ORIGINAL ARTICLE

PRACTICE OF INFORMED CONSENT FOR THE TREATMENT OF TUBERCULOSIS

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ABSTRACT

Objective: To find out the practice of informed consent obtained and opinion for seeking it, from patients enrolled under direct observation treatment short course for the treatment of tuberculosis in three public sector chest clinics of Karachi and recommendations accordingly.

Study design: A cross-sectional hospital based survey.

Methodology: This survey was conducted on 138 patients selected by systematic random sampling method from Lyari, Nazimabad and Malir chest clinics of Karachi. Independent variables of this study were age, gender, educational level, socio-economic status, place of residence and habits of the patients enrolled in direct observation treatment short course. Dependent variables of this study were information about the diagnosis of the disease, drug's dose, duration, intake method, its side effects and voluntary consent/approval for enrolling in the treatment regime prescribed by the health care provider. Inclusion criteria of this study were confirmed diagnosed case of tuberculosis according to criteria set by the said clinic, in the initial intensive phase of the treatment. Exclusion criteria were patients of tuberculosis given treatment on trial basis or patients in the continuation phase of treatment.

Results: It was found that 100% patients had no knowledge of informed consent. Patients were informed only verbally about their diagnosis, drugs required to treat their illness, its dose, duration, intake method and side effects by the health staff. Thirty percent patients were unable to recall which part of their body was affected by the disease; 90% remembered the duration of therapy without understanding the difference of initial intensive or continuation phase of the treatment, 57% were taking drugs in the presence of a responsible person; 48% recalled the reason for direct observation of drug intake and 72% were found to be in favor of seeking consent before enrolling themselves in direct observation treatment short course.

Conclusion: In this study it was found that the practice of obtaining informed consent was below the standard level of international and ethical acceptability in the studied public sector chest clinics of Karachi.

Keywords: Informed consent, Direct Observation Treatment Short Course, ethics.

INTRODUCTION

Informed consent is a process by which a patient authorizes health care provider for medical care after discussing its pros and cons.[1] In the past it was not necessary to obtain permission for medical care, at present in order to respect patient's autonomy it has become essential requirement to obtain permission prior to treatment.[2] Informed consent comprises of two components-information and consent. Information refers to the disclosure of the diagnosis, treatment options, its benefits and risks which has to be explained to the patient, consent refers to voluntarily decision of the patient to proceed with the medical care.[3] Tuberculosis is one of the diseases included in top 10 global mortality causes and Pakistan ranks 6th among 22 high burden countries.[4,5] Despite the availability of National Tuberculosis Control Programme, major problem in controlling this disease is non-adherence to treatment regime resulting in drug resistant strains.[6] In order to tackle this problem of non-adherence, WHO launched Direct Observation Treatment Short Course (DOTS) for the treatment of Tuberculosis in 1994. It has five core

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components, one of which is direct observation of drug intake of patient by health staff/family member or any other responsible person.[7] DOTS implementation has caused ethical dilemma throughout the world as individual autonomy and privacy is curtailed when asked to take drug in the presence of another individual. It has also raised question of un-acceptable intrusion in the privacy and liberty of individual.[8]

Informed consent is ethically, morally and legally mandatory. Law has given right to the patient to draw voluntarily decision for his/her own health care. This study will help to create awareness among individuals about their legal rights and autonomy for drawing independent decision for their own health care besides the responsibilities of health care providers to disclose pertinent medical information to the patient and respect for their decision of autonomy. In order to argue the practice of informed consent in DOTS. This study was conducted with the objectives to find out the practice of informed consent obtained, opinion for seeking it from patients enrolled under DOTS in three public sector chest clinics of Karachi.

