REVIEW

by

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Concerning:

Dissertation for the acquiring of an educational and scientific degree "Doctor" under the doctoral program "Organization and management outside the field of material production / in healthcare /", in professional field 3.7.

Administration and Management on "Access to Dental Care in Bulgaria" by Elena Petrova Todorova.

Reason for presenting the review: I present this review as a member of the Scientific Jury appointed by Order No P-109-478 OF 16.11 2023 of the Rector of the Medical University "Prof. Dr. Paraskev Stoyanov"— Varna to provide a procedure for a public defense of the dissertation.

Information about the PhD student

Elena Petrova Todorova is enrolled as a full-time doctoral student in the doctoral program "Organization and management outside the field of material production / in healthcare / in the field of higher education 3. Social, Economic and Legal Sciences, professional field 3.7 Administration and Management, with topic of dissertation: "Access to dental care in Bulgaria". Scientific supervisor: Associate Professor Dr. Elka Ignatova Atanasova, D.E.

The training was organized and conducted at the Department of Health Economics and Management, Faculty of Public Health, Medical University "Prof. Dr. P. Stoyanov" - Varna. The PhD student works under an employment contract at the Medical University "Prof. Dr. P. Stoyanov" – Varna.

Brief biographical data

Elena Petrova Todorova was born in Varna. Communication data as follows:

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Elena Petrova graduated in 2010 the National High School of Humanitarian Sciences and Arts "Konstantin Preslavski" in Varna. In 2014 the dissertant graduated from the University of Economics - Varna with a Bachelor's degree in management and in 2015 the University of Economics - Varna with a Master's degree, specialty: Corporate Business and Management.

Professional Experience

In 2013 Elena Petrova has worked for about two months as an Assistant Organizer "Marketing, Procurement and Public Procurement", Medical University "Prof. Dr. P. Stoyanov" Varna and since October 2014 she has been an organizer at "Medico and Dental Center", Faculty of Dental Medicine, Medical University "Prof. Dr. P. Stoyanov"

General characteristics of the dissertation

The presented dissertation is in accordance with the Law on the Development of the Academic Staff of the Republic of Bulgaria, the Rules for the Development of Academic Staff at the Medical University "Prof. P. Stoyanov" - Varna with regard to:

- 1. Relevance of the work and scientific justification of the goal, the tasks and the main thesis
 - 2. Awareness of the issues addressed in the dissertation
 - 3. Volume
 - 4. Scientific and applied research results obtained
 - 5. The main contributions

Since oral diseases are largely preventable and the timely use of dental care is of utmost importance for the prevention and treatment of these diseases, I believe that the topic is more than relevant and of great importance for the overall health of the patients.

The comparisons made for oral diseases in the different modern health systems show where Bulgaria stands for this significant health problem in Europe. About 466 million people in Europe are affected by oral diseases, which are among the most common non-communicable diseases worldwide. More than half of European families (52%) suffer from oral diseases, which is the highest recorded level. The link between oral health and general health is noted of patients, as research in this area proves the reciprocal link between gum disease and diabetes. Periodontitis is a major cause of tooth loss in old age. Bacteria in the oral cavity, especially in periodontal pathogens, can lead to respiratory diseases and changes in the endocrine system of the human body. These and other facts mentioned in the paper prove a well-grounded statement that this dissertation is of importance for the management in our healthcare and is particularly relevant for the effective use of scarce financial resources for health care processes in Bulgaria.

Knowledge of the problem

The author has in-depth scientific knowledge on the developed topic, reflected in the literary review of the dissertation which is unfolded on 27 pages. The review, its conclusions and discussions are the result of the detailed analysis of 211 bibliographic sources, of which 22 in Cyrillic (10% of the book script) and 189 in Latin. Of all titles 87 / 41% / are from the last five years. The studied literary material is critical and creative which allows the dissertant to make a competent analysis of the results obtained and the theoretical formulations.

Content and structure of the dissertation

The dissertation has a total volume of 154 pages and is structured in: introduction of seven pages, main text in three chapters of 104 pages, conclusion two pp., list of literature used 14 pp. and Annexes 19 pp. The main text contains 27 tables and seven figures. There are 211 titles from Bulgarian and foreign authors.

