

Health Related Quality of Life norm data of the general population in Italy: results using the EQ-5D-3L and EQ-5D-5L instruments

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ABSTRACT

BACKGROUND: Many studies have been conducted in Italy to assess Health-Related Quality-of-Life (HRQoL) in subjects with different diseases. However, no recent HRQoL population norm data were available to make comparisons with diseased populations. We assessed HRQoL norm data using the generic instrument EQ-5D in its standard version (EQ-5D-3L) and with the recently introduced version (EQ-5D-5L).

METHODS: A survey was conducted on 6,800 individuals, representative of the Lombardy general adult population for age, gender and geographical distribution. Each participant underwent a telephone interview with questions using the EQ-5D-3L and the EQ-5D-5L descriptive systems, the visual analogue scale (EQ-VAS) and socio-demographic data.

RESULTS: participants were 48% male, aged on average 51.9 years. With the 3L version, men and women aged 18-35 years reporting a full health state were 71.3% and 56.5%, respectively, those aged ≥ 76 years decreased to 29.5% and 13.5%, respectively. The proportion of respondents reporting no problems decreased with the 5L version. The mean (standard deviation) of the EQ-VAS was 87.7(12.1) and 85.0(15.2) among men and women aged 18-35 years, and 68.0(20.6) and 64.4(23.2) in men and women aged ≥ 76 years. The mean (standard deviation) utility obtained from the 3L version ranged from 0.965(0.068) and 0.944(0.086) among men and women aged 18-35 years, to 0.880(0.123) and 0.829(0.137) in men and women aged ≥ 76 years. Similar results were obtained with the 5L version.

CONCLUSION: HRQoL norm data are now available for the general adult population in Italy, to be used as a reference in clinical sector, economic evaluations and in policy settings.

Key words: Health Related Quality of Life, utility, norms, EQ-5D-3L, EQ-5D-5L

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INTRODUCTION

Health Related Quality of Life (HRQoL) is a useful measure of health and outcomes used in research, in clinical practice and in health policy. During the early nineties, HRQoL was recognized as an important parameter to be considered, together with the traditional and standard clinical parameters, when measuring individuals' overall health and outcomes of interventions [1, 2]. HRQoL can assume a primary role in different areas, e.g., in cancer, especially at stages when patients have no more hope of staying alive [3-6], or in chronic lifelong conditions such as thalassemia [7], haemophilia [8-10] or rheumatic diseases [11-13], which seriously affect patients and their families for many years. Also, there are conditions that from a purely clinical point of view may appear less severe than others, e.g., gastroesophageal reflux, atopic dermatitis, hand eczema, which are not life-threatening and might appear less compromising to a patient's physical ability of doing everyday things than other conditions; actually, these diseases can seriously affect an individual's wellbeing for years, since they can provoke serious concerns and disturbances in the everyday life of patients and their families. [14-17] In these individuals, aspects such as social, working and emotional components of health can be greatly impaired, making helping patients better cope with their condition the main objective of the treatment, rather than the eradication of the disease.

HRQoL measures have been increasingly employed in several studies, mostly aimed at assessing the burden of illnesses [e.g. 7, 18-20], and in economic evaluations [e.g. 13,21,22].

Especially for economic evaluations, Health Technology Assessments (HTA) and decision-making processes, the use of generic preference-based measures have been recommended by bodies such as the National Institute for Health and Care excellence (NICE) [23]. Also in Italy, national-regional health authorities and national health economic associations have increased their interest in these measures for the assessment of health technologies and interventions. [24-28].

Generic preference-based measures provide a multidimensional description of health suitable to generate a utility index, which multiplied by the duration of time an individual experiences a given health state,

or his/her survival, generates an index named quality-adjusted life-year (QALY), which is used to conduct economic evaluations of health technologies [e.g.13,21,23]. Among the generic preference-based instruments, the EQ-5D is one of the most frequently used since the early nineties and is recommended by NICE [22].

A number of surveys have been conducted in various countries that measured the HRQoL of the general population with the EQ-5D [29-32]. These studies have been informative in providing new data on population health characteristics, complementing the traditionally collected morbidity and mortality data. Such data, named population norm or reference data, can be used to compare health profiles or QALYs for patients with specific conditions with those for the average person in the general population in a similar age and/or gender group.

In the past years, several health economic and HRQoL studies were conducted in Italy using the EQ-5D-3L [7,8,10-22,33]. However, no recent norm data were available for Italy: in 2001-2003 Mantovani et al. [33] collected EQ-5D data from 1,956 Italians aged 40-79 years recruited by general practitioners in a population-based survey, and König et al. [34] collected EQ-5D data from 4,709 non institutionalized Italians.

In the last few years a new version of the descriptive system, including 5 levels per domain and named EQ-5D-5L, was introduced and tested to obtain more precise HRQoL information and to reduce the ceiling effect [34]. Surveys aimed at producing EQ-5D-5L norm data are being conducted in some Countries [31]. However, norm HRQoL data from the new descriptive system with 5 levels were completely lacking in Italy.

The objective of the present study was to assess general population reference HRQoL data for Italy using the generic instrument EQ-5D in its current available versions for adults: EQ-5D-3L and EQ-5D-5L.

METHODS

Subjects

A large-scale telephone survey was conducted in November 2013 on a sample of 6,800 subjects from the adult general

population of the Lombardy region. Recruitment and data collection was undertaken by a survey agency (IPSOS).