PATIENTS AND METHODS

This was a cross-sectional hospital based survey conducted in three public sector chest clinics i.e. Lyari, Nazimabad and Malir, of Karachi, from November 2007 to May 2008. Keeping the anticipated population proportion of 10% and 95% confidence level with absolute precision of 5 percentage points. A total of 138 samples were collected.[9] Systematic random sampling procedure was adopted for the selection of samples and every 3rd patient (as decided by the ethical review committee of DUHS) attending the said clinic were selected for the study. Inclusion criteria for this study were diagnosed cases of tuberculosis according to criteria set by the said clinic and in the initial intensive phase of treatment. Exclusion criteria were tuberculous patients given treatment on trial basis or patients in the continuation phase of the treatment. Independent variables of this study were age, gender, educational level, socio-economic status, place of residence and habits of patients enrolled under direct observation treatment short course.

Dependent variables were elements of informed consent i.e. information about the diagnosis of the disease, treatment required, drugs, its dose, duration of therapy, method of intake, its side effects and voluntary consent i.e. approval/option from the patient for enrolling them in the treatment method prescribed by the health staff. A questionnaire was designed for the collection of data. Principal investigator interviewed the respondents which took 10- 15 minutes per performa.

The study was approved by Ethical Review Committee of Dow University of Health Sciences, Karachi no. 02-PMRC/ERB-30 DUHS/ October 2007. Verbal consents were taken from the respondents. Data was analyzed on SPSS version 10;chi-square was used as a test of significance at 0.05 alpha level to find out the association of the variables studied.

RESULTS

A total of 138 patients fulfilling the inclusion and exclusion criteria were selected from Lyari, Nazimabad and Malir chest clinics of Karachi . Twenty-one incomplete performa (due to language problem) were discarded and remaining 117 complete performa were analyzed.

There were 58% female and 42% males; 64% were less than 30 years of age; 51% were illiterate; 45% were housewives and 69% were not addicted to anything. In this study 88% patients were diagnosed for the first time and 12% were re-treatment cases due to default, relapse or recurrence. All 100% had not heard about informed consent, but all patients recalled that they were informed by health staff, about their diagnosis, drugs required, dose, its side effects and methods of intake verbally. Thirty percent were not able to recall the part of their body affected by the disease, 90% remembered the duration of treatment without understanding the difference of initial intensive or continuation phase of the treatment, 57% patients were taking drugs in the presence of a responsible person, 48% recalled the reason as to why the drugs should be taken in the presence of a responsible person and 50% patients knew the side effects of anti-tuberculous drugs (Table1). Nearly all patients were unaware, that there was another modus operandi i.e. conventional/domiciliary method for the treatment of tuberculosis. When patients were inquired about their consent for enrolling them in DOTS, it was found that none had been asked for it. On the other hand it was also found that all patients diagnosed positive for tuberculosis in these clinics had to take the anti-tuberculous drugs as prescribed by the health staff. Seventy two percent patients were found to be in favor of obtaining consent before they were enrolled in DOTS. Age was the only variable found to be statistically significant for direct observation of drug intake($p = 0.006$)

and duration of the therapy (p = 0.04).

DISCUSSION

Successful relationship between physician and patient depends on trust and to maintain trust, patient's autonomy should be respected by obtaining consent for treatment which is essential for good clinical practice. The purpose of informed consent is to encourage patient's awareness of risks and complications associated with the treatment and to obtain consent to encounter those risks.[10] In this study 100% patients had no knowledge of informed consent. It was obtained neither verbally nor in writing. Some information about the diagnosis, drugs, its dose, intake methods and side effects were given verbally. This finding was found consistent with the study conducted to determine the practice of informed consent in 16 public and 10 private radiological centers consulted by patients for advanced radiological procedure where some information was provided by the radiologist which was below the standard to international and ethical acceptability.[11] According to law, health care provider should disclose all pertinent information including risks and benefits of alternative treatment/procedure, required by the patient. It is also essential for the patient to decide for his/her own health care and health care provider should respect his/her decision and autonomy, but the patients in the afore-mentioned study were satisfied with the given information to some extent.[11] Similarly a study conducted on 200 post operative patients in a public sector hospital to determine the practice of informed consent found that in 8% of the cases surgeons were themselves involved in obtaining consent, 45% were told about the nature and purpose of surgery, 45% knew the possible complications of surgery and 20%were allowed to ask questions.[12] This was due to the large number of the patients on operation list and less time available to the health care providers in public sector hospitals. Even then most of the patients were satisfied with the information provided.[12] In the present study, 51% patients were illiterate and they had no knowledge of their rights. This was due to cultural factors also, health care providers were allowed to do what is good for the patient. This was one of the reasons as to why practice of informed consent was a neglected procedure. Similarly review showed that informed consent was taken only as a causal formality both by the doctors and by the patients, due to local cultural factor and social customs, this practice needs to be rectified.[13] In the present study, it was also noted that patients were satisfied, despite incomplete information being provided to them. This was due to lack of knowledge and lack of importance of their autonomy. The practice of informed consent in our country have many practical problems including inefficient health care system, low literacy rate, poor concept of individual rights and higher social status of the health care provider, all of which needs consideration.[14]

