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Evaluation of the colorectal cancer screening pilot program and investigation of the disease burden of colorectal cancer

Doctoral (Ph.D.) thesis

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1. INTRODUCTION

Cancer is a leading public health problem worldwide. The International Agency for Research on Cancer (IARC) estimates that in 2018, colorectal cancer was the third most common cancer in Europe among men and the second most common in women. Hungary ranks first in Europe in both sexes in terms of colorectal cancer mortality. According to national data, this is the third most common cancer and the second most common cause of death in both genders. In the European Union, the mortality rate of colorectal cancer has been declining in case of men since 1993, in women since the 1970s, although the rate of decline varies in certain countries.

Identified risk factors for colorectal cancer include alcohol consumption, smoking, obesity, diabetes, sedentary lifestyle, and unhealthy eating habits (consumption of red meat and processed meat). Primary preventive action to modify lifestyle factors may reduce incidence and mortality in long term.

In Europe, health authorities of most countries decided in the early 2000s that more structured screening strategies were needed for colorectal cancer - either by publishing recommendations or organizing screening programs. Currently opportunistic and / or organized screening programs are available in all European countries.

Among the screening methods, the guaiac Faecal Occult Blood Test (gFOBT) based on the chemical detection of faecal haemoglobin and the human specific immunochemical Faecal Occult Blood Test (iFOBT) with more positive predictive values and higher efficiency or the Faecal Immunochemical Test (FIT) have been shown to reduce mortality. Screening is recommended between the ages of 50 and 70, in every two years. During the "two-step" screening program, a colonoscopy is performed after a non-negative gFOBT or iFOB test, while in the case of

a "one-step" program, a colonoscopy is performed first. A colonoscopy may be recommended at least once in a lifetime at age 50, repeated every 10 years at risk. In Hungary, the introduction of the two-step screening strategy is supported by professionals.

In Hungary, both the previous and the newer version of the Public Health Program treat organized screening, including organized screening of colorectal tumours, as a priority issue. In Hungary, a number of projects dealing with colorectal cancer screening could be found since the 1990s, but these programs have remained at the local level, national extension has not been implemented so far.

The basic objective of the pilot screening programs is to explore the possibilities of mobilizing the population and involving GPs, to ensure the transparency of the screening process, and to provide information on the implementation and effectiveness of the screening.

Participation rates are crucial to the success of screening programs. According to the directive, a minimum of 45% of attendance would be recommended, and the desired value would be above 65%. Significant progress has been made in the treatment of colorectal cancer in recent decades, and as a result of in-time treatment, 5-year survival of the colorectal tumour is 90% in case of localized tumours.

Treatment costs are constantly rising, in which, population growth and life expectancy also play a role in addition to more costly treatment procedures. In respect with the significant burden of the disease, the implementation and continuous development of CRC screening programs should continue to be a priority in the health policies of European countries.

2. OBJECTIVES

The aim of my dissertation is to review the morbidity and mortality indicators due to colorectal cancer both in international and national context, to present the international and domestic practice of colorectal screening, to analyse the quality indicators and attitudes of a colorectal cancer screening pilot program at Csongrád county and to present the degree of the disease burden resulted from colorectal cancer disease.

The main objectives of the research can be summarized as follows:

- 1. To evaluate the incidence, mortality and prevalence of colorectal cancer in an international and domestic context;
- 2. To review international screening practices and their results;
- 3. To determine the quality indicators and performance indicators of a pilot screening program based on the data of the public health colorectal cancer screening of the National Office of Chief Medical Officer (OTH) Oncology Screening System (OSZR) Communication module implemented within the framework of the tender entitled TÁMOP-6.1.3.A-13 / 1-2013-0001, "Support the extension of pilot screening programs (women's cervical screening and colorectal cancer screening programs)" in the light of the available benchmarks and the results of the international screening practice;
- To evaluate the attitudes of patients participated in the colorectal screening pilot program regarding screening and their opinions about the program;
- To determine the annual burden of disease treatment for colorectal cancer in 2018, based on the funding database of the National Health Insurance Fund (NEAK).