The aim of the dissertation is to study and analyze the access to dental care in Bulgaria for persons over 18 years of age, identifying barriers to access and assessing their impact on different groups of users and usability of dental services and thus formulating recommendations for improving access to dental care against the results obtained. Perhaps it is more appropriate that the first research task "to study the theoretical foundations of access to health dental services on the basis of an overview of the specialized scientific literature and to deduce an approach to research into access to dental care" to be beyond the scope of the research tasks. The other research tasks concern several barriers to an access to the health dental services: structural barriers, financial barriers and personal barriers, etc.

In this case, there is little discrepancy that the access to dental care can be assessed by its basic dimensions and personal barriers and are not expected to hinder consumers. This means that one of the tasks is considered in advance not so essential for the access to dental care.

The following methods were used: A documentary method with an overview of the 211 publications described in the bookwriting and the conclusion is that following the new scientific developments in the field of access to dental services, the dissertant has chosen this approach to study the barriers of access, which can be represented by six dimensions of access and thus assess their degree of influence on users.

Sociological methods were also used with an anonymous survey and two types of questionnaires were made "Questionnaire for studying the dimensions of access to dental care by patients" and "Questionnaire for dentists". The questionnaire was disseminated through an online platform by the method of respondents and a wide range of potential respondents from all over the country received an invitation to participate in the survey through social networks. The survey was conducted in June 2022, with 953 users who responded 80% of them and 151 dentists - 86% of respondents responded. A standardized anonymous survey with questions with different dimensions of access was used, with the questionnaire for patients containing a total of 25 questions and patients were given the opportunity on a likert scale from 1 to 5 to assess the degree of influence of the different reasons, on the postponement of the visit to the dentist.

The questionnaire for dentists includes a total of 22 questions and for the analysis of the changes physical accessibility, availability, convenience, financial accessibility, acceptability, awareness and usability - all these categories are analyzed after receiving the questionnaires.

Modern statistical methods were used. The limitations of the survey are shown correctly and only persons who have access to an electronic device can take part in it. This leads to restrictions probably for older people.

The first chapter "Theoretical Foundations in the Study of Access to Health and Dental Services" is 27 pages long and actually represents the literature review with a historical overview of the concept of "access" and the different aspects of this category. The dissertant shows that different authors develop models and conceptual frameworks that specify access to healthcare and they have their strengths and weaknesses. Thus, she chooses to group the

level of correspondence between the characteristics and the the expectations of healthcare providers and patients as characteristics are grouped into 5 categories: financial affordability - reflects the ability of the consumer to pay for services; availability - represents the provision of the provider of health services, staff, equipment; physical accessibility - measures physical access to the ability to reach the service provider; convenience - the organization of the doctor's practice in a way that corresponds to the patient's perceptions - hours of work, communication; Acceptability - associated with a sense of comfort that the patient feels with his doctor and vice versa.

It is noted that certain authors further develop the concept of access beyond service availability and place emphasis on some of the barriers, in particular personal, financial and organizational barriers. Perhaps it is correct to mention here that the further presentation discusses the severity of each of the access categories that violate the dental health of patients. Mention is made of the use by some authors of three of the five categories, in particular financial accessibility, acceptability and availability, without detracting from the importance of the other two categories.

It is further believed that the dimensions from other authors are reduced to only three: physical accessibility, financial accessibility and acceptability. And so financial accessibility, availability, acceptability, relevance are examined. It is noted that there is no consensus in the scientific literature on a comprehensive concept of access to health services and its dimensions.

Access to dental services in the access theories has evolved over the years continuously and based on the literature review, the approach of Susan McKernan and co-authors has been chosen. For analysis and assessment of access to dental care in Bulgaria, which is specifically focused on dental care and is presented as a process of four separate stages: need for dental services, barriers to access, use of dental services and health outcomes. Extremely important is the last degree in this approach health outcomes which objectifies in fact the removal or overcoming of barriers of access to dental care.

As well noted in the literature report, health outcomes are an integral part of the concept of access as well as the usability of services. The need for dental services defines the state of oral health and assessment of dental services perceived as the main health service (it is more accurate to say help and care), as they evaluate, diagnose, prevent and treat oral diseases that can affect overall health. Most dental diseases can be prevented to a large extent by performing regular check-ups at the dentist, realizing the need to use this service, but it is usually noted that users proceed in the presence of toothache, tooth decay, broken or missing teeth and much less often for prophylactic purposes during visits to the dentist.

