office (art. 4, par. 6). Secondly, because the legislator has specifically outlined the boundaries within which the patient’s wishes may legitimately be expressed and be respected: therefore, judicial authorisation will no longer be required in order to respect a refusal that directly results in death – something that was previously approved and sometimes required from the standpoint (in part understandably) of defensive medicine. Consequently, the tutelary judge will only rise in the case of conflict between doctor and legal representative (whether they be the parents of a child, the guardian of an incapacitated person; the carer of a disabled person or support administrator of a beneficiary) *i.e.* where the healthcare staff and the proxy do not agree as to the contents and the procedure for application of the DAT. This could be due to uncertainty or an omission regarding the individual’s genuine wishes and a lack of agreement between *guarantor* and expert (doctor), who objectively considers and pursues the best interests of the incapacitated person, and an individual equally acting as guarantor who does not protect the person through a specific profession, but by means of a power (in any case attributed by the court or by legislation) mostly justified by closeness, a relationship with the sick person. Consequently, where such a discrepancy of opinions and views does not occur judicial intervention is not envisaged, as it would result in the (incompetent) examination of the evaluation carried out by medical staff, also *verified* by the proxy (for example, for DAT that do not provide for the case that actually occurred) or by the legal representative. Therefore, if, in a case of equity interests (acts of extraordinary administration) of the incapacitated person is brought before a judge, it is because the work of the representative is not acknowledged. On the other hand, if the cessation of treatment results in the patient’s death this is certainly an extreme and very serious result, but justified by an evaluation of the lack of “appropriateness” and “need” (art. 3, par. 5), *i.e.* treatment that is no longer proportionate nor justifiable, endorsed by a person who, by law, pursues nothing but the interests of the incapacitated person.

<sup>iii</sup>Art. 1 (Informed consent) Paragraph 4 of Law n. 219/ 2017 establishes that informed consent, acquired in the ways and with the instruments best suited to the conditions of the patient, shall be documented in written form or through video recordings or, for people with disabilities, through devices that allow them to communicate. Informed consent, in whatever form expressed, shall be included in the clinical dossier and in the electronic health file.

The seal of the judge would add nothing new, different or further, to a similar, joint evaluation, unless there is doubt over whether the healthcare staff may be driven by the aim of conserving resources and the legal representative may have gone against their appointment.<sup>12</sup>

The difference between shared care planning and advance care directives fully lies in the prior establishment, or not, of the doctor-patient relationship. This distinction, however, not only operates in terms of timeliness of the consent and “relationship” between the individual and healthcare staff, but also with regard to the disclosure and knowledge of these documents, where the provision for their inclusion in medical records (art. 5, par. 4) presupposes precisely that the patient already has a medical record and one or more attending physicians. If, instead, this has not already been undertaken, the problem of recording such documents becomes of capital importance, capable of invalidating the innovativeness of a good part of the reference legislation, only requiring the delivery of a copy to the proxy in person (in terms of timeliness and effectiveness of knowledge of the document, without counting the non-mandatory nature of the designation of a ‘trusted’ person). The only tool useful for this purpose – a single computerised national register – has not yet been established, as well known.

The Italian Data Protection Authority issued an opinion on 29 May 2019 on the draft decree for the institution at the Ministry of Health of a national database for the collection of advance care directives.<sup>13</sup>

This database, established at the Ministry of Health, will have the purpose of recording DAT, promptly updating them in case of renewal, amendment or revocation and providing full access to the doctor who is treating the patient in the case of incapacity to make their own decisions, as well as to any possible trustee appointed by the patient; the database will also record the possible appointment of a proxy and the database functions will also be guaranteed for persons not registered with the National Health Service.

The data will be kept for 10 years from the death of the person concerned and may be accessed by the doctor who is treating the patient unable to express their wishes, and the proxy, where appointed.

The database will be fed by municipal civil registry officials, notaries and the person in charge of the relevant organisational unit of the Regional Authorities that provide the service, with which the “original copies” DAT are filed.

Pending the completion of the national database the Data Protection Authority has asked for greater safeguards as regards the procedures for access to DAT by the doctor who is treating the patient or by the proxy; the Authority has also asked for the correct identification of the parties who, as data controllers, are authorised to transmit the DAT to the database. The Ministry must therefore identify procedures that better comply with privacy regulations in order to provide the doctor and the proxy with information about the existence of the declaration and the place where it is stored.

