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Communicating medical information: a little lesson from italian patients

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ABSTRACT. Objective: To construct and validate a questionnaire that could be used to investigate the clarity of the medical information received by patients and their satisfaction with it, as well as their knowledge and opinions concerning advance directives and their associated variables.

Methods: We administered a 30-item questionnaire to 157 adult patients affected by progressive neurological, oncological and nephrological diseases.

Results: The results indicate the good reliability and structure of the questionnaire, which identifies three factors: "information and knowledge" ($\alpha .91$), "need for physical and mental support" ($\alpha .89$), and "determination and decision-making capacity" ($\alpha .75$). The amount of time dedicated to medical communication proved to be one of the variables determining the patients' knowledge of their disease and their capacity to express their needs, neither of which changed over time. The oldest patient, a man in the most advanced phase of disease, was the most fragile in expressing his needs and making decisions. Advance directives, living wills, active/passive euthanasia and therapeutic obstinacy¹ at most only marginally reach the cognitive and emotional sphere of the patients.

Conclusion: Patients' needs unequivocally lead us back to the primary matrices of medical act: paying attention to patients, offering adequate time, listening to him/her concerns and asking when no question emerges. This so obvious evidence does not match with the increasingly techno-oriented attitude of health professional, who also have to guarantee more productivity in less time. The quality of medical information received by patients impacts their decision making process, particularly in the oldest people. In Italy, as well as in other countries, it is necessary to pay more attention to this issue, keeping in mind that nobody can really choose without knowing exactly what it is going to happen.

Key words: medical information, communication, questionnaire

RIASSUNTO. COMUNICARE INFORMAZIONI MEDICHE:

UNA LEZIONE DA PAZIENTI ITALIANI. **Obiettivo:** Il diritto all'informazione medica e il testamento biologico costituiscono, tuttora, in Italia, argomenti di dibattiti e controversie. Tuttavia, poco si conosce sulle conoscenze e sulle opinioni dei cittadini, specie se malati.

Il nostro lavoro, senza avere la pretesa di esaudire la necessità di chiarezza su tale lacuna, né di pervenire a generalizzazioni, si propone di offrire alcune indicazioni meritevoli certo di ulteriori approfondimenti.

Metodo: È stato costruito un questionario di 30 item per indagare la chiarezza delle informazioni mediche ricevute, bisogni, conoscenze e opinioni sulle direttive anticipate. Il questionario è stato somministrato a 157 soggetti adulti, affetti da malattie croniche progressive diverse (neurologiche, oncologiche e nefrologiche).

Risultati: I risultati hanno evidenziato soddisfacenti proprietà psicometriche del questionario che identifica tre fattori: "informazioni e conoscenze" ($\alpha .91$), "necessità di supporto fisico e psicologico" ($\alpha .89$) e "determinazione e capacità di processo decisionale" ($\alpha .75$).

L'analisi di tali costrutti rispetto a variabili sociodemografiche e di processo ha evidenziato che il tempo dedicato dal medico è una di quelle che determina il grado di conoscenza della malattia da parte del paziente così come la sua capacità di esprimere i propri bisogni. Genere, sesso e stadio di malattia sono altrettanto influenti: il paziente più in difficoltà in questo senso è risultato essere parkinsoniano, anziano, di sesso maschile e in fase avanzata di malattia.

Conclusioni: Relativamente ai concetti di direttive anticipate, eutanasia e accanimento terapeutico, essi sembrano ancora difficoltosi da elaborare sia sul piano cognitivo che affettivo dalla maggioranza dei pazienti del presente studio.

In conclusione, qualunque decisione normativa in merito, come il consenso informato o il testamento biologico, continuerà ad essere solo un atto formale se non si riconsidererà sul piano comunicativo il processo, non solo informativo, che fonda la capacità decisionale in merito alla salute. L'uso del questionario proposto può essere una buona occasione per riflettere.

Parole chiave: informazione medica, comunicazione, questionario.

