Ethical issues in the treatment of tuberculosis

Knowledge and attitudes of health professionals in three Greek hospitals

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- Tuberculosis,
- Informed consent,
- Patient rights,
- Compliance,
- Autonomy

Abbreviations
WHO: World Health Organization

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ABSTRACT

AIM: This study aimed to investigate the attitudes and knowledge of health professionals with regard to the ethical issues arising in the treatment of tuberculosis patients. METHODS: The research was carried out with the use of a questionnaire to a sample of *n*=105 health professionals. RESULTS: 61.9% of the respondents have knowledge of the WHO Guidance document. 41.9% are cautious regarding consent. 47.2% believe that patients reach erroneous a decisions because of insufficient prior information. As far as communication with foreign patients is concerned, there is no systematic practice. 89.5% inform the patient's family regarding her health conditions as well as the risks arising from the disease and 63.5% informs the employer, if they know him. Non-compliance to treatment is attributed to low educational level of patients (71.8%), lack of social support (70.2%) and limited access to health services (68.3%). 41% believe that detention measures do not constitute a violation of human rights as the protection of public health always prevails. 94.3% believe that further education in ethics is required. CONCLUSIONS: The results (e.g. questioning the purpose of consent, violation protection of the patient's privacy, abuses in disclosure of information to third parties and lack of systematic communication with non-native patients) reveal lack of organized management of the ethical aspects of TB. These issues require further investigation and continuing education of health professionals in Bioethics.
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INTRODUCTION

This paper attempts to investigate the ethical issues regarding tuberculosis, as they are faced in our country, for which TB has been a constant public health challenge and remains so.[1] Following HIV it is globally the second cause of death from infectious diseases, despite the availability of effective medication.[2,3] The ethical aspects and the importance of social determinants which have a significant impact on the success or the failure of effective TB control, largely converge with those regarding HIV/AIDS.[4-9]

Today the biggest burden of the disease is observed in countries where access to basic health services is limited and where there exist conditions of poverty, massive immigration, political instability, environmental pollution, under-nutrition, unhealthy accommodation and exposure to infectious diseases.[10] In Greece, in particular, during an earlier period, an increased frequency of TB and MR-TB cases was observed due to the massive entrance of immigrants from countries in which TB was inadequately controlled, but also because of insufficiency of national epidemiological surveillance, prevention and treatment.[11] For some years now, TB incidence has been falling at an average rate of 4.3% per year.[12] The ethical issues however, still remain and additionally, several studies reveal the linear correlation between the global economic crisis, the loss of productivity and the increase of TB cases, bringing to the surface the necessity of developing special skills, programs and relationships. The latter in particular, does not only concern relationships between health professional and patients but relationships of values such as protection of public health, autonomy, solidarity, reciprocity, effectiveness, participation, transparency and accountability.[13-15]

Given all the above, the World Health Organization published in 2010 a text of "Guidance on ethics of tuberculosis prevention, care and control", based on the respect of fundamental human rights and ethical values.[16] The aim of this paper has been to study the knowledge and attitudes of health professionals dealing with TB patients on a daily basis with regard to a number of ethical issues addressed in the WHO Guidance.

METHODS

Given the small number of the target population, no specific method of sampling was followed. The sample was homogeneous and defined with accuracy, namely medical doctors (lung-/TB specialists and infectious diseases specialists), nursing personnel and health visitors daily involved in the management of TB patients in the cities of Athens and the wider area of Thessaloniki. Due to the limited scale of the study and its focus on the ethical issues, no distinction was deemed necessary between various types of TB.

An anonymous and self-completed questionnaire, especially designed for this study was used, including 28 closed questions addressing the following topics: information and consent, follow-up reminding practices, risks and containment of transmission, confidentiality and restriction measures.. No standardization process was performed due to the small sample. Overall 107 individuals participated and 105 questionnaires were deemed valid. Written consent was obtained from the participants after provision of written information regarding the purpose, the method, the time, the place of the study, details of communication with the principal investigator, the voluntary and anonymous character of participation and confirmation that results of this study would not be used for any other purpose. The research protocol was approved by the Research Ethics Committee of the National School of Public Health. Distribution and collection of the questionnaires took place in October-November 2012.

