

**Medicine & Pharmacy University**

**Craiova**

**DOCTORAL DISSERTATION**

**Summary**

**Project for implementation, monitorization and  
evaluation of a program for improving TB patient's  
treatment compliance**

**Scientific conductor:**

**Cristian Didilescu, Assoc.Prof.,MD,MPh.**

**Scientific Researcher I**

**Doctorandus:**

**Manuela Gheorghiu-Brânaru,**

**MD/MPH**

**2010**

## Content

### Introduction

#### Chapter I

- General impressions on tuberculosis
- Tuberculosis in Romania and its containment at national level
- Tuberculosis - disease. General information
- Receptive population
- Tuberculosis infection and disease- diagnosis, treatment

#### Chapter II

- Therapeutic compliance
- Tuberculosis compliance
- Factors that increase the tuberculosis treatment compliance
- Strategies of improving compliance to tuberculosis treatments
- Studies on compliance world-wide and in Romania

#### Chapter III

- Personal investigations
- Study on the factors influencing therapeutic compliance on TB patients in Romania
- Results & conclusions of the study

#### Chapter IV

- Proposition – Project
- The logical scheme of the project

#### Chapter V

#### Final conclusions

Key words – tuberculosis ,compliance , treatment compliance , patients, incentives, project

## **Introduction**

Tuberculosis represents an important public health issue in Romania.

Increasing patients' compliance to the anti-tuberculosis treatment by offering incentives or other facilities, together with the huge efforts made for improving the health education level and the communication between the patient and the medical staff, all would contribute to stop TB.

The efforts for stopping tuberculosis need to be approached both multi-disciplinary and inter-sector in order for them to prove themselves efficient.

## **Chapter. I General impressions on tuberculosis**

Tuberculosis keeps displaying its history of over 3000 years, infecting at the present time a third of the world's population and killing some 2 million people every year. Tuberculosis is considered by the Global Health Organization to be an international emergency situation beginning with 1993 and up to this day.

It is estimated that in the last decade of the last century, over 32 million new TB contaminations and over 10 million TB related deaths were registered world-wide.

In the Europe region, 16 out of 51 countries are struggling with dynamic growths of the incidence in the past few years. 77 % of the entire European endemic is concentrated amongst these countries. Romania places 3rd in what concerns endemic severity. Regardless of the existence and constant application of the so-called DOTS strategy, tuberculosis continues to make victims.

## **Tuberculosis in Romania and its containment at national level**

Tuberculosis is a serious matter of public health in Romania and is recognized and treated as such, with seriousness and responsibility.

According to the forecasts, the analysis of the statistical data shows a decrease of tuberculosis incidence in our country in the last few years. **In Romania**, after 1985, as well as with other diseases influenced continuous decay of living conditions; tuberculosis incidence has started to register a progressive growth, slightly more accelerated after 1990, peaking in 2002 - 142.2‰. Since 2003, an incidence decrease was registered, to as low as 107,8‰ in 2008.

## **Tuberculosis - disease. General information.**

Tuberculosis is one of the most, curable" infection diseases. The treatment is remarkably efficient in killing the germs and in allowing for the lungs to heal. The earlier the treatment is started, the better for patient's healing. A healed tuberculosis patient becomes a normal person; that can socially integrate himself again and can continue his life from where it was halted by the disease. Untreated, tuberculosis cannot heal, ultimately evolving towards the patient's decease. It should not be forgotten that, until the antibiotic era, phthisis diagnosis was synonymous with certain death.

## **Receptive population**

The receptiveness for the M. tuberculosis infection is general. A high risk of exposure to the infection is prone to some population categories, in close connection with the social-professional factors: TB patient contacts, people crowding, medical staff, people with bad immunity, like drug consumers, HIV infected people, homeless people, prisoners,, etc.

## **Tuberculosis infection and disease**

Tuberculosis is a classic example of a germ-induced disease, towards which the body reacts particularly. A characteristic of the cyclic evolution of tuberculosis is the fact that it is not the actual break-in of the bacillus in the organism that necessarily

triggers the disease; it is only possible for the infection to start. It's generally agreed that only 10% of all infected persons will actually develop tuberculosis in the following 50 years.