Blatant inconsistencies in the DAT (or lack of correspondence with the actual medical condition of the patient), moreover, allows (*i.e.* forces) the physician to disregard them (art. 4, par.5). Within this projection, on the other hand, it seems reasonable to include the hypothesis of excessive vagueness (*i.e.* insufficient detail), inherent in an automatism and bureaucracy that poorly marry with an adequate and authentic evaluation of personal wishes.

More broadly, it concerns the possibility of respecting DAT where not adequately expressed in terms of the accuracy of the language, informed choices and knowledge of the relative consequences. There is a problem, therefore, of terminology; of the passing of time (since there is no deadline, the healthcare staff could feel less and less constrained, as the years go by); of a change in

the state of the art, but also the evolution of the disease (what seemed “extraordinary” and unacceptable becomes ordinary and easily conceivable, even in one’s own body). In this sense, moreover, the further we move from the expression of wishes by the person directly concerned, the greater the risk that the proxy will interpret them, rather than respecting and applying them.<sup>11</sup>

The intervention of the legislator takes on, first and foremost, a strong and distinct ethical meaning, with regard to both health and judicial operators; it states and specifies the aegis of the Fundamental Charter; it reinforces and supports the guidelines and the developments of ordinary, administrative and constitutional rulings in recent decades.<sup>14</sup> The result, therefore, is that it relieves the Code of Ethics of inappropriate deputising functions and creates *ad hoc* legal institutions to resolve the problems in question (against the efforts made by the courts to adapt the existing institutions). The legislator’s wish, therefore, is not to establish and regulate liability *ex post* from the additional or sole perspective of sanctions, but rather to encourage, as far as possible, the adoption of consensual doctor/patient decisions, reconstructing and humanising the relationship, relaxing the tone and clarifying the mutual rights and obligations.<sup>15</sup> It is the role of the judge, however, to come out the other side changed, where their intervention is required only as a last resort in cases of otherwise irresolvable conflict between science and personal wishes - against the activism and creativity requested of them more or less recently.<sup>3</sup>

Measures have been taken to recover the data relating to the filing of DAT with notaries in Brescia or with the Municipal Authority; up to June 2019, only 8 DAT have been filed with notaries (8 notaries involved), of which 3 men and 5 women, 7 Italians and 1 German (of 98 notaries, 50 responded to our request); the men were aged 43, 60 and 72 years, while the women were aged 60, 66, 69, 75 and 83.

As regards filing with the Municipal Authority, the legal documents were accessed at our request by a Municipal Councillor.

We would like to specify that 169,219 persons of legal age are registered with the Brescia Municipal Registry. As at 27 June 2019, 758 DAT have been received and filed with this Municipal Authority. There are no other data available since the Ministry of the Interior, with Circular no. 1 of 4.2.2018 laying down the operational instructions for Civil Registry Officials on the matter, specifies that the Office having received the DAT, must limit itself to recording an ordered chronological list of the declarations made and ensure their appropriate storage in conformity with the principles of confidentiality of personal data referred to in Legislative Decree no. 196 of 30.6.2003.

In accordance with this Circular, the Office periodically discloses the number of DAT received to the above-mentioned Ministry, by means of the Territorial Government Office - Prefecture of Brescia. DAT are registered at the counters for registering Civil Registry declarations in full compliance with the confidentiality and protection of personal data required by law for these special and particular declarations. Up to June 2019, the data at our disposal revealed that only a small segment of the population has “responded” to the possibility of drawing up advance care directives. This is probably due to several factors: first and foremost, last year and even now there is very little information on the subject. In fact, the legislation may well be not at all well-known and only a small proportion of the population knows what advance care directives are. Whereas, on the one hand, we have all become accustomed to being asked for our consent, for example for processing personal data, or in healthcare, it has become common practice to ask for consent to “act” on the body of patients, it is not yet in our mind-set to think in advance about what we would want or, more importantly, not want to happen in the event that, in the

more or less immediate future, we were to find ourselves needing medical care. In this latter case we refer, for example, to the refusal of certain treatments, such as blood transfusions, by Jehovah's Witnesses, who could therefore be interested in DAT precisely for the purposes of such refusal. Such declarations would therefore explain and legalise a refusal motivated by religious choices.

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