#### REVIEW

# Development and Validation of a Questionnaire investigating the Knowledge, Attitudes and Practices of Healthcare Workers in the Field of Anesthesiology concerning the Italian Law on Advance Healthcare Directives: a Pilot Study

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Abstract. Advance healthcare directives are legal documents, in which the patient, foreseeing a potential loss of capacity and autonomy, makes in advance decisions regarding future care and, in particular, end-of-life arrangements. In Italy, advance healthcare directives are regulated by the Law 219 of 22 December 2017. Objectives of the study were: i) to develop and validate a questionnaire dedicated to evaluate the knowledge of the Law in a sample of 98 anesthesiologists, and ii) to shed light on the process of health-related decision-making and its determinants (age, gender, doctor/training resident, religious beliefs). A second part of the survey not analyzed in the present study, aimed to assess, through two simulated clinical scenarios, how patient' directives, relatives and the medical staff could influence physicians' clinical decision. Overall Cronbach's alpha coefficient of the questionnaire resulted 0.83. Three factors explaining up to 38.4% of total variance (communication and relationship with the patient; critical life-threatening situations and binding nature of the advance directive for the physician; and involvement of patients). Most of the doctors (58.7%) did not fully know the recent legislative provision. The lack of knowledge is critical in view of the specificity of the clinical area investigated (anesthesiology and intensive care), which has to cope with ethical issues. An adequate revision and implementation of the traditional curricula could help medical students and trainees develop the aptitudes and skills needed in their future profession. (www.actabiomedica.it)

**Keywords:** advance healthcare directives, knowledge, attitudes and practices questionnaire, survey, development and validation of questionnaire, exploratory factor analysis, bioethics

## Introduction

Advance healthcare directives are legal documents, in which the patient, foreseeing a potential loss of capacity and autonomy, makes in advance decisions

regarding future care and, in particular, end-of-life arrangements. Advance health directives can pave the way for a truly authentic patient-tailored management, in which the patient is empowered, actively and mutually involved in the therapeutic process.

Patient's opinions, considerations and preferences are highly valued by healthcare providers, being taken into account in the development and implementation of health plans, and the risk of interferences is counteracted or, at least, minimized. In Italy, advance healthcare directives ("Disposizioni anticipate di trattamento" or DAT), commonly referred to as "biological testament", are regulated by the article 4 of the Law 219 of 22 December 2017, entered into force on 31 January 2018. In anticipation of a possible future loss of self-determination and having previously acquired adequate medical information on the consequences of one's own choices and having understood it, the Law provides the possibility for each person to express his/ her will in terms of consent or denial, regarding diagnostic tests, therapeutic choices and healthcare treatments. The objectives of the present study were: i) to develop and validate a questionnaire specifically dedicated to evaluate the knowledge of the Law number 219/2017 in a sample of anesthesiologists daily facing ethical issues in their clinical practice, and ii) to shed light on the process of health-related decision-making and its determinants (age, gender, doctor/training resident, religious beliefs).

# **Experimental Section**

## Ethical Approval

The Ethical Committee of Liguria Region fully approved the conduct and publication of the present investigation. The latter was carried out in accordance with the ethical research principles delineated by the Helsinki Declaration.

# Questionnaire Development

The questionnaire was developed by: i) experts on bioethics, legal medicine, anesthesiology and medical statistics, ii) based on an extensive literature search, iii) some focus groups with a number of physicians, and iv) expert opinions. The survey was composed by two parts. The first part comprised of different sections: namely, i) a general section, including sociodemographic variables (age, gender, type of physician),

ii) a single item in which the subject was asked to self-rate his/her knowledge on a scale from 0 to 5, and iii) a set of 17 items investigating clinician agreement (on a scale from 0 - "totally disagree" to 5 - "totally agree") on how DAT may influence patient-doctor communication and clinical decision-making regarding controversial clinical issues (Table 1).

The second part aimed to assess, through two simulated clinical scenarios, how patient' directives, relatives and medical staff could influence physicians' clinical decision. The present article focus only on the analysis and validation of the first part of the survey. The questionnaire was distributed to all the intensivists working in emergency room, intensive care units (ICUs) and operating rooms of the Policlinico San Martino Hospital of Genoa, Italy. The questionnaire was generated and distributed via email invitation using a commercial survey software (SurveyMonkey; https://www.surveymonkey.com). Answers were collected anonymously.