Introduction

Informed consent in the health context is universally considered an important instrument to guarantee the respect of a person's right to understand and participate to his/her health management. However, many studies in the world underline that it is used very superficially and, in most cases, just to assure a legal protection to the health professional. Itis (1) refers that there is an overestimation of people's understanding, without considering that cognitive "normal" persons who don't have a specific culture in the topic have difficulties with medical terms. Many authors have shown that methods to simplify the informed consents (use of multimedia communication, graphic aids etc.) do not increase their comprehensibility and that it is preferable to use different form of communication (verbal,

¹ The neo-Latin term "accanimento terapeutico", which is very well known and widely used in Italy, has been translated as "therapeutic obstinacy", "over-treatment", "aggressive medical treatment" and "futility" (for example, see ref.1). We have chosen the first translation as it seems to us to be clearer and less ambiguous than the others.

written etc.) (2). Certainly, time dedicated by the health professional to the patient has been proved to be an important variable in influencing a better decision making (3). The problem is even more difficult regarding living wills and advance directives: they have been studied in some European countries, such as The Netherlands and Denmark, where they are already subject to legislative regulation, but they have not been studied in Italy despite a long and active debate concerning the principles of "patient autonomy", "freedom of choice" and the "right to information". In fact, there is still controversy and even open conflict concerning advance directives which involves the political parties, the religious agencies and the health professionals themselves (4,5). Surprisingly, there are no studies evaluating whether the medical information given as the basis of informed consent is actually clear to patients, or assessing their knowledge and opinions concerning advance directives and the related variables.

The aim of this study, which was approved by our Institute's Ethics Committee, was to construct and validate a questionnaire that could be used to make a first study.

Methods

Two of the authors (Pasetti & Zotti, the first a neurologist with experience in bioethics, and the second a psychotherapist with experience in chronic diseases) formulated the questionnaire in order to explore:

- patients' awareness and knowledge of their disease;
- the amount and quality of the information received concerning its diagnosis and evolution;
- their wishes concerning the treatments that can be administered to them in the case of decision-making incapacity;
- the types of mental and physical support needed in relation to different personal values and wishes.

In a first phase, the questionnaire (which included an introductory note explaining the meaning of "advance directives" and a page for collecting demographic data) consisted of 51 items with responses based on a 3-point scale (from 1 = not at all, to 3 = completely). This version was administered to 40 patients with different chronic diseases who were hospitalised for rehabilitation purposes. Immediately after its administration, the subjects were asked about their understanding of the items, and their responses to the questionnaire underwent frequency and distribution analysis. After deleting the items that had been poorly understood and those that had not achieved a discriminating capacity (Kurtosis $>+1$ or >-1), the revised questionnaire (called 'Communication and Consent') consisted of 46 items, and was used in the present study.

Over a period of two months, and after having obtained their informed consent, we enrolled 157 consecutive patients attending outpatient appointments because of Parkinson's disease (PD), chronic renal insufficiency (RI),

or neoplasms of various origin (NEOP). The exclusion criteria were the presence of any obvious alterations in cognitive capacity or treatment with psychoactive drugs capable of impairing consciousness or the level of vigilance.

The questionnaire was administered by health personnel with experience in psychometrics who were not involved in caring for the patients.

Statistical analysis

The responses to the multiple-choice items of the questionnaire underwent factorial analysis by means of extraction of the principal components, a scree test, and analysis of internal consistency (Cronbach's α). Analysis of variance, Covariance by age, Student's *t* test, and Bonferroni's *post hoc* test were used to evaluate the intervening effect of the correlated socio-demographic and disease variables.

Results

Table I shows the patients' socio-demographic characteristics distributed by disease type: 65 (41.4%) were affected by Parkinson's disease (PD), 43 (27.4%) by chronic renal insufficiency (IR) treated with dialysis, and 49 (31.2%) by intermediate or advanced neoplasms of various origin (NEOP) not yet in terminal phase. Mean disease duration from the time of diagnosis was 69.5 ± 71.1 months (range 1-372).

The patients' mean age was 63 ± 13.4 years and 58.6% were female; 65% were married, 66% retired, 45% had had eight years' education, and 95.5% were Catholics.

Given the convenience sample and different diseases, the mean ages of the groups were significantly different ($F=31.66$; $p<.0001$), with a preponderance of elderly subjects among the PD patients. The subsequent analyses were made bearing this in mind.

