EUROCHIP-II FINAL SCIENTIFIC REPORT ANNEX 15b

REPORT OF EUROCHIP-2 ACTION IN SLOVAKIA

Colorectal carcinoma screening program in Slovakia 2002-2007
A short information

October 2007

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Introduction

Digestive cancers account for the highest incidence and mortality of cancers worldwide. Colorectal cancer (CRC) is the fourth most common cause of cancer in the world in both sexes toghether and the second in the developed countries of Northern America and Europe. In Czech and Slovak republic is CRC the leading cancer in incidence together in both sexes (tab1,2).

Mortality rates from CRC in Slovakia and Czech republic,- despite better prognosis of this cancer site in comparison with in the past decades dominating stomach and lung cancers -is on the second place just behind the lung cancer mortality. (tab.1,2) CRC incidence and mortality represents the most serious health problems of Slovakia. Every year 1700 people die in Slovakia from colorectal cancer.

Controlling colorectal cancer is an immediate challenge, but it should be approached in a positive way, since death from colorectal cancer is frequently preventable.

Representatives of national health policy in Slovakia decided to concern with the secondary prevention of CRC.

The first condition of secondary CRC prevention success in the whole population is the national screening program aimed to persons aged over 50 years.

Slovakia has perfect dispositions for running the screening program successfully. The small size of country, adequate number of inhabitants, a dense net of GPs and gastroenterology ambulances (out-patiernt clinics), very easy communication possibilities and nearly 100% health insurance of population are ideal conditions for the success of the screening program. All those attributes and many others enabled in the year 2002 to launch the national

screening program of colorectal carcinoma in Slovakia .based on biennial fecal occult blood test (FOBT) and subsequent colonoscopy of FOBT positive persons.

The main supervisors of the program were Ministry of Health and Slovak Gastroenterologic Association. A working group was created in the cooperation of these two subjects, which established collaboration of gastroenterologists with GPs and insurance companies.

Tab. 1 Colorectal carcinoma

The age-standardized incidence[ASR(W)] new cancers and deaths per 100 000 persons in year 2000. GLOBOCAN 2000: Cancer Incidence, Mortality and Prevalence Worldwide, Version 1.0. IARC CancerBase No.5. Lyon, IARCPress, 2001.

Population	Gender	No of cases	Incidence	No of deaths	Mortality
World wide	M	498 754	19.11	254 816	9.78
global	W	445 963	14.44	237 595	7.58
Developing	M	180 059	9.91	102 640	5.75
countries	W	154 064	7.88	88 121	4.53
Developed	M	318 694	37.30	152 178	17.38
countries	W	291 877	25.37	148 170	12.27
East	M	60 325	32.88	33 570	18.12
Europe	W	60 148	21.50	36 727	18.39
Slovak	M	1578	50.58	885	28.04
Republic	W	1156	26.55	786	16.10
Czech	M	4325	60.29	2477	34.19
Republic	W	3130	31.53	1955	18.55

TAB 2Incidence comparison of the six most frequent carcinomas in different populations

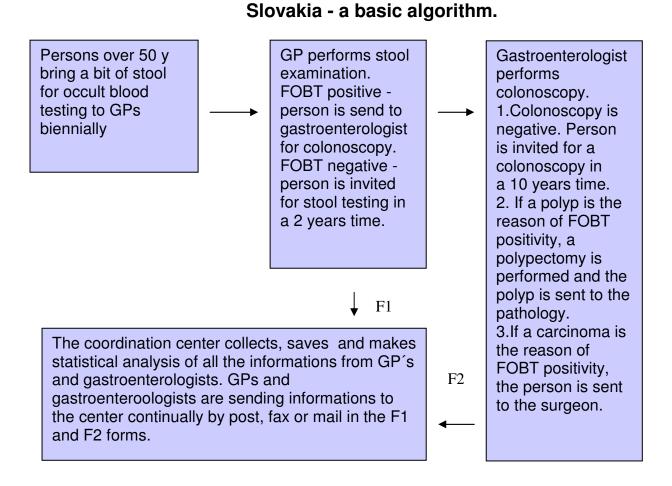
The age-standardized incidence [ASR (W)] of new cancers and deaths per 100 000 pers in a year 2000.Modified by GLOBOCAN 2000: Cancer Incidence, Mortality and Prevalence Worldwide, Version 1.0. IARC Cancer Base, No.5. Lyon, IARCPress, 2001.