The sample size was decided considering a number of issues, including the experience with past similar surveys [29-32] and the availability of resources to conduct the present study. Past similar surveys conducted in other European countries differed in sample sizes, e.g. the smallest samples (around 500-700) were in Greece and Slovenia, while more than 32,000 subjects were interviewed in the Stockholm area [32]. In more recently published studies, sample sizes of 2,469 (in Germany using the EQ-5D-5L) [31], 3,941 (in Poland, using the EQ-5D-3L) [29] and 5,555 in Queensland, Australia (using the EQ-5D-3L) [30] were used. In our survey we considered that a sample of 5,000-10,000 adults living in the Lombardy region, which includes more than 8 million residents aged 18 years and over, was sufficient to obtain reliable estimates. Our budget was sufficient to obtain data from 6,800 respondents, hence we decided on this sample size.

A quota sampling approach was adopted to recruit a sample representative of the Lombardy general adult population for age (18 years and over), gender, and geographical distribution according to the most recent ISTAT (Italian National Institute of Statistics) census [36]. For each quota, IPSOS randomly selected telephone numbers to invite people to participate. Those who accepted underwent the telephone interview. No ethical approval was required for the present study, because this is a naturalistic and not an interventional study (e.g., randomized clinical trial) and because the participants were not recruited at healthcare providers such as hospitals, in which the Ethical Committees require to must review and approve the research studies to be conducted.

EQ-5D Description

The EQ-5D is a simple generic HRQoL instrument for the measurement, description and valuation of health on the day of administration [37], which provides a simple generic measure of health for clinical and economic evaluations of health care and in population health surveys. The EQ-5D is suitable for self-completion and takes only a few minutes to complete in postal or web-based surveys, and in face-to-face or telephone

interviews. The EQ-5D-3L was introduced in 1990 and is now available in more than 160 different languages. The EQ-5D-5L was introduced in 2009 [35] to improve the sensitivity and discriminatory power of the EQ-5D-3L. It is currently available in more than 100 languages: its Italian version was obtained following the established EuroQoL Group translation methodology [38] and tested psychometrically for the first time in a large sample of patients with chronic liver diseases [39], the data of which were also included in a cross-walk study together with the data of other disease conditions and countries [40] and used to obtain a mapping [41]. In addition, a youth version of the instrument (EQ-5D-Y) was introduced some years ago to be used in children [42-44]

The EQ-5D consists of two pages: the descriptive system and the Visual Analogue Scale (EQ VAS). A copy of the paper versions of the EQ-5D-3L and EQ-5D-5L descriptive systems and of the VAS included in the 5L version, used in this survey, is reported in the appendix. The descriptive system comprises five domains (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), each one with three (no problems, some problems, unable to do/extreme problems) or five possible levels (no problems, slight problems, moderate problems, severe problems and unable to do/extreme problems), in the EQ-5D-3L and the EQ-5D-5L versions, respectively. In the 5L version, levels 1, 3 and 5 are fairly similar to the 3 levels of the 3L version (however, in the mobility domain, "confined to bed" was changed to "I am unable to walk about"), while levels 2 and 4 were introduced to describe intermediate levels of severity between the existing ones. In both the 3L and the 5L systems, 11111 represents the best health state, while 33333 and 55555 represent the worst health states in the 3L and 5L versions, respectively. By combining every characteristic level of the 3L descriptive system, a total of 243 (3⁵) health-state descriptions can be obtained, while a total of 3,125 (5⁵) health-states can be described with the 5L descriptive system. The EQ VAS is used to rate individuals' current health on a scale from 0 (worst imaginable health) to 100 (best imaginable health).

Values can be assigned to the health states generated with responses given to the descriptive system. For this reason, the EQ-5D is currently one of the most commonly used instruments estimating QALYs in health

economic evaluations [23] In particular, the responses to the dimensions of the EQ-5D descriptive system can be combined with an algorithm that includes the so named so-called social tariffs, based on individuals' preferences, which generate a single utility index for each health state. Specific valuation studies are conducted to estimate the social tariffs for the conversion of the health states into utility indexes on a scale anchored at 1, corresponding to full health, and 0, corresponding to death. Actually, because some very severe health states can be considered as worse than death, the utility index can be negative. In these studies, representative samples of the general population of a specific country or region are generally involved (e.g. the valuation study conducted in Italy by Scalone et al [45]).

Data collection

During the interview each participant answered the questions included in the EQ-5D-3L and EQ-5D-5L descriptive systems, questions on socio-demographic data and finally the visual analogue scale (EQ VAS). Firstly, the participants had to respond to the questions of one descriptive system. In preliminary research on the EQ-5D-5L [46] it was noticed that the responses given to the version of the descriptive system completed first might influence those given to the descriptive system completed after. To check for possible influences of responses of one version over the other, the order of the two versions was reversed in half of the study sample. In addition, after answering the first descriptive system, they were asked to report their socio-demographic data and were then presented with the second descriptive system. Furthermore, to minimize memory effect between the two descriptive systems, the participants were told that the 3L and 5L versions are independent ways of assessing their health state and were invited not to think about how they answered previously.

