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Adriana Miroslavova Dacheva

Application and implementation of the TDABC (time-driven activity-based costing) methodology in Bulgarian ophthalmic clinics for the treatment of patients with macular degeneration

AUTHOR'S SUMMARY

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Prof. Dr. P. Dimitrov, MD Prof. Dr. T. Vekov, PhD

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Contents	
ABBREVIATIONS USED	3
INTRODUCTION	4
Chapter I. LITERARY OVERVIEW	6
Chapter II. AIMS AND OBJECTIVES OF THE STUDY	9
2.1. Aim of the study	9
2.2. Objectives of the study	9
2.3. Hypotheses	9
2.4. Subject of the study	10
2.5. Object of the study	10
Chapter III. Research Design & Methods	11
Chapter IV: Presentation of Research	13
4.1. Eye Clinic 1	13
Example steps required to achieve expected result	18
4.2. Eye Clinic 2	21
CHAPTER V. DISCUSSION	27
CONCLUSION	32
References	33
MAIN CONCLUSIONS, RECOMMENDATIONS, CONTRIBUTIONS	34
PUBLICATIONS AND PARTICIPATION IN SCIENTIFIC FOON THE THEME OF THE DISSERTATION	
APPLICATIONS	39

ABBREVIATIONS USED

- MP medicinal product
- MD macular degeneration
- AMD age-related macular degeneration
- NHIF National Health Insurance Fund
- $HTA-health \ technology \ assessment$
- GP general practitioner
- RS reference source
- ABC activity based costing
- CEA cost-effectiveness analysis
- HBS Harvard Business School
- TDABC activity based costing and its duration
- VA visual acuity
- VBHC value-based healthcare

INTRODUCTION

Health technology assessment (HTA) is a multidisciplinary discipline that generates evidence-based decisions. It provides a systematic examination of a health technology's features and impacts, addressing both direct and predicted effects as well as indirect and unexpected repercussions, in order to provide reliable data for decision-making.

Innovative healthcare organizations worldwide are redefining healthcare by implementing Value Measurement For Health Care (VMHC), which seeks to enhance patient outcomes while lowering costs. Value-Based Health Care (VBHC) is a Harvard Business School (HBS) approach that investigates best practices for reorganizing and coordinating health care, improving process efficiency, incorporating innovative approaches to paying for the entire treatment cycle to achieve outcomes that matter to patients rather than volume of activity, and integrating into practice.

In the health care system, value measurement enables the transition from a fee-for-service model to a system of value-based care.

In health care, "value" is defined as patient health outcomes achieved relative to the costs of care. If patient-related outcomes do not improve, the value obtained is insufficient. The methodology permits simultaneous monitoring and enhancement of patient-related outcomes and cost optimization.

VMHC comprises health services geared toward measuring the added value, utilizing the methodologies TDABC (time-driven activity-based costing) and measuring final results (health outcomes and outcomes related to the patient's quality of life).

The present doctoral thesis focuses on the application of the TDABC methodology.

The methodology "TDABC – time-driven activity-based costing" is focused on providing appropriate treatment to fulfill the patient's own objectives (personal value) and obtain the best possible outcomes with the given resources (technical value). The application of this methodology is a long-term strategy that aims to structure the measurement of clinical and patient quality-of-life outcomes in order to

improve performance through regular data processing and analysis, as well as the monitoring of a particular therapy's effect on patients' quality of life.

Age-related macular degeneration (AMD) represents a serious problem, being the leading cause of blindness among the population over 60 years of age in developed countries.

The objective of the current dissertation thesis is to undertake an external assessment, cost analysis, process analysis, management team structure, and technological solutions in two eye clinics as a concept for completing an intravitreal VEGF-inh application ophthalmic treatment utilizing the value-based healthcare approach, and more specifically the TDABC methodology - time-driven activity-based costing - in patients with macular degeneration.

The cost optimization and the importance of measuring patient's outcomes associated with TDABC implementation are discussed. Possible ways of introducing the methodology into routine practice in Bulgaria have been outlined and implemented.

The importance of measuring patient-reported outcomes associated with TDABC deployment is emphasized, as well as cost optimization. Methods for incorporating the methodology into ordinary practice in Bulgaria have been proposed and implemented.

Chapter I. LITERARY OVERVIEW

The first chapter of the dissertation consists of a literature review that aims to present various leading examples from global practice regarding the application of the value-based healthcare methodology, and particularly - the application of the TDABC methodology - activity-based costing and its duration, the measurement of outcomes, and the role of HTA in measuring value in health care.

The dissertation examines the role of health technology assessment (HTA) and the relationship with the concept of benefit measurement in health care. The similarities and differences between the two are indicated.

The first example from the dissertation work is the assessment of patient expenses at Boston Children's Hospital and the implementation of the TDABC methodology in the Department of Plastic and Oral Surgery (DPOS). RCC and TDABC calculation techniques are compared. The advantages of TDABC application are emphasized.

The second example given is the assessment of health outcomes and patient-related outcomes (PROs) in prostate cancer patients at the Martini Klinik in Germany. Martini Klinik became one of the leaders in the number of treated patients and in terms of achieved results - both health and scientific- care for patients, organizations, and times better than all other clinics in Germany, based on the concept of value-based health care and the reorganization of medical care with a focus on the patient and the measurement of final results.

The third example is the assessment of clinical indicators in kids with congenital heart abnormalities at Texas Children's Hospital in Houston, Texas. By 2014, each patient's in-hospital mortality, rehospitalization rates, surgical complication rates, and a wide range of intraoperative process metrics had been examined. Better assessment of other outcomes, such as quality of life and emotional well-being, continues the process of improving treatment. Based on one-year and three-year neurodevelopmental follow-up data, children who underwent heart surgery at Texas Children's had cognitive and motor function

equivalent to children who did not undergo surgery, as evaluated by the BSID-II. Following that, the assessment of neurodevelopmental outcomes was extended to five years.

The next example from international experience described in the dissertation is the implementation of bundle payments for hip and knee replacement in Stockholm. The OrthoChoice package includes a pre-operative visit, surgery (including the prosthesis), inpatient care, and a three-month follow-up appointment. All physician fees, staff expenditures, sick leave, drugs, tests, imaging, and other consumables are included. The bundle contains a projected inpatient stay of six days, including physical therapy, based on the current diagnosis-related group, and is not altered for shorter or longer hospitalizations. The package does not include outpatient rehabilitation. In the case of difficulties linked to the procedure, such as infection or the need for modification or reoperation, the package contains a guarantee.

Complications and patient-reported outcomes such as the EQ-5D are among the OrthoChoice patient outcome data gathered. The service is then valued based on the severity of the sickness and the expenses of complications, i.e. the value to the patient.

OrthoChoice certainly emphasizes two critical points. The first is the valuation of a full suite of services - bundle payments. The second is an improvement in end health outcomes, because deteriorated final results (for example, complications) are at the expense of the service provider and hence reflect on profit.