Site	Gender	World wide global		Develor countri	U	Develor countri		Slovak Republ	ic	Czech Republic		
	Gen	Incid.	Mort.	Incid.	Mort.	Incid.	Mort.	Incid.	Mort.	Incid.	Mort.	
Lung	M	34 . 92	31 . 43	24 . 79	22 . 02	55 . 62	50 .50	68 . 49	60 . 66	68 . 92	65 . 28	
	W	11.05	9. 53	8. 44	7 . 40	15 . 62	13 .14	8 . 99	7 . 75	12 . 73	11. 55	
Colon and rectum	M	19 . 11	9. 78	9. 91	5 . 75	37 . 30	17.38	50 . 58	28 . 04	60 . 29	34 . 19	
	W	14 . 44	7 . 58	7. 88	4 . 53	25 . 87	12 .27	26 . 55	16 . 10	31 . 53	18. 55	
Stomach	M	21 . 46	15 . 62	19 . 87	15 . 32	24 . 63	16 .16	20 . 34	16 . 87	15 . 81	13 . 47	
	W	10 . 38	7. 81	9 . 97	7. 20	10 . 96	7 .73	8. 89	7.31	8 . 68	7. 52	
Prostate	M	21 . 23	7. 95	7 . 71	4 . 61	46 . 65	13 .70	28 . 65	14 . 30	36 . 30	15 . 74	
Cervix	W	16 . 12	7. 99	12 . 73	9 . 79	11. 35	4 .08	16 . 59	5. 40	15 . 09	6. 25	
Breast	W	35 . 66	18. 51	23 . 07	9 . 12	63 . 12	18 .61	45 .61	18 . 40	34. 08	21 . 00	

Aims of the program (Figure 1)

- 1. Examination of the whole population aged over 50 years should enable to detect and treat the most early forms of CRC. By this way it is possible to reduce CRC mortality in a whole population.
- 2. We have to convince every person over 50 years of age to give a bit of their own stool for occult blood test examination in GP's ambulance in two years time interval.
- 3. To fulfil two aims mentioned above, we were obliged to create a good working recurrent process among patients GPs gastroenterologists and the coordination centre. This process may enable to every person aged over 50 years to visit his own GP, which is competent to perform FOBT examination and to send FOBT positive persons to gastroenterologist for performance of colonoscopy. GPs and gastroenterologists then fill form F1 resp. F2 and send them to the coordination centre for collecting and statistical analysis of all data. It helps to built up a feedback mechanism, which is a base for any dependable working recurrent process.
- 4. The program schedule should cower 5 years in this first period. We hoped, that during this time period, we will be able to implement all principles mentioned above not only to general practitioners but also to general public. Thereso, there should be no doubt of using FOBT examination for the population aged over 50 also in following years.

The National Biennial Colorectal Cancer FOBT Screening Program in



Physical and logistic conditions of screening program

The basic epidemiological and demographic data

Figure 2. Czech republic and Slovakia belong to the leading group of countries with the highest CRC incidence in the world. The persistence on this road leads to an abyss.

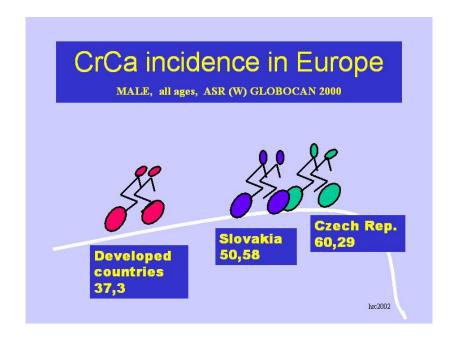


Figure. 3 Slovakia has 5,4 mil. inhabitants. More than 1,2 millions are older than 50 years. We expected that the compliance with the screening program will be not higher than 30% of population over 50 years. It represents 400 000 persons biennially.



