Letter to the Editor

Reconfiguration of anti-TB (MDR and XDR) budgetary allocations, in the context of following "Berlin Declaration"

Ioan Hurjui, Ionel Bostan*

Abstract: In this paper we focus on the institutional area of fighting against TB in Romania, investigating mostly the issue of funding specific measures. In our approach we consider the context that followed the Berlin Declaration on Tuberculosis, analyzing the financial parameters of combating this disease in the European Union. We noticed that in the last 10 years the EU budgetary allocations summed up over 125 million euros, directed to research TB, comparing to almost 1 billiard euros for global fund of fight against HIV/AIDS and malaria. In Romania, the state of affairs related to TB is critical, as long as 25 000 of new cases of disease annually occur, and the number of deaths is of approximately 1 500 per year. That is why, for a more effective combat of this disease, a more adequate funding is necessary. In reality, on the grounds of an underfunding which has been dallying for several years (there is a need for 93 million USD for 4 years, but currently, the allocated budget is only ¼ of this level), introducing the methods of rapid detection of chimioresistance and providing a fair, complete and ongoing treatment of TB fails to happen.

Key Words: anti-TB institutional measures, strategies, funding programmes, difficulties/incoherence.

Nowadays, tuberculosis (TB) is one of the multiple threats of health security in the European region of WHO. As stated on the Ministerial Forum specially assigned to this topic [1], which took place in Berlin, on October, the 22nd, 2007, major efforts for solving this problem must be done. The European Parliament requested the European Commission [2] to immediately look for new and innovative funding ways, such as establishing a financial guarantee of the member states and/or Union, which allows fund raising for TBVI from The European Investment Bank in order to guarantee the funding of research on neglected and little profitable diseases from developing countries. In the same time, it requested the Commission and member states to keep their funding commitments and to take all necessary measures so that the funds directed to health services reach the poorest people in developing countries. We remind here that approximately one third from the

population of the Earth is infected with Koch's bacillus, annually causing death of approximately 3 million yearly [3]. In the European WHO region, the multidrugresistant tuberculosis (TB-MDR) and extensively drugresistant tuberculosis (TB-XDR) spread relatively fast [4]: over 81 000 (18.4%) from the total of 440 000 ill people estimated on international level are living in this region. This enforced the implementation of modern ways of rapid diagnosis and models of patient-centered care, simultaneously with service provision adapted for highrisk populations [5]. The goal is that until 2015 127 000 TB-MDR patients, to prevent the disease 250 000 TB-MDR people and 13 000 TB-XDR people thus, saving 120 000 lives.

In Romania, the incidence of the disease is 116 cases to 100 000 inhabitants[6], which makes it the country with the highest prevalence in Europe. We emphasize that the European average is 30 cases to a

Doctoral School of Economics, Stefan cel Mare University, Street Universității 13, 720229 Suceava, Romania

^{*} Corresponding author: PhD, Law, Email: ionel bostan@yahoo.com

hundred thousand inhabitants; judging by the number of TB cases, Romania is placed in the first 18 countries with a high load of TB-MDR and TB-XDR from the European region of WHO [7]. The studies undergone by World Health Organization [8] lead to the conclusion that the TB situation in Romania is critical, with 25 000 new cases annually, the number of deaths being of approximately 1500 per year. In this context, our endeavor insists upon the institutional area of fighting against TB, investigating mostly the issue of funding specific measures.

Berlin Declaration on Tuberculosis and financial parameters of fighting this scourge in European Union

The Ministers of Health from the states included in the European Region of WHO adopted the "Berlin Declaration on Tuberculosis" [9], which emphasize this disease to be a major threat to public health. For instance, it was found that [10] only two years prior to this Forum, in the European region of WHO 445 000 new cases of TB and 66 000 deaths associated to the namely disease occurred; in the countries of the former Soviet Union were recorded approximately 3/4 from the total number of the cases, while Greece, Sweden and The United Kingdom of Great Britain faced an alarming increase in the number of infections. In addition, it was pointed out that the incidence of the disease was higher in high risk categories - immigrants, homeless people, prisoners etc. Starting from all these, concrete measures to strengthen TB prevention and control were conceived. In this mainframe, the need to obtain a synergy in funding TB control and prophylaxis programmes is very important, while the priority would be the issue of budgetary allocations to serve this goal. We could have an idea of the anti-TB costs in EU-27, reading the study performed by Roland Diel (coord.) from Schleswig-Holstein University Hospital in Kiel [11], which considered the data of 2011. The researchers coordinated by Roland Diel divided the countries in two groups, depending on GDP per capita. In the case of the old 15 member states of EU, plus Cyprus, Malta and Slovenia, the average cost on typical