When bioethics were started in late 1950s, in western countries, concept of autonomy was largely developed for non-infectious diseases which cannot be applied to infectious disease like tuberculosis where patients act both as a victim and a vector.[15] One central reason of WHO to treatment for implementing DOTS was non-adherence of patients due to 8-9 months treatment besides other reasons like poverty, illiteracy and lack of health care. Another question raised was that TB patients once informed of the condition and its infectiousness, will still be persistanty non-adherent to the treatment or not? This dilemma can be solved by discussion among various school of thoughts for consensus. Those having Utilitarian approach would advocate patient's attitude of non-adherence to treatment as unethical due to potentially harmful effect on the society. Therefore the State should enforce treatment disregarding the consent of the patient. On the other side of the spectrum are pure Libertarians who intend to protect the privacy and autonomy of the individual and thus disregard DOTS.[16] In case of tuberculosis where patient acts both as a victim and a vector, due to its mode of transmission, implementing DOTS was violation of individual rights on one hand but on the other hand not implementing DOTS was violation of the rights of others. Therefore, in infectious disease like tuberculosis individual rights could be justifiably over-ridden for example by not obtaining consent for DOTS in order to protect the interest of larger community to protect others from multi-drug resistant strains. Therefore in tuberculosis, Utilitarian approach can be followed after calculating risk benefit ratio. It is the duty of the State to protect others by promoting good practices for the larger community.[17]

Childress and Faden had also proposed an ethical framework which consists of five considerations which can be used for considering ethical dimension of public health.[18]

These considerations include effectiveness, proportionality,

necessity, least infringement and public justification.[18] The logic of WHO behind DOTS was supported by data reflecting decrease relapse and resistance rate after its implementation as seen in results.[19] However, studies conducted in WHO regions on DOTS strategy, including Pakistan, had not found its superiority over self administered method.[20]

This was a cross-sectional hospital-based study and had many limitations. Firstly, the study was conducted in only three public sector chest clinics and the practicability of informed consent obtained from patients enrolled in DOTS at private clinics was not reflected in this study. Cross-sectional studies are useful for formulation of hypothesis which has to be confirmed in analytical studies. Alpha test was applied with respect to internal validity of the study which revealed 80% reliability meaning that this study is internally valid. Internal validity is tested by alpha test which is a reliability test. It is applied to find out if independent and dependent variables are connected or not for drawing causal inference.

RECOMMENDATIONS

The information of the disease and treatment procedures should be provided to all patients enrolled under DOTS/domiciliary/conventional in chest clinics for the treatment of tuberculosis and it should also be documented to protect health care staff from repercussion of nontreatment of patients including their own family members. Options should be sought from patients for DOTS presenting with TB for the first time and compulsory DOTS should only be implemented in patients who are defaulted because principle of autonomy in this disease due to its transmission method and non-adherence to treatment regime demands Utilitarian approach by the State in order to diminish the threat of multi-drug resistant strains in the interest of the community. Based on the option of patients to agree for DOTS or for conventional/domicillary therapy, effectiveness of DOTS strategy could be studied in our settings.