Tuberculosis - disease, may appear in continuance of the infection, usually taking place during childhood years (primary tuberculosis) and after a period of time the remaining viable bacilli in the infections lesions begin to multiply and trigger the disease (secondary tuberculosis). The diagnosis methods are epidemiological, clinical and para-clinical. Confirmation of the TB diagnosis is made by the identifying of the bK in microscopy or culture from the clinical samples specific to the TB location.

The treatment of tuberculosis ensures the healing of the patients, lowering the risk of relapse, preventing deceases, preventing the installment of MT chemo-resistance, preventing the complications and limiting the spread of the infection. The anti-tuberculosis treatment is a standardized therapy, stage zoned (bi-phase regimes), realized by associating several anti-TB drugs. Briefly, the long-term, with numerous drugs treatment is difficult to be accepted by the patient.

ROMANIA has a long tradition regarding tuberculosis control.

The National Tuberculosis Program (NTP) in Romania is ,at the present time structured after DOTS strategy and the main objective of the program is constituted by the most urgent limitations of the spreading of the disease and infection amongst the population .

## **Chapter II – Therapeutic compliance**

The most frequently quoted conceptual definition of the treatment compliance is „the measure in which the behavior of one individual complies to the to the recommendations of the doctor” , or „the measure in which the patient’s behavior corresponds to the recommendations of the medical services suppliers” ,

The definition for compliance to long term therapies , derived from Haynes’ definitions is : the action through which the behavior of an individual (ex: taking medication, respecting the diet, making a change in one’s life-style) corresponds to the recommendations agreed by any health services supplier.

The definition adopted by the project regarding compliance for chronicle diseases is „the disease where one or more of the following statements /characteristics are permanent, leave sequels, and caused by irreversible pathological alterations, need the patients’ efforts for rehabilitation or might need a long period for supervision, observation and care”.

### **Tuberculosis compliance**

If individuals with high risk of low compliance can be identified on time during case management, then the implicated medical personnel should , theoretically, be capable of intervening in adjusting the treatment administration module, so that the patient will be capable of finishing the therapy. Unfortunately, the existing evidence, show that those working in the health system are not capable to predict which of the patients will be non-compliant.

Specialty literature indicates over 200 variables associated with non-compliant patients. Most of the determinant factors are non-modifiable, thus, demonstrating that age, sex, level of training influence compliance, isn’t leading to a remedy of the situation. Moreover, the demographical, social, economical factors as well as others place poverty in relation with the patient’s motivation and fail to explain why some TB patients adhere to the treatment, although experiencing several unfavorable factors. On the other hand, one cannot deny the existence of some patients that, in spite of the favorable factors of compliance (ex. Training level), refuse to correctly follow the treatment.

Administering the treatment can be pleasant both for the patient and the therapist. If the patient feels that is treated with deference, a relationship can be developed with positive repercussions both on the patient's behavior in the DOT, but also, long-term, in life.

Ensuring material support of the TB patients, in conditions of affecting an individual through this disease determining alienation or marginalization, in the sphere of current activities, with social, professional and family related longing ,up to negative behavior and retaking current activities, can increase compliance to the treatment.

#### **Factors that increase the tuberculosis treatment compliance**

- Geographical and social-economical factors
- Factors related to the health system and the doctor-patient relationship
- Factors related to tuberculosis-the disease
- Factors related to the treatment and its complexity
- Patient related factors

**Increased compliance** is a model factor of the effectiveness of the health system and increases patients' security.

Improving the compliance represents the best investment for the effective restraining of the conditions of chronicle diseases.

Analysis studies find significant growth in the cost/benefit ratio and increases of efficiency in the low-cost interventions for modifying compliance. In most cases the investment is quickly recovered through savings made in the health department and otherwise, through boosting the achievements in the health department, fully justified in the investments.

#### **Strategies of improving compliance to tuberculosis treatments**

According to many studies ,a single intervention is not enough for achieving the goals set and most studies utilize a combination of interventions, amongst which most used are the following: health education ,amelioration of the behavioral attitudes, compensations, social support, follow-up by phone or SMS ,etc.