Studies have shown that in practice, the assessment of the patient and the attending dentist rarely coincide. The differences of the opinion between the two parties about the need for professional dental care are a prerequisite for a lack of cooperation on the part of the patient and difficulties in the planning treatment. The barriers in the access to dental care are in three main groups: according to FDI classification by the patient, by the dentist and by the society. More precisely, by the patient-lack of awareness of health need, anxiety or fear, financial constraints and lack of access, by the dentist - insufficient workforce, unequal geographical distribution and training, and by society - insufficient public support for obtaining health knowledge and insufficient support for conducting research.

Again, the barriers of pre-dental care are considered as physical barriers, lack of available dentists in the area. Second inability to overcome physical barriers and transport. Third, financial barriers - high cost of dental services. Fourth, barriers related to cultural incompatibility relations between the supplier and the consumer.

Access according to some sources, explains the dissertant is identified with the usability of health services, but use is actually only one aspect of access. Various factors can have an impact on the use of the personal health service, which can be basically divided into two groups: on the supply side and on the demand side. Everywhere in labor is written "health service" as the better term is "health care and help". In practice, it is structured Attention to three main types of barriers: **structural, financial and personal**, which are an obstacle to receiving medical care, and these barriers interact in a complex way. The availability and physical accessibility are related to each other, reflecting the possibility of offering dental services that are appropriately geographically located to the needs generated by consumer demand. A commonly used

indicator for reporting is the provision of the population with dentists and for comparison is the ratio of dentists to population.

It is explained that currently the training of dentists is carried out in the three Medical Universities in Sofia, Plovdiv and Varna and the curriculum includes basic and special dental disciplines. Over the past 10 years, the number of dentists per capita has increased. It remained stable in most European countries while in our country dentists are increasing, leading to an oversupply of dentists in certain regions and one of the highest levels in the ratio of dentists: population in the European Union.

In the country there are mechanisms which regulate the number, subject and location of outpatient dental care institutions. This is one of the reasons why there is an uneven distribution of dental practices and their higher concentration in certain areas on the territory of the country.

It is noted that there is such a trend in other European countries and perhaps it should be more clearly noted that the reasons are precisely financial dependencies, both for revealing dental practices in certain settlements and regions, and the financial capacity of the population in the region concerned. Globally, one of the main causes of health inequalities in the field of dental care is limited access, arising due to an unbalanced geographical distribution of dentists. The project "National Health Strategy 2020-2030 for Bulgaria" also confirms that despite the average number of dental practitioners, access to dental services in Bulgaria is not the same for urban and rural areas. And studies have shown that the patients who need dental care the most are the least likely to have access to it.

The study of access to dental care is described in the second chapter and for the study of the access to dental care in Bulgaria a complex approach is used, applying a documentary, sociological and statistical research method. Through the documentary analysis, the scientific literature is studied, in which the main dimensions of access are outlined. Thus, based on the literature, the two questionnaires for the respective target groups of users and providers of dental care have been developed. In one questionnaire 953 respondents took part in an online survey, with a predominance of women - 95.9%, the average age of the participants is 41.9 years, over 60.4% live in a regional city, 70.7% have higher

education. On the other hand, the questionnaire was fully completed by 151 dentists and in this sample the majority of the participants were women 75.5%. The majority of people are up to 50 years old, most of the dentists do not have a recognized specialty in the healthcare system.

Structural barriers. Availability. The dental team consists of a group of people who work together. This team approach in dentistry increases the effectiveness of the overall treatment of the patient. When we talk about the provision of doctors, by the end of 2022 in Bulgaria there were a total of 7,602, the number of doctors, according to statistical data for 2017-2022, increased by a little by 2% in the country. Bulgaria is divided into 6 planning regions and one of the figures in the dissertation presents the relative proportion of dentists distributed in these areas in 2022

It can be seen that the Northwest, North Central and South-East regions are the regions with the lowest collateral at the end of 2022 for dentists in general in the country.

On the other hand, more than half of the dental profession practices its profession in the Southwest region and the South Central region. Here it should be noted that the problem of equal pay by the NHIF regardless of the remoteness of a geographical area, social situation of the population, etc., is something that is noted by the dissertant. With the decision of the Council of Ministers at the end of 2022, the "National Map for Long-term Need for Health Services" was adopted, which is used as a tool to address the main challenges, analyzes objective data on the existing structure of the healthcare system and the needs of the population to optimize health services.