RESULTS

The study consisted of investigation of greek and foreign bibliography, field work (questionnaires) and description of the study results. Statistical analysis was performed using the SPSS 20. From the resulting variables, mean, frequency and dispersion were studied. Missing values did not constitute a problem for the statistical analysis. Beside the general description of the data, chi-square test and Kolmogorov-Smirnov test were used.

Demographic data are shown in Table 1. There were 71 women and 34 men with a mean age of 41.8 years. From the application of chi-square test and recording of data no differentiation was observed on gender for the

TABLE 1. Demographic data

	f	%
Gender (*n*=105)		
Men	34	32.4
Women	71	67.6
Specialty(*n*=105)		
MD	81	77.1
Nurse	17	16.2
Health Visitor	7	6.7
Place of work (*n*=104)		
Hospital Clinic	81	77.9
TB health Center	20	19.2
Health Center	2	1.9
Other	1	1.0

questions regarding knowledge of the WHO Guidance Text ($p = 0.66$).

The majority of the respondents were medical doctors (77.7%), nurses (16.2%) and health visitors (6.7%) whose participation is especially important in the provision of DOTs.[17] The majority of the participants worked in hospital clinics (77.1%) whereas the rest worked in TB centres (19%) and health centres (1.9%). The average time of experience with TB patients was 11.36 years. Knowledge of the ethical guidance according to place of work of the respondents is shown in Table 2: 61.9% of the respondents confirmed knowledge of the WHO Guidance text while the rest have no knowledge. From the application of chi-square test and and recording of data, it was shown that those who work in hospital setting have better knowledge than other professionals ($p = 0.048$).

Data regarding provision of information to the patient regarding various aspects of the disease, are shown in Table 3. The great proportion of respondents (>83%) provides sufficient information regarding the nature and the transmissibility of the disease, the reason for which testing is necessary, the risks and the side effects of the recommended treatment, the importance of compliance and of protective measures. However, 41% of the respondents believe that processes of provision of consent and participation of the patient to decision-making causes delays in the course of the treatment. 2.4% of justify this view by supporting the fact that patients make wrong decisions due to lack of information, 21.9% believe that this is due to cultural and religious beliefs and 14.3% that this is due to bias and prejudices against doctors as authorities.

Data regarding provision of information according to specialty are shown in Table 4: from the application of chi-square test and recording of data, it is shown that medical doctors provide information more often that

TABLE 2. Distribution of respondents according to issues for which information is provided to the patient

	Yes (%)	No (%)
Basic information regarding the nature and the transmissibility of disease	92.4	7.6
Description of the reasons for which testing is necessary	83.8	16.2
Information regarding risks (side effects) and benefits of the proposed treatment	87.6	12.4
Importance of compliance to treatment	90.5	9.5
Importance of prophylactic measures for avoiding transmission of the disease	93.3	6.7

TABLE 3. Factors which affect non-compliance to treatment

	A lot (%)	A Little (%)	Not at all (%)	Don't know/ not sure (%)
Low income	53.8	38.5	7.7	-
Lack of social support	68.3	29.8	1	1
Low educational status	71.8	23.3	4.9	-
Difficulty in understanding instructions for taking medication	39.8	55.3	3.9	1
Difficulty in understanding the language during communication with the doctor	48.1	44.2	7.7	-
Age of patient >50 years	6.9	47.1	43.1	2.9
Inadequate knowledge about the disease	37.5	50	12.5	-
Ignorance of the importance of following treatment	53.8	36.5	9.6	-
Fear of stigmatization	46.5	40.6	11.9	1
Inadequate care by the health personnel	8.7	35.9	53.4	1.9
Negative attitude of patients towards health personnel	12.5	49	33.7	4.8
Lack of medication	25	42.3	28.8	3.8
No access (geographical, financial) and no insurance	70.2	25	4.8	-
Strong side effects	26.9	51.9	21.2	-
Temporary improvement of the patient	31.1	56.3	10.7	1.9