# Descriptive Statistics

Before commencing any statistical analysis, data were visually inspected for potential outliers. Normality of data distribution was checked using the Pearson-D'Agostino omnibus test. Questionnaire scores were also checked for skewness and kurtosis, computing the Mardia's multivariate skewness and kurtosis statistics. Internal consistency/reliability analysis The reliability of the questionnaire was investigated computing the Cronbach's alpha coefficient, the magnitude of which was interpreted according to the following rule of thumb: the coefficient was deemed excellent if the estimate was >0.90, whereas it was judged good in the range 0.80–0.90, acceptable in the range 0.70–0.80, adequate in the range 0.60–0.70, poor in the range 0.50–0.60, and unacceptable if <0.50.

## Exploratory Factor Analysis

Given the nature of the present investigation (pilot study), an exploratory factor analysis (EFA) was carried out in order to capture the structure underlying the questionnaire. Sampling adequacy for the factor analysis was measured by the Kaiser-Meyer-Olkin

(KMO) test. The number of factors to be extracted was based on simulations conducted by means of parallel analysis and on the visual inspection of the Cattell's scree plot. Factor loadings were rotated with varimax rotation. For properly interpreting the factors, the following criteria were used: i) loadings were retained if properly saturating a factor (that is to say, loading greater than 0.30), ii) in case of cross-loading, the factor in which the saturation was characterized by the highest loading was chosen, also taking into account both the salience of the loading and the theoretical framework, which was used to inform and guide the development of the questionnaire.

# Software

Psychometric properties were assessed utilizing the open-source software Jamovi. All other statistical analyses were conducted by means of the commercial software "Statistical Package for Social Sciences" (SPSS for Windows, version 24.0, IBM, Armonk, NY, USA).

### Results

A sample of 115 subjects volunteered to participate to the present study. Since 17 questionnaires were returned with missing data, the final analysis involved 98 questionnaires (completion rate of 85.2%). Each item is reported in Table 1.

Fifty-six subjects were females (57.1%), whereas 42 (42.9%) were males. Concerning religious beliefs, 32 (32.7%) were atheists, 57 (58.2%) Christians, and 1 (1.0%) Orthodox. Eight (8.2%) individuals self-defined as belonging to other faiths or creeds. Twenty-five participants (25.5%) were aged in the range 24-29 years, 30 (30.6%) in the range 30-39 years, 21 (21.4%) were from 40 to 49 years, 18 (18.4%) from 50 to 59 years, and 4 (4.1%) were 50 years and older. Concerning marital status, 35 subjects (35.7%) were married, 25 (25.5%) were single, 4 (4.1%) were divorced, 3 (3.1%) were separated, and 31 (31.6%) were living together with their partners. 21 (21.4%) had one child, 18 (18.4%) two or more children, whereas 59 (60.2%) no children. Forty-five (45.9%) were training

**Table 1.** Items of the questionnaire investigating the knowledge, attitudes and practices of healthcare workers in the field of anesthesiology towards the Law regulating the advance healthcare directives (DAT).

Options	Number	Percentage			
"Personal level of knowledge of the new law on medical consent and treatment DAT"					
0	4	4.1%			
1	9	9.2%			
2	20	20.4%			
3	37	37.8%			
4	23	23.5%			
5	5	5.1%			
Question 1: "It drafting	is appropriate for t of the DAT with fa	he patient to share the mily members"			
0	6	6.1%			
1	3	3.1%			
2	11	11.2%			
3	27	27.6%			
4	23	23.5%			
5	28	28.6%			
Question 2: "T	he new law is an op dialogue with the	oportunity to improve carer"			
0	2	2.0%			
1	4	4.1%			
2	16	16.3%			
3	39	39.8%			
4	37	37.8%			
5	2	2.0%			
DAT can be an		of knowledge about colve the patient in the are path"			
0	0	0.0%			
1	0	0.0%			
2	1	1.0%			
3	9	9.2%			
4	35	35.7%			
5	53	54.1%			
	tunity to improve p	knowledge about DAT atient-healthcare team			
	communicatio				
0	0	0.0%			
1	0	0.0%			
2	3	3.1%			
3	7	7.1%			