Data analyses

The study sample is described according to socio-demographic characteristics and HRQoL. A comparison of the study sample with the Italian general population is reported for the

available information, i.e. age, gender and marital status. HRQoL results are reported using the responses obtained with both the descriptive systems EQ-5D-3L and EQ-5D-5L, and with the VAS. Furthermore, the responses obtained with the 3L descriptive system were converted into a utility index using the Italian specific social tariffs [45], while those collected with the 5L version were converted into utilities using the mapping algorithm developed by van Hout et al. [41] and applied on the Italian social tariffs. Because age and gender are recognized as being generally associated with HRQoL in any population or group of persons [32], we report the results overall and by stratifying the study sample according to gender and the following age classes, which generally correspond to the age classes that are of main interest in the healthcare sector, where we expect these data will be more used: 18-35, 36-45, 46-55, 56-65, 66-75 and ≥ 76 years. Results are reported using absolute and relative frequency for categorical data, mean, standard deviation, minimum, maximum, median, 25° and 75° percentiles for continuous variables.

RESULTS

In order to obtain data from 6,800 participants, 76,795 persons were contacted to check their eligibility and willingness to participate. Hence, an 8.9% response rate was achieved, consistent with the response rate that is generally reached in telephone surveys involving individuals from the general population. [47] The participants were 48% male, with a median age of 52 years (maximum age =101 years) and a mean(SD) age of 51.9(17.6). Gender, median age and marital status of the participants were similar to those of the whole Italian population aged 18 years and over (table 1).

With both versions of the descriptive system, women and older people reported problems in each domain of the descriptive system more frequently than men and younger people (tables 2 and 3). As a result, the mean utilities ranged from 0.965 (3L) and 0.959 (5L) in 18-35 year-old men to 0.829 in ≥ 76 year-old women, and the medians ranged from 1 (3L and 5L) in 18-35 year-old men to 0.850 in ≥ 76 year-old women (table 4). The VAS scores show a trend that is consistent with the one

TABLE 1

STUDY SAMPLE CHARACTERISTICS AND COMPARISON WITH THE ITALIAN GENERAL POPULATION			
VARIABLES		STUDY SAMPLE *	ITALIAN GENERAL POPULATION** [36]
Gender (male)		3,264 (48.0)	48.4
Age §§	Mean (SD) Median (minimum-maximum)	51.9 (17.6) 52 (18-101)	n.a. § 55 (18-n.a.)
Age class in men	18-35	750 (23.0)	26.1
	36-45	506 (15.5)	20.0
	46-55	799 (24.5)	18.1
	56-65	516 (15.8)	15.1
	66-75	418 (12.8)	11.7
	≥76	275 (8.4)	9.0
Age class in women	18-35	683 (19.3)	23.4
	36-45	410 (11.6)	18.4
	46-55	912 (25.8)	17.2
	56-65	550 (15.6)	14.8
	66-75	529 (15.0)	12.5
	≥76	452 (12.8)	13.6
Education	None	19 (0.3)	n.a.
	Primary school	634 (9.3)	
	Lower secondary school	1,395 (20.5)	
	Upper secondary school	3,415 (50.2)	
	Graduate/Post graduate	1,337 (19.7)	
Marital status †	Married	4,288 (63.1)	58.9
	Unmarried	1,678 (24.7)	29.5
	Widow/widower	576 (8.5)	9.1
	Separated/Divorced	255 (3.7)	2.5
	Other (e.g. nun, priest)	3 (0.04)	n.a.
Main working status††	Paid work	3,160 (46.5)	n.a.
	Unpaid work (e.g. as a volunteer)	232 (3.4)	
	Student	409 (6.0)	
	Housewife	835 (12.3)	
	Retired	1,789 (26.3)	
	Unemployed	364 (5.4)	
	No working activity or data not available	11 (0.2)	

* If not otherwise specified values are N (%);

** If not otherwise specified values are %

§ n.a.: not available

§§ Details on age above 100 years were not available from the general population data source, hence we did not calculate the mean, which is sensitive to the extreme values, nor could we report the highest age level. Instead, for comparison with the age of the study sample, we calculated the median age, which is less influenced by the extreme values.

† In the “study sample” column, common-law husbands or wives are included in the category of married people. Instead, in the “Italian general population” column, common-law husbands or wives are included in the category of unmarried people.

†† Many people reported they did several activities (e.g. a paid job and being a student, or being retired and a housewife). We report the main activity of each respondent in the table.

shown with the descriptive system responses: the mean (median) VAS scores range from 87.7 (90) in 18-35 year-old men to 64.4 (70) in >76 year-old women (details in table 4).

With the two descriptive systems, the respondents reported 97 different health states generated with the 3L descriptive system, and 349 different health states generated with the 5L