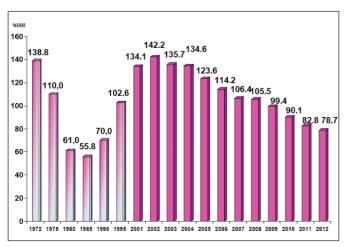


Figure 1. Global TB incidence (GI) in Romania (1972-2012) [15].

TB case was 10 282 Euros, but it exceeded 57 200 Euros for MDR cases and 170 700 Euros for XDR cases. In the other states of EU, the average costs were 3 427 Euros, for TB with standard treatment and approximately 24 100 Euros for drug-resistant cases. The total cost of treating TB cases in 2011 was of 536 890 315 Euros, but also the cost of productivity losses should be added, which is of about 5.3 billion of euros [12]. From the point of view, the European Commission is able to [13] spend important resources from structural funds of the European Union for the infrastructure of investments in health, social care, access to medical assistance granted to social vulnerable groups, promoting the health system, prevention of disease and training the medical staff. In the last 10 years, the allocations from the EU budget summed up over 125 million euros directed to TB research, comparing to almost 1 billion euros for the global Fund for fight against HIV/AIDS, TB and malaria.

Budget support directed to TB prevention and fight in Romania

Given the social, economic implications of TB, in all its forms, most countries spend large amounts of money for the diagnosis and treatment of TB-MDR and TB-XDR TB. Romania has additional reasons to act more in this respect, especially due to the fact that because of this disease there are 7.1 deaths every one hundred thousand inhabitants, an indicator which places our country on the second place among the states of community block (the European average of 1.6 deaths), after Lithuania, with eight deaths every one hundred thousand inhabitants [8, 14]. In the context of an increased TB incidence (Fig. 1), concerning the entire territory of the country (Fig. 2) the implemented policies aim at free of charge diagnosis and treatment of TB patients, control of their contacts, preventive treatment and information, education and communication activities.

In Romania, TB treatment cost needs a budgetary allocation of over 3 750 000 euros/year (for all 1 500 de patients) [7].

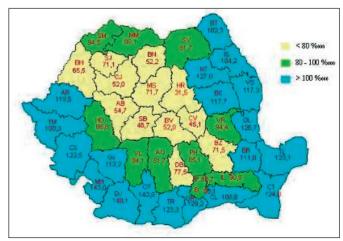


Figure 2. TB incidence per county [16].

Evolution of granting system

TB-MDR and TB-XDR continues to be a public health issue in Romania [17]. Currently TB-MDR treatment in Romania is financed from two sources [18, 19]: DOTS-plus programme (through which the second line medicine are provided) via TB grant financed by Global Fund to fight HIV/AIDS, TB and Malaria (FG), and from the state budget, via the National Programme of Tuberculosis Control (PNCT). European Union is one of the major financiers of GF, Romania benefiting from two grants within the period [18]:

In November 2006, in the mainframe of the 6th funding round, GF approved the country applications of Romania, for the two programmes addressed to preventing, treatment and care of people with HIV/AIDS and TB, approving for Romania a total funding of 10 224 387 Euros, out of which 3 620 427 Euros for TB component (first phase) of the programme "Towards Universal Access to HIV/AIDS prevention, treatment and care for vulnerable people and disfavored populations" and for the first phase of the Programme "Expanding TB control by focus on poor and vulnerable populations";

Further on, GF approved the undergoing of the second phase for the Programme "Expanding TB control by focus on poor and vulnerable populations" in compliance to Amendment no. 4 to financing Agreement ROM-607-G04-T (Geneva, 2009), regarding the phase II of the programme between Romanian Angel Appeal Foundation (FRAA), as main recipient and GF, with a 3 years duration (2009-2012) with an approved funding of 3 949 733 Euros.