Options	Number	Percentage			
4	35	35.7%			
5	53	54.1%			
Question 5: "The most controversial issues with family members concern: How much do you agree on the binding nature of DAT for the doctors?"					
0	6	6.1%			
1	8	8.2%			
2	10	10.2%			
3	18	18.4%			
4	33	33.7%			
5	23	23.5%			
	Nutrition and artificermanent vegetative	icial hydration in the ve state"			
0	9	9.2%			
1	16	16.3%			
2	8	8.2%			
3	22	22.4%			
4	30	30.6%			
5	13	13.3%			
Q	uestion 7: "Deep s	edation"			
0	5	5.1%			
1	7	7.1%			
2	11	11.2%			
3	22	22.4%			
4	31	31.6%			
5	22	22.4%			
Que	stion 8: "Assisted v	entilation"			
0	12	12.2%			
1	16	16.3%			
2	13	13.3%			
3	12	12.2%			
4	24	24.5%			
5	21	21.4%			
	Question 9: "Pain t	herapy"			
0	3	3.1%			
1	5	5.1%			
2	15	15.3%			
3	27	27.6%			
4	27	27.6%			
5	21	21.4%			

Options	Number	Percentage
	: "Transfer to the i	ntensive care unit"
0	2	2.0%
1	4	4.1%
2	9	9.2%
3	19	19.4%
4	33	33.7%
5	31	31.6%
	he binding nature ho has become inc	of the will of the person
0	2	2.0%
1	7	7.1%
2	8	8.2%
3	20	20.4%
4	29	29.6%
5	32	32.7%
Question	12: "Evaluation of	patient capacity"
0	3	3.1%
1	4	4.1%
2	6	6.1%
3	21	21.4%
4	22	22.4%
5	42	42.9%
Question 13: "	The truthful infor	mation to the patient"
0	3	3.1%
1	3	3.1%
2	7	7.1%
3	20	20.4%
4	30	30.6%
5	35	35.7%
the patient in		ow how to present to ng his illness and the lequate manner"
0	0	0.0%
1	5	5.1%
2	16	16.3%
3	22	22.4%
4	25	25.5%
5	30	30.6%
	L	L

(continued)

Options	Number	Percentage			
Question 15: "The level of training needs to present the patient with information regarding his illness and the treatments proposed in an adequate manner"					
0	1	1.0%			
1	1	1.0%			
2	10	10.2%			
3	29	29.6%			
4	33	33.7%			
5	24	24.5%			
		anizational problems on the decision shared nt"			
0	9	9.2%			
1	7	7.1%			
2	15	15.3%			
3	19	19.4%			
4	32	32.7%			
5	16	16.3%			
	he patient does no essary to make a tr	t possess the skills and reatment decision"			
0	2	2.0%			
1	1	1.0%			
2	6	6.1%			
3	22	22.4%			
4	32	32.7%			
5	35	35.7%			

residents. Mean self-rated knowledge of the Italian law on advance directives resulted 2.83±1.17 (median 3).

Most of the doctors who responded to the survey (58.7%) did not fully know the recent legislative provision, with 28.3% considering themselves competent in the matter. Score distribution, descriptive statistics, and correlation analysis for the 17 items are reported in Tables 1, 2 and 3, respectively.

Overall Cronbach's alpha resulted 0.83 and sampling adequacy as measured by the KMO was 0.74 (ranging from 0.52 for item 17 to 0.83 for item 11) (Supplementary table 2). Three factors (i) "communication and relationship with patients", ii) "binding nature of the DAT", and iii) "critical situations for the physician") explaining up to 38.4% of total variance were extracted.

Table 2. Descriptive statistics of the questionnaire.

		C. 1 1	Sko	ewness	Kı	ırtosis
Item	Mean	Standard deviation	Value	Standard error	Value	Standard error
Q1	3.45	1.41	-0.82	0.24	0.17	0.48
Q2	4.07	0.94	-1.04	0.24	1.05	0.48
Q3	4.43	0.70	-1.01	0.24	0.45	0.48
Q4	4.41	0.76	-1.28	0.24	1.43	0.48
Q5	3.36	1.47	-0.82	0.24	-0.21	0.48
Q6	2.89	1.55	-0.47	0.24	-0.95	0.48
Q7	3.36	1.40	-0.78	0.24	-0.10	0.48
Q8	2.85	1.73	-0.28	0.24	-1.29	0.48
Q9	3.36	1.29	-0.58	0.24	-0.11	0.48
Q10	3.73	1.23	-1.00	0.24	0.62	0.48
Q11	3.66	1.32	-0.90	0.24	0.13	0.48
Q12	3.85	1.32	-1.14	0.24	0.80	0.48
Q13	3.80	1.26	-1.15	0.24	1.09	0.48
Q14	3.60	1.22	-0.43	0.24	-0.89	0.48
Q15	3.67	1.05	-0.61	0.24	0.40	0.48
Q16	3.08	1.50	-0.64	0.24	-0.52	0.48
Q17	3.88	1.12	-1.14	0.25	1.65	0.49