TABLE 2

EQ-5D-3L FREQUENCIES STRATIFIED FOR AGE AND GENDER																	
	18-35 YS		36-45 YS		46-55 YS		56-65 YS		66-75 YS		≥76 YS		ALL AGES		FULL SAMPLE		
	MEN N(%)	WOMEN N(%)	MEN N(%)	WOMEN N(%)	MEN N(%)	WOMEN N(%)	MEN N(%)	WOMEN N(%)	MEN N(%)	WOMEN N(%)	MEN N(%)	WOMEN N(%)	MEN N(%)	WOMEN N(%)	N(%)	N(%)	
MOBILITY NO PROBLEMS SOME PROBLEMS EXTREME PROBLEMS/ UNABLE TO DO	739(98.5) 10(1.3) 1(0.1)	662(96.9) 19(2.8) 2(0.3)	480(94.9) 26(5.1) 0	396(96.6) 14(3.4) 0	735(92.0) 59(4) 5(0.6)	813(89.1) 97(10.6) 2(0.2)	457(88.6) 57(11.0) 2(0.4)	455(82.7) 92(16.7) 3(0.5)	344(82.3) 73(17.5) 1(0.2)	382(72.2) 146(27.6) 1(0.2)	187(68.0) 87(31.6) 1(0.4)	230(50.9) 219(48.4) 3(0.7)	2942(90.1) 312(9.6) 10(0.3)	2938(83.1) 587(16.6) 11(0.3)	5880(86.5) 899(13.2) 21(0.3)		
SELF CARE NO PROBLEMS SOME PROBLEMS EXTREME PROBLEMS/ UNABLE TO DO	748(99.7) 2(0.3) 0(0.0)	672(98.4) 10(1.5) 1(0.1)	499(98.6) 7(1.4) 0	401(97.8) 9(2.2) 0	777(97.3) 21(2.6) 1(0.1)	887(97.3) 24(2.6) 1(0.1)	491(95.2) 24(4.7) 1(0.2)	535(97.3) 12(2.2) 3(0.5)	396(94.7) 20(4.8) 2(0.5)	494(93.4) 34(6.4) 1(0.2)	247(89.8) 25(9.1) 3(1.1)	388(85.8) 61(13.5) 3(0.7)	3158(96.8) 99(3.0) 7(0.2)	3377(95.5) 150(4.2) 9(0.3)	6535(96.1) 249(3.7) 16(0.2)		
USUAL ACTIVITIES NO PROBLEMS SOME PROBLEMS EXTREME PROBLEMS/ UNABLE TO DO	725(96.7) 23(3.1) 2(0.3)	636(93.1) 45(6.6) 2(0.3)	473(93.5) 32(6.3) 1(0.2)	384(93.7) 26(6.3) 0	733(91.7) 60(7.5) 6(0.8)	804(88.2) 103(11.3) 5(0.5)	467(90.5) 46(8.9) 3(0.6)	477(86.7) 67(12.2) 6(1.1)	367(87.8) 43(10.3) 8(1.9)	417(78.8) 109(20.6) 3(0.6)	216(78.6) 49(17.8) 10(3.6)	285(63.1) 156(34.5) 11(2.4)	2981(91.3) 253(7.8) 30(0.9)	3003(84.9) 506(14.3) 27(0.8)	5984(88.0) 759(11.2) 57(0.8)		
PAIN/ DISCOMFORT NO PROBLEMS SOME PROBLEMS EXTREME PROBLEMS/ UNABLE TO DO	648(86.4) 99(13.2) 3(0.4)	539(78.9) 142(20.8) 2(0.3)	373(73.7) 128(25.3) 5(1.0)	267(65.1) 141(34.4) 2(0.5)	544(68.1) 248(31.0) 7(0.9)	463(50.8) 430(47.1) 19(2.1)	309(59.9) 202(39.1) 5(1.0)	222(40.4) 317(57.6) 11(2.0)	212(50.7) 200(47.9) 6(1.4)	163(30.8) 346(65.4) 20(3.8)	123(44.7) 144(52.4) 8(2.9)	108(23.9) 312(69.0) 32(7.1)	2209(67.7) 1021(31.3) 34(1.0)	1762(49.8) 1688(47.7) 86(2.4)	3971(58.4) 2709(39.8) 120(1.8)		
ANXIETY/ DEPRESSION NO PROBLEMS SOME PROBLEMS EXTREME PROBLEMS/ UNABLE TO DO	593(79.1) 152(20.3) 5(0.7)	459(67.2) 216(31.6) 8(1.2)	401(79.3) 100(19.8) 5(1.0)	283(69.0) 117(28.5) 10(2.5)	564(70.6) 226(28.3) 9(1.1)	562(61.6) 330(36.2) 20(2.2)	357(69.2) 152(29.5) 7(1.4)	313(56.9) 222(40.4) 15(2.7)	295(70.6) 117(28.0) 6(1.4)	289(54.6) 225(42.5) 15(2.9)	178(64.7) 95(34.6) 2(0.7)	230(50.9) 211(46.7) 11(2.4)	2388(73.2) 842(25.8) 34(1.0)	2136(60.4) 1321(37.4) 79(2.2)	4524(66.5) 2163(31.8) 113(1.7)		
FULL HEALTH STATE (11111)	535(71.3)	386(56.5)	306(60.5)	210(51.2)	416(52.1)	339(37.2)	232(45.0)	157(28.6)	151(36.1)	110(20.8)	81(29.5)	61(13.5)	1721(52.7)	1263(35.7)	2984(43.9)		