Ameliorating the patient-therapist relationship, Implementing the DOT System, Using incentives ,Motivating the medical staff, supervising , the training and management of the amelioration process in patient relations, IEC ,etc, psychotherapeutically intervention .

#### **Studies on compliance world-wide and in Romania**

Beginning with 2004, projects financed by the Global Fund for Fighting HIV/ AIDS, Tuberculosis and Malaria were run in Romania following the objectives of The National Tuberculosis Program that mainly pursued training the medical staff in the implementing of DOTS strategy;

- Supplying the pneumo-phtisiology units with medical and IT equipment;
- Creating and implementing software in the purpose of reporting and centralizing the TB cases at national level;
- The permanent supervision of the activities held within The National Tuberculosis Program;
- The HIV testing of tuberculosis patients;
- The elaboration of medical guides for good practicing in the field of tuberculosis, destined to the medical staff in the pneumo-phtisiology network;
- The ensuring of high-quality second line drugs, to patients with multi-drug resistant tuberculosis;
- The rehabilitation 2 buildings meant for the caring of patients with TB-MDR, in Bucharest and Bisericani, and equipping them with furniture and devices;

- The rehabilitation of 3 hospitals (Bucharest , Calarasi and Rosiori de Vede) meant for the caring of tuberculosis patients;
- The elaboration of and implementing communication campaigns on the subject of tuberculosis, meant for the general population;
- The elaboration of informative material on the subject of tuberculosis, disseminating them amongst the general population;
- The organizing of informative caravans especially in the rural unfavorable populations areas;
- The organizing of seminars with journalists, in the purpose of promoting the TB issue in the written press;
- The organizing of advocacy activities, in purpose of implicating the decision factors from central and local level in ensuring the conditions necessary for tuberculosis control in Romania.

During the 5 years of implementing these projects, the success rate in the treatment of tuberculosis has constantly risen, though, in the last 2 years a slight lagging has been noticed .

### **Chapter III. Personal investigations – Study on the factors influencing therapeutic compliance on tuberculosis patients in Romania**

In order to study these factors, we have used a pre-formed questionnaire, automatically applied to tuberculosis patients under ambulatory treatment in the specially designed units.

The study situates itself amongst the stipulations from the research chapter within *The Methodological Standards of Implementing The National Tuberculosis Program*. We've set as our goal to study the factors which influence the patient's compliance to the anti-tuberculosis treatment, their opinions regarding the methods used in the Romanian health system together with their specific needs, through the application of a preset questionnaire, in representative sample specific to national level in purpose of obtaining pertinent results, by respecting the scientific formalities.

**Purpose** – To determine the factors which are influencing treatment compliance of tuberculosis patients in Romania.

**Objectives** – Determining the social-economical characteristics of patients with tuberculosis in Romania; Determining the level of knowledge regarding tuberculosis on patients with TB that are under treatment in Romania; Identifying the opinions, attitudes and behaviors of tuberculosis patients under treatment regarding the treatment and caring conditions from which they benefit in the Romanian Health System; Identifying the opinions and attitudes of the tuberculosis patients under treatment about the methods of stimulating compliance in the treatment of tuberculosis;

The compliance to anti-tuberculosis treatment can be increase as result of applying simulative methods. The result of this fact is the transformation of patients with pulmonary tuberculosis with bk + in sputum microscopy, from dangerous epidemiologic sources to non-contagious persons, through fast, reliable and long-termed healing as result of a specific treatment correctly applied and respected by the patient. On medium and long term, the expected result will be the diminishment of the epidemiologic TB sources and the decrease of tuberculosis endemic.

The possibility of generalizing the accumulated positive experiences to a national scale on this same occasion will uncover new perspectives on the strictly supervised treatment administration and the correcting of some elements which will prove rewarding , under the cost/benefit ratio.

### **Material, Method, Subjects, Instruments.**

The used questionnaire was a preset type, it was conceived by consulting a specialist in the field, as well as the factors implicated in NTP.

The size of the representative sample, resulting from the application statistical calculus formula on the total number of tuberculosis cases registered in 2007 specifically a total number of 26.263 new cases plus relapses, was of 1025.

The sampling and the application of the questionnaire were done in 2008, the number of registered patients in 2007 being taken into consideration, year of which at that particular time all the necessary information was available.