The first factor, including items related to communication and relationship with the patient, explained up to 16.8% of the total variance; the second factor, including items related to specific treatment decision and binding nature of the advance directive for the physician, explained up to 10.9% of the total variance; and the third factor, including items related to the involvement of the patients, explained up to 10.6% of the total variance (Table 4).

At the correlation analysis (Table 5), the association between the first two factors yielded a coefficient of 0.57 (p<0.0001), while the associations between the first and the third factors and between the second and the third factors a coefficient of 0.27 (p=0.0079) and a coefficient of 0.20 (p=0.0496), respectively.

At the multivariate regression analysis (table 6), younger age (regression coefficient=-2.03, p=0.0029), being female (regression coefficient=-2.31, p=0.0427), and having a religious creed (regression coefficient=3.23, p=0.0080) resulted independent predictors of the score obtained for the first factor ("communication and relationship with patients"). Younger age (regression coefficient=-3.16, p<0.0001)

Table 3. Item-total correlation analysis.

Item	Scale mean if item deleted	Scale variance if item deleted	Corrected item- total correlation	Squared multiple correlation	Cronbach's alpha if item deleted
Q1	57.94	114.78	0.30	0.35	0.83
Q2	57.31	117.50	0.36	0.36	0.82
Q3	56.97	121.27	0.26	0.37	0.82
Q4	56.98	120.69	0.27	0.41	0.82
Q5	58.06	110.92	0.41	0.42	0.82
Q6	58.51	106.30	0.53	0.57	0.81
Q7	58.05	111.40	0.42	0.41	0.82
Q8	58.58	104.04	0.53	0.50	0.81
Q9	58.04	113.79	0.38	0.26	0.82
Q10	57.66	109.32	0.59	0.55	0.81
Q11	57.72	108.96	0.55	0.47	0.81
Q12	57.54	107.91	0.59	0.59	0.81
Q13	57.61	108.56	0.60	0.60	0.81
Q14	57.79	111.47	0.49	0.57	0.81
Q15	57.72	115.32	0.41	0.39	0.82
Q16	58.32	112.31	0.35	0.28	0.82
Q17	57.52	121.45	0.13	0.20	0.83

**Table 4.** Findings of the exploratory factor analysis.

Item		Loadings	
Item	Factor 1	Factor 2	Factor 3
Q1	0.39		
Q2			0.62
Q3			0.56
Q4			0.63
Q5		0.64	
Q6		0.56	
Q7		0.65	
Q8		0.42	
Q9		0.31	
Q10		0.37	
Q11	0.53		
Q12	0.75		
Q13	0.50		
Q14	0.64		
Q15	0.47		
Q16	0.38		
Q17			0.31

**Table 5.** Correlation analysis among the factors of the questionnaire.

	Correlation analysis		F2	F3
F1	Correlation coefficient Significance Level P	-	0.57 <0.0001	0.27 0.0079
F2	Correlation coefficient Significance Level P	0.57 <0.0001	-	0.20 0.0496
F3	Correlation coefficient Significance Level P	0.27 0.0079	0.20 0.0496	-

and having children (regression coefficient=3.65, p=0.0114) were found to be independent predictors of the score of the second factor ("binding nature of the DAT"). No statistically significant determinants could be found for the score of the third factor ("critical situations for the physician"). Younger age (regression coefficient=-5.50, p<0.0001), being a female (regression coefficient=-4.25, p=0.0456) and having children (regression coefficient=6.31, p=0.0205) resulted predictors of the total questionnaire score.

**Table 6.** Multivariate regression analyses investigating co-variates associated with the questionnaire scores, for each factor (F1, F2, and F3) and for the total questionnaire.