3. DETAILED ANALYSES

3.1 INCIDENCE, MORTALITY AND PREVALENCE OF COLORECTAL CANCER

Introduction: The examination of the territorial distribution of morbidity and mortality data provides important information for the planning and organisation of prevention and care.

Objectives: The aim of this current study is to demonstrate the incidence, mortality and prevalence of colorectal cancer worldwide, in Europe and at the national, county and district level in Hungary.

Methods: International data are presented from the Global Cancer Observatory (2018) database, the National Statistical Office (2018), the National Cancer Register (2016) and the Public Health Analysis Centre Information System (2014-2019), using the standardized incidence and mortality rates for the 0-X-year population by gender.

Results: In Europe, colorectal cancer is the third most common cancers in men (23,6 cases per 100,000 people) and the second in women (16,3 cases per 100,000). Hungary ranks first in Europe based on mortality indicators (men 31,2/100.00 people, women: 14,8/100.000 people). In Hungary, in 2016, colorectal (7,065 people), rectal (3,715 people) and anus (29 people) tumours accounted for 15.3% of the total incidence, as the second most common disease after lung cancer. According to national data, it is the third most common cancer and the second most common cause of death in both genders. At the county level, the incidence is highest for both genders in Vas and Zala counties, the lowest in Baranya County. In Vas County, high incidence is associated with high mortality rates, and low incidence with high mortality rates can be found in Baranya County. In general, a difference of around 10% is observed compared to national

values. The incidence is higher than the national average in men at Pápa and Kapuvár districts, and in women at Lenti district.

The mortality rate of men in Tamási district is 55% higher while in Tatabánya district the mortality rate of women is 40% higher than the national average.

Conclusions: Women's morbidity rates in all areas remain below those of men and do not show any variability across regions. The mortality rate of men in Tamási and women in Tatabánya district is higher than the national value. Even in relation to European data, high morbidity and mortality indicators clearly point to the tasks of reducing the mortality of colorectal cancer.

3.2 PRACTICE OF COLORECTAL CANCER SCREENING IN EUROPE

Introduction: Colorectal cancer is a serious public health problem in developed countries. The presence or absence of screening programs plays a significant role in assessing the burden of colorectal cancer, as screening can increase incidence through detection of tumours in the short term and reduce incidence in the long term through removal of cancer-preventing polyps. Effective treatment can be provided in the early stages of the disease.

Objectives: Our aim is to review the main features, indicators, and outcome indicators of international colorectal cancer screening practice.

Data and methods: Data sources were the announcements of the screening programs available in Medline, Pubmed databases, as well as the online interfaces of the Ministries of Health and other Health Authorities of certain countries. During the review, we focused on the following variables: form of the organization, start of the screening program, duration, affected age group, screening interval, screening method, method of organization, participation rate, colonoscopy screening.

Results: Countries show great variation in terms of colorectal screening methods, screening methods, extent of extension and age groups. The programs started typically in the second half of the 2000s and national action plans were adopted that laid the foundations for the implementation of future organized screening. Organised screening operates in 10 countries in Europe: Sweden, Finland, Denmark, UK, Ireland, Czech Republic, Croatia, Slovenia, Malta, Italy. Opportunistic screening is available in 12 countries: Latvia, Belgium, Germany, Austria, Luxembourg, Switzerland, Poland, Romania, Bulgaria, Greece, Serbia and Hungary. The most used screening method is the two-step screening with iFOBT or gFOB test, in case of non-negative cases it is followed by colonoscopy. IFOBT test is used in 8 countries. Poland is the only country in Europe where the first-line screening method is colonoscopy. The screening interval for the FOB test is usually 2 years, except in Bulgaria and Germany, where screening is recommended annually. In most countries at the age of 50 it is recommended to start screening and the upper limit in most cases is 74 years. All these are in line with the recommendations and evidence. The problem is that the participation rate lags the desired level even in countries where organized screening is available for several years.