In 2012 GF approved the country application of Romania in order to continue the funding of the programme directed to TB prevention and treatment, part of the Transitional Funding Mechanism, according to Amendment No.8 to financing agreement ROM-607-G04-T (Geneva, 2009), related to phase III of the programme, between FRAA and FG, with a 2 years duration (2012-2014), with an approved funding of 3 606 830 Euros.

However, despite all efforts made in this period, there still were underfunding - related problems in this area [7].

Anti-TB activities, recently implemented in Romania

The TB National Control strategy 2013-2017 and the National TB prevention, monitoring and control programme, drawn up and implemented by the Ministry of Health [20, 21], by "Marius Nasta" Pneumo-Phtisiology Institute, the technical coordinator of the Programme, includes multiple activities.

The goals followed via the above mentioned programme are:

a) reducing TB prevalence and mortality;

- b) maintaining a detection rate of new cases of TB positive sputum microscopy;
- c) treatment of patients and maintaining the success rate in new TB positive cases.

In the mainframe of the National Programme, the priority goal of the Ministry of Health [22] is to organize centralized purchase of specific medicine for treatment of TB patients, providing medicine in hospital and ambulatory, as well as providing sanitary materials specific to bacteriologic and radiologic examinations. In the same time, as pointed out above, a series of medicine are purchased by FRAA, with funds from Global Drug Facility. The funds allocated to prevention and provision of treatment, for year 2013, were of 7 160 000 lei, but only for provision of continuous, complete and quality treatment for TB (MDR and XDR) patients.

The financial need was double (14 532 000 lei/year). As a matter of fact, the update of the value of evaluation indicators, according to the resulted data in year 2012, reveal modest levels of the used resources [23]:

- a) Physical indicators:
- a.1. number of infected people who received chimioprophylactic treatment: 20 000 people/year;
- a.2. number of treated TB patients: 27 000 people/year;
- a.3. number of treated patients with MDR TB intensive phase: 600 people/year;
- a.4. number of treated patients with MDR TB in continuation phase: 800 people/year.
 - b) Efficiency indicators:
 - b.1. average cost/ TB treated patient/year: 491 lei;
- b.2. average cost/ treated patient with MDR TB in intensive phase: $10\,470$ lei
- b.3. average cost/treated patient with MDR TB in continuation phase: 710 lei.

All aspects we refer to in our work ask for consolidation and provision of adequate funding of PNCT [24], in order to provide the rapid diagnosis means of TB people and the continuous treatment with effective medicine, as well as social and psychological support measures, like food allocations and therapy on duration of treatment.

CONCLUSIONS

Given the TB threat, in Romania, with technical assistance from WHO, it was created The Romanian national action plan to prevent and manage multidrugresistant tuberculosis for 2012-2015 period. The aim is to reduce the sufferance and social-economic problems given by TB in Romania, by provision of the right management and prevention of multidrug-resistant tuberculosis. It is estimated that at the end of the targeted period, at least 85% from the cases of TB-MDR/XDR will be diagnosed and at least 75% of the diagnosed cases will

be cured. Yet, in order to reach this goal, it is necessary to solve the remaining legislative and procedural coherence problems and a more adequate funding. The costs associated to implementation of the National Plan are estimated to USD 93 million for 4 years, but presently, the allocated budget is only ¼ of this level, besides the disadvantage given by the extended role of the external funding, which is unpredictable and with restrictions related to goals and deadlines. Hence, introducing the

rapid detection of chimioresistance (purchase equipment and stationery) and financing in order to provide a fair, complete and continuous treatment of TB cases, remain important challenges.

Acknowledgment. We would like to thank the two reviewers for their insightful comments and suggestions.

