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Knowledge, opinion and attitude about the Italian law on advance directives: a population-based survey

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Abstract

Introduction: Advance directives are legal documents which individuals draw up to declare their treatment preferences and to appoint well-informed proxies to safeguard patient autonomy in critical situations when that individual is temporarily or no longer able to communicate these preferences. On December 22, 2017, the Italian Parliament approved the first law on end of life (“Provisions for informed consent and advance directives” L.219/2017), after a heated public and political debate lasting almost twenty years. **Objective:** The aim of this study was to investigate the awareness, knowledge, opinions and attitudes regarding Italian Law 219/2017 and advance directives among the Italian population 15 months after its entry into force. **Methods** A nationwide population-based survey was conducted by a certified public opinion survey company. A sample size of 2000 interviews was planned. A structured questionnaire was developed to investigate awareness, opinions and attitudes concerning the law by a multiprofessional research team. The agreed-on version was pretested on a sample of 70 selected participants. **Results:** The sample included 2000 valid interviews; 70.1% of respondents declared they had heard about the law on informed consent and advance directives. Respondents were asked to express their overall opinion on the law’s utility and importance: 88% declared that the law was quite or very important and 76% had a positive attitude towards making/registering advance directives. **Conclusion:** The principles of Italian Law 219/2017 are aligned with the ethical sentiment of the vast majority of the Italian population. It is crucial to stimulate discussion to increase knowledge and awareness in order to increase the number of advance directives.

Key words: Advance Directives, Informed Consent, Ethics, Survey

Running Title: A population-based survey on Advance directives

Key message: This population-based survey investigated the awareness, knowledge, opinions and attitudes regarding Italian Law 219/2017 and advance directives 15 months after its entry into force. The study shows

a positive attitude towards and substantial agreement with the law, including controversial issues. It is crucial to stimulate discussion in order to increase the number of advance directives.

Introduction

Advance directives – also known also as a living will or advance care planning dispositions – are legal documents which individuals draw up to declare their treatment preferences and to assign well-informed proxies to safeguard patient autonomy in critical situations when that individual is temporarily or no longer able to communicate these preferences. (1) Advance directives valorize personal autonomy because they allow individuals to express their wishes “now for then” on end-of-life care. The ethical debate on advance directives revolves around the concept of autonomy, the issue of quality of life, the meaning of care and treatment and the role – and limits – of medicine. It stimulates medical, ethical, social and cultural reflection.

The legal status of advance directives throughout Europe varies greatly, with some countries having no specific legislation yet and which have no concrete plans to introduce it. While the contents of the laws differ to some degree, all describe advance directives as legally binding, with the exception of France: advance directives there only give physicians guidance on shared end-of-life decision-making. (2)

Despite efforts to respect patients’ preferences in end-of-life decisions, more than 34.6% of cancer patients still die in hospital, even though we know that almost all of them wished to die at home. (3)

On December 22, 2017, the Italian Parliament approved the first law on end of life (“Provisions for informed consent and advance directives” L.219/2017), (4) after fervent public and political debate lasting almost twenty years. The process of passing the law began in 2004; its basis is in a regulatory framework that clearly states the principle of voluntariness of receiving healthcare treatments (5). Despite the fact that the Italian Constitution (6), national and international documents (7,8) and the Italian code of medical ethics (9) provide for individual agency in healthcare, the country was divided politically and culturally on certain fundamental issues such as the withdrawal of life-sustaining treatments, often assimilated to euthanasia (5), palliative sedation, physicians’ conscientious objection and the importance meaning of advance directives. While there are many who supported the full rights of every capable individual to make autonomous choices

regarding medical treatments, even in anticipation of future events, there were also those who believed that the right to exercise autonomy should have some limitations (10). Two high-profile cases guided public debate: the case of Eluana Englaro (11) and that of Piergiorgio Welby (12).

Eluana Englaro's death occurred in 2009, after 18 years in a vegetative state caused by a car accident. She died after the withdrawal of artificial hydration and nutrition after the Italian Supreme Court had ruled, for the first time in Italy, that treatment should be stopped (13). Her father fought against Italian public opinion (11) for 18 years to respect his daughter's prior wishes that she not receive futile treatments.