Conclusion: Low participation rates are considered as a common problem. In order to solve the problem, in addition to media campaigns, several countries supported the establishment of online and telephone information centres, as well as suggested the examination of the reasons for absence and the exploration of the characteristics of the given country.

3.3. QUALITY AND PERFORMANCE INDICATORS OF COLORECTAL CANCER SCREENING PILOT PROGRAM IN CSONGRÁD COUNTY, HUNGARY

Introduction: The high incidence and mortality of colorectal cancer urges the introduction of a screening program in Hungary.

Objectives: Our analysis aimed to present and evaluate the quality and performance indicators of the colorectal cancer screening pilot programme

Data and methods: The colorectal cancer screening pilot programme was carried out in 2015 involving an average-risk population aged 50-69 in Csongrád county, Hungary. Altogether 117 practices joined the program. The processed data come from the National Screening System Communication module of the Office of the Chief Medical Officer. We evaluated the recruitment, attendance, and participation rates, as well as the results of laboratory, colonoscopy and histological examination in the light of international recommendations.

Results: 21.1% invitation rate (22130 persons), 51.2% attendance and 47.3% participation rates were recorded with a higher female participation rate (p<0.001). The average participation rate in practices was 45.3%, and in 32 practices it was over 50%. Participation rate was far lower than the expected 65%. The rate of non-negative results (13.1%) exceeds the international reference rate. The participation rate on the colonoscopy screening reached the expected value (90.1%). Compared to the number of actual colonoscopies performed, adenomas were found in 2.5% and malignant lesions in 0.3% of the cases. (Table 1.)

Conclusion: Our results have highlighted the deficiencies regarding the follow up and data recording of the screening results in the IT system as well as the lack of communication between the GP and the diagnostic laboratories.

Table 1. Screening tree of colorectal cancer screening pilot program in Csongrád county (2015)

Indicator	Male	Female	TOTAL
Target population determined by NHIF (round one/round two)	24.240 /	29.158 /	53.398 /
(person)	23.162	28.114	51.276
Number of invitations sent (piece)	8.597	13.533	22.130
Delivered invitations (piece)	8.510	13.440	21.950
Screening packages issued by a family doctor (piece)	3.791	7.456	11.247
Participation rate (%) - compared to the number of issued screening	44,5	55,5	51,2
packages /delivered invitations			
Screening packages received at chemical laboratory (piece)	3.368	7.006	10.374
Participation rate (%) – compared to the number of packages received at chemical lab /delivered invitations	39,6	52,1	47,3
Total findings (total implemented screenings) (piece)	3.368	7.005	10.373
Negative findings (piece)	2.751	6.266	9.017
Rate of negative findings compared to total (%)	81,7	89,5	86,9
Non-negative findings (piece)	617	739	1.356
Rate of non-negative findings - compared to total (%)	18,3	10,5	13,1
RESULTS OF COLONOSC	OPY		
Number of referrals to colonoscopy (person)	399	528	927
Rate of referred to colonoscopy compared to the number of screening packages received in chemical laboratory (%)	11,8	7,5	8,9
Acceptance of referral to colonoscopy (person)	353	482	835
Rate of accepted referrals compared to the total number of referrals (%)	88,5	91,3	90,0
Total results of colonoscopy (person)	158	318	476
Rate of participation in colonoscopy compared to the number of accepted referrals (%)	44,8%	66,0%	57,0%
Result of colonoscopy "adenoma" (person)	95	162	257
Result of colonoscopy "adenoma" incidence compared to the total number of referrals (%)	23,8%	30,7%	27,7%
Result of colonoscopy "adenoma" incidence compared to the total number of screenings (%)	2,8%	2,3%	2,5%
Result of colonoscopy "malignant" (person)	11	15	26
Result of colonoscopy "malignant" incidence compared to the total number of referrals (%)	2,8%	2,8%	2,8%
Result of colonoscopy "malignant" incidence compared to the total number of screenings (%)	0,3%	0,2%	0,3%
RESULTS OF HISTOLO	GY		
Result of histology total (person)	94	179	299
Result of histology "non-malignant" (person)	82	163	245
Result of histology "non-malignant" incidence of cases compared to performed screening tests (%)	2,4%	2,3%	2,4%
Result of histology " malignant " (person)	12	14	26
Result of histology " malignant ,, incidence of cases compared to performed screening tests (%)	0,4%	0,2%	0,3%
Result of histology " malignant in situ" (person)	6	4	10
Result of histology " malignant stage I." (person)	6	10	16
Result of histology " malignant stage II." (person)	0	0	0
Result of histology " malignant stage III." (person)	0	0	0
Result of histology " malignant stage IV." (person)	0	0	0