The questionnaire was applied on the tuberculosis patients, that were under treatment, in all the counties in the country, during 1.11.2008 and 15.12.2008. The patients were interviewed a single time in the order of their making appearance at the treatment cabinets, after obtaining their consent on the issue.

The questionnaire comprises 3 groups of questions: social-demographical, knowledge testing related to tuberculosis and treatment compliance; the questionnaire can be found in the appendixes. After centralizing of the data, the result was a number of 1055 completed questionnaires. The information filled in the completed questionnaires was imputed in a database, centralized and analyzed.

The patients answered the questions in the attached questionnaire, the following aspects being emphasized: gathering of social-demographical data (D1-D10), knowledge testing on tuberculosis (T1-T25) and treatment compliance (C1-C24).

The information obtained from the centralizing of the data were analyzed considering sex, age, studies, social status, income, and some were statistically processed, where applicable.

### **Results & conclusions of the study**

*The study of the demographic data helps us to outline the tuberculosis patient profile **being under treatment in Romania**: male, aged 41 – 60, coming from urban area, medium studies, has no job and a monthly income of under 600 lei.*

The profile of the tuberculosis patient has a strictly statistical value, however it can create basis for the elaboration of some general measures, plans, campaigns and government strategies which will be implemented for the upcoming interventions that target the tuberculosis affected population.

*Upon these results we can reach the conclusion that, the competence of the medical staff and the patients' confidence in it are not the factors negatively influencing patients' compliance. Therefore we can once more observe, the high level of patient reliability in what concerns the competence of the medical staff.*

The conclusion is that most of the patients that benefited from stimulants **during the treatment, never interrupted it**, being highly motivated by the material stimulants.

The drawn conclusion is that the anti-tuberculosis treatment is perceived differently from one patient to another, the differences circling „it's very easy” and „I need assistance, I can't make it on my own”. Following the treatment prescribed by the doctor is perceived by the patients as not being impossible to follow, but at the same time they don't find it easy to do either.

Thus, the patients under treatment need assistance, support, stimulation, and understanding. Identifying their needs is the first step in maintain their compliance.

*The conclusion referring to the opinions of TB patients on the methods of stimulating compliance is that, although at statement level, the tuberculosis patients find that the most important methods are: improving hospital conditions, increasing the quality of drugs, developing the level of professional training of the medical staff etc., in reality the perception of the tuberculosis patients is that the most efficient*

stimulation method, effective only for each person itself, is „rewarding those that correctly follow the treatment, with a certain amount of money”.

Other methods for stimulating therapeutically compliance found as being efficient only for every person itself, are the following:

- Improving the conditions in hospitals and dispensaries (19,34%)
- Granting meal tickets for the patients correctly following the treatment (18,86%)
- Rewarding those correctly following the treatment, with certain amounts of money every month (13.36%)
- Ensuring free transportation in purpose of the treatment and medical investigations (12,99%)
- Ensuring free drugs to help in the treatment of the patients, in diminishing the symptoms (12,04%).

*The conclusion is that most TB patients consider that improving the conditions offered by the Romanian health system and the necessary material support on the period of the treatment are conditions of growing therapeutically compliance .*

#### **Chapter IV. Proposition – Project**

Upon the results obtained within the current research, a project was developed in purpose of increasing the compliance level of tuberculosis patients in Romania, being based on the statistical data supplied through the NTP database.

#### **“IMPROVE TUBERCULOSIS CONTROL BY MEASURES OF COMPLIANCE INCREASE OF TB PATIENTS BEING UNDER TREATMENT IN ROMANIA”**

The project goes for the completion of the national strategy of tuberculosis control, by measures of increasing tuberculosis patients’ compliance being under treatment, in the right directions, identified in the study on the factors influencing the compliance on the patients.

Efficient communication with tuberculosis patients ,informing them about the gravity of the disease and about the risks involving the incorrect and incomplete following of the treatment, training doctors in the pneumo-phthisiology network are activities in the project. The most efficient method for stimulating compliance of TB patients of TB patients is, according to the results in the study performed on the factors influencing compliance on TB patients, the granting of material stimulants. Therefore, the project in discussion sets as its goal the activity of handing meal tickets in value of some. 100 Ron (25 Euro) monthly / patient that correctly and completely followed the treatment every month.