TABLE 4. Bivariate distribution of specialty with the question "Information regarding risks (side effects) and benefits of the recommended treatment"

			Information regarding risks (side effects) and benefits of the recommended treatment		**Total**
			Yes	**No**	
Specialty	MD	*f*	78	3	81
		%	96.3	3.7	100.0
	Other	*f*	14	10	24
		%	58.3	41.7	100.0
Total		*f*	92	13	105
		%	87.6	12.4	100.0

other specialties ($p = 0.001$) but there is no differentiation regarding their opinions on the issue of consent ($p = 0.098$).

The concept of information includes reminding of follow-up appointments to the patients: 45.7% remind by telephone, 3.8% in a written form, 1% by e-mail, 13.3% with a combination of the above-mentioned methods and 35.2% do not systematically follow one of the above mentioned methods.

As far as medical confidentiality and privacy are concerned, 69.5% of the sample believe that this right is covered in a satisfactory way, whereas 21.9% support the opposite view, giving as reasons lack of space and time. 8.6% believe that in case of infectious diseases like TB, confidentiality and privacy are not an issue.

Regarding confidentiality in relation to third parties, i.e. family and employers, 89.5% of the sample reply that they inform the family environment for the patient's condition and risks of transmission and 63,5% reply that if they had access to the employer they would also inform her. On the contrary, 26.9% reply that they do not inform third parties but try to persuade the patient to do so. 9.6% believe that informing third parties is against medical deontology. Regarding the question of whether medical data concerning the patient must be made publicly known against the patient's will for the protection of public health, 24% reply positively, 67.3% also reply positively but solely for cases where the risk to public health is very high, whereas only 8.% state that in no case *at all* should the patient's data be made public.

Attitudes regarding communication with non-native patients are shown in Figure 1: the majority of the respondents (57.4%) follow the practice of approaching a compatriot of the patient who knows the greek language and asks him/her to act as an interpreter, 25.3% address special services of the hospital, 12.3% provide the patient with written instructions hoping that a third person will help her follow the treatment and 4.9% of the respondents ask the patient to leave and come back with a person who could act as an interpreter.

Regarding the issue of receiving treatment, 20.9% -29.1% of the respondents believe that patients provide the necessary information to the health personnel regarding the problems they face and their medical history.