References

- All Against Tuberculosis EUR/07/5061622/5, WHO European Ministerial Forum 74415, Berlin, October 22nd, 2007.
- 2. Resolution of European Parliament related to "Tuberculosis Vaccine Initiative" a concrete application of the EU-2020 Strategy in order to contribute to reaching the ODM 6 and elimination of TB until 2050. Official Journal C-182 E, 2011, pp. 9-11.
- 3. Neagu O. Despre TB, 2012. Available: http://www.romedic.ro/tuberculoza-pulmonara
- 4. World Health Organization. GLC/EUROPE Mission, abstract of the Report of Evaluation Mission of the National Programme for Tuberculosis Control, WHO Green Light Committee, 2012. Available: http://stop-tb.raa.ro
- 5. World Health Organization. Guidelines for the programmatic management of drug-resistant tuberculosis (Update), 2011.
- 6. Stop-TB Partnership. Information on TB, April 7, 2012. Available: http://www.medo.ro/media/articole-presa-medo/page/3
- 7. Viasu M. Tuberculoza multidrog rezistenta, PaginaMedicala.ro, September 25th, 2012.
- 8. World Health Organization. Report: Global Tuberculosis Control, 2011.
- 9. WHO/European Ministerial Forum. All Against Tuberculosis, EUR/07/5061622/5, Berlin, 2007.
- 10. British Medical Journal, Europa nu este suficient de vigilentă în privința combaterii tuberculozei, April 11, 2008. Available: http://www.bmj. ro/articles/2008/11/04/europa-nu-este-suficient-de-vigilent%C4%83-%C3%AEn-privin%C5%A3a-combaterii-tuberculozei
- 11. Diel R, Vandeputte J, De Vries G, Stillo J, Wanlin M, Nienhaus A. Costs of tuberculosis disease in the European Union: a systematic analysis and cost calculation. Eur Respir J. Feb; 43(2):554-65, Epub 2013 Aug 15.
- 12. Miron I. Tuberculoza in cifre, 2011. Available: http://e-sanatate.md/News/856/tuberculoza-o-bomba-cu-ceas-care-genereaza-numai-in-europa-cheltuieli-de-miliarde-de-euro-pe-an#sthash.2MSuXo5s.dpuf
- 13. Reprezentanța Comisiei Europene în România, România sprijină lupta împotriva tuberculozei rezistente la medicamente, Bucharest, 2011. Available: http://ec.europa.eu/romania/news/02102012_romania_lupta_impotriva_tuberculozei_ro.htm
- 14. Cronica Romana, Romania-UE: Numărul deceselor cauzate de tuberculoză, Nov. 23, 2011, Available: http://cronicaromana.com/?p=173030
- 15. Popescu G, Spînu V, Dumitru M. Actualele provocări ale endemiei TB în România și implicarea PNSPCT. Institutul de Pneumoftiziologie "Marius Nasta", Bucharest, 2013, pp. 5, 29.
- 16. Ibraim E. Tuberculoza în România, realități la timpul prezent. Viata medicala, no. 12(1158), March. 28, 2012. Available: http://www.viata-medicala.ro/Tuberculoza-rezultatele-sunt-incurajatoare.html*articleID_6651-dArt.html)
- 17. Simon-Gruita A, Duta-Cornescu G, Constantin N, Pojoga M, Saitan T, Stoian V. Apa I and Taq I polymorphisms of VDR (vitamin D receptor) gene in association with susceptibility to tuberculosis in the Romanian population. Rom. Biotech. Lett., 2013, 18(1): 7956-7962.
- 18. Government of Romania, substantiation note of the EO related to provision from the state budget via the budget of Ministry of Health or the necessary amounts of money to cover the VAT for the goods and services purchased during the programme related to fighting against tuberculosis in Romania, implemented by Romanian Angel Appeal Foundation, 28th of November, 2013. Available: http://www.juridice.ro/294600/acoperirea-platii-tva-aferente-bunurilor-si-serviciilor-achizitionate-in-cadrul-programului-privind-combaterea-tuberculozei-in-romania-proiect.html
- 19. Ministry of Health. Programul național de control al tuberculozei, 2011. Available: www.ms.ro/documente/136_311_ANEXA.doc
- 20. Government of Romania, Bill no. 124 to approve the national health programmes for 2013-2014, Bucharest, 2013.
- 21. Ministry of Health. Common Bill of the Minister of Health and Chairman of the National Health Insurance Agency no. 422/190 to approve the technical norms for national health programmes for 2013 and 2014, Bucharest, 2013.
- 22. Ministry of Health. Informare catre Camera Deputatilor, EN-4730, June 10, Bucharest, 2013.
- 23. Ministry of Health. Bill no. 422 on modification and completion of technical norms for national health programmes for 2013 and 2014, Bucharest, 2013.
- 24. Asandi S. Romanian Angel Appeal Foundation, July 25, Bucharest, 2012. Available: https://www.stop-tb.raa.ro/wp-content