**Purpose:** Increasing the level of compliance on tuberculosis patients under treatment in Romania

#### **Objectives:**

- The training, by the end of the project implementation period, of a number of 42 county trainers in the field of efficient communication with tuberculosis patients;
- The training of a number of 1000 PNF specialists in the field of patient communication from the units disposing of tuberculosis patients under treatment;
- The insurance of psychological support for the hospitalized tuberculosis patients by specialists in psychology, in all PNF hospitals,;
- The elaboration, multiplication in 5000 copies and distribution of the Tuberculosis Patient Guide to the tuberculosis patients under treatment and to the members of their families;
- The granting of value tickets of 25 Euro monthly, for a number of 5000 tuberculosis patients being in the ambulatory phase of the treatment

- The organizing and finalization, up to the end of the implementation period of the project, of a study on the compliance of tuberculosis patients and on its being influenced by the granting of stimulants to TB patients under treatment.

The aimed target group/beneficiaries of the project shall be the TB patients, the general population, the medical staff in the TB network, the scientifically community in Romania.

Forecasted strategies and methods in reaching the objectives of the project:

- Collaboration with NTP;
- The elaboration and distribution of information material meant for TB patients;
- The informing and education of TB patients;
- Training courses in the field of efficient communication with the patients;
- Ensuring psychological support for the TB patients, granting stimulants to the patients having correctly and completely finished the treatment;
- Running a study on TB patient compliance in Romania.

The total budget of the one year long project is of 1.215.280 euro.

### **The logical scheme of the project**

Activity 1 – Organizing the project

Activity 2 – Training PNF doctors in communicating with TB patients

Activity 3 - Ensuring psychological support for hospitalized TB patients

Activity 4 – Ensuring information materials meant for TB patients under treatment and for their families

Activity 5 – Granting stimulants (vouchers) for TB patients that are in the ambulatory phase of the treatment

Activity 6 – making a national level study regarding TB patient compliance as well as the impact of granting stimulants on the level of their compliance

Activity 7 – External audit

**Monitoring and evaluating the project.** All the activities that will be held within the project will be permanently monitored and visited annually through the external audit activity. The monitoring chart of the project will be filled regularly by the M&E /Project coordinator in the locations where the project is running.

## **Chapter V. Final conclusions**

The increase of the level of therapeutically compliance of these patients plays specially important role in achieving the general objectives of the National Tuberculosis Program in Romania and is situated amongst the issued tendencies at global level by the international forums that target tuberculosis control.

Tuberculosis, dreaded epidemiologic threat, still being considered a global emergency is a perfectly treatable and curable disease. The treatment of tuberculosis in a complex and durable manner puts the patients' compliance into trial. Studies performed at national and international level have proven that the projects for stimulating patients' compliance have paid off. These resulted in the fast and durable negativity of the patients, that have correctly and completely finished their treatment being helped by different methods of compliance increase. At epidemiologic level the up most important effect being registered is the decrease in terms of morbidity and mortality due to tuberculosis.

The Anti – TB treatment can be perceived differently from one patient to another, the differences balancing between „it is very easy” and „I need assistance, I cannot

make it on my own". Following the treatment prescribed by the doctor is perceived by the patients as being neither impossible nor easy to follow.

Thus, the TB patients under treatment need assistance, support, stimulation, understanding and care. Identifying their needs is the first step in supporting their treatment compliance.

The conclusion referring to the opinions of the tuberculosis patients regarding the methods of stimulating compliance is that, although at statement level, tuberculosis patients find the most important methods to be improving hospital conditions, improving the quality of the drugs, improving the level of professional training of the medical staff etc, in reality the perception of tuberculosis patients is that the most efficient method of stimulation valid only for each person separately is „rewarding those that correctly and completely follow the treatment by granting sums of money”.

The other methods of stimulating therapeutic compliance which the patients found as also being valid for each separately are the following:

- Improving conditions in hospitals and dispensaries;
- Granting vouchers for patients following the treatment correctly;
- Rewarding those that follow correctly the treatment by granting sums of money monthly;
- Ensuring free of charge transportation for the treatment location and medical investigations;
- Ensuring free adjuvant drugs to help the diminishing of adverse reactions and vitamins.