ORIGINAL ARTICLES

TABLE 3

	EQ-5D-5L FREQUENCIES STRATIFIED FOR AGE AND GENDER												FULL SAMPLE N (%)			
	18-35 YS		36-45 YS		46-55 YS		56-65 YS		66-75 YS		≥76 YS			ALL AGES		
	MEN N (%)	WOMEN N (%)	MEN N (%)	WOMEN N (%)	MEN N (%)	WOMEN N (%)	MEN N (%)	WOMEN N (%)	MEN N (%)	WOMEN N (%)	MEN N (%)	WOMEN N (%)		MEN N (%)	WOMEN N (%)	
MOBILITY																
NO PROBLEMS	734(97.9)	653(95.6)	475(93.9)	392(95.6)	804(88.2)	443(85.9)	435(91.1)	330(79.0)	338(67.7)	175(63.6)	217(48.0)	2868(87.9)	2859(80.9)	5727(84.2)		
SLIGHT PROBLEMS	10(1.3)	23(3.4)	19(3.8)	11(2.7)	73(8.0)	48(6.3)	71(12.9)	47(11.2)	99(18.7)	51(8.6)	104(23.0)	233(7.1)	381(10.8)	614(6.0)		
MODERATE PROBLEMS	3(0.4)	6(0.9)	10(2.0)	7(1.7)	28(3.1)	20(2.9)	36(6.5)	30(7.2)	61(11.5)	36(13.1)	94(20.8)	121(3.7)	232(6.6)	353(3.2)		
SEVERE PROBLEMS	2(0.3)	0(0.0)	2(0.4)	0	5(0.6)	3(0.6)	6(1.1)	10(2.4)	10(1.9)	11(4.0)	32(7.1)	33(1.0)	53(1.5)	86(1.3)		
EXTREME PROBLEMS/ UNABLE TO DO	1(0.1)	1(0.1)	0	0	2(0.2)	2(0.4)	1(0.2)	1(0.2)	1(0.2)	2(0.7)	5(1.1)	9(0.3)	11(0.3)	20(0.3)		
SELF CARE																
NO PROBLEMS	743(99.1)	674(98.7)	496(98.0)	402(98.0)	875(95.9)	482(93.4)	520(94.5)	379(90.7)	483(91.3)	233(84.7)	354(78.3)	3098(94.9)	3308(93.6)	6406(94.2)		
SLIGHT PROBLEMS	3(0.4)	6(0.9)	7(1.4)	6(1.5)	25(2.7)	26(5.0)	18(3.3)	17(4.1)	24(4.5)	24(8.7)	40(8.9)	95(2.9)	119(3.4)	214(3.1)		
MODERATE PROBLEMS	2(0.3)	1(0.1)	2(0.4)	2(0.5)	11(1.2)	6(1.2)	6(1.1)	13(3.1)	17(3.2)	11(4.0)	48(10.6)	47(1.4)	85(2.4)	132(1.9)		
SEVERE PROBLEMS	1(0.1)	1(0.1)	1(0.2)	0	1(0.1)	2(0.4)	3(0.5)	8(1.9)	1(0.2)	6(2.2)	5(1.1)	20(0.6)	11(0.3)	31(0.5)		
EXTREME PROBLEMS/ UNABLE TO DO	1(0.1)	1(0.1)	0	0	0	0(0.0)	3(0.5)	1(0.2)	4(0.8)	1(0.4)	5(1.1)	4(0.1)	13(0.4)	17(0.3)		
USUAL ACTIVITIES																
NO PROBLEMS	720(96.0)	623(91.2)	464(91.7)	372(90.7)	707(84.4)	439(85.1)	455(82.7)	352(84.2)	391(73.9)	207(75.3)	259(57.3)	2900(88.8)	2870(81.2)	5770(84.9)		
SLIGHT PROBLEMS	24(3.2)	49(7.2)	30(5.9)	32(7.8)	100(11.0)	56(10.9)	55(10.0)	30(7.2)	83(15.7)	35(12.7)	82(18.1)	235(6.9)	401(11.3)	636(9.2)		
MODERATE PROBLEMS	5(0.7)	7(1.0)	10(2.0)	6(1.5)	36(4.0)	15(2.9)	34(6.2)	24(5.7)	48(9.1)	19(6.9)	84(18.6)	96(2.9)	215(6.1)	311(4.6)		
SEVERE PROBLEMS	0(0.0)	3(0.4)	1(0.2)	0	6(0.7)	3(0.6)	3(0.5)	11(2.6)	4(0.8)	9(3.3)	20(4.4)	29(0.9)	36(1.0)	65(1.0)		
EXTREME PROBLEMS/ UNABLE TO DO	1(0.1)	1(0.1)	1(0.2)	0	0	3(0.6)	3(0.5)	1(0.2)	3(0.6)	5(1.8)	7(1.6)	14(0.4)	14(0.4)	28(0.4)		
PAIN/ DISCOMFORT																
NO PROBLEMS	601(80.1)	487(71.3)	328(64.8)	245(59.8)	421(46.2)	269(52.1)	199(36.2)	194(46.4)	157(30.0)	114(41.4)	92(20.3)	1991(61.0)	1601(45.3)	3592(52.8)		
SLIGHT PROBLEMS	118(15.7)	159(23.3)	137(27.1)	114(27.8)	317(34.8)	180(34.9)	223(40.5)	153(36.6)	201(38.0)	86(31.3)	134(29.6)	898(27.5)	1148(32.5)	2046(30.1)		
MODERATE PROBLEMS	30(4.0)	35(5.1)	38(7.5)	51(12.4)	160(17.5)	60(11.6)	114(20.7)	61(14.6)	143(27.0)	59(21.4)	185(40.9)	330(10.1)	688(19.5)	1018(15.0)		
SEVERE PROBLEMS	1(0.1)	2(0.3)	3(0.6)	0	12(1.3)	5(1.0)	12(2.2)	9(2.1)	25(4.7)	14(5.1)	34(7.5)	38(1.2)	85(2.4)	123(1.8)		
EXTREME PROBLEMS/ UNABLE TO DO	0(0.0)	0(0.0)	0	0	2(0.2)	2(0.4)	2(0.4)	1(0.2)	3(0.6)	2(0.7)	7(1.6)	7(0.2)	14(0.4)	21(0.3)		
ANXIETY/																
DEPRESSION	527(70.3)	408(59.7)	366(72.3)	266(64.9)	514(64.3)	338(65.5)	290(52.7)	283(67.7)	286(54.1)	175(63.6)	226(50.0)	2203(67.5)	1993(56.4)	4196(61.7)		
NO PROBLEMS	165(22.0)	211(30.9)	104(20.5)	102(24.9)	257(28.2)	122(23.6)	179(32.5)	92(22.0)	147(27.8)	50(8.2)	117(25.9)	734(22.5)	1033(28.6)	1747(25.7)		
SLIGHT PROBLEMS	53(7.1)	58(8.5)	33(6.5)	31(7.6)	121(13.3)	48(9.3)	74(13.5)	35(8.4)	87(16.4)	47(17.1)	94(20.8)	292(8.9)	465(13.2)	757(11.1)		
MODERATE PROBLEMS	2(0.3)	2(0.3)	1(0.2)	4(1.0)	9(1.0)	6(1.2)	7(1.3)	6(1.4)	7(1.3)	2(0.7)	7(1.6)	20(0.6)	36(1.0)	56(0.8)		
EXTREME PROBLEMS/ UNABLE TO DO	3(0.4)	4(0.6)	2(0.4)	7(1.7)	8(0.9)	2(0.4)	0(0.0)	2(0.5)	2(0.4)	1(0.4)	8(1.8)	15(0.5)	29(0.8)	44(0.6)		
FULL HEALTH STATE (11111)	460(61.3)	321(47.0)	255(50.4)	192(46.8)	296(32.5)	201(38.9)	140(25.4)	133(31.8)	103(19.5)	70(25.4)	53(11.7)	1478(45.3)	1105(31.3)	2583(38.0)		