In the dissertation's literature review, an example of TDABC implementation, **this time in** patients with type 1 diabetes mellitus by Medtronic **in the Diabeter Clinics in the Netherlands**, is described. Diabeter is aiming to change the payment model to a 10-year contract with an annual charge that covers all expenditures for each type 1 diabetes patient registered. The development of such packaged contracts necessitates the use of activity-based pricing (TDABC) to calculate the overall expenses incurred by the integrated healthcare team method. Diabeter had cared for 2,400 individuals by 2018, accounting for 18% of all type 1 diabetes patients in the Netherlands. Depending on the

treatment technique, 40-82% of these patients achieve satisfactory glucose control (HbA1c below the goal range), placing them among the country's most successful diabetes clinics. Diabeter saves 8.7% on yearly costs, particularly by lowering hospitalization rates.

An example of cost estimation in an ophthalmology department from Turkey is also shown. The records of patients treated in the ophthalmology department of a public hospital in Turkey between January and December 2017 were reviewed in this single-center, retrospective analysis. The goal of this study is to calculate the cost of treatment for a patient using the TDABC method, which includes surgical treatment with local anesthesia, fluorescein fundus angiography (Fundus Angiography, FFA), and laser treatment Fluorescein (laser photocoagulation with argon laser, Nd:YAG laser capsulotomysynechiotomy, electrolysis (by argon laser) in distichiasis). The study demonstrates that the TDABC approach may be used in hospitals to generate reliable cost information and can help hospital management make strategic decisions. Furthermore, the approach assists hospitals in reducing resource waste by estimating their expenses in a realistic manner using the TDABC method, which also benefits the environment by reducing the usage of medical consumables and the quantity of medical waste.

The literature review, which includes examples from worldwide practice, is followed by a presentation of the Santeon program, which is a working example of a program based on the value-based health care concept. Santeon is an organization created in 2007 by six independent hospitals in the Netherlands working in close collaboration with the main purpose of enhancing patient care and treatment outcomes. Clinics share their ideas, expertise, and experience.

The literature review describes in detail the TDABC approach, the importance of value measurement in the assessment of health technologies for medical activities, and cost measurement. There is also information regarding the illness itself, which is the focus of the current study - age-related macular degeneration.

Chapter II. AIMS AND OBJECTIVES OF THE STUDY

2.1. Aim of the study

The study's aim is to conduct an external evaluation, cost analysis, management team structure, and technical solutions in two eye clinics (Eye Clinic 1 and Eye Clinic 2) as a concept when performing an ophthalmic procedure for intravitreal application of VEGF -in. in patients with macular degeneration using the TDABC methodology - time-driven activity-based costing.

2.2. Objectives of the study

- 1. To investigate the literature on the interactions between health technology assessments and value measurement in health care.
- 2. To review the literature on practical applications of the valuebased health care paradigm in the patient care delivery cycle.
- 3. To investigate cost measurement methods and the role of value measurement in health technology assessment for medical activities.
- 4. To research and provide the most prominent examples of the chronological introduction of final outcomes measurement, including their sequence and time frames.
- 5. To examine the role of TDABC and the mechanisms for its application in practice.
- 6. To conduct an external evaluation, analysis of costs, processes, management team structure and technical solutions in two eye clinics serving patients with macular degeneration using the TDABC methodology.
- 7. To examine the differences that resulted from using the TDABC methodology in the individual clinics.

2.3. Hypotheses

The following working hypotheses underpin the research:

- The concept of value-based health care (VBHC), and particularly the TDABC approach, has the potential to transform the health model and rearrange the cycle of providing medical treatment with a patient-centered focus.

- The TDABC methodology can optimize management and technical.
- decisions by introducing a fair valuation methodology based on the activity and its duration.
- Through the application of the TDABC methodology, capacity can be freed to be redistributed to another activity, with a higher added value, which will enhance the entire cycle of health care provision, centering on the patient. This will lead to an overall improvement in the quality of care provided to patients.
- Medical treatment may be improved using the TDABC methodology because it places a premium on outcomes (both those directly connected to the patient's health and those that measure the patient's quality of life).
- TDABC score data from different countries can be adapted for analysis and comparison.

2.4. Subject of the study

The study investigates the feasibility of implementing the TDABC approach to patients with macular degeneration in eye clinics under Bulgarian health-care circumstances.

2.5. Object of the study

The object of the present study is intravitreal application of VEGF-inh. in patients with macular degeneration in Bulgarian ophthalmology clinics.

Chapter III. Research Design & Methods

In two eye clinics (Eye Clinic 1 and Eye Clinic 2), an external assessment, cost analysis, process analysis, management team structure, and technical solutions were performed as a concept for performing an ophthalmic procedure of intravitreal VEGF-inh application in patients with macular degeneration. The "TDABC - time-driven activity-based costing" methodology is used, in terms of providing appropriate treatment to accomplish the patient's personal goals (personal value) and obtain the best possible results with available resources (technical value).

Questionnaires, individual interviews with clinic senior management, group interviews with medical personnel, on-site clinic observations, and electronic registers with a database were used to develop a map of the processes in patients with macular degeneration in Eye Clinic 1 and Eye Clinic 2.

To analyze the activities at each phase of the medical care process, a model created in Microsoft Excel was employed.

The timing approach was utilized to analyze the time necessary to execute intravitreal application of VEGF-inh. in an operating theater All patients seen in Eye Clinic 1 and Eye Clinic 2 were documented. For the purposes of the analysis, the operation was performed in both clinics at an average value.

The utilized interdisciplinary strategy, which includes qualitative and quantitative research approaches, attempts to discover any gaps or lack thereof, assess them, and give evidence-based recommendations on the factors of labor productivity and their improvement.

Within six months, a total of four visits were made to Eye Clinic 1. During the initial clinic visit, a presentation was provided to familiarize her staff with the fundamentals of TDABC and the project's objectives. During the first two visits, interviews were held with a part of the personnel engaged in the intravitreal injection of a medication for the treatment of macular degeneration. The interviews comprised questions on pre-prepared questionnaires in order to determine the roles, number, and duties of all individuals participating in the procedure, as well as the order of all procedure steps. During the third and fourth clinic appointments, the time necessary to execute an intravitreal VEGF-inh treatment on 51 patients with macular degeneration was assessed.

Following the conclusion of the interviews, the intra-vitreal application process was observed in the clinic (so-called field work) during the third and fourth visits, and the time needed to conduct the different phases of the operation was measured. On the basis of this, an analysis impacting the optimization of management and technical decisions under the method was carried out. Following the acquisition, processing, and analysis of the collected results, the analysis is presented, upon which optimization proposals are made and debated at a meeting with senior management.

During the interviews and observation of the intravitreal application procedure in Eye Clinic 1, the "Initiating Questionnaire for Macular Degeneration" and "Initiating Questionnaire for Macular Degeneration -Process Plan" were completed. As a result of their analysis, a process map was created, reflecting the sequence and duration of the processes of the procedure (process mapping), a financial model calculating the payment of the participating personnel, and an analysis was carried out, including recommendations concerning management and technical solutions through the TDABC methods.

There were five visits to Eye Clinic 2 and sixty-five patients with macular degeneration were seen. During the visits, interviews were performed with members of the staff engaged in the intravitreal delivery of VEGFinh. to macular degeneration patients. The interviews included questions to determine the roles, numbers, and duties of all personnel involved in the operation, as well as the order of all procedural steps. Observation of the intravitreal application process and assessment of the time required to do the various phases of the operation were also conducted, with the resulting analysis influencing the optimization of management and technical choices pertaining to the execution of the treatment. To determine the quality and organization of the obtained health data, a review/observation of the medical software utilized by the Clinic was also accomplished.