3.4. ATTITUDE OF PARTICIPANTS OF COLORECTAL SCREENING PILOT PROGRAM

Introduction: In 2015, in Csongrád County (Hungary), a general practitioner based colorectal screening model program was implemented by the financial support of the European Union.

Objectives: Our aim was to evaluate the screening program and to analyse the experiences and attitude of participants of colorectal screening pilot program.

Data and methods: Out of the questionnaires completed by the participants, 3,410 were included in the database during the first screening round, and 2,682 in the second round, of which, after cleaning due to data gaps, the responses of a total of 5,580 (1,524 men and 4,056 women) were analysed. (Table 2.) The self-edited questionnaire included the following sets of questions: sociodemographic data, questions about the current screening program and its implementation, problems with stool sampling, expectations regarding the appearance and content of the invitation letter, information sources about screening, acceptance of screening test, willingness to participate and attitude towards screening. In addition to descriptive analysis non-parametric tests (Mann-Whitney and Kruskal-Wallis test), and logistic regression analyses were applied (p<0.05).

Results: 46.7% of the respondents had not heard about colorectal screening prior to the screening program. Participants with elementary education level mostly indicated physicians as primary information sources [OR: 2,72 (CI: 1,59-4,66)] than patients with higher education. 67.5% of patients decided alone about participation on screening. Among women, decisions supported by acquaintances were specific [OR: 2,05 (1,06-3,95]. 82.6% determined FOBT test as a fully accepted screening method. Medical advice is an important predictor of screening participation. 91.5% would be involved in the screening if they were to receive an invitation after two years.

Respondents were generally satisfied with the screening program. The provision of information as well as the recommendation of a GP, may increase the participation rate in future screening particularly in case of men, those with lower level education and those living in larger cities.

Table 2. Sociodemographic characteristics of the sample and gender distribution (n=5580)

Attribute	Male n (%)	Female n (%)	Total
Age groups			
50-54 years	270 (17,7)	877 (21,6)	1.147 (20,6)
55-59 years	374 (24,5)	1.145 (28,2)	1.519 (27,2)
60-64 years	475 (31,2)	1.100 (27,1)	1.575 (28,2)
65-69 years	369 (24,2)	863 (21,3)	1.232 (22,1)
>70 years	36 (2,4)	71 (1,8)	107 (1,9)
total	1.524 (100)	4.056 (100)	5.580 (100)
Education			
elementary or lower	200 (13,1)	822 (20,3)	1022 (18,3)
vocational school	598 (39,2)	1.068 (26,3)	1.666 (29,9)
high school degree	323 (21,2)	1.165 (28,7)	1.488 (26,7)
technical school	122 (8)	265 (6,5)	387 (6,9)
college/university	281 (18,4)	736 (18,1)	1.017 (18,2)
total	1.524 (100)	4.056 (100)	5.580 (100)
Marital status			
living alone	207 (13,6)	860 (21,2)	1.067 (19,1)
partner/spouse	424 (27.8)	1.033 (25,5)	1.457 (26,1)
partner/spouse and children	811 (53,2)	1726 (42,6)	2.537 (45,5)
other relative	82 (5,4)	437 (10,8)	519 (9,3)
total	1.524 (100)	4.056 (100)	5.580 (100)
Residence			
county seat	349 (22,9)	754 (18,6)	1.103 (19,8)
city	497 (32,6)	1.597 (39,4)	2.094 (37,5)
village	687 (44.5)	1.705 (42)	2.383 (42.7)
total	1.524 (100)	4.056 (100)	5.580(100)

Conclusion: Increasing the participation in screening is a key to achieve the desired impact of screening resources, in which GPs, community nurses and local health promoters have a significant role to play in supporting the preventive behaviour and positive attitudes of the population towards screening. To raise awareness, the main target groups of health promotion programs and awareness-raising campaigns are men, the lower educated, those living in larger cities, and those who miss out regular medical visits.