TABLE 4

VAS AND UTILITY RESULTS STRATIFIED FOR AGE AND GENDER

VAS*	18-35 YS		36-45 YS		46-55 YS		56-65 YS		66-75 YS		≥76 YS		ALL AGES		FULL SAMPLE
	18-35 YS	36-45 YS	46-55 YS	56-65 YS	66-75 YS	≥76 YS	ALL AGES	18-35 YS	36-45 YS	46-55 YS	56-65 YS	66-75 YS	≥76 YS	ALL AGES	
	MEN	WOMEN	MEN	WOMEN	MEN	WOMEN	MEN	WOMEN	MEN	WOMEN	MEN	WOMEN	MEN	WOMEN	
MEAN	87.7	85.0	83.5	82.6	80.2	78.9	76.9	74.7	72.0	70.1	68.0	64.4	79.9	76.7	78.22
SD	12.1	15.2	14.4	14.9	16.7	17.2	17.0	18.5	18.5	19.8	20.6	23.2	17.2	19.3	18.39
MEDIAN	90	90	90	89.5	80	80	80	80	75	70	70	70	80	80	80
25TH PERCENTILE	80	80	80	80	75	70	70	70	65	55	55	50	70	70	70
75TH PERCENTILE	95	95	90	90	90	90	90	90	80	80	80	80	90	90	90
MINIMUM	1	1	2	15	1	0	5	0	0	0	0	0	0	0	0
UTILITY FROM 3L*															
MEAN	0.965	0.944	0.949	0.935	0.932	0.906	0.921	0.889	0.907	0.868	0.880	0.829	0.933	0.899	0.915
SD	0.068	0.086	0.077	0.078	0.102	0.103	0.098	0.121	0.102	0.115	0.123	0.137	0.096	0.113	0.107
MEDIAN	1	1	1	1	1	0.902	0.905	0.902	0.902	0.869	0.902	0.850	1	0.902	0.905
25TH PERCENTILE	0.905	0.905	0.902	0.902	0.902	0.85	0.869	0.85	0.869	0.85	0.827	0.775	0.902	0.850	0.860
75TH PERCENTILE	1	1	1	1	1	1	1	1	1	0.905	1	0.902	1	1	1
MINIMUM	0.163	-0.036	0.251	0.496	-0.38	-0.262	0.139	-0.38	0.333	-0.021	-0.026	-0.026	-0.380	-0.380	-0.380
UTILITY FROM 5L*															
MEAN	0.959	0.941	0.945	0.936	0.930	0.912	0.919	0.895	0.907	0.877	0.879	0.829	0.930	0.902	0.915
SD	0.065	0.074	0.068	0.069	0.090	0.084	0.094	0.102	0.099	0.104	0.120	0.136	0.090	0.102	0.097
MEDIAN	1	0.925	1	0.925	0.925	0.921	0.921	0.905	0.921	0.887	0.902	0.850	0.925	0.921	0.921
25TH PERCENTILE	0.925	0.905	0.905	0.873	0.881	0.873	0.873	0.861	0.873	0.841	0.834	0.784	0.884	0.861	0.873
75TH PERCENTILE	1	1	1	1	1	1	1	1	1	0.925	1	0.905	1	1	1
MINIMUM	0.230	-0.035	0.433	0.698	0.173	0.144	0.188	-0.210	0.287	0.236	0.163	-0.084	0.163	-0.210	-0.210