Chapter IV: Presentation of Research

4.1. Eye Clinic 1

Eye Clinic 1 was visited on-site, and 51 patients with macular degeneration were documented. An arrangement illustrating the order and length of the steps in the procedure (process mapping) was made as a result of an analysis of the responses to the completed "Initiating Questionnaire for Macular Degeneration" and "Initiating Questionnaire for Macular Degeneration" and "Initiating Questionnaire for Macular Degeneration, a time comparison between the IVI processes' execution times before and after optimization, an analysis of the current data, and a financial model used to determine the compensation of the involved staff members are all included. Recommendations affecting management and technical decisions are also included.

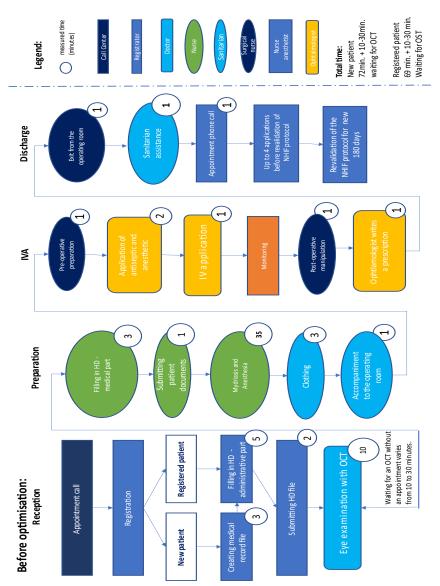
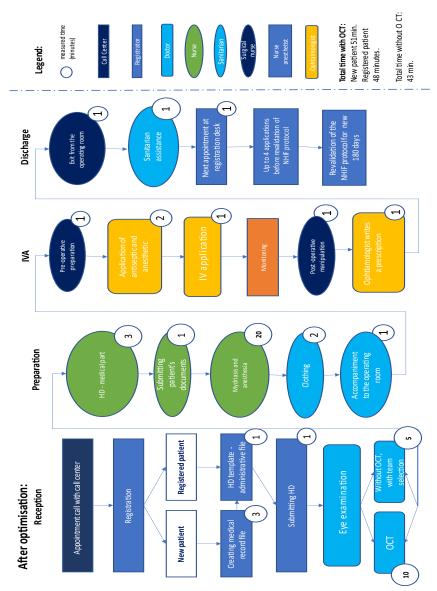


Figure 1. Sequence and duration of the processes under the IVI procedure in current conditions (Mapping)

Plan of current processes



Process plan after possible optimization

Figure 2. Sequence and duration of the processes under the IVI procedure after optimization

	Current process, time in minutes	Process after optimization, time in minutes		Minutes saved	Saved time, in %
Registrar	11		7	4	36,36%
Attending physician	10		0 3	0	0,00% 70,00%
Nurse	39	2	3	16	41,03%
Sanitarian Surgery nurse	5		5 3	0	0,00%
Anesthesiology nurse	4		4	0	0,00%
Ophthalmolog ist	6		4	2	33,33%
Newly registered patient	74	5	2	22	29,73%
Registered patient	71		.9	22	30,99%
Puttent		No OCT 4	2	29	40,85%

Table 1. Comparison of the time required to complete the IVI procedures.

* In patient time, waiting time is not included, which varies from 10-30 min (before optimization). Patient waiting time after optimization is minimized as much as possible.

As a result of the conducted interviews and observations, an analysis of the current status of the intravitreal application procedure and possible changes to the procedure are made and reflected in the following table.

Table 2. Current status of the intravitreal application procedure and possible changes in Eye Clinic 1

Parameter	Current status	Possible changes
1.Reference sources (RI)	Missing tracking of: - RI (doctor, medical center, hospital, advertising, etc.) - number of referred patients from the relevant RI - the reasons for referral	 Track RI Maintain RI database: data number of patients reasons Establishing feedback with RS
2.Number of patients	Maintaining a database of patient numbers - unclear	 Database analysis for: number of recorded hours % showed up/ did n't show up per month number of enrolled and % conducted procedures IVT application per month reasons for non-appearance
3.Number of procedures	Maintaining a database of number of procedures per patient - unclear	 Maintaining a database of number of procedures per patient Analysis for average expected number of procedures per patient
4. Save time for next application	The next appointment is made by calling the patient 1-2 weeks before the procedure	 MC can make a phone call to book the next class The MC can remind patients about the relevant time by phone call
5. Tracking	MC rarely proactively follows up with patients	Proactive monitoring of patients' status by calling

		patients at certain time intervals
6. Pharmacy	There is a lack of follow-up of the pharmacies from which patients receive MP	 Tracking where and when LP is received Preliminary preparation of LP for the respective patient before the scheduled time Provision of LP from a pharmacy near the MC
7. GP	A phone call to the GP to record the patient's illness and follow-up training	 Calling the General Practitioner Sending a brochure/training video Maintaining a database with OPL and RI

*RS - reference source

*MP - medicinal product

*GP – general physician

As a result of the recommendations and their implementation, the following results were achieved in Eye Clinic 1:

- Time optimization
- Free capacity –

The optimization of time and freed up capacity enables emphasis on the engagement and development of medical professionals.

- Increase in patient flow
- Better organization of the overall work process, predictability of processes, planning

Example steps required to achieve expected result

- Reorganization of the work process
- **Technological solution** a combination of software solution and call center
- Working with referral sources to increase the flow of patients an opportunity to increase the flow of patients that passes through Eye Clinic 1 by:
- working with a database;
- ability to track patients;
- providing feedback to RI that is proactive;

- organizing events to increase the number of RIs - local meetings, specialized meetings, active communication

As a result of the analysis, it is proposed to carry out regular measurements of key performance indicators (KPI). The types of KPIs and the purpose of their measurement are reflected in the following table.

k	KPIs Comment				
	Number of patients				
	 Referral sources (MCs, doctors, hospitals) that refer patients Reference database - address, phone, e- mail Classification of reference sources – SIMP, hospital, GP, self- referred, etc. Number of patients referred by the relevant referral source Quality control of the diagnosis of referred patients 	Enables classification and periodic analysis of reference sources and feedback from them			
2.	Number of patients who booked an appointment - new	This and the next KPI will provide an opportunity to plan patients, flow, revenue, occupancy			
3.	Number of patients who made an appointment for an examination - consecutive	Analysis and proactive management of the number of procedures per patient			
4.	Classification of patients by number of remaining procedures	Planning			
5. - -	Number of recorded reviews rejected by: Patient reason Reason for the clinic % no- shows of patients per month, despite an appointment	Analysis by reasons			
6. - -	Monthly analysis Target number of patients seen, month Patients examined per month Target number of patients per month receiving an IVT injection Number of IVT injections given	Analysis to fulfill the set goal			

Table 3. Key Performance Indicators (KPIs)