Knowing that the population is provided with a sufficient number of dentists, even practicing 17% more than necessary, while registering a deficit of 520 dentists in the Northwest, North Central and Southeastern regions. In order to ensure equal access of the population throughout the country, it is necessary to ensure an adequate territorial distribution of practices. This can be ensured by redistributing medical staff in order to cover the deficits in the provision of dental practitioners in the respective Northwest, North Central and Southeastern regions. In a market economy, this cannot happen without

financial incentives and this is something that should be more definitely noted in the dissertation.

For the provision of nurses and dental assistants, it is noted that in the surveys, most dentists who took part in the online survey indicated that they work permanently with a nurse or dental assistant and 20% only in some cases, in 25% of the cases the dentists work independently in their practice. Lack of staff is the least frequently cited reason for this, but it should also be noted that this is an indicator of the quality of medical dental care which was not noted in the study.

Dental technicians are also part of the dental team. They do not have direct contact with patients, but make prosthetic structures and orthodontic devices and splints aimed at restoring defects in the tooth rows. The provision of dental technicians per 1000 people again repeats the distribution of dentists.

Physical accessibility. This dimension is presented and analysed by results of the questionnaire survey among users and dentists. Practices are mainly concentrated in cities and this makes it difficult for patients from smaller settlements to have a physical access. 81.4% of dental users do not have to travel to another location to receive the necessary dental care.

Again, the analysis shows a statistically significant difference for those living in villages and in smaller towns. Participants with higher education, low income and inactive participants to take a trip. Going to the dentist can be complicated due to lack of transport or a long distance.

Convenience. Dental service providers are important to be reached not only physically but also in a timely manner. The dimension of convenience is associated with the organisation of the dentist's practice in a user-friendly way, the main focus being the provision of dental services on time and usually considering working hours, reception hours, etc.

In 43% of dentists, due to schedule occupancy, enroll patients between one and three weeks. Only 2.6% of dentists said they could provide a service on the same day. One-third of the dentists said they were taking patients overtime, while 18% were reluctant to work outside their scheduled schedule. One convenience dentists use to optimize their schedule and enable patients to be

flexible in choosing the time frame for booking an appointment is to use an online appointment recording system.

Financial barriers

Dental care in Bulgaria is financed mainly through patients' own funds, and they usually pay for dental services that are not included in the basic package provided by the NHIF or when sharing the costs of the services covered by the health system. The NHIF pays fully or partially within a certain scope and volume of dental care under the package "Dental Activities" of health-insured persons (SOL) in Bulgaria and fully covers the funding in a certain scope of several special categories of persons: children under the guardianship of the state, children up to 18 years with mental disorders and prisoners. An additional single examination for pregnant women, regardless of their age, is also provided by the NHIF.

Dentists in one of the studies (76.3%) are adamant that the scope of the package "Dental activities" covered by the health system is not enough to cover the needs of consumers for basic dental services and offer to expand it by indicating in ascending order the following three dental services to be included: tartar cleaning, endodontic treatment and orthodontic examination/treatment in children.

In the other survey, regarding how to cover the costs of dental services, the largest share of respondents (86%) reported paying with their own funds for the dental services received.

The analysis of the data on the payment of the costs of dental services with own funds shows as significant between the factors income and also the place of residence and self-assessment for dental health.

A mechanism used to alleviate the financial burden on patients in bearing the costs of dental services is the use of voluntary health insurance, as well as payment of costs for dental services through borrowed money.

Personal barriers

Health literacy, knowledge, emotions and previous experience can modify a patient's behavior to take action to improve their dental health but they can also be personal obstacles to receiving dental care.

2.4.1 Awareness

Oral health literacy is defined as "the degree to which an individual has the ability to receive, communicate, process and understand health information in a way that enables him or her to make appropriate health decisions." Effective communication between the dental specialist and the patient, speaking and presenting information in a clear and appropriate format can contribute to improving the patient's health literacy. Respondents highly rated communication with their dentists, with only a lower score giving encouragement to ask questions.