Piergiorgio Welby was affected by facioscapulohumeral dystrophy. After his condition gradually deteriorated over the course of 35 years to the point that he could no longer breathe on his own, he was kept alive by invasive mechanical ventilation against his will. He was competent and asked for the withdrawal of mechanical ventilation and for palliative sedation. After many legal appeals that were fruitless, Welby died in 2006 with the assistance of the only Italian physician willing to help him. After Welby's death, the physician was charged with consensual murder. The judge in the case, however, dismissed the case against the doctor. Law n. 219 regulates not only advance directives but also several rights citizens have regarding healthcare issues, including the right to be fully informed about one's health status and to give consent (or dissent) to treatment, the right to withhold consent to lifesaving treatments, the right to be assisted until death and the right to express preferences and wishes through advance directives (Box 1). Moreover, the law states that the physician has a duty to respect the patient's wishes; as a result, the physician cannot be held liable under civil or penal law for doing so. Nevertheless, this obligation to respect the patient's wishes remains one of the most controversial issues of the law for healthcare professionals. In the absence of any clear legislative definition, fear of litigation may have contributed in the past to an increased risk of not respecting patients' wishes (10).

Despite the fact that this law deals with an individual's fundamental rights, that it affects healthcare policy and that its impact and implementation only depend on citizens' awareness and knowledge of these rights,

to date only one survey on awareness of and opinions on advance directives has been conducted, using a journalistic rather than a scientific approach. (14)

Given the absence of any nationwide scientifically collected data, we conducted a survey on the Italian population to discover whether they knew about the law, how they perceived it and whether they had exercised their rights under the law.

The aim of this study was to investigate the awareness, knowledge, opinions and attitudes regarding Italian Law 219/2017 and advance directives among the Italian population 15 months after its entry into force.

Methods

Design and participants

A nationwide population-based survey was conducted by a certified public opinion survey company between April and May 2019. A sample size of 2000 interviews was planned to obtain a precision of $\pm 2\%$, with 95% confidence, in estimating a hypothetical prevalence of 25%, i.e., the average expected prevalence for each answer on a four-point Likert scale. The random sample, stratified by geographical macro area, age [18-34; 35-54; >54] and sex, reflecting exactly the same distribution as the Italian adult population, was planned. It included 1000 individuals drawn from a list of telephone contacts and 1000 from the e-mail list of website contacts. The two lists were composed of people who had been actively contacted by the certified public opinion survey company for any reason and who voluntarily signed up to become members of survey panels. The samples were uploaded onto an integrated CATI/CAWI (computer-assisted telephone interviewing/computer-assisted web interviewing) platform that managed the data inserted by the interviewer or directly by the interviewee.

Individuals that were not reached or who refused to participate were automatically randomly substituted by other individuals drawn from the same stratum of the lists. Formal verbal consent was obtained at the beginning of phone interviews, while an electronic consent form was collected before the online interviews.

Measurements

A structured questionnaire was developed to investigate awareness, opinions and attitudes concerning Italian Law 219/2017 by a multiprofessional research team. The questionnaire was based on a review of the literature and on discussions among the researchers. During this phase, we conducted 10 cognitive interviews (15) with a convenience sample to test the comprehensibility of this version of the questionnaire. The 10 sample subjects were stratified by sex, education level and age. In one-to-one interviews, we solicited verbalization by using 'think aloud' and verbal probing techniques (16) to access respondents' thoughts and feelings and to understand their ideas and interpretations. (17) The thematic analysis of the cognitive interviews allowed us to make the questionnaire items simpler and more understandable.

Finally, the version revised accordingly was pretested on a sample of 70 selected participants, who were asked to give feedback on the questionnaire. Some questions were changed slightly based on the pretest participants' suggestions.

The final version of the survey addressed the following topics: 1) sociodemographic variables (sex, age, education level, employment status, place of residence, health status, religion); 2) awareness of the law; 3) awareness and opinion regarding the rights guaranteed under that law; 4) awareness and opinion of advance directives; 5) willingness to write an advance directive and how it was done. Specifically, participants were asked about informed consent, the right to be informed of one's health status, the right not to know one's health status, the right to withdraw from or withhold treatment, physicians' conscientious objection, palliative sedation and advance directives. The English translation of the survey questions is provided in Box 2.

CATI interviewers attended a two-day training course during which the objectives of the study were explained, as was the content of each question. Role play exercises were conducted to train the interviewers on how to respond to interviewees' questions and to manage possible requests about privacy issues and data protection. Finally, the interviewers were tested on their interviewing skills through a videotaped simulation.

