

Review Article

by

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member of the Scientific jury of procedure for defense of a
dissertation work on the topic

“Research and analysis of the process of health technologies
assessment and the economical aspects of the introduction in
Bulgaria”

for acquisition of educational and scientific degree “Doctor” of
the scientific specialty “Social Medicine and Healthcare
Management”

with candidate Anelia Hristova Nikolova

On the basis of the order (№ RD – 417) / 02.11.2020 of the director of NCPHA and with the decision of the scientific jury (protocol №1 / 06.11.2020) I am chosen for a member of the scientific jury according to the specified procedure and I’m set to prepare a review article.

The review article is prepared according to the requirements of The Law for development of the academic staff in The Republic of Bulgaria and the Rules for conditions and the order for acquisition of scientific degrees and taking over academic positions in the National Center on Public Health and Analysis (NCPHA).

Biographical data

Anelia Nikolova was born in 1979. In 2002 she finished higher education with a Bachelor’s degree and a professional qualification “economist” in the Varna Free University “Chernorizets Hrabar”.

In 2017 Anelia Nikolova finished her Master's Degree in "Pharmaceutical Management" in the Medical University – Varna. Since 2017, the candidate specialized in "Medical Informatics and Healthcare Management" at the Medical University – Sofia, base NCPHA

Since 2014, Anelia Nikolova has worked in the field of healthcare therefore as chief expert in the Sofia Health Insurance Fund (SHIF) and the National Center on Public Health and Analysis (NCPHA).

Assessment of the relevance of the topic

The present dissertation work is focused on researching and analyzing the process of introducing the health technologies assessments (HTA) as one of the major instruments for taking objective and justified decisions for pricing and reimbursement of the innovative medical products in Bulgaria.

The topic is very relevant considering the pace of increasing expenses for healthcare, which is significantly higher than the growth of the gross domestic product (GDP) in most of the countries in EU, including Bulgaria.

A lasting tendency has been established for the health expenses to increase their size as value and as relative share from the general state budget.

The increase of expenses for medical products is a natural process, conditioned mainly from the demographic characteristics of the countries in EU and the constant entry of innovative and expensive health technologies, which despite of their improved therapeutic efficacy, significantly increase the cost per unit of the health result. Precisely, the HTA are the modern scientific approach, based on medical and economical evidence, for the effective control of the medical expenses on a population level.

Assessment of the structural parts of the dissertation

1. Literature review

The literature review is thematically focused on analyzing the concept for assessments of the health technologies, its historical development, applicable models in the EU countries with established institutional bodies, the goals of the economical

assessments as well as the establishment of the process for assessments of health technologies in Bulgaria.

Analyzed are the application and design of analysis of the budgetary impact, analysis of the sensitivity and the structure of the assessments of the health technologies.

The literature review consists of 55 pages and represents 36% of the bulk of the dissertation work. Enough and suitable literary sources have been used, from which more than 90% were published in the last 10 years.

2. Goal, tasks and methodology

The goal of this research is directly linked to the topic of the dissertation work – a complete analysis of the introduction stage of normative construction, organizing and conducting evaluations of the innovative health technologies in Bulgaria and the economical aspects of their application, by bringing out key factors for the development and effective control.

6 main tasks have been formulated meeting the set goal.

Subject of the study is the structure, the organization, the processes and the results of the work of the expert working commissions, the commission and the HTA department. Extensive and intensive indicators like provision of the process with experts, technical security, intensity and resilience of the process and also the end results of the procedures have been researched and analyzed.

Historical and sociological methods, like surveillance, survey and documentary method, have been used for the gathering of primary data. For the processing and analysis of the information, statistical methods (alternative, variational, graphic), economical analysis and an expert assessment have been used.

The author of the dissertation has been professionally engaged with the whole process of HTA in Bulgaria since the beginning of its application in the country, which provides the necessary access to valid information and guarantees the adequate application of the research methods.

The quantitative results of the research are presented schematically and graphically.

3. Set of own research

The organizational structure and the course of the process on assessments of the health technologies, the provision with experts, composition of the working commissions, the awareness regarding the process of an economical assessment, the results from the activity and the budgetary impact analysis (BIA) are analyzed and explained.