2.4.2 Acceptability

The previous unpleasant experience of the dental chair can also change the patient's health behavior, leaving an impact on his attitudes. Patients during manipulation may experience unpleasant feelings such as discomfort, pain, etc. and it is therefore fully expected that a large share of respondents agree with the statement that "unpleasant experiences of dental procedures lead to postponement of visits to the dentist". The average score, which gets on this statement is 3.56 out of 5. In 34% of the participants, a previous unpleasant experience could most likely prompt them to change their health behavior and they respectively reduce the use of dental care. Patients' opinions on this issue show statistical significance related solely to dental health self-esteem.

Study of the usability of dental care in Bulgaria

The six dimensions of access to dental care are examined in the model of McKernan and co-author and are associated with structural, financial and personnel barriers which may limit the usability of dental care. In the study, 56.7% (n=541) of users indicated that they had to postpone a visit to the dentist ($\chi 2 = 51.79$, p<0.001). The analysis shows that the degree of influence of individual barriers is not the same and a statistically significant difference between them is found, with the two most severely restrictive barriers being the

payment of dental services and the lack of time. Next is the fear of dental manipulations and the least restrictive effect turns out to be the trip to the dentist.

Chapter Three "Guidelines for improving access to dental care in Bulgaria" clarifies the possibilities for guidelines for improving access to dental care. Availability, physical accessibility and convenience, the good saturation for the population of Bulgaria as in the European Union of the population with dentists is noted. Also the number of active students in the professional field of "Dentistry", optimal ratio between dentists and population. But the dimensions of access only with the availability of health personnel in the system is not informative enough there are other factors to consider when assessing access to dental care.

Availability. One can expect difficulty in accessing the Northwest, North Central and South-East regions. In these areas, the economic microclimate should first be improved through targeted state and municipal policy in order to become attractive centers for dental practitioners. This conclusion is quite hypothetical, because the economic microclimate depends on many more factors and for a longer time. And the health status of the population including oral health is of utmost importance for the general health status of the population. Therefore, it seems that the more important conclusion to be drawn is differentiated remuneration in certain areas with a burden for the specified area of the same prophylactic or curative activities and emphasizing prevention and health education in terms of dental health.

Regional differences in the distribution of dentists lead to inequality in the use of dental services. Patients living in villages visit a doctor less often than other respondents. A step taken in this differentiated payment is the envisaged "Framework Contract 2023-2025" additional funding for providing medical staff in outpatient dental care establishments that provide dental services in remote hard-to-reach areas or only perform the relevant activity in the municipality. Outpatient dental care can be provided by medical institutions with open mobile structures, but the NHIF covers the costs of the activities provided only if in settlements with unfavorable conditions and the activities are carried out continuously in the same settlement not less than 3 months.

In addition to the education, a significant factor in the dimension of access physical accessibility is also the age of patients. Patients over 50 were the most prevented from seeing a doctor due to difficulty in movement which corresponds to studies done in Europe and the self-assessment of patients' digital dental health also found to be a significant factor in physical accessibility.

Financial accessibility. The cost of dental services in the literature is often identified as an important and probably a major barrier to receiving dental care in the opinion of various authors. Out-of-pocket payment is a major mechanism in the financing of dental services, this has a significant burden on households. For one of the oral diseases with the highest frequency "caries of permanent teeth" in the package of the NHIF is provided for treatment only the service "Amalgam obturation or chemical composite" and the application of high quality photopolymers, even less used amalgam and chemopolymers. In practice, it often happens that patients pay the difference between one and the other opturating materials to ensure a higher quality of the treatment applied. The package "Dental Services" provided by the NHIF also does not provide treatment of periodontal diseases, gum diseases, etc. The main focus in the publicly covered program is on treatment while the prevention of oral diseases and the promotion of dental health are poorly covered. The lack of mandatory prophylaxis among the population is cited as one of the leading causes of poor oral health of the population.

In the current analysis, the dissertant finds that in three of the considered factors that choose patients to cover their services, income is a significant factor. The NHIF offers partial coverage of the costs of examinations and treatment, while in the meantime a share of patients resort to borrowing money to cover their services. Voluntary health insurance is a very small percentage of the population - about only 10 % of the population has voluntary health insurance as opposed to Netherlands, where 84% of the population are thus used to cover expenses.