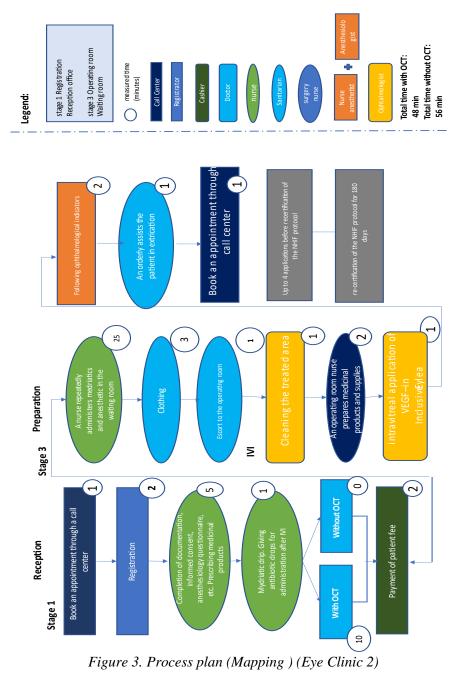
7. Annual analysis	
- Total number of procedures per patient per	
year	
- Planned	
- Performance against target	
Optimization - time	
8. Planning	Load analysis
- Scheduled review dates and times	Load analysis Load planning
 Scheduled review dates and times Scheduled procedure dates and times 	
1	Analysis and optimization Analysis of the unplanned
- Average waiting time for a standard booked	Analysis of the unplained
appointment, in days	
Arrived without scheduled date and time	
9. Average IVT procedure time per patient	Are there time variations
(from registration to discharge) (in minutes).	on individual days? For
	individual specialists
10. Dwell time from check-in to exit from	
operating theater?	
11. Time to fill in history of the disease, other	Process optimization as
documentation, administrative processes	needed
Planning a follow-up application	
12. Proactive organization and reminder	Proactive flow control
- Number of patients presenting for follow-up	
administration after reminder	
- Number of patients who alone	
13. Number of patients who showed up for a	Process quality control
procedure after an active reminder	
Follow-up observation	
14. Patient follow-up	Proactive tracking
- Define tracking periods	
- Verification of documentation for an	
upcoming visit	
15. Communication with a referral source for	Proactive communication,
specific patients	ability to influence
16. Tracking analysis	
- Number tracked	
- Feedback from patients	
- Feedback from references	
17. Intervals of patients presenting for follow-	Ability to plan
up, in days	

4.2. Eye Clinic 2

During a visit to Eye Clinic 2, 65 patients with macular degeneration were observed. Completed " Macular Degeneration Initiation Questionnaire" and "Macular Degeneration Initiation Questionnaire - Process Plan" As a result of an analysis carried out on the basis of conducted interviews and observation of the procedure of intravitreal application in Eye Clinic 2, the following documents were created: a schematic presentation of the sequence and duration of the processes of the procedure (process mapping), a financial model calculating the pay of the participating personnel and analysis and recommendations affecting the management and technical decisions on the procedure. As a result of the observation of the medical software "Gamma Codemaster " used by the Clinic, the final health results that are monitored during the application of intravitreal injections for the treatment of macular degeneration and the possible fields for recording in the software with the potential for optimization have been established - in this particular case it becomes a question of the very way of entering the measured final health outcomes into the software. Example health outcomes that can be measured are included in the following table.

Table 4. Health outcomes in patients with macular degeneration

Health outcome measures		
• Percentage of patients who maintain vision, i.e. such as a loss of less than 15		
letters of visual acuity at each visit		
15-letter improvement in best-corrected visual acuity (BCVA)		
Mean change in BCVA from baseline		
• Anatomical indicators - reduction (mean change) of central retinal thickness		
[CRT] in OCT; percentage of patients without fluid at OCT		
Health outcomes reported in randomized clinical trials (RCTs)		
• At week 52, the percentage of patients with a loss of < 15 letters from baseline		
is 95.33% (RCP VIEW1 and VIEW2) OR AT week 52		
• At week 52, patients with 2-week corrections (time to next injection) gained		
an average of 9.0 letters from baseline compared to 8.4 letters for those with		
4-week corrections (RCP – ALTAIR) OR AT 52- hi week		
• In the second year of treatment, the mean improvement from baseline was 7.6		
letters for the 2-week correction group and 6.1 letters for the 4-week		
correction group (ARC – ALTAIR)		



As a result of the conducted interviews and observations, an analysis of the current status of the intravitreal application procedure and possible changes to the procedure, reflected in the following table, was performed.

Parameter	Current status	Possible changes		
1. Reference	Tracking of domestic RIs only	1. Creation of a database with		
sources (RS)	- number of referred patients	external RS		
	from the relevant RI	2. Establishing contact and ensuring		
	- the reasons for referral	sufficient awareness of external		
		reference sources by organizing		
		meetings, creating brochures, etc.		
		3. Tracking external RS		
2. Pharmacy	1. There is a lack of follow-up	1. Provision of MP from the hospital		
	of the pharmacies from which	pharmacy of the Ili Clinic		
	patients receive MP	1. Tracking where and when MP is		
		taken		
		2. Preliminary preparation of MP for		
		the respective patient before the		
		appointment		
3. GP	1. Phone call to the GP to	1. Calling the GP		
	record the patient's illness	2. Sending a brochure/training video		
	and follow-up training	3. Maintaining a database with GP		
		and external MP		
	1. The clinical results of each	1. Change in the way clinical results		
health - related	patient are entered into a text	are entered - enter only numerical		
results)	box in the medical software	values, not in a text box as free		
	and are reflected in the	text.		
	patient epicrisis.			
		1. Periodic measurement of the		
related to the	patients' quality of life when	patient 's quality of life using a		
patients' quality	intravitreal injections are	standardized EQ-5D questionnaire		
of life (patient-	administered	2. Training of staff at the Clinic for		
related results)		periodic performance and analysis		
		of standardized EQ-5D		
		questionnaires		

Table 5. Current status and possible changes

*RS - reference source *MP - medicinal product *GP – general physician

When performing the analysis after a visit to Eye Clinic 2, the following recommendations were made to improve productivity:

- 1. Creation and maintenance of a database for external RIs who refer patients to the Clinic for the purpose of:
- 2. Communicating with patients' GPs and maintaining a database in order to:
- **3.** Tracking or provision of the medication from the Clinic's hospital pharmacy/other pharmacy from where patients can take the medicinal product. In this way:

The projected average annual profit that can be generated in the Clinic's hospital pharmacy by providing the medicinal product VEGF- inh, reimbursed by the NHIF, is presented in the following table.

Table 6. Estimated value of average annual profit in the hospital pharmacy of Eye Clinic 2 when providing the medicinal product VEGF- inh for patients with macular degeneration

Medicinal product, marketing authorization holder	Wholesaler price	Retailer price	LP profit value	Average annual profit per patient*	Average annual profit value**
Medicinal product VEGF- inh	BGN 1,407.80	BGN 1,437.80	BGN 30.00	BGN 210.00	BGN 67,200.00

- 4. Insertion of instructions for use of the Amsler test in a separate booklet
- 5. Change in the method of entering eye parameters in the software used
- 6. Collection and measurement of data related to the quality of life of patients receiving intravitreal injections for the treatment of macular degeneration.

As a result of the analysis, it is proposed that regular measurements of key performance indicators (KPI) be carried out in the Clinic. The types of KPIs and the purpose of their measurement are reflected in the following table.