People completing the survey on the CAWI platform could call a toll-free number if they needed any help; trained interviewers answered these calls.

Statistical analysis

We report frequencies for the main concepts of interest: awareness of the law, knowledge of its main content, ethically relevant issues of the law, attitudes and whether the rights under the law had been exercised. For each proportion we give the 95% confidence interval; variance was estimated with SPSS statistical package, taking into account sampling design.

The analysis of the specific knowledge of the main concepts and rights was restricted to people who were aware of the law; results are presented also stratified by age (<65 and ≥65).

The proportion of individuals who were aware of the law and their opinions on ethically relevant issues of the law are also presented by sex, age, geographical macro area, urban/rural residence, education level, self-reported health condition and religion. Attitude towards and actual experience with AD are presented by all the covariates above and also according to the opinions reported on ethically relevant issues.

No formal test of hypothesis was performed. P values should be interpreted as continuous variables representing the probability that the observed difference, or a larger one, would occur under the hypothesis that the groups, defined by age or other stratifying variables, would have the same proportion of answers for a given item. No significance threshold was set.

Results

Knowledge and awareness of the law on informed consent and advance directives

The substitution rate was 25% for CATI, 23% for CAWI, 12% for refusals and 12% for those who were unreachable. The sample included 2000 valid interviews, in 70.1% of which (No. =1403) (Table 1) the respondent declared he/she had heard about the law on informed consent and advance directives.

The proportion of people who reported having heard about the law was slightly higher among females, those over age 65, those with a high education level and those living in an urban area (more than 30,000 inhabitants). Instead, there was no difference in awareness by religion, geographical area or perceived health status (Table 1). The vast majority of those who had heard about the law had learned about it on TV or in the newspaper (76.6%), with a higher proportion among people aged 65 or over (81.3%). Conversely, only 16.2% and 15.1% reported having learned about the law on online news outlets and social media, respectively. These proportions were lower for people aged 65 or over (11.6% and 11.1%, for online news outlets and social media respectively) (Table 2).

The vast majority of the 1403 who had heard about the law declared they knew about each of the specific rights stated by the law. The most known right was the right to be informed about one's own health status (95.4%), while the least known rights were the right not to be informed of one's health status (53.1%), the right to palliative sedation (68.5%), the right to withdraw ongoing treatment (72.9%) and the right to withhold artificial nutrition and hydration (75.4%) (Table 3). All the other rights under the law (Box 1) were known by 80%-90% of respondents (Table 3). Knowledge was substantially similar in people under and over age 65, with only slightly more knowledge in older than in younger people concerning the right not to be informed, the right to withhold artificial nutrition and hydration, the right to avoid aggressive treatments and the right to appoint a patient advocate.

Opinions about ethically relevant issues

All the respondents, regardless of their previous knowledge of the law, were asked for their opinion on a controversial point of the law: the physician's obligation to respect a patient's wishes, including that of withholding and/or withdrawing life-saving treatment. The vast majority of the participants agreed with the law: 82% and 80% to withhold and to withdraw treatment, respectively. There were only slight differences between groups, with slightly greater agreement for those over age 65, for those residing in northern and central Italy and for agnostics or atheists. The pattern was almost identical for withholding and/or withdrawing treatment (Table 4).

Respondents were asked to express their overall opinion on the law's utility and importance: 87.6% declared that the law was quite or very important (Table 5).

Attitude towards and experience with AD, by all covariates and opinions

Of the total sample, 76% had a positive attitude towards making/registering advance directives, and 4.9% (95% CI = 3.9-6.0) declared they had already made an advance directive. Positive attitudes and actual experience were more frequent in those who agreed with the part of the law stating physicians' obligations and in agnostics and atheists. Older people showed a higher proportion of positive attitude but a lower proportion of practice than did younger people. It should be noted that 8 out of the 98 respondents who declared having made an advance directive also declared that they had never heard about the law.

Discussion

The study investigates the awareness, knowledge, opinions and attitudes regarding Italian Law 219/2017 and advance directives among the Italian population after the entry into force of that law. To our knowledge, this is the first Italian population-based study addressing these issues.