Independent variables	Coefficient	Standard Error	Т	P	r partial	<b>r</b> semipartial
		F1			partial	J. Sempartar
(Constant)	23.92					
Age	-2.03	0.66	-3.07	0.0029	-0.31	0.29
Gender	-2.31	1.12	-2.06	0.0427	-0.22	0.19
Having children	1.63	1.43	1.14	0.2591	0.12	0.11
Marital status	0.65	1.25	0.52	0.6048	0.06	0.05
Religious beliefs	3.23	1.19	2.72	0.0080	0.28	0.25
Working in the ICU	0.54	1.33	0.40	0.6885	0.04	0.04
Working in the ER	2.43	1.64	1.48	0.1423	0.16	0.14
Working in the operating theatre	1.67	1.35	1.23	0.2206	0.13	0.11
Having a family member with end-of-life related issues	1.34	1.17	1.15	0.2521	0.12	0.11
		F2	•			
(Constant)	20.05					
Age	-3.16	0.65	-4.85	<0.0001	-0.46	0.44
Gender	-1.48	1.11	-1.33	0.1860	-0.14	0.12
Having children	3.65	1.41	2.59	0.0114	0.27	0.24
Marital status	0.73	1.23	0.59	0.5564	0.06	0.05
Religious beliefs	0.41	1.17	0.35	0.7256	0.04	0.03
Working in the ICU	-0.20	1.31	-0.15	0.8785	-0.02	0.01
Working in the ER	1.63	1.61	1.01	0.3157	0.11	0.09
Working in the operating theatre	1.53	1.33	1.15	0.2527	0.12	0.11
Having a family member with end-of-life related issues	0.69	1.15	0.60	0.5528	0.06	0.05
		F3	•			
(Constant)	15.36					
Age	-0.31	0.31	-1.00	0.3192	-0.11	0.10
Gender	-0.46	0.53	-0.88	0.3828	-0.09	0.09
Having children	1.03	0.67	1.53	0.1305	0.16	0.16
Marital status	0.67	0.59	1.13	0.2599	0.12	0.12
Religious beliefs	0.22	0.56	0.40	0.6922	0.04	0.04
Working in the ICU	0.61	0.63	0.97	0.3346	0.10	0.10
Working in the ER	0.37	0.77	0.48	0.6302	0.05	0.05
Working in the operating theatre	0.54	0.64	0.84	0.4020	0.09	0.09
Having a family member with end-of-life related issues	0.50	0.55	0.91	0.3655	0.10	0.09
		All items				
(Constant)	59.33					
Age	-5.50	1.23	-4.46	<0.0001	-0.43	0.40
Gender	-4.25	2.10	-2.03	0.0456	-0.21	0.18

Independent variables	Coefficient	Standard Error	Т	P	r partial	r semipartial
Having children	6.31	2.67	2.36	0.0205	0.25	0.21
Marital status	2.05	2.34	0.88	0.3832	0.09	0.08
Religious beliefs	3.86	2.22	1.74	0.0850	0.18	0.16
Working in the ICU	0.94	2.48	0.38	0.7051	0.04	0.03
Working in the ER	4.43	3.06	1.45	0.1510	0.15	0.13
Working in the operating theatre	3.74	2.52	1.48	0.1420	0.16	0.13
Having a family member with end-of-life related issues	2.53	2.18	1.16	0.2483	0.12	0.10

#### Discussion

In this article, we have reported the findings of the validation and the preliminary results of an ad hoc developed questionnaire aimed to investigate the knowledge, attitudes and practices concerning the Italian Law on DAT in a sample of healthcare workers in the field of anesthesiology in an Italian Hospital. We found that the questionnaire was well accepted by the healthcare workers, with a high compliance rate and with very few missing item values, supporting, as such, the feasibility of its administration in clinical settings. A psychometrically sound tool is of crucial importance in that it enables to obtain valid and reproducible measurements. As such, a thorough assessment of its reliability involves a series of statistical analyses aimed to determine the internal consistency of the given questionnaire. More in detail, the reliability is evaluated according to each domain of the tool, with the assumption that all the questions/items belonging to the same domain are strongly interrelated and investigate the same topic. From the literature, it is well-known that the internal consistency coefficient tends to increase with the increasing number of questions/items belonging to the same specific domain. Generally, the reliability is commonly evaluated by means of the Cronbach's alpha coefficient, with ideal values ranging between 0.70 and 0.80. In the present study, the overall coefficient measuring DAT-related knowledge, attitudes and practices was 0.83, which can be considered more than satisfactory. Although being adequate for a pilot-testing and validation analysis, the single-center nature and the small size of the sample under examination allow purely indicative and partial considerations, calling for