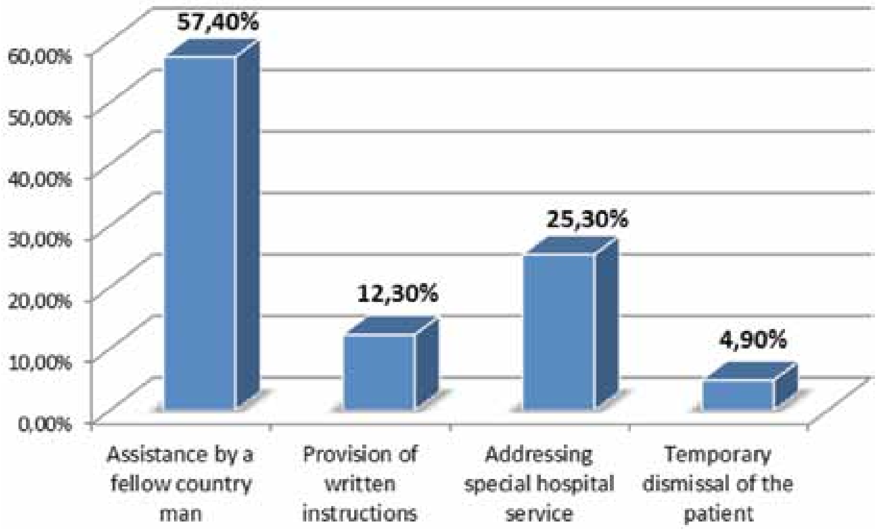

FIGURE 1. Communication with foreigners

Factors affecting non-compliance are shown in Table 5: A great proportion of the respondents (71.8%) believe that the major reason for non-compliance is low educational status, followed by lack of access to health services (70.2%), lack of social support (68.3%), low income (53.8%), ignorance of the importance of treatment (53.8%) and language barriers (48.1%). The age of the patient and the provision of insufficient care by the health personnel do not seem to constitute factors enhancing non-compliance.

Not surprisingly, a great proportion of the respondents has faced circumstances where it was necessary to proceed to isolation of a patient. 53% support the view that although isolation is tantamount to a violation of the rights of the patient, they would agree to such measures if these are imposed in accordance with the law and the International Health Regulation. On the contrary, 41.9% believe that there is no issue of violation when public health is at risk (Figure 2).

TABLE 5. Bivariate distribution of the Dept of work and the question "Do you know the WHO Guidance on ethics of tuberculosis prevention, care and control?"

			"Do you know the WHO Guidance on ethics of tuberculosis prevention, care and control?"		**Total**
			Yes	**No**	
Dept of work	Hospital Clinic	*f*	47	34	81
		%	45.6	33.0	78.6
	Other	*f*	18	4	22
		%	17.5	3.9	21.4
Total		*f*	65	38	103
		%	63.1	36.9	100.0

According to the respondents, when restrictive measures are applied, health care is often (32%) or always (57.3%) provided, whereas opinions on the simultaneous provision of social welfare measures, are divided. 42% believe that fear of isolation rarely prevents patients from accessing health services.

Finally, the majority (94.3%) believe that education in the ethical and human rights aspects of TB treatment falls short of what it should be. The most appropriate methods of further education seem to be workshops (28.3%), seminars (26.2%), as well as courses on a graduate (21.3%) and post-graduate (24.3%) level.

DISCUSSION

In the present study we found that despite a certain knowledge of the WHO Guidance text, in practice a lack of a systematic approach is observed regarding a number of ethical issues in the daily management of TB (consent, data protection and privacy, communication with the patient, restrictive measures). The opinions of the population study, albeit reflecting a long standing experience, do not seem to be based on theoretical and educational background

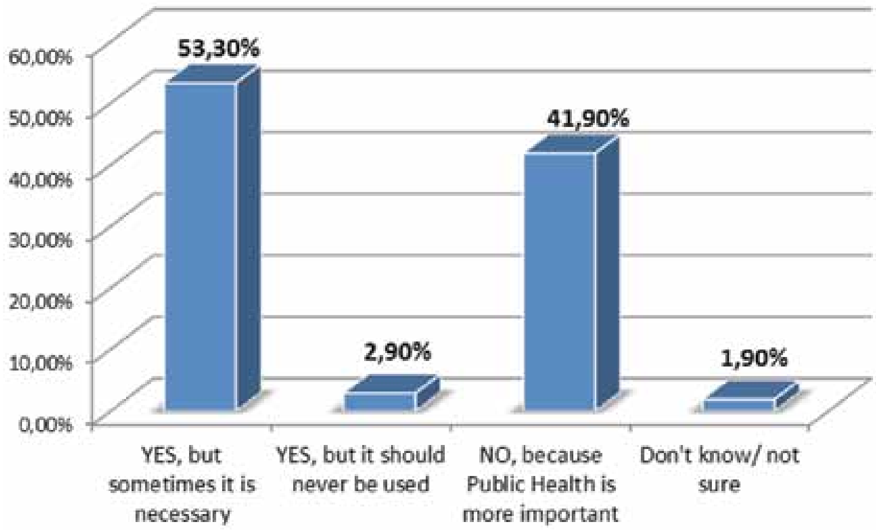

FIGURE 2. Restrictive measures as violation of human rights?

in Bioethics. As a result additional interventions, further research and continued systematic education of health professionals in ethics seem to be imperative.