The conclusion drawn from the analysis of the results obtained, referring to the opinion of the patients in the matter of compliance stimulation methods is that most of the tuberculosis patients consider as being the most suitable the ones that refer to the improvement of the conditions offered by the Romanian health system and offering material support for TB patients (ex. Vouchers, meals, covering transport expenses and even sums of money be offered monthly as a reward for the correct following of the treatment).

The research exposed is in accordance with the research chapter from the technical norms of NTP.

The presented results confirm, statistically demonstrated and proven that, beside the necessity of medical and psychological support of TB patients, the material support can also be decisive in increasing treatment compliance.

The implications of the project are important on lowering the levels of endemic through tuberculosis.

The personal study made on compliance of the patients has indicated some directions to be followed in the highlighting of some national level projects, pursuing an increase in treatment compliance.

The proposed project could represent the model for a real project to be implemented in Romania.

# CURRICULUM VITAE

## MANUELA IOANA GHEORGHIU-BRANARU

---

**Marital Status** Married, one child

**Nationality** Romanian

**Objective**

- Career development
- Performance and skills improvement

**Work experience**

- 1985 –present - PNEUMOLOGY CENTER nr 6, Institute Dr. M. Nasta, BUCHAREST
- 1992 - present : regional manager of the TB National Programme
- responsibilities -surveying TB endemy in the 6<sup>th</sup> arrondissement of Bucharest ( report new cases, apply treatments, prevent, etc )as well as other pulmonary diseases since 1994
- TB program manager in the 6<sup>th</sup> Bucharest arrondissement , since 1994
- TB control at regional level / Bucharest region, since 2006
- Counselor for TB problems in Roma communities

**Education**

- 1969-1973 THEORETICAL LYCCEUM , PITESTI
- 1973 - 1979 MEDICINE UNIVERSITY , BUCHAREST
- 1979 MD DIPLOMA
- 1985 PNEUMOLOGY SPECIALIST
- 1984 IMUNOLOGY and IMUNOPATHOLOGY COURSE
- HOMAEOPATHY SPECILIZATION
- 1991 PNEUMOLOGY SCHOLARSHIP, BAYONNE HOSPITAL, PNEUMOLOGY DEPARTEMENT, FRANCE
- 1997 COURSE for REGIONAL MANAGEMENT of TUBERCULOSIS

- 1998 POST –GRADUATING PNEUMOLOGY COURSE
- 1998 POST –GRADUATING COURSE ON LUNG CANCER
- 1999-2001 Master in The Management of Medical&Social Services / University of Bucharest
- 2001 COMPETENCE in The Management of Medical&Social Services
- 2004 - trainer in National TB Program course
- 2005 – MDR-TB course
- 2005 - DOT strategy implementation course
- 2005- present MD studies : Project of implementation, monitoring and evaluation of a program for TB patients' compliance developing
- 2007 - trainer course

**Professional memberships**

member of :

- The Romanian Pneumology Society
- Romanian Homoeopathy Society
- European Respiratory Society
- IUATLD.

**References**

- Conf.Dr.NICOLAE GALIE, “Dr. Nasta” Inst.,Bucharest
- Prof.Dr.MIRCEA IOAN-POPA, “Dr. Cantacuzino” Inst. ,Bucharest
- Prof. Dr. CRISTIAN DIDILESCU, “Dr. Nasta” Inst. ,Bucharest
- Prof. Dr. MIRON BOGDAN, “Dr. Nasta” Inst. ,Bucharest
- Dr.MARIE-EVE LAMOULIATTE, Pneumology Service,  
Bayonne Hospital, France

<b>Languages</b>	English& French, fluent in writing and speaking.
<b>Computer skills</b>	Word, Excel Corel Draw, Adobe PhotoShop
<b>Hobbies</b>	Traveling, reading, music
<b>Assets</b>	Myself – good planner of future activities Pro-active person, receptive to new ideas, hard working
<b>Needs</b>	Environment – enhance team spirit Team – confidence, friendship ness