3.1 Analysis of the constructs

A first extraction factorial analysis of the principal components of the multiple-choice items indicated that 41% of the variance was explained by three factors, and the scree test (see Fig. 1) and analysis of factorial weights suggested excluding the items with a factor loading of less than .30.

The subsequent factorial analysis of a total of 29 items (Tab. II) again identified three factors, but these explained 52.44% of the total variance².

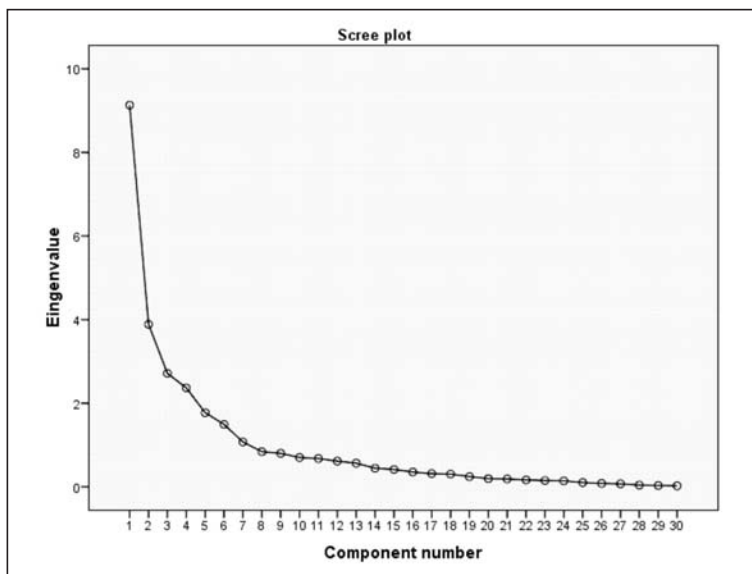
The first factor consisted of 18 items with a degree of internal consistency of .91 (Cronbach's α), and was called "Information and knowledge"; the second consisted of six items with an α of .89, and was called "Need for physical and mental support"; and the third consisted of five items with an α of .75, and was called "Determination and decision-making capacity".

Table III shows the distribution characteristics of the three factors in the sample as a whole. Gender significantly differentiated ($t=2.09$; $p<.03$) the factor *Need for physical*

² The final version of the questionnaire is in Appendix. Item 6 "When you were told the diagnosis, how much time were you given to talk about your disease?" was always removed from analysis.

Table I. Sociodemographic characteristics of the study sample by type of disease

		PD (n = 65)	RI (n = 43)	NEOP (n = 49)	TOTAL (n = 157)
Age (years)		71.4 ± 6.1	60.7 ± 13.8	54.7 ± 14.1	63.2 ± 13.4
Gender	M	30 (46.2%)	20 (46.5%)	15 (30.6%)	65 (41.4%)
	F	35 (53.8%)	23 (53.5%)	34 (69.4%)	92 (58.6)
Education in years	≤5	43 (68.3%)	19 (45.2%)	9 (18.4%)	71 (46.1%)
	8	13 (20.6%)	14 (33.3%)	13 (26.5%)	40 (26.0%)
	13	6 (9.5%)	9 (21.4%)	19 (38.8%)	34 (22.1%)
	>13	1 (1.6%)		8 (16.3)	9 (5.8%)
Marital status	Single		7 (16.3%)	5 (10.2%)	12 (7.6%)
	Married	39 (60%)	27 (62.8%)	36 (73.5%)	102 (65%)
	Divorced	1 (1.5%)	1 (2.3%)	4 (8.2%)	6 (3.8%)
	Widowed	25 (38.5%)	8 (18.6%)	4 (8.2%)	37 (23.6%)
Occupation	Employed		3 (7.0%)	24 (49%)	27 (17.2%)
	Housewife	8 (12.3%)	11 (25.6%)	7 (14.3%)	26 (16.6%)
	Retired	57 (87.7%)	29 (67.4%)	18 (36.7%)	104 (66.2)
Disease length (months.)		80.9 ± 60.6	87.7 ± 94.3	38.4 ± 47.6	69.5 ± 71.1
Self-evaluation of disease severity/stage	Initial	25 (39.7%)	8 (18.6%)	9 (20.0%)	
	Moderate	25 (39.7%)	20 (46.5%)	23 (51.1%)	
	Severe	13 (20.6%)	15 (34.9%)	13 (28.9%)	

**Figure 1. Factor analysis: scree plot**

and mental support, with males being less capable of coping than females. Age (<67 vs ≥67 years) significantly differentiated both the first ($t=2.66$; $p<.009$) and the third factor ($t=2.35$; $p<.02$), with the oldest subjects having less information and decision-making capacity. Education (expressed in years) significantly differentiated both information ($F=4.22$; $p<.01$) and determination and decision-making capacity ($F=6.92$; $p<.001$), with lower scores among the subjects with only primary education.