The first part of the study concerned demographical data and knowledge of WHO Guidance document: according to the results the majority seems to know the document, which serves as a model framework to be adapted in each country, albeit without qualitative deductions.[18]

The second issue that was investigated was informed consent. The relatively high percentage of the respondents who believe that informed consent is an obstacle to treatment, righly creates the impression of a serious deviation from the internationally existing norm regarding necessity of consent. This finding therefore should be analyzed by distinguishing two issues: offering *testing* and offering *treatment*. Given that TB is a disease that must be notified to the authorities and that albeit in a lower level than HIV/AIDS in the 1980s,[20] it remains highly stigmatized, testing and screening belong to an intermediate legal point: When *testing* is offered "there is usually no need for a specific process of confirming the patient's agreement, as consent to go through necessary diagnostic testing is implicit in general agreement given to undergo medical examination. An exception is situations where there is no treatment available and only testing can be performed". In case of refusal of consent, the role of the health personnel is to advise and understand reasons of refusal.[19] This mostly regards subsaharian countries where second-line treatment is not available.[16,20] When however, patients are offered *treatment*, "their specific consent should be sought as it would be for other significant medical interventions" (WHO Guidance, p. 14).

Reminding of follow-ups is considered absolutely necessary not only for the positive outcome of the treatment but for the establishment of a good relationsgip and cooperation with the patient. The active location of defaulters (for more than 2 months) and of those who appear to follow-ups with a delay, also raises issues of consent.[21] Today, mobile health has significantly contributed to compliance.[22-24]

The third group of questions concerned protection of privacy and confidentiality with regard to third parties. Systematic and compulsory notification of TB cases according to existing legislation, which is required for effective epidemiological surveillance, is a different thing from occasional breach of medical confidentiality and personal data. Regarding information of the greater social environment and of employers (and here it should be mentioned that TB can affect a significant number of workers in many fields),[25,26] the Code of Medical Ethics (Act 3148/2005) stipulates that personal medical data can be communicated to a third party following the written consent of the patient. Publication of personal data, according to recent experience in Greece , lead to phenomena of stigmatization and social exclusion without any real benefit to public health.[27]

Communication in particular with foreign patients, was also investigated. Lack of knowledge of the dominant language is confirmed as a major obstacle regarding the accessibility of health services.[28-31] The study reveals that there is no systematic way of dealing with the problem, as only *ad hoc* solutions are being sought by the health personnel (assistance by a fellow country man of the patient, appeal to intercultural mediators, or recommendation to the patient to leave and come back accompanied by a person who knows the Greek language).[32] The latter in particular, albeit well intentioned, may have a reverse effect on patients who, feeling rejected may default.

The next group of questions concerned reliability of the patient and compliance to the recommended regimen. Compliance is not only important for a positive outcome, it also reflects a change of behaviour and adaptation to a new kind of reality in the patient diagnosed with TB, which may lead to personal empowerment and increased sense of personal responsibility,[17] not only with regard to treatment but also to prevention through health education.[33] Empowerment has deep roots in the history of TB (as was later the case of HIV/AIDS and education in safe sex practices) and has been based on the assumption that TB cannot be eradicated, it can just enter into remission, prevention therefore with regard to lifestyle, is especially important.[34,35] As far as the behaviour of health professionals towards TB patients is concerned, "*Any practitioner treating a a patient for tuberculosis is assuming an important public health responsibility. To fulfil this responsibility the practitioner must not only prescribe an appropriate regimen, but also be capable of assessing the adherence of the patient to the regimen and addressing poor adherence when it occurs*".[36] This is repeated in the guidelines of the National Drug Organization (EOF) for the management of pulmonary tuberculosis, according to which "*the responsibility of the completion and the successful outcome of the treatment belongs to the treating physician and the health system*".*