caution in interpreting and generalizing the present findings. Nevertheless, given the systematic recruitment of healthcare workers from the same medical specialization and working in similar wards (first aid, intensive care and operating theater) and, as such, facing similar bioethical issues, it is possible to make some reflections, even if preliminary. From the data analysis, it seems to emerge, as a significant critical factor, the lack of knowledge of the law by professionals, who, for the peculiar clinical activity carried out, are constantly engaged in the front-line and have to cope with particularly critical, life-threatening situations. An important results of this study is the relative higher importance assigned to controversial issues related to communication compared to that related with decision on specific treatments. These data are in line with a the results of a recent survey among Italian anesthesiologists endorsed by the Italian Society of Anesthesiology Analgesia Reanimation and Intensive Care (SIAARTI) that showed important lack in training in palliative/supportive care, a field strictly connected with that explored in the present study. A process of constant training and updating represents or, better, should represent, for this type of professionals, an unavoidable need, both from a personal and a professional standpoint. This need is even more crucial for doctors in training, for whom studying and being updated are qualifying, essential, aspects.. The findings of the present data analysis, therefore, call for the urgency of a profound reflection and in-depth study regarding the knowledge of bioethical topics, attitudes and practices within the medical community. Appropriate initiatives aimed at increasing the development of ethical competences and skills are indispensable to support healthcare personnel in clinical practice.

The lack of synergy and integration between technical, scientific and ethical skills can, in fact, entail negative consequences on the correct professional work of health personnel, affecting, at least partially, their qualification. The training should also include non-technical skills such as relational and communicative skills, including introspection, mindfulness, management of complex professional issues such as mourning and the relationship with death. More specifically, based on the data, the legislation concerning DAT is generally positively perceived by the majority of the interviewed doctors, who consider it as an opportunity to improve the dialogue and the relationship with the patient. This may also suggest an experience of general difficulty in the daily life of the clinical practice in dealing with complex and, also, ethically controversial issues, in the absence of certain reference parameters. Therefore, specific regulations on delicate and crucial bioethical aspects can therefore be considered from healthcare personnel as suitable guidelines and checklists that can facilitate the process of therapeutic alliance. On the other hand, the juridical provision, especially that regarding controversial topics, is the result of extremely complex activities in which the legislator has made several efforts in order to reach a balance between different opinions, ideological positions and points of view. The binding or merely indicative nature of the provisions has been, indeed, a central issue in the national debate in which various social promotion associations have actively participated, together with the public opinion. Briefly, the Italian National Bioethics Committee (NBC) issued an opinion in 2013 in which, while generally acknowledging the validity of the DAT, considered their application being subject to a discretionary appreciation from the doctor, on a case-by-case basis.

According to this opinion, the choice of considering the DAT as indicative and not binding will was a compromise between a therapeutic abandonment and a disproportionate and futile excess of care. Also the 2014 Medical Ethics Code, which, before the law came into effect, had already provided indications on the DAT, had established that the doctor was not obliged to respect the DAT, but only to "take them into account". The law on the DAT has operated a significant shift, both theoretical and practical, by replacing

the "discretion/appreciation" of the doctor with the "binding" nature of the DAT, which is a "disposition/ directive", and not a mere "declaration". The legislator has, indeed, introduced the concept of a "mitigated constraint", depriving the physician of the discretionary possibility of ideologically evaluating the choice made by the individual, but, at the same time, indicating well-defined, precise areas in which it is possible to disregard such indications (being incongruous, contradictory or superseded by the scientific progress). For instance, in situations where the treatment would be perfectly suitable to ensure an improvement in health conditions, the doctor is not obliged to comply to the DAT. Moreover, the choice of the Italian legislator of acknowledging a general binding nature (in the fulfillment of some requirements) of the DAT is aligned with decisions established by different legislations, i.e. Germany, Belgium, Austria, Finland, Hungary, Netherlands, Spain, some cantons of Switzerland, and UK. In the debate concerning the binding nature of the DAT, one of the most crucial controversial bioethical aspects concerned the anticipated rejection of artificial nutrition and hydration practices.