The most common problems related to organizing the process and preparing the project for a report of the working commissions are summarized.

4. Results and discussion

In 82 figures and 3 charts, accompanied with an understandable, logical and clear text, the doctoral student introduced the received results. The sequence of the set tasks is observed, and the idea of the scientific development is followed.

A detailed analysis of the organizational structure of the process related to HTA, the normative base, the successive stages of the process, analysis of the relevant documents to the procedure, the time frame and the expert commissions is done. Through a survey method, the awareness regarding the process of HTA in Bulgaria is researched and analyzed. The respondents include groups of academic lecturers, experts, representatives of the medical community, pharmaceutical industry, the media and the patients. A big part of the respondents evaluated positively the organization of the process of the health technologies assessments and the work done so far, however some of the respondents considered that the process was not independent enough and impartial.

An exhaustive analysis of the results of the activity on HTA is conducted, regarding the dynamic of submitted applications for a three year period, the therapeutic areas of the medical products application and the results of the finished procedures. 93 positive and 24 negative recommendations are registered. The motives for a negative recommendation mainly include 1) The medical product is not cost-effective; 2) Lack of convincing data for efficacy; 3) The presented report for an assessment of the health technology is of low quality and does not meet the regulatory requirements.

The dissertation work also includes analysis of the economical indicators and the budgetary impact of the assessed health technologies. The average cost for treatment

in therapeutic areas is analyzed for a three year period and also the budgetary impact of the medical products with a positive recommendation for a five year period.

5. Conclusions and recommendations

Several conclusions are formulated in accordance with the assigned tasks, adequately reflecting the received results and showing the potential of the author of the dissertation work to summarize and prioritize.

The conclusion that the HTA leads to optimizing and taking decisions for reimbursement of health care services and herewith saving public funds is of great importance.

Saving funds is realized by stopping the access of cost-ineffective medical products on the one side, and on the other side, with the possibility of setting certain conditions, with which the pharmaceutical industry should take into account – lower the cost, reduce the number of patients or payment based on the result of the therapy. Conditions for payment of the marketing authorization holder of specific research or additional expenses, related to medical products accompanying the treatment can also be included among the recommendations in the HTA report.

An important recommendation is the optimization of the system for experts training.

6. Abstract

It reflects the content of the dissertation very accurately and presents the most important results, conclusions and recommendations of the research.

7. Contributions

The formulated conclusions are with a scientific-theoretical and applied (practical) nature.

For the first time in Bulgaria, the organization is studied and analyzed in detail, as well as the expert and administrative potential and the problems connected to the HTA. A developed algorithm is introduced for a detailed description of the

organization and the stages of the process, the work procedures and rules, as well as the relevance and contribution of the expert potential.

The main factors, which have an impact on the duration of the procedures and the quality of the reports are defined; a complete assessment of the process organization of the HTA in Bulgaria for the first three years since the introduction of the practice was also made.

A critical analysis and a comment about the advantages, disadvantages and the expected impact of the changes are made, concerning the legislative framework, introduced after 31.03.2019.

8. Bibliography

It includes 142 literature sources on Cyrillic and Latin. The bibliography is characterized with relevance and connectivity with the goals and tasks of the dissertation work.

4 articles are published in connection to the dissertation in scientific publications.

Conclusion

The results of the present dissertation work of Anelia Nikolova are based on a well thought out methodology of the scientific research. They are scientifically solid and applicable in the practice.

The contributions with a theoretical-cognitive and applicable character are relevant for the science and practice in the area of HTA and the economy of the healthcare. They are quite clearly formulated and can be used for updating the regulations in the country with the goal of guaranteeing the objectivity and transparency when taking decisions for pricing and reimbursement of the innovative medical products, payed with public funds.

Anelia Nikolova's dissertation work is an interesting and needed research of the process on HTA in Bulgaria and the possibilities for its optimization.

The conclusion that the HTA is an objective and transparent process for taking decisions regarding the reimbursement of therapeutically efficient and cost-effective medical products is quite important.

I have enough reasons and confidence to express my positive opinion and to recommend to the esteemed scientific jury to award Anelia Hristova Nikolova with the educational and scientific degree "Doctor" of the scientific specialty "Social medicine and health management."

Sofia

25.11.2020



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