The study shows a positive attitude towards and substantial agreement with the law, including controversial issues such as the physician's obligation to respect a patient's wishes concerning withholding and/ or withdrawing life-saving treatment. This result is interesting, given that there was fervent debate in the years before the law was passed and several attempts had been made to implement regulations using a variety of approaches.(18) Italian Law 219 does not provide for a physician's conscientious objection; it explicitly and unequivocally defends the patient's right to freedom of choice (including the right to refuse life-sustaining treatment). A physician's professional autonomy is limited by the recognition of the patient's autonomy, which is expressed by the right to have his/her wishes respected. (19)

According to our study, there are no or small differences in attitude by sex, age, geographical area, education level and religion. We were surprised to find that attitudes towards AD were not influenced by variables that, in other health-related problems, are known to have enormous influence on behaviours, self-efficacy, access

to healthcare services and expectations of public services in general (20). In fact, other studies have underlined the impact of demographic and religious factors on making advance directives (21).

Despite the fact that over 70% of the respondents had heard about the law, about two third declared they were well or quite well informed. There are specific differences in knowledge: participants reported little knowledge especially regarding the right not to be informed, the right to withdraw ongoing treatment and palliative sedation. While limited knowledge of the first issue is not surprising since it applies to very specific situations, limited knowledge is surprising for the other two, which were the focus of a debate in the Italian media for two reasons: physicians' conscientious objection and the difference between palliative sedation and euthanasia.(22)

According to a recent Italian Ministry of Health report, 62,030 advance directives were officially registered up to May 2019, accounting for 0.12% of the adult population (23). In the same period, slightly less than 5% of respondents in our survey declared that they had already made advance directives. Such a large discrepancy suggests that many people are not aware of what advance directives are and/ or do not know the legal procedures needed to make them. Nevertheless, the percentage we registered is in line with the international literature, where the percentage ranges from 0.5% (China) to 24% (Switzerland) (24-26).

The data presented in this paper were collected while implementation of the law was still incomplete; in particular, an Italian National Registry of Advance Directives will come into operation only in February 2020. This national registry will make any individual's wishes as expressed in an advance directive available to all physicians throughout the country, which is particularly important in light of the several kinds of barriers to implementing advance directives in daily clinical practice reported in the literature. These barriers include ethical and legal concerns, healthcare providers' knowledge of and confidence in the law, subjective perception and understanding and concerns about advance directives (27).

The principle of Italian Law in terms of respecting a patient's present and future autonomy is aligned with the ethical sentiment of the vast majority of the Italian population.

The prevalence of people who have made an advance directive seems to be in line with other countries with similar laws, but it is crucial to promote public initiatives and use online resources to increase the number of advance directives (28-30).

Limitations of the study

We used self-reported information, which can be rather imprecise when trying to measure the number of registered advance directives, as discussed above. However, it is the only method available to assess knowledge, attitudes and opinions on this topic. Data on the number of advance directives made are probably overestimated; the relatively high proportion (8%) of people who stated they did not know about the law but who also declared they had made advance directives suggests that these were in fact only informal expressions of their wishes.

Some of the items on the questionnaire may have been misunderstood or some concepts may have been hard to grasp. For example, while respondents reported the same high score for both the utility and the importance of the law, with the vast majority thus having positive attitudes, very few had actually already made or planned an advance directive. This implicitly means that even if respondents perceived the law as important, they did not actually consider it useful or urgent for themselves.

The sample size was large enough to give very precise estimates of awareness, knowledge and attitude towards the law at the national and geographical macro area level, while for some subpopulations of particular interest, for example non-Catholics, the sample was too small. The substitution rate is low compared to other similar studies using online interviews (31) but in line for telephone interviews, (32,33) which is reassuring. Nevertheless, telephone and e-mail lists of people accepting to be contacted for future surveys are not a random sample of the general population, even if the final sample accurately reflected the Italian adult population in terms of age, sex and geographical distribution. Thus, we do not know how the initial selection may have biased the sample.

Conclusions

The study shows that Italian public opinion of the law on advance directives is positive, but also that many people do not know the legal procedures to make advance directives. Our results highlight the need to activate public information services and campaigns to ensure that citizens know their rights as granted under this law, which is crucial to improving the quality of end-of-life care. Moreover, based on these results, further studies that investigate healthcare professionals' knowledge of and opinions on the law would help to guarantee patients' quality of life.

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Conflict of interests:

None declared.

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