KPIs	Comment
Reference sources	
 External referral sources (MCs, doctors, hospitals) that refer patients Database for external reference sources - address, phone, e-mail Classification of external reference sources - SIMP, hospital, GP, self- referred, etc. Number of patients referred by the relevant external referral source Quality control of the diagnosis of referred patients 	Enables classification and periodic analysis of external reference sources, feedback from them
Follow-up observation	
Communication with an external referral source for specific patients	Proactive communication, ability to influence
Tracking analysis Number tracked Feedback from external references	Proactive communication, ability to influence
Measuring end results	
Measuring and tracking health outcomes in numerical values	Allows easy and fast reporting of changes in clinical results and traceability for a specific health indicator, tracking, introducing changes and measuring results; publications
Measuring patients' quality of life	It allows tracking the health benefits and changes in the patient's quality of life as a result of the application of intravitreal injections, for a specific period, introducing changes and measuring the results; publications

As a result of the recommendations and their implementation, the following results were achieved in Eye Clinic 2:

- **Increasing patient** flow through Eye Clinic 2 by improving medical care with a primary focus on end results
- Creation and maintenance of a database for external reference sources (RI) and GPs, active communication with them, which in turn will lead to an increase in the **revenue of the medical facility**
- Through a reconfiguration in the medical software, the way of entering the patients' health indicators (measurement of visual acuity and central retinal thickness) has been changed. Currently, the data is only entered in numeric value, which allows for a detailed report at the patient level, reflecting the changes in the two health indicators.
- An additional module concerning patients diagnosed with macular degeneration and diabetic macular edema has also been added, which allows the preparation of a historical reference with dynamics reflecting changes in the specific two health indicators
- The clinic's nursing team were successfully trained to use the questionnaires to measure the quality of life of patients with macular degeneration, resulting in quality of life data for patients with macular degeneration already being collected
- A process for collecting, processing and analyzing health outcomes for patients with macular degeneration has also been successfully launched

CHAPTER V. DISCUSSION

Value-based health care (VBHC) is a relatively new concept that provides a lens through which cost-effectiveness analysis CEA may give a more comprehensive assessment for more efficient health resource investment $^{1-4}$.

The present study applied the VBHC perspective by conducting an external evaluation, cost analysis, process analysis, management team structure, and technical decisions when performing an ophthalmic procedure of intravitreal VEGF- inh administration in patients with macular degeneration.

In the first part (Eye Clinic 1), the introduction of the methodology is related to the reduction of a significant part of the costs and the improvement of productivity through the optimization of processes through the application of TDABC - time-driven activity-based costing, valuation based on the performed activity and its duration.

The introduction of the methodology in the second phase (Eye Clinic 2) focuses on the introduction of a methodology dedicated to the measuring of accomplished outcomes (health and outcomes relating to the quality of life of patients), which is relevant to guaranteeing a competitive advantage. The TDABC approach was used again, and based on the evaluation, it was determined that the medical facility does not require process or cost optimization, and the system performs properly.

Improving the value of the healthcare service can only occur when providers align the focus of their clinical teams and their marketing strategy to achieve excellent results and in turn invest the resources to measure and report them ⁵.

The TDABC technique is centered on providing appropriate treatment to patients in order to fulfill their own objectives (personal value) and obtain the best possible results with the given resources (technical value).

The simplest definition of benefit in healthcare is:

Benefit = result/cost

Experts typically design quality measurements. The majority of these are technical in nature, with little or no patient engagement. However, from the patient's perspective, benefit is defined as the quality of the product received at the appropriate price.

The majority of quality indicators assess procedure, such as adherence to practice guidelines. These metrics do not track results. So-called "bundles of care" are a good illustration of how outcome assessment might be integrated. Bundles improve treatment by focusing on a limited number of evidence-based strategies that have been shown to improve patient outcomes. They are narrow enough in scope to allow all participants to specify their particular function, reducing fragmentation and optimizing efficiency while assuming relatively minor financial risks. This is the first step in providing value-based care. Bundling care can result in the establishment of clear, validated, and successful therapeutic processes to increase patient value. Medical conditions, rather than a particular sector of the health care system, are used to assess outcomes. Outcomes must be measured across the continuum of care, including inpatient and outpatient care. On Mistake! The reference source could not be located. A model of orthopedic treatment for joint replacement is presented.

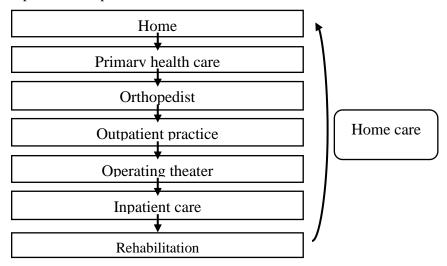


Figure 4. Spectrum of care for joint replacement

The care cycle depicted in Figure 6 begins with the patient's diagnosis, continues through the preparatory examination, operating theater, hospital care, and rehabilitation, and concludes when the patient could return to work. Important patient-defined outcomes include complications, discomfort, inpatient nutrition, the hospital staff's response to the patient's requirements, and the patient's return to normal daily activities. As part of an overall measure that decides whether hospitals receive the entire bundled payment or simply a portion, payment should also be based on patient-defined outcomes.

Bundles can be excellent instruments for enabling the health-care delivery system to improve performance and value metrics by requiring providers to achieve cost-efficient results. This strategy can also assist to save direct and administrative expenditures. Bundles of discrete episodes of care with longer durations, such as cancer or chronic pain therapy, can be investigated to discover outcomes that are beneficial to the patient and family ⁷.

Cost estimation is a key aspect of the quality question. Currently, almost all hospital spending is done by different wards and is driven by traditional contracts (eg clinical pathways or fee-for-service). It is not based on a whole cycle of therapy for a specific medical issue. Furthermore, activity- and time-based costing can assist health systems boost productivity by allowing clinicians to exercise their whole skill set as a team rather than individually. This will result in greater utilization of available capacity, more standardized processes, and the most costeffective treatment feasible.

In addition to bundled care, which is anticipated to give significant benefits in terms of improving both treatment and outcome accuracy, two more improvements should be addressed and perhaps adopted. First, clinical integration must occur at both the individual physician and the health care delivery system levels. Combining the two enables for gauge comparison and integration. Changes at the system level enable opportunity to remove service fragmentation and redundancy, resulting in better outcomes for patients. The second reform should focus on improving patient participation by providing chances for clinicians to inform patients about their health condition and appropriate patientcentered care plans. These initiatives will result in a collaborative relationship between patients and their healthcare providers. Patients may then take part in collaborative decision-making about acute and chronic diseases, as well as preventative care. This allows people to become more involved and assume responsibility of their health. Patients may and should collaborate with healthcare providers to identify desired objectives, resulting in improved benefit and individualized treatment.

The notion of successful aspects obtained by shifting from paying for service to payment for value transforms from an abstract high vision into a necessity. Paying for results would alter the market dynamic fundamentally.

Porter and Lee suggested a fundamentally new strategy in 2013⁸. The ultimate goal for patients is to achieve the greatest results at the lowest possible expense.

Transformation is not a one-step process, but rather a multifaceted plan. It demands changing the organization, measurement, and reimbursement of health care. The following table lists the essential components for implementing the value-based health care (VBHC) paradigm.