The disease was the variable that determined the differences between the scores of all three factors (Table IV).

Analysis of variance showed that the subjects with PD were less informed ($F=19.72$; $p<.0001$), less capable of defining the support necessary ($F=12.38$; $p<.0001$), and had less decision-making capacity ($F=8.5$; $p<.0001$) than

those with RI or NEOP, who did not differ from each other at the *post hoc* test. These results are even confirmed by considering patients' age as covariate: PD patients, in fact, showed results significant different from the other subjects ($F=3.751$; $p<.05$).

The time since the initial diagnosis of the disease (divided on the basis of a median of <48 and ≥48 months) did not seem to influence any of the constructs significantly, whereas the stage of disease did: the more advanced the disease, the less the need for information ($F=6.39$; $p<.002$) but the greater the need for physical and mental support ($F=3.39$; $p<.03$).

Analysis of the individual items

It is interesting to note that, contrary to expectations, qualitative analysis of the individual items showed that the subjects' General Practitioner was not their direct interlocutor in terms of disease management (7.2% of the sample as a whole): 82.5% had received information about the disease from a specialist, and 4.6% had entrusted their knowledge to searches in magazines and the on the Internet. Only 41.7% considered that they really knew about their disease and its evolution. The medical time dedicated to communicating the diagnosis was less than ten minutes for 37.7% of the subjects, thus creating a greater need for information ($F=21.59$; $p<.0001$) and physical and mental support ($F=3.22$; $p<.04$) in comparison with the patients who had had more than ten minutes of dedicated time.

Almost all of the patients expressed their belief in the right to know the truth about their disease and a physician's duty to inform them even in the case of a progressive disease with a poor prognosis. Finally, 93.5% declared that

Table II. Factor loading of each item of the questionnaire (see Appendix)

	Factor 1	Factor 2	Factor 3
Item 5a	.778		
Item 5b	.767		
Item 5e	.766		
Item 8a	.744		
Item 5d	.726		
Item 5c	.714		
Item 8c	.698		
Item 5f	.677		
Item 8b	.672		
Item 4	.664		
Item 8d	.586		
Item 7	.526		
Item 10c	.507		
Item 10a	.488		
Item 2	.471		
Item 14d	.463		
Item 3	.460		
Item 1	.444		
Item 13a		.729	
Item 13c		.722	
Item 13b		.667	
Item 14a		.638	
Item 14c		.626	
Item 14b		.618	
Item 11			.795
Item 12			.790
Item 15			.521
Item 9			.464
Item 10b			.431

they did not even approximately know the meaning of “advance directives” and, although the word “euthanasia” was well known by 83% of the subjects, “therapeutic obstinacy” and “invasive therapy” proved to be less clear (not known by respectively 49.3% and 58.3%).

After having had the meaning of “advance directives” explained to them, 11.6% of the subjects did not consider them a useful means of safeguarding their wishes and were unwilling to use them; half of the 42.5% who were totally in favour of the use of a card indicating one’s wishes in the case of a disease with a poor prognosis were in the NEOP group.

Discussion

The proposed questionnaire, reduced to a total of 30 items, proved to be valid and reliable, and immediately capable of providing ethically important findings. It identifies differences arising from socio-cultural variables as well as some critical aspects of medical practice. As previously revealed by other studies (6,7), it was found that dedicated medical time is one of the variables determining the amount of information patients have about their disease and their capacity to express their needs, which do not change over time.

It also emerged that General Practitioners do not seem to play a prominent role in accompanying patients through the management of progressive chronic diseases and, paradoxically, provide less information than the Internet.