*the maximum value of the VAS was 100 and of the utility index it was 1 in every subgroup of respondents.

descriptive system. Among the differences in the responses given, the percentage of respondents reporting no problems in each domain with the 5L version was slightly lower than with the 3L version. This trend corresponds to a reduced percentage of respondents reporting a full health state, corresponding to the health state in which the first level was chosen for every domain (i.e. 11111): namely, with the 3L version, men and women aged 18-35 years and reporting a full health state were 71.3% and 56.5%, respectively, while those aged ≥ 76 years were 29.5% and 13.5% respectively (table 2). With the 5L version, men and women reporting a full health state were 61.3% and 47.0% respectively, in the 18-35 year range, and 25.4% and 11.7% respectively, in the ≥ 76 age range (tables 3). These differences between the two versions of the descriptive system are attributable to the fact that a number of respondents moved their responses from one level with the 3L version to other levels of health with the 5L version. Namely, most of the participants reported the same responses in one or more domains (from 63.7% in pain/discomfort to 95.0% in self-care) of the two versions of the descriptive system. In particular, 36.0% confirmed the state 11111, while other respondents changed their answers: 3.6% in self-care, 10.0% in mobility and 10.4% in usual activities, 26.4% in anxiety/depression and 31.7% in pain/discomfort moved their responses from no problems or moderate problems (levels 1 or 2 in the 3L version) to slight problems (level 2 in the 5L version), or from moderate problems (level 2 in the 3L version) to severe problems (level 4 in the 5L version), or from extreme problems (level 3 in the 3L version) to severe problems (level 4 in the 5L version).

DISCUSSION

With this study we developed population norms for the EQ-5D descriptive system in its two versions with 3 and with 5 levels of severity, for the utility index derived from both versions, as well as for the EQ VAS. The results of this study, obtained from data collected in the Lombardy region, the most populated region of Italy with around 16% of Italian residents, can be considered valid and applicable to the full Italian adult population and can be used as a reference in clinical research, in cost of illness studies, in health technology assessment

and in policy. In particular, these data can be used to compare HRQoL of patients with specific conditions with the average person in the general population in a similar age and/or gender group. Furthermore, as a future objective, HRQoL norm data could be linked with healthcare administrative data, in order to obtain more complete databanks useful in tracking and monitoring, using data of large numbers of individuals observed for conspicuous time periods, the different health conditions, to define their burden in health surveillance, to plan health services, to evaluate strategies in prevention, and to control and assess outcomes [48-52].

Two studies were conducted in early 2000 on the general population norms with the EQ-5D-3L. The study by Mantovani and colleagues was limited as it involved individuals from the general population aged 40-79 years through their general practitioners, while in the study by König et al [34] data were collected through personal computer-based home interviews on a national sample of non-institutionalized individuals from the general adult Italian population aged 18 years and over. Our results are similar to those obtained in the study by König et al in some domains (mobility, self-care, usual activities), but different in other domains: in pain/discomfort the percentage of participants without problems was 72.4 in the study by König et al. and 58.4 in our study, while the percentage of participants without problems in anxiety/depression was 90.7 in the study by König et al and 66.5 in our study. These differences can depend on several reasons. The socio-demographic characteristics of the participants were different in some aspects: in the study by König et al, the mean age and probably the education level were lower, and fewer people declared paid employment. In any case, that study was conducted more than ten years before the present one, which may have contributed to a different health state perception in the general population. Since health perceptions can change with time, this could justify the need for updated HRQoL information to be used in health care and in decision making.

Some limitations could be ascribed to the present study. A first aspect that could be considered a limit is that only people from the Lombardy Region were involved. However, our study sample is shown to be quite comparable

to the Italian general population for the data that are available in the national databases, i.e. gender, age and marital status, and which do not consider the slight differences that can be found in the younger age groups as compromising the external validity of the results. A further potential limitation is that very ill subjects could have been excluded from the sample, because they were unable or not willing to participate, or others were not available at home because they were institutionalized for health reasons. As a consequence, individuals with very severe/extreme problems could be under-represented. One further limitation can be attributed to the utilities estimated from the 5L responses, using the interim mapping instead of an ad hoc valuation study for the 5L, which in Italy is not available yet. Although this calculation was based on the Italian 3L value sets, the results of the mapping may deviate compared to the actual responses.

To conclude, the present study provides policy makers with reference HRQoL data for the Italian general adult population obtained with the EQ-5D. In particular, the description of health can be more useful in clinical settings, where details on the single aspects (domains) of health that are compromised can be of

special interest, while summary indexes make it possible to quantify health states and can be more useful in economic analyses, in particular the utilities can be used to calculate QALYs for the conduction of cost-utility analyses.

A further novelty of this study is that it provides information obtained with both the 3L and the 5L versions of the descriptive systems, together with the VAS values, which is straightforward for users that still collect and have data with the standard version (3L) and for users that decide to implement the new version (5L), which is expected will be used more frequently in the next years.

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APPENDIX

Indicare quale delle seguenti affermazioni descrive meglio la sua salute oggi, segnando con una crocetta (così) una sola casella di ciascun gruppo.