Key components for implementing the value-based healthcare (VBHC) concept	Organizing into IPUs (integrated treatment units) or re -designing and improving the health care delivery model in order to increase the benefit of treatment for patients during the entire treatment cycle
	Regular meetings between the teams of the cardiology clinic, between departments, as well as with external consultants
	Regular measurement of patient-relevant outcomes and clinical outcomes of the medical condition throughout the treatment cycle
	Regular measurement of outcomes that matter to patients: PROMs for continuous improvement

 Table 8. Key components for the implementation of the concept of value-based health care (VBHC)

	Regular measurement of costs at the patient level
	Change in the direction of digitization of processes and services in the cardiology clinic, construction and integration of an IT platform, electronicization of documents
	An integrated model for health care delivery in individual units
Others	Using the measured and collected outcomes (health and patient-related outcomes) to make clinical decisions and to improve the health care model for patients
	Periodic evaluation of organizational culture change in a cardiology clinic
	Involving patients in clinical and organizational decisions

Six components comprise the strategy blueprint for transitioning to a high-value health care delivery system. They are interconnected and additive, thus they should be introduced together.

It is unclear how long this change will take. Some healthcare practitioners in other countries would want to see such a change implemented ⁹. Inevitably, providers will be required to transition to value-based care since the fee-for-service model will become unsustainable.

CONCLUSION

The concept of value-based healthcare (VBHC) and the application of the methodology "TDABC - time-driven activity-based costing" is based on providing appropriate care to patients in order to achieve their personal goals (personal value) and achieve the best possible results with the resources available (technical value). The use of this methodology is a long-term strategy that aims to structure the measurement of clinical outcomes and outcomes related to patient quality of life in order to improve the activity, through regular data processing and analysis, as well as tracking the effect of a specific therapy on patients' quality of life.

The introduction of the methodology in the first part of the scientific work (Eye Clinic 1) is related to the release of capacity of the most valuable resource in health care - the human resource - which leads to improved productivity through process optimization and frees up practical capacity to be reallocated to higher value added activities.

The introduction of the methodology in the second part of the scientific work (Eye Clinic 2) focuses on the implementation of measurement of achieved results (health results and results related to patient quality of life), which is related to ensuring a competitive advantage and providing more - quality patient care.

TDABC overcomes gaps by offering evidence-based suggestions to enhance outcomes and the determinants of labor productivity through a multidisciplinary approach encompassing qualitative and quantitative methods.

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MAIN CONCLUSIONS, RECOMMENDATIONS, CONTRIBUTIONS

Main conclusions

- 1. The TDABC methodology is centered on providing appropriate treatment to patients in order to fulfill their own objectives (personal value) and obtain the best possible results with the given resources (technical value).
- 2. Implementing the TDABC methodology is a long-term strategy with the aim of defining an accurate measure of labor productivity in primary care and identifying its determinants, which include resource allocation, technological advancements, and individual patient characteristics.
- 3. The capacity of TDABC to clarify how costs are determined allows for simultaneous process and cost improvement. Process optimization is accomplished by the reduction of resource waste, non-value-added procedures, and waiting time. Some data gathering approaches, such as direct observations and interviews, enable a thorough knowledge of the costs of care delivery procedures.
- 4. TDABC provides cost information that has the potential to guide physician and administrator decisions concerning payment systems and outcomes-based incentives. TDABC's capacity to reliably collect care costs can help the VMHC program by harmonizing condition-specific costs and reimbursement models.
- 5. TDABC is an effective method for controlling the complicated expenses associated with healthcare settings.
- 6. The system provides for cost savings without sacrificing quality, since each specialist works within their area of competence.
- 7. The implementation of TDABC at Eye Clinic 1 freed up the capacity of the medical personnel, allowing them to conduct new tasks or increase their ability to complete the same activity. This results in the generating of additional revenue. The enhanced capacity provides a chance to allocate and reinvest resources in

higher-value activities. The freed up capacity and optimized time allows the eye clinic to focus on the involvement and development of medical workers.

8. TDABC was used in Eye Clinic 2 to determine which step to take and how to successfully implement and launch a process of data collection, processing, and analysis for quality of life of patients with macular degeneration, as well as data collection, processing, and analysis of health outcomes in the same group of patients.

Recommendations

- 1. The VMHC methodology can be successfully applied in Bulgarian eye clinics, as it leads to a change in the way health outcomes are measured and leads to transparency, finer traceability and optimization of treatment and the patient pathway.
- 2. TDABC to be implemented as a methodological approach in which the focus of the health system is patient-centered and organized around the needs of the patient, which in turn allows to improve health outcomes, optimize costs and processes, and free up capacity of human resource, which is also the highest paid resource in the health sector.
- 3. In connection with the practical application of the methodology focusing on a specific diagnosis of patients and active participation of senior management during the entire process.
- 4. The methodology to be applied by teams after specialized training and to be implemented in medical activities oriented around certain health conditions. It is important to keep in mind that the approach is strictly individual and tailored to the needs and characteristics of individual clinics. It is not recommended that a developed financial model and process map for the same medical condition in one clinic be transferred directly for the same medical condition in another.

Contributions

Contributions of a scientific and theoretical nature

1. For the first time in Bulgaria, an external evaluation, cost analysis, process analysis, management team structure and technical solutions in ophthalmology for patients with macular degeneration was

conducted by introducing the concept of benefit-based healthcare, and in particular - application of the TDABC methodology.

- 2. Data from the scientific literature on health technology assessments in the measurement of benefits in health care were analyzed.
- 3. Ways to measure cost and the role of health benefit measurement in health technology assessment for medical activities are analyzed.

Contributions of a scientific and applied nature

- 1. The benefits of introducing the TDABC methodology in ophthalmology for patients with macular degeneration in Bulgaria have been analyzed.
- 2. An algorithm (initiating macular degeneration questionnaire, process plan and financial model) has been created that is applicable at the local level and leads to significant optimization of processes and release of practical capacity.
- 3. A methodology for evaluating the quality of the activity (through regular measurements of key performance indicators) has been introduced, which can provide a competitive advantage and help to track the effect of the applied therapy.

PUBLICATIONS AND PARTICIPATION IN SCIENTIFIC FORUMS ON THE THEME OF THE DISSERTATION

Publications

- <u>Dacheva A</u>, The relationship between health technology assessment and the measurement of benefits in health care. Presentation of the Time-Driven Activity-Based Costing (TDABC) methodology, Bulgarian journal of public health, vol. 1/2022
- Dacheva A., Vutova Y., Mekov E., Encheva M., Guldemond N., Djambazov S., Implementation of the Value-Based Healthcare (VBHC) Concept with a Focus on Outcome Measurement, Journal of Health and Environmental Research, August, 2022
- <u>Dacheva A.</u>, Vutova Y., Mekov E., Djambazov S., Introduction of the methodology based on measurement of benefits in health care (VBHC) by application of TDABC in an ophthalmology clinic in Bulgaria, Bulgarian Journal of Public Health, vol. 3/2022
- 4. <u>Dacheva A</u>., Vutova Y., Djambazov S., Value-based healthcare (VBHC): Application of TDABC methodology in an ophthalmic clinic for patients with macular degeneration, ISPOR Europe 2022
- Encheva M., Vutova Y., <u>Dacheva A</u>., Djambazov S., Tzekova N., Measurinig the quality of life of patients with age-related macular degeneration, ISPOR Europe 2022
- Vutova Y, <u>Dacheva A</u>., Djambazov S, Measuring health-related and patient-related outcomes for patients with age-related macular degeneration (AMD) in an ophthalmic clinic, ICHOM Annual Conference Boston 1-3 November, 2022
- Dacheva A., Vutova Y., Encheva M., Tzekova N., Djambazov S., Implementation of ICHOM recommendations for measuring quality of life among patients with macular degeneration in a Bulgarian ophthalmology clinic using standardized questionnaires EQ-5D-5L/VAS and Impact of Visi-on Impairment, ICHOM Annual Conference Boston 1-3 November, 2022
- 8. **Dacheva A.,** Vutova Y., Djambazov S., Application of Time-drivenactivity-based costing (TDABC) methodology and process mapping for integration of outcome measurement in an ophthalmic clinic for patients with macular degeneration (MD), ICHOM Annual Conference Boston 1-3 November, 2022