This debate was mainly fostered by the case of Eluana Englaro, an Italian woman in a persistent vegetative state, whose father, being her legal guardian, initiated a legal battle for the suspension of artificial feeding and hydration. The Italian Court of Cassation sentenced that nutrition and hydration could not be considered as medical treatment, allowing Englaro's father the right to ask to stop his daughter being artificially fed. This juridical provision ignited a highly polarized discussion, with the Italian Roman Catholic Church being fiercely against the Supreme Court's decision. Another controversial, complex ethical issues are how to communicate patient's illness and the possible treatment options, and the patient's deliberative capacity, which can be impaired, in a temporary or permanent way, by mental pathologies or chronic-degenerative, progressing diseases. The possibility of appointing a legal trustee/guardian as proxy decision-maker can constitute a precious element in order to acquire clarifying elements regarding future choices. The issue of deep palliative sedation is a further topic of concern for the population interviewed. Even this question had been addressed by the Italian NBC that circumscribed

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it to the condition of an incurable, refractory, terminal illness with impending death. Concerning these topics, the interviewed population expressed a high need of being advised and updated regarding the latest juridical provisions. Therefore, initiatives aimed at increasing training, communication competence and relational skills (such as seminars, interactive lessons) should be introduced in the medical curriculum, in line with what is explicitly established by the new law. In fact, a huge body of research has shown that good communication skills in a doctor can improve patient's compliance, reduce the frustration of both in situations of high emotional stress and increase job satisfaction. To the best of our knowledge, the present questionnaire is the first to explore knowledge, beliefs and attitudes towards DAT among the workers in the field of anesthesiology in Italy. However, our study suffers from a number of limitations which should be properly acknowledged. The major shortcoming is represented by the small sample size. Second, given the exploratory nature of the present pilot study, a Confirmatory Factor Analysis (CFA) was not performed. Future studies should replicate the factor structure, using CFA and larger sample sizes.

#### **Conclusions**

The present article reported the development and validation of an instrument aimed to assess DAT-related knowledge, attitudes and practices among healthcare workers. The tool appeared to be well-accepted and psychometrically sound and reliable. The findings, although preliminary and, as such, merely indicative, showed a poor knowledge of the law concerning DAT and its related ethical principles and aspects among healthcare personnel specifically working in the field of anesthesiology. This lack of knowledge is particularly critical in view of the specificity of the clinical area investigated (anesthesiology and intensive care), which constantly and daily has to cope with ethical issues. An adequate revision and implementation of the traditional curricula, together with the introduction of innovative teaching methods, aimed at stimulating methodological reflections through a systematic dialogue

on ethical problems frequently encountered during the professional practice, could help medical students and trainees develop the aptitudes and skills needed in their future profession. However, based on the above-mentioned shortcomings, future multicenter studies should be carried out to confirm the present findings in a more statistically robust way. Therefore, subsequent phases are planned in order to distribute the questionnaire to larger and more representative samples and to obtain useful data at the national level.

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#### References

- 1. Gristina RG, Busatta GR, Piccinni LM. The Italian law on informed consent and advance directives: its impact on intensive care units and the European legal framework. Minerva Anestesiologica 2019;85(4):401-11.
- Ciliberti R, Gorini I, Gazzaniga V, De Stefano F, Gulino M. The Italian law on informed consent and advance directives: New rules of conduct for the autonomy of doctors and patients in end-of-life care. J Crit Care. 2018 Dec;48: 178-182.
- 3. Di Paolo M, Gori F, Papi L, Turillazzi E. A review and analysis of new Italian law 219/2017: 'provisions for informed consent and advance directives treatment'. BMC Med Ethics. 2019; 20: 17.
- 4. Giannini A, Miccinesi G. Mechanical ventilation withdrawal at end of life: terminal extubation and terminal weaning. Minerva Anestesiologica 2017;83:350-2.
- Cortegiani A, Russotto V, Raineri SM, Gregoretti C, Giarratano A, Mercadante S. Attitudes towards end-of-life issues in intensive care unit among Italian anesthesiologists: a nation-wide survey. Support Care Cancer 2018;26: 1773-80.
- Chin M, Lagasse RS. Assessment of competence: developing trends and ethical considerations. Curr Opin Anaesthesiol 2017;30:236-41.
- 7. Rasoal D, Skovdahl K, Gifford M, Kihlgren A. Clinical Ethics Support for Healthcare Personnel: An Integrative Literature Review. HEC Forum 2017; 29: 313346.
- 8. Ciliberti R, Baldelli I, Gallo F, Patuzzo S, De Stefano F, Bonsignore A. Physicians' perception of the importance of ethical and deontological issues in a major Italian Province: pilot questionnaire and its validation. Acta Biomed 2019;90:56-67.