Awareness and acceptability. The study shows that, to a large extent, the sample in the population does not have enough information about the role of the dentist in the prevention of oral diseases. Studies are reported on the lack of awareness of routine oral examinations, the benefits of regular visits to the dentist for further dental health. Especially for patients with secondary

education and below, residents of villages and respondents with poor dental health according to their assessment. More respondents visit a dentist in the presence of pain and very rarely for prophylactic purposes.

In this study, various researchers point out that factors such as age, gender, place of residence, income and employment, as well as a higher level of education lead to increased use of dental services. The present study does not reach the same conclusions in terms of age, gender and place of residence and does not find a significant difference in the number of visits associated with these factors. The importance of education, income and employment have been confirmed. The claim also confirms that patients mainly seek a dentist in the presence of pain.

Evaluation of the abstract

The review presents reliably the structure and content of the dissertation with an emphasis on the most important results and conclusions. It is shaped according to the requirements and edited with the main and necessary sections.

Submitted publications

In connection with the problems discussed in the dissertation, the PhD student presents in the autoabstract 3 real publications, of which 3 in our scientific journals. He is the first author of three of them. One study with no publication date was added.

- E Todorova, E Atanasova, Coverage of dental services by the National Health Insurance Fund in Bulgaria, Varna Medical Forum 12 (1),2023
- E Todorova, Anxiety and fear: a barrier to accessing and accepting dental care, Varna Medical Forum 12 (1), 2023
- E Todorova, E Atanasova, Patient payments for dental services in Bulgaria, BULGARIAN JOURNAL OF PUBLIC HEALTH 15 (2), 71, 2023
- V Panov, E Todorova, Historical development of dental care in Bulgaria, Varna Medical Forum 11 (1), 155-159

CONCLUSION

In conclusion, I can make the following remarks and conclusions about this dissertation:

- 1/ The structure of the dissertation work is not entirely appropriate, as I believe that the literary review as such should be more clearly separated.
- 2/ Later this affects the tasks set, one of which is the literary review.
- 3/ The annexes and tables are more appropriate to be at the end of the presented work.
- 4 / The presentation of only 3 / 4 / publications is not the best attestation for a dissertation.
- 5/ I also have several linguistic remarks, one of which is the use of the expression "service". I think this term is insufficiently prestigious for highly qualified work of medical professionals it is better to talk and write about medical help and care.

Summing up the merits of the dissertation, I allow myself to note:

- 1/ This paper raises the extremely important thesis of health education and prevention, as well as topical issues for the organization of dental care. Due to the predominantly private nature of this medical activity in society, these issues are discussed very shyly till now.
- 2/ The important conclusion about the impact of dental health on the general health of the population with the impact of dental status on the gastro intestinal, endocrine, infectious, etc. diseases .The impact of this morbidity on economic indicators is discussed.
- 3/ A very good literature review has been made, comprehensive, with authors from over 40% of the last five years.
- 4/ In the second chapter of the work, a significant volume of material is presented, which is a good prerequisite for statistical processing with great confidence.
- 5/ A modern toolkit analyses of the reasons for reduced access to dental care are produced. The presence of dental staff is not a sufficient condition for full-fledged dental care of the population. On top of that, there is a gross unevenness in the distribution of dental care in Bulgaria and the correlation of

this phenomenon with the economic condition of the population in certain regions of the country.

6/ The need for serious differentiated payment for dental care and care in the relevant regions of the country after the timid attempts of the state in this regard is pointed out.

7/ A comparative analysis of access to the dental care in Bulgaria and internationally has been made.

When reviewing the remarks and merits on the dissertation, the merits weigh on and these is a good literary review, more than 40% of the titles from the last five years, good material in volume for statistical processing and well-grounded clarification of the reasons for reduced access to dentistry in Bulgaria, compared to countries in the European Union.

The opportunities for improving the dental health of the population through extended pay by the NHIF for preventive examinations and differentiation pay for different regions are outlined. It justifies the need to introduce modern methods and means of anesthetizing procedures for suppressing the fear of dental care and care.

In view of the above, I give my positive assessment of this dissertation for acquiring educational and scientific degree "Doctor" under the doctoral program "Organization and management outside the field of material production / in healthcare /", in professional field 3.7. Administration and management on the topic "Access to dental care in Bulgaria" by Elena Petrova Todorova.

Date: 24.01.2024

Reviewer:

Заличено на основание чл. 5, §1, б. "В" от Регламент (ЕС) 2016/679