The findings of the present study regarding lack

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* http://www.eof.gr/c/document_library/get_file?p_l_id=34765&folderId=33979&name=DLFE-1007.pdf.

of compliance are in line with international references which also give as reasons low socio-economic status and ignorance of the importance of treatment.[37-40] Older bibliography was pointing out to the fact that in some cases especially "compliant" patients either build a wall around them or develop hostility towards their environment.[41] Today there is concern about the power of health professionals as stigmatisers and the language used in TB health services and support is growing against use of words such as *defaulter*, *suspect* and *control*, as these are considered *inappropriate, coercive* and *disempowering*.[42,43] The way health professionals perceive the ethical aspect of restrictive measures, was also considered of special importance. A broad range of legislative models can be found in the control of TB, ranging from the most authoritarian to the least restrictive.[44] Isolation of TB cases consist one of the most burdensome measures in most European countries although its effectiveness has been heavily criticized. In a comparative research, Martin has supported that in France where the legal framework is less severe, TB is better controlled than in the UK where stricter measures are applied.[45] The focus of this study is not the analysis of the existing legal framework, rather the way in which health professionals perceive the sense of isolation as an act which, albeit necessary, is a violation of rights and should be applied only under very specific conditions and should follow a very high *evidential standard*. The risk of discrimination or stigmatization caused by isolation, even for a short period, raises an ethical problem.[46-49] It is important that information has been previously provided to the patient in question regarding her options and provision of consent. Informing the patient also has a secondary effect, namely enhancing trust to the health system.[50] According to the WHO Guidance, isolation is accompanied by treatment only if the patient agrees and cooperates otherwise a continuous violation of her bodily integrity and continuous risk for the health personnel would arise.[51]

It is encouraging that the majority of the respondents is aware of the ramifications of the restrictive measures but also of the importance of social determinants, as they believe that whereas medical care is almost always provided to the isolated patient, this is not the case regarding parallel application of social measures.[52]

The last issue was education. The respondents underlined the necessity of further education regarding the ethical aspects confirming the fact that the knowledge and skills required for the management and treatment of TB are not limited το the medical field. Such education would significantly contribute to the achievement of the strategic aims of STOP-TB (improvement of quality of DOT, acknowledgement of the social determinants of health, general empowerment of the patients[7] and participation of more professionals) and should focus on skills and tools addressed to the management of serious and complex ethical dilemmas.[53-54]

Despite some limitations in the study, such as lack of relevant Greek bibliography, the need to design a new questionnaire and small sample size, the originality of the topic, the specialties involved in the study population and the range of issues investigated can be considered as strong points. The National Action Plan for the prevention of Infectious Diseases which had been drafted before the WHO Guidance text, does not make any specific reference to bioethical issues with regard to TB, it provides however actions for the education of health professionals.[55] This education should include: a) a general overview of the basics of public health ethics, b) implementation of these principles as tools for appropriate decision making, c) exploration of the relation of ethics and law, d) discussion of case studies in order to identify ethical issues, e) finding practical ways to integrate ethical considerations in the day-to-day decision making.[56] Moreover a common helpful practice is the the publication of short collections pertaining to the legal framework, the organization of educational seminars with international participation as well as with the contribution of the World Health Organization on issues regarding training, human rights, dissemination of good practices and experiences and creation of protocols including all the steps that have to be taken in cases of isolation or quarantine[57,58]. As a conclusion the implementation of international guidelines in combination with continuing education and acquisition of specific skills of health professionals working in this difficult and value laden field, in Bioethical issues, could prove especially beneficial importance for better management of TB in our country.

COMPETING INTERESTS

The authors have indicated no financial or other conflicts of interest.

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