CAPACITÀ DI MOVIMENTO

- | | |
|--------------------------------------|--------------------------|
| Non ho difficoltà nel camminare | <input type="checkbox"/> |
| Ho lievi difficoltà nel camminare | <input type="checkbox"/> |
| Ho moderate difficoltà nel camminare | <input type="checkbox"/> |
| Ho gravi difficoltà nel camminare | <input type="checkbox"/> |
| Non sono in grado di camminare | <input type="checkbox"/> |

CURA DELLA PERSONA

- | | |
|---|--------------------------|
| Non ho difficoltà nel lavarmi o vestirmi | <input type="checkbox"/> |
| Ho lievi difficoltà nel lavarmi o vestirmi | <input type="checkbox"/> |
| Ho moderate difficoltà nel lavarmi o vestirmi | <input type="checkbox"/> |
| Ho gravi difficoltà nel lavarmi o vestirmi | <input type="checkbox"/> |
| Non sono in grado di lavarmi o vestirmi | <input type="checkbox"/> |

ATTIVITÀ ABITUALI (*per es. lavoro, studio, lavori domestici, attività familiari o di svago*)

- | | |
|--|--------------------------|
| Non ho difficoltà nello svolgimento delle attività abituali | <input type="checkbox"/> |
| Ho lievi difficoltà nello svolgimento delle attività abituali | <input type="checkbox"/> |
| Ho moderate difficoltà nello svolgimento delle attività abituali | <input type="checkbox"/> |
| Ho gravi difficoltà nello svolgimento delle attività abituali | <input type="checkbox"/> |
| Non sono in grado di svolgere le mie attività abituali | <input type="checkbox"/> |

DOLORE O FASTIDIO

- | | |
|-----------------------------------|--------------------------|
| Non provo alcun dolore o fastidio | <input type="checkbox"/> |
| Provo lieve dolore o fastidio | <input type="checkbox"/> |
| Provo moderato dolore o fastidio | <input type="checkbox"/> |
| Provo grave dolore o fastidio | <input type="checkbox"/> |
| Provo estremo dolore o fastidio | <input type="checkbox"/> |

ANSIA O DEPRESSIONE

- | | |
|---|--------------------------|
| Non sono ansioso/a o depresso/a | <input type="checkbox"/> |
| Sono lievemente ansioso/a o depresso/a | <input type="checkbox"/> |
| Sono moderatamente ansioso/a o depresso/a | <input type="checkbox"/> |
| Sono gravemente ansioso/a o depresso/a | <input type="checkbox"/> |
| Sono estremamente ansioso/a o depresso/a | <input type="checkbox"/> |

Indicare quale delle seguenti affermazioni descrive meglio il suo stato di salute oggi, segnando con una crocetta (così) una sola casella di ciascun gruppo.

CAPACITÀ DI MOVIMENTO

- Non ho difficoltà nel camminare
- Ho qualche difficoltà nel camminare
- Sono costretto/a a letto

CURA DELLA PERSONA

- Non ho difficoltà nel prendermi cura di me stesso
- Ho qualche difficoltà nel lavarmi o vestirmi
- Non sono in grado di lavarmi o vestirmi

ATTIVITÀ ABITUALI (per es. lavoro, studio, lavori domestici, attività familiari o di svago)

- Non ho difficoltà nello svolgimento delle attività abituali
- Ho qualche difficoltà nello svolgimento delle attività abituali
- Non sono in grado di svolgere le mie attività abituali

DOLORE O FASTIDIO

- Non provo alcun dolore o fastidio
- Provo dolore o fastidio moderati
- Provo estremo dolore o fastidio

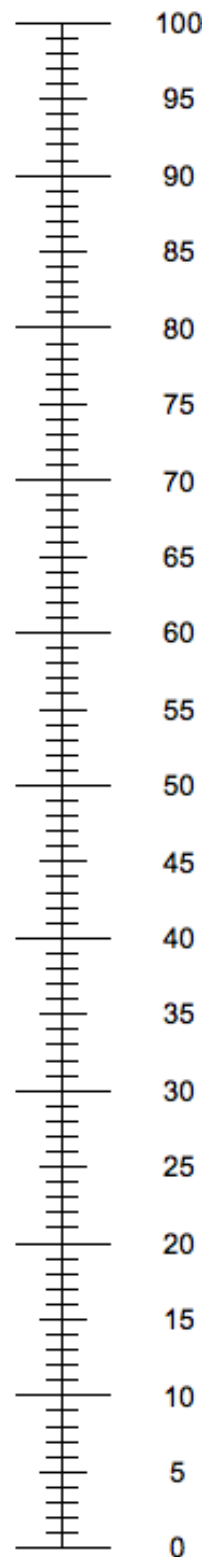
ANSIA O DEPRESSIONE

- Non sono ansioso o depresso
- Sono moderatamente ansioso o depresso
- Sono estremamente ansioso o depresso

- Vorremmo sapere quanto è buona o cattiva la sua salute OGGI
- Questa è una scala numerata che va da 0 a 100.
- 100 rappresenta la migliore salute che può immaginare
- 0 rappresenta la peggiore salute che può immaginare
- Segni una X sul punto della scala numerata che indica quanto è buona o cattiva la sua salute OGGI
- Adesso, scriva nella casella qui sotto il numero che ha segnato sulla scala numerata

La sua salute OGGI =

La migliore salute che può immaginare



La peggior salute che può immaginare