Finally, it was found that older male patients in the most advanced stage of disease are the most fragile in exposing their needs and taking decisions, which it is probable they cannot make also because they do not know about outcomes. Fried *et al.* (8) also point out that especially elderly patients’ decisions concerning treatment depend on how much they know about their possible results.

The large questions, such as advance directives, living wills, active/passive euthanasia and therapeutic obstinacy, which in Italy are shaking political debate and the medical world (5), only marginally enter the cognitive and emotional spheres of patients. However, even in the USA, where the federal Act of Self-determination goes back to 1990, and where the last decade has seen referendums held and special laws enacted, there is still confusion concerning the meaning of some terms and the available options (9,10). Once again, communication and dedicated time prove to be an essential condition for the promulgation and especially the application of ethical-juridical principles.

People suffering from precarious and worsening clinical conditions seem to be more favourably inclined to the adoption of a card indicating their wishes in the case of a disease with a poor prognosis. This has also been highlighted by other European authors, who have pointed out that debates and laws are not sufficient to increase knowledge and over-

Table III. Psychometric characteristics of the investigated constructs (sample as a whole)

	Mean	SD	Median	Mode	Range	Skewness	Kurtosis	α Cronbach
Information and knowledge	44.8	8.37	46	54	23-57	-.446	-.598	.91
Need for physical and mental support	12.9	4.02	12	18	6-18	-.201	-1.197	.89
Determination and decision-making capacity	11.1	2.53	11	9	5-15	.093	-.962	.75

Table IV. Analysis of the constructs by type of disease

	PD (n = 65)	RI (n = 43)	NEOP (n = 49)	p <
Information and knowledge	38.5 ± 7.5	47.8 ± 7.3	47.1 ± 7.3	.0001
Need for physical and mental support	10.5 ± 3.6	13.4 ± 3.6	14.4 ± 3.9	.0001
Determination and decision-making capacity	9.8 ± 2.2	11.1 ± 2.7	12.1 ± 2.2	.0001

come ambivalence, and that only worsening health favours a wish for self-determination (11).

The diseases considered in our study certainly represent one of its limitations because of the characteristics of the people affected by them: patients with Parkinson's disease are older and less educated than those affected by cancer but, as described above, this did allow us to verify the discriminating capacity of the questionnaire. Other studies are therefore necessary, involving patients with other diseases, healthy subjects, and caregivers.

Some studies have shown that caregivers declare a continuing need for clarity concerning disease management and that, although they think about the possible death of their partner, they find it very difficult to talk about and live the resulting emotional state in solitude (12, 13).

Conclusions

Ethics and deontology suggest that the current major issues are communicating with patients and the quality of life. As shown by our study, patients' needs unequivocally lead us back to the primary matrices of the medical act in its most exquisitely anthropological sense: paying attention to patients, offering information that is compatible with their education, and knowing how to interpret needs even when patients are incapable of asking. Time, a synonym of productivity and efficiency in a society that is increasingly characterised by the prevalence of techno-science, seems to be a clearly disturbing element when taking responsibility for a patient with a chronic disease as it impedes the establishment of a doctor-patient relationship founded on a therapeutic alliance and truly global supportive care. The British Medical Journal has recently dedicated considerable space to discussing the incomprehensibility of informed consent (14), but is it like that merely transforming technical language into "friendly" language will be enough to overcome the problem?

Recovering the language of clinical relationships does not mean adopting anti-scientific attitudes, but simply reintroducing ontology and considering the social dimension of disease and dying (15-16), while being aware that public debate and regulations can only constitute a generic cultural base that then needs to be modelled on the individual.

This is all the more important, the more one has relationships with patients who can and must decide what they are prepared to accept in therapeutic or palliative terms, prolongation or discontinuation - in other words in terms of the quality of life and the quality of death.

Practice implication

Although it is known that the quality of medical information received by patients impacts their decision making process, in Italy, as well as in other European countries and in USA, we continue to observe that the informed consent is, in general, a little comprehensible instrument.

The same seems to happen with the advance directives. Many authors call for more attention to this issue and there is a general agreement about the importance of time dedicated to communication and of the frontal relationship, especially in discussing the consequences of medical acts. Health professionals should try to make this evidence a real daily practice.

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