Participation in international forums

- 1. Virtual ISPOR Europe 2020, November 16-19, 2020
- 2. ISPOR Europe 2019, 2-6 November 2019, Copenhagen, Denmark
- 3. ISPOR Europe 2018, 10-14 November 2018, Barcelona, Spain
- 4. ISPOR Europe 2017. 4-8 November 2017, Glasgow, Scotland
- 5. ISPOR 2022, May 15-18, Washington, DC USA
- 6. TDABC in Healthcare Consortium 1st International Conference, 27-28 May, Lisbon, Portugal, 2022
- 7. ISPOR 2022, November 6-9, Vienna, Austria

APPLICATIONS

Application 1. Internationally certified questionnaires and methodologies for assessing patients' quality of life

A. EQ-5D-5L



Health Status Questionnaire EQ-5D-5L

For each group of statements below, please indicate which statement most accurately describes your health today. Place a cross in the box opposite the statement you have chosen (there is only one possible answer)

Mobility

□ I don't have any difficulty walking

 \Box I have some difficulty walking

□ I have moderate difficulty walking

□ I have severe difficulty walking

 \Box I am unable to walk

Self-service

□ I don't have any difficulty when I wash myself

or dress;

 \Box I experience some difficulty when washing or dressing

- \Box I experience moderate difficulty when washing or dressing
- \Box I experience severe difficulty when washing or dressing
- \Box I am unable to wash or dress myself

• Daily activities (eg work, study, housework, family or leisure activities)

- □ I do not experience any difficulties in carrying out my daily activities
- □ I experience some difficulties in carrying out my daily activities
- □ I experience moderate difficulty in carrying out my daily activities
- □ I experience serious difficulties in carrying out my daily activities
- □ I am unable to carry out my daily activities

• Pain / discomfort

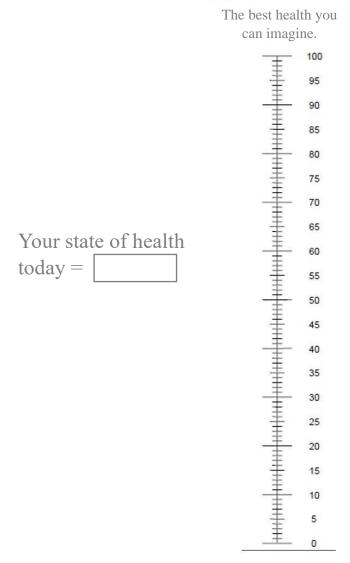
- \Box I do not feel any pain or discomfort
- □ I experience mild pain or discomfort
- □ I experience moderate pain or discomfort
- □ I experience severe pain or discomfort
- □ I experience extreme pain or discomfort

Anxiety/depression

- □ I am not anxious or depressed
- □ I am slightly anxious or depressed
- □ I am moderately anxious or depressed
- \Box I am very anxious or depressed
- □ I am extremely anxious or depressed

To help you determine how good or bad your health is today, we've introduced a thermometer-like scale. At the top, 100 is the best imaginable condition, and 0 is the worst.

Please mark on the scale how good or bad you think your health is today. To do this, please mark with an "X" the point on the scale that most accurately reflects your state of health today.



The worst health you can imagine.

B. Baseline Patient-Reported Form

Patient and institutional identifying information

Include on this and all forms appropriate patient identifying information in order to link data across time and care settings (e.g., name, sex, date of birth, and patient identification number).

What is your ethnicity?

	Asian	Mixed/multiple ethnic origins
	Black	Other
	Hispanic	Unknown/Undisclosed
	White	
Do	you smoke?	
С	Current smoker	
С	Former smoker	
С	Never smoked	
0	Unknown/Undisclosed	

The remaining questions are from the BImpact of Vision Impairment Questionnaire (IVI). (Questions correspond to variable IDs [IVI_Q01] through [IVI_Q28])

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In the PAST MONTH, how much has YOUR EYESIGHT INTERFERED with the following activities:

			A fair e amount		Don't do this for other reasons
Your ability to see and enjoy TV?	0	0	С	С	С
Taking part in recreational activities such as bowling, walking or golf?	C	0	С	0	С
Shopping? (finding what you want and paying for it)	0	0	С	С	С
Visiting friends or family?	0	0	С	0	0
Recognizing or meeting people?	0	0	С	С	С
Generally looking after your appearance? (face, hair, clothing etc.)	C	0	С	0	С
Opening packaging? (for example, around food, medicines)	0	0	0	C	С

Don't do

Not	А	A fair	А	this for
at all	llittle	amount	lot	other
				reasons

Reading labels or instructions on medicines?	0	0	С	С	0
Operating household appliances and the telephone?	0	С	С	С	0
How much has your eyesight interfered with getting about outdoors? (on the pavement or crossing the street)	С	С	С	C	С
In the past month, how often has your eyesight made you go carefully to avoid falling or tripping?	С	С	С	0	С
In general, how much has your eyesight interfered with travelling or using transport? (bus & train)	С	С	С	C	0
Going down steps, stairs, or curbs?	0	С	0	0	0

In the PAST MONTH, how much has YOUR EYESIGHT INTERFERED with the following activities:

In the PAST MONTH, how much has YOUR EYESIGHT INTERFERED with the following activities:

	Not a all	tA fair amount	A lot	Don't do this for other reasons
Reading ordinary size print? (for example newspapers)	0	C	С	С
Getting information that you need?	0	С	0	С

In the PAST MONTH, how often has YOUR EYESIGHT MADE YOU CONCERNED OR WORRIED about the following:

	Not at all	Occasionally	Frequently	A lot of the time
Your general safety at home?	С	С	C	C
Spilling or breaking things?	С	С	C	C
Your general safety when out of your home?	0	С	C	0

	Not at al	Occasionall	yFrequentl	A lot yof the time
How often has your eyesight stopped you doing the things you want to do?	С	С	С	С
How often have you needed help from other people because of your eyesight?	0	С	С	С
Have you felt embarrassed because of your eyesight?	0	С	С	С
Have you felt frustrated or annoyed because of your eyesight?	0	С	С	С
Have you felt lonely or isolated because of your eyesight?	С	С	С	С
Have you felt sad or low because of your eyesight?	0	С	0	С
How often have you worried about your eyesight getting worse?	С	С	С	C
How often has your eyesight made you concerned or worried about coping with everyday life?	С	С	С	С

	Not at all	Occasionally	Frequently	A lot yof the time
Have you felt like a nuisance or a burden because of your eyesight?	С	С	С	С
How much has your eyesight interfered with your life in general?	0	С	С	С

Macular Degeneration Baseline Clinical Assessment

Distance visual acuity in affected eye

[DVA; DVA_FLWEYE]