- 9. SIAARTI Le cure di fine vita e l'anestesista rianimatore: raccomandazioni per l'approccio alla persona morente update 2018 http://www.siaarti.it/SiteAssets/Ricerca/documento-siaarti-fine-vita/Documento%20SIAARTI%20 Fine%20vita.pdf
- 10. Caruso R, Rocco G, Dellafiore F, Brognoli G, Magon A, Conte G, et al. 'Nosce te ipsum': An Italian national survey to explore choice's differences in End of Life (EoL) care between healthcare professionals and general public. Appl Nurs Res 2019;46:8-15.
- 11. National Bioethics Committee. Advanced treatment statements 18 December 2003. Available from: http:// bioetica.governo.it/media/1869/p58\_2003\_dichiarazioni\_ anticipate\_trattamento\_it.pdf
- 12. Federazione Nazionale degli Ordini dei Medici Chirurghi e Odontoiatri (FNOMCeO) Italia. Codice di deontologia medica. 2014. Available from: https://portale.fnomceo.it/ fnomceo/showArticolo.2puntOT?id=115184.
- 13. Wiesing U, Jox RJ, Hessler HJ, Borasio GD. A new law on advance directives in Germany. J Med Ethics 2010;36:779-83. 14. Brauer S, Biller-Andorno N, Andorno R. Country reports on advance directives. Available from: https:// www.ethik.uzh.ch/dam/jcr:00000000-14d5-886d-fffffffff1488f30/Country\_Reports\_AD.pdf
- 14. Andorno R, Brauer S. Advance Health Care Directives: Towards a Coordinated European Policy? Eur J Health Law 2009;16(3):207-27.
- 15. Geppert CM, Andrews MR, Druyan ME. Ethical issues in artificial nutrition and hydration: a review. JPEN J Parenter Enteral Nutr 2010;34:79-88.
- 16. Brody H, Hermer LD, Scott LD, Grumbles LL, Kutac JE, McCammon SD. Artificial Nutrition and Hydration: The Evolution of Ethics, Evidence, and Policy. J Gen Intern Med. 2011;26: 1053-8.
- 17. Druml C, Ballmer PE, Druml W, Oehmichen F, Shenkin A, Singer P, et al. ESPEN guideline on ethical aspects of artificial nutrition and hydration. Clinical Nutrition (2016), http://dx.doi.org/10.1016/j.clnu.2016.02.006.

- 18. Moreschi C, Da Broi U, Rodriguez D, Froldi R, Porzionato A, Macchi V, et al. The Eluana Englaro Case: cause of death after the withdrawal of artificial nutrition and hydration in a subject in a permanent vegetative state and with quadriplegia. Forensic Sci Int 2013;231(1-3):e24-9.
- 19. Solarino B, Bruno F, Frati G, Dell'Erba A, Frati P. A national survey of Italian physicians' attitudes towards endof-life decisions following the death of Eluana Englaro: reply to M.Y. Rady. Intensive Care Med 2011;37:1394-5.
- 20. Mallia P. Are clarifications on feeding and hydration in PVS needed by Catholic authorities? J Int Bioethique 2012;23(3-4):179-88.
- 21. Latronico N, Manenti O, Baini L, Rasulo FA. Quality of reporting on the vegetative state in Italian newspapers. The case of Eluana Englaro. PLoS One 2011;6:e18706.
- 22. Sulmasky D.P. Italy's New Advance Directive Law When in Rome. JAMA Intern Med 2018;178:607-8
- 23. Comitato Nazionale di Bioetica. Sedazione palliativa profonda continua nell'imminenza della morte. 29 gennaio 2016. http://www.fedcp.org/images/news/CNB\_sedazione\_profonda.pdf
- 24. Ranjan P, Kumari A, Chakrawarty A. How can Doctors Improve their Communication Skills? J Clin Diagn Res 2015; 9(3): JE01-JE04.
- 25. Chiapponi C, Dimitriadis K, Özgül G, Siebeck RG, Siebeck M. Awareness of ethical issues in medical education: an interactive teach-the-teacher course. GMS J Med Educ 2016;33(3): Doc45.

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