CONCLUSION

In the studied public sector chest clinics of Karachi, it was found that in spite of available guidelines, the practice of informed consent was below the standard level of international and ethical acceptability

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Table 1: Practice of informed consent for treatment of Tuberculosis

Independent and dependent variables	
Independent Variables	**N = 117**
Gender	
Male	49(41.9%)
Female	68(58.1%)
Age Group	
10 – 29 years	75(64.1%)
30- 60 + years	42(35.9%)
Education	
Illiterate	60(51.3%)
Primary	17(14.5%)
Secondary & Higher	40(34.2%)
Dependent Variables	
Know the part of body involved by disease	
Yes	82(70.1%)
No	35(29.9%)
Know the duration of therapy	
Yes	105 (89.7%)
No	12 (10.2%)
Know the reason of direct observation of drug in take	
Yes	56(47.9%)
No	61(52.1%)
Know the side effect of drug	
Yes	58(49.6%)
No	59(50.4%)
Treatment with direct observation (DOTS)	
Yes	67(57.26%)
No	50(42.74%)

REFERENCES

1. Ethells E, Sharpe G, Walsh P et al. Bioethics for clinicians 1; consent.CMAJ 1996; 155: 177-80

2. Blackhall LJ, Murphy ST, Frank GV et al. Ethnicity and attitude towards patient autonomy. JAMA 1995; 274: 820-5.

3. Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. New York: Oxford University Press 2001:79.

4. Dye C, Scheele S, Dolin P et al. Global burden of tuberculosis.Estimated incidence prevalence and mortality by country. JAMA 1999; 282: 677-86.

5. Global tuberculosis control: surveillance, planning, financing. WHO report, Geneva, World Health Organization 2007 (WHO/HTM/TB/2007.376).

6. John DH, Ogden JA. Public health ethics and tuberculosis. Ind J Tub 1999; 46: 3-9.

7. Garner P, Volmink J. Directly observed treatment for tuberculosis. (Editorial) BMJ 2003; 327: 823-4.

8. Bayer R, Dubler N. The dual epidemics of tuberculosis and AID, ethical and policy issues in screening and treatment. Am J Public Health 1993; 83:649.

9. Lwanga SK, Lemeshow S. Sample size determination in health studies; WHO, Geneva 1991: 25

10. Doyal L. Good clinical practice and informed consent are inseparable. Heart 2002; 87: 103-25.

11. Haq T, Ahmad B, Akhtar W et al. National Survey for practice of informed consent in the radiology departments. J Pak Med Assoc 2003; 3:172-6.

12. Amin MF, Jawaid M, Rehman S. An audit of information provided during preoperative informed consent. Pak J Med Sci 2006; 22: 10-3.

13. Saaiq M, Zaman K. Causal consent to treatment: a neglected issue in our health care system. Ann Pak Ins Med Sci 2006; 2: 207-9.

14. Khan RI. Informed consent and some of its problems in Pakistan. J Pak Med Assoc 2008; 58: 82-4.

15. Beers MH. Polio the Merck manual of medical information. 2nd ed. Pocket Books USA; 2003: 712

16. Selgelid MJ. Ethics and infectious disease. Bioethics 2005; 19: 277-8.

17. Francis LP. How infectious disease got left out and what this omission might have meant for bioethics? Bioethics 2005; 19: 307-22.

18. Childress JF, Faden RR, Gaare RD et al. Public heath ethics: mapping the terrain. J Law Med Ethics 2001; 30: 170-8.

19. Weis SE, Solcum PC, Blais FX et al. The effect of directlyobserved therapy on the rates of drug resistance and relapse in tuberculosis. N Engl J Med 1994; 330: 1179-84.

20. Khatri G, Frieden TR. Controlling tuberculosis in India. N Engl J Med 2002; 347: 1420-5.