Affected eye Fellow eye Best corrected (best of Best uncorrected. corrected (best of corrected using uncorrected, corrected glasses or using glasses or contact contact lenses, lenses, or pinhole if or pinhole if required) required) Distance visual acuity Chart Type

[DVA_CHART]

LogMAR

С Snellen

Distance at which Distance visual acuity is measured

[DVA DIST]

Type of macular degeneration

[TYPEMDG]

Neovascular age related macular degeneration
 Myopic neovascular macular degeneration
 Other neovascular macular degeneration
 Polypoidal choroidal vasculopathy
 Dry/non-neovascular age related macular degeneration
 Baseline clinical status

	Not present	Subfoveal	Extra-foveal			
Geographic atrophy [GEOATR]	С	С	С			
Subretinal fibrosis [SUBFIB]	C	С	С			
Pigment epithelial detachment [PED]	С	С	С			
Pigment epithelial detachment type						

[PEDTYPE]

C Solid

C Fluid

Ocular comorbidities

[OCCOMORB]

	Retinal vascular disease		Amblyopia		
	Other macular pathology		Media opacity		
	Glaucoma or other optic neuropathy		Other		
Previous macular degeneration treatment in affected/study eye					
[PR	REVTREATMDG]				
	None		Retinal radiation therapy		
	Previous intravitreal anti- VEGF treatment		Transpupillary thermotherapy		
	Intravitreal steroid		Retinal surgical treatment		
	Photodynamic therapy		Other		
	Thermal laser photocoagulation		Unknown/Undisclosed		

Macular Degeneration Each Clinical Visit Clinical Assessment

Distance visual acuity in affected eye

[DVA; DVA_FLWEYE]

Affected eye

Fellow eye

Best corrected	
(best of	
uncorrected,	
corrected using	
glasses or	I
contact lenses,	
or pinhole if	
required)	

Distance visual acuity Chart Type

[DVA_CHART]

C LogMAR

C Snellen

Distance at which Distance visual acuity is measured

[DVA_DIST]

Endophthalmitis

[ENDOPH]

C _{No} Infectious endophthalmitis O Non-infectious endophthalmitis Presence of fluid, edema, or hemorrhage [FLUID] O Active С Inactive Name of treatments received [TREATRECEIV NAME] Thermal laser None photocoagulation Ranibizumab (Lucentis) Retinal radiation therapy Transpupillary \square Bevacizumab (Avastin) thermotherapy Pegaptanib (Macugen) \Box Retinal surgical treatment Aflibercept (VEGF-Other trap/Eylea) Intravitreal steroid Unknown/Undisclosed Photodynamic therapy

For the following 3 questions, check for change at each clinical visit

Type of macular degeneration

[TYPEMDG]

- ^C Neovascular age related macular degeneration
- ^C Myopic neovascular macular degeneration
- ^C Other neovascular macular degeneration
- C Polypoidal choroidal vasculopathy
- ^C Dry/non-neovascular age related macular degeneration

Clinical status

Not presentSubfovealExtra-foveal

Geographic atrophy [GEOATR]	С	С	С
Subretinal fibrosis [SUBFIB]	С	0	С
Pigment epithelial detachment [PED]	C	С	С

Pigment epithelial detachment type

[PEDTYPE]

C Solid

C Fluid

Other ocular treatments

Other ocular treatments

	No	Yes	Date (DD/MM/YYYY)
Cataract surgery [CATSURGTX; CATSURGTXDATE]	0	0	
YAG laser capsulotomy [YAGLASERTX; YAGLASERTXDATE]	0	0	
Retinal laser therapy [RETLASERTX; RETLASERTXDATE]	C	0	
Vitrectomy [VITRTX; VITRTXDATE]	С	0	
Corneal surgery [CORNSURGTX; CORNSURGTXDATE]	0	0	

Macular Degeneration Follow-Up Patient Assessment

In the PAST MONTH, how much has YOUR EYESIGHT INTERFERED with the following activities:

Please answer about YOUR eyesight with GLASSES, CONTACT LENSES, or MAGNIFIERS, if you use them.

	1.00		A fair amount		Don't do this for other reasons
Recognizing or meeting people?	0	0	0	С	С
Reading labels or instructions on medicines?	С	0	0	С	С
Operating household appliances and the telephone?	С	С	С	0	С
In the past month, how often has your eyesight made you go carefully to avoid falling or tripping?	С	С	С	C	С

In the PAST MONTH, how much has YOUR EYESIGHT INTERFERED with:

In the PAST MONTH, how much has YOUR EYESIGHT INTERFERED with:

		tA fair amount	A lot	Don't do this for other reasons
Reading ordinary size print? (for example newspapers)	C	0	0	C

In the PAST MONTH, how often has YOUR EYESIGHT MADE YOU CONCERNED OR WORRIED about the following:

	Not at all	Occasionally	Frequently	A lot of the time
Your general safety at home?	С	С	С	С
Spilling or breaking things?	С	С	C	С
Your general safety when out of your home?	С	С	C	C

	Not at all	Occasionall	yFrequentl	A lot yof the time
How often have you needed help from other people because of your eyesight?	С	С	С	0
Have you felt frustrated or annoyed because of your eyesight?	С	С	С	С
Have you felt lonely or isolated because of your eyesight?	C	С	С	С
How often have you worried about your eyesight getting worse?	С	С	C	C
How often has your eyesight made you concerned or worried about coping with everyday life?	C	с	С	С
Have you felt like a nuisance or a burden because of your eyesight?	С	С	С	С
How much has your eyesight interfered with your life in general?	С	С	С	C

1 Year Post-Initiation of Treatment

In the PAST MONTH, how much has YOUR EYESIGHT INTERFERED with the following activities:

Please answer about YOUR eyesight with GLASSES, CONTACT LENSES, or MAGNIFIERS, if you use them.

	1.00		A fair amount		
Recognizing or meeting people?	0	0	С	С	С
Reading labels or instructions on medicines?	0	0	0	С	С
Operating household appliances and the telephone?	С	С	С	0	С
In the past month, how often has your eyesight made you go carefully to avoid falling or tripping?	C	C	С	C	С

In the PAST MONTH, how much has YOUR EYESIGHT INTERFERED with:

In the PAST MONTH, how much has YOUR EYESIGHT INTERFERED with:

		tA fair amount	A lot	Don't do this for other reasons
Reading ordinary size print? (for example newspapers)	C	0	0	C

In the PAST MONTH, how often has YOUR EYESIGHT MADE YOU CONCERNED OR WORRIED about the following:

	Not at all	Occasionally	Frequently	A lot of the time
Your general safety at home?	С	С	C	С
Spilling or breaking things?	С	С	С	С
Your general safety when out of your home?	С	С	C	C

	Not at all	Occasionall	yFrequentl	A lot yof the time
How often have you needed help from other people because of your eyesight?	С	С	С	0
Have you felt frustrated or annoyed because of your eyesight?	С	С	С	С
Have you felt lonely or isolated because of your eyesight?	C	С	С	С
How often have you worried about your eyesight getting worse?	С	С	C	C
How often has your eyesight made you concerned or worried about coping with everyday life?	С	С	С	С
Have you felt like a nuisance or a burden because of your eyesight?	С	С	С	С
How much has your eyesight interfered with your life in general?	С	С	С	C