3.5 EXAMINATION OF EPIDEMIOLOGICAL HEALTH INSURANCE DISEASE BURDEN OF COLORECTAL CANCER IN HUNGARY, 2018

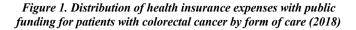
Introduction: Colorectal cancer is the third most common type of cancer and the second most common cause of mortality in Hungary in both genders, thus, their treatment imposes significant costs on health care.

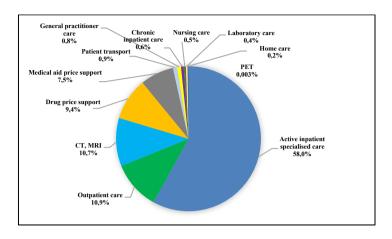
Objectives: Our aim was to determine the annual epidemiological disease burden and health insurance cost of colorectal cancer in Hungary.

Data and methods: Data were derived from the financial database of the Hungarian National Health Insurance Fund (NHIF), for the year 2018.

Types of cancer were identified with the following codes of the International Classification of Diseases 10threvision: C18, C19, C20, C21, D010-D014, D12. Data analysed included annual patient numbers according to age groups and sex, prevalence of care utilisation per 100,000 population, and annual health insurance costs for all types of care and all cancer types.

Results: In 2018, the NHIF spent 21.7 billion Hungarian Forints (HUF) (80.2 million American Dollars (USD), 68.0 million Euros (EUR) on the treatment of colorectal cancer. 58.0% of costs was spent on acute inpatient care. Regarding total costs, the highest costs were found in the 65-74 agegroup in both men (4.98 billion HUF) and women (3.25 billion HUF). The highest patient numbers were in outpatient care: 88,134 patients, general practice care (55,324 patients) and CT, MRI scans (28,426 patients). Annual health care treatment cost per patient was 1.206 million HUF (4,463 USD/3,782 EUR) in men, 1,260 million HUF (4,661 USD/3,950 EUR) in women. Active inpatient specialised care proved to be the main cost factor. The incidence of colorectal tumours is 15-20% higher in men.





Conclusion: The economic costs associated with the treatment of colorectal cancer can usually vary depending on many factors, such as the stage of the disease at the time of diagnosis, the age of the patient, the time of observation in the individual analysis, and the types of medical services. Since the 2000s, days of care spent in inpatient care by cancer patients have shown a declining trend as part of the process of enabling outpatient care and home treatment with new therapies, oral dosage forms. The cost of colorectal cancer has nearly doubled in the last 10 years. Higher inpatient care costs are associated with men, although previous research has indicated higher costs associated with women, particularly for home and hospice care.

4. DISCUSSION

Based on the incidence of colorectal cancer, Hungary is in a leader position in the Central and Eastern European region and within Europe. Based on national data, it is the third most common cancer type and the second most common cause of death in both sexes. At county level, the

incidence is highest for both sexes in Vas and Zala counties, and the lowest in Baranya county. In Vas county, high incidence is associated with high mortality, while in Baranya county, low incidence is associated with a significantly higher mortality rate than the national level for both sexes. High morbidity and mortality have become a public health task urging the introduction of colorectal cancer screening programs. Several pilot programs took place in Hungary between 1997 and 2015. In 2008, a professional consensus was reached to adopt a two-step screening program, within which iFOBT became the primary screening method, followed by a colonoscopy in case of a non-negative result. Following the evaluation of pilot programs, Hungarian health policy leaders committed themselves to the introduction of a national colorectal screening program, however, significant progress had not been made outside the pilot programs by 2018.

The overall aim of the pilot program implemented in Csongrád County in 2015, which affects the largest target population compared to the previous programs, was to explore the possibilities of mobilizing the population, involving GPs, and the traceability of screenings in the electronic central screening system in order to reach transparency for the screening process and status. The evaluation of the program also highlighted problems that will definitely need to be addressed in order to implement nationwide extension, such as motivation to participate, recording results in the system, tracking patient pathways or motivating GPs.

Following the pilot program, steps were taken to extend the screening program nationwide. The program will be implemented within the framework of the National Centre for Public Health through the priority project EFOP-1.8.1-VEKOP-15-2016-00001 "Complex public health screenings". The project aims to improve the health awareness of the population, including the willingness to participate in screening, and to extend the organized two-stage colorectal screening of the population

nationwide to the entire 50-70 age group. The program was suspended in 2020 due to the COVID-19 epidemic.

In case of a non-negative result, the second stage of filtration is followed by colonoscopy. In the pilot program, 90% of those referred participated at colonoscopy. The increase in capacity resulting from the nationwide extension of screening necessitated a review of colonoscopy laboratories and the creation of conditions for performing qualitative colonoscopy. Currently, 51 of the 112 colonoscopy laboratories joined the program. During the pilot program, an average of 52 days elapsed between the laboratory result and the completion of the examination, based on a survey of patients undergoing colonoscopy. In order to organize care and to avoid possible overload, special attention should be paid to the participation of those with non-negative results as soon as possible.

In 2019, a number of regulations related to screening were amended, including the issues of funding, minimum conditions, and outpatient specialized care, which were introduced in the document related to targeted colorectal screening for public health purposes within certain ministerial amendments of Decree 10/2019. (VI. 19.) EMMI. The maintenance and operation of screening systems is only effective if the participation rate is appropriate. GPs have a significant role in increasing compliance. To this end, a compliance-proportionate premium system has been developed to motivate GPs.

In addition to the role of GPs, community nurses and assistants, Health Development Office workers can provide significant support to the population in order to motivate participation in screening and sending the sample to the laboratory. There are currently Health Development Offices operating in 114 districts.

In 2018, the National Health Insurance Fund spent 21.7 billion HUF on the treatment of colorectal cancer. Costs are rising year by year due to the modern therapeutic interventions applied. Between 2010 and 2017, costeffectiveness analyses (including data from 17 European countries) of annual gFOBT or iFOBT, biennial colonoscopy, and five-year flexible sigmoidoscopy proved cost-effective against non-screening.

In addition, 10-year colonoscopy is less expensive and / or more effective than other strategies in the United States. Screening can also reduce costs in the short term, partly by reducing the risk of treating a cancer-preventing condition (removing polyps) and by significantly cheaper treatment options for early-stage cases. Gradually extending screening to the entire 50-70 age group, for which we can see European examples, could help to reduce the resources associated with screening.

Another important question is whether GPs and assistants have the capacity to actively participate in the extended program. The high age of GPs, general overload, the increase in administrative burdens, and the growing number of unfilled practices are not negligible for the successful implementation of the screening program. Health Promotion Offices can help to bridge the problem; however, health promotion offices are unavailable in certain areas of the country and on the other hand, the future of the offices is currently questionable. These facts may fundamentally affect a subsequent nationwide extension.

5. NOVEL RESULTS

Our new results presented in the dissertation are summarized as follows:

Novel results:

- We presented the regional inequalities in morbidity and mortality of colorectal cancer, such a detailed analysis of the public health weight of colorectal cancer in Hungary has not been designed yet.
- We determined the quality and performance indicators of the colorectal cancer screening pilot program based on the tests received by 10,374 laboratories.
- 3. Based on the responses of 5,580 participants in the screening program, we surveyed the attitude of patients towards screening, their opinions about the program, sampling, information received, and invitation letter.
- 4. Based on the financing database of the National Health Insurance Fund, we determined the incidence of colorectal tumours calculated on the basis of the national utilization indicators of the health care system, as well as the annual public health insurance expenditures for the treatment of these patients.

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7. PUBLICATION LIST

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Impact factor of the publications used for the dissertation: 6,770.

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