Figure. 4

In Slovakia exists a very sufficient network of 2160 ambulances (out-patient clinics) of general practitioners. At the very beginning of the screening we had 72 gastroenterologic units able to perform high quality colonoscopy and colonoscopic polypectomy. In the year 2005 we had 84 colonoscopy units. Distribution of colonoscopy units through Slovakia is suitable from the availability point of view.

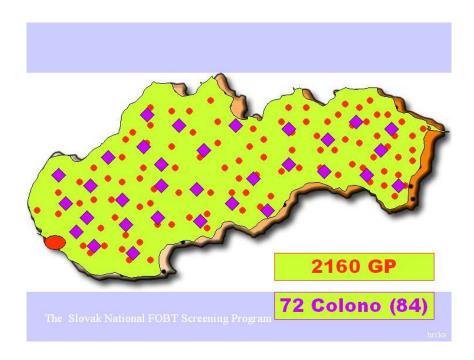


Figure 5 Theoretically, we could reach results presented on this picture if all prerequisites of the screening program would be fulfilled.

How many CrCa and polyps							
	can we detect ?						
1.	Expected screening participation (30%)	393 898					
2.	Expected FOBT positivity (3%)	11 818					
3.	Expected participation on colonoscopy (80%)	9453					
4.	Nº of participating colonoscopic centers	72					
5.	Nº of FOBT posit. patients / colono-center/year	135					
6.	Expected CrCa (8,5%)	808					
7.	Expected polyps (28%)	2612					
8.	Expected adenomas (22%)	2050					
		hrc20					

Activities before launching of the screening program.

Figure 6
The first step to launch the screening program was the release of a financial budget from the Slovak Ministry of Health in January 2002.



Figure 7. During a 3 months period, we prepared the project in a written form.

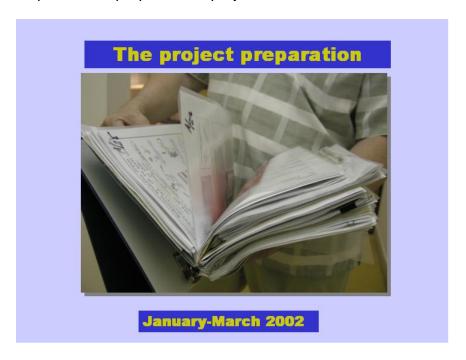


Figure 8.

In April 2002 we organized a workshop with gastroenterologists. We discussed the tasks and problems, connected with realisation of the CRC screening. All gastroenterologists received the F2 form, which is necessary not only to fulfill after the colonoscopy of FOBT positive patients, but also to send them to center for statistical analysis. 90% of all the gastroenterologists promised to attend the screening program in the presented shape.

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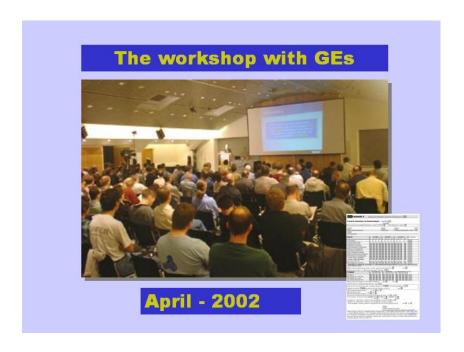


Figure 9.

In May 2002 we published the project in the local Journal of Internal Medicine and the free copy of journal; was sent to all GPs and gastroenterologists. They all had the possibility to become familiar with the project in details and by this way to prepare conditions for a detailed discussions during workshops planned in the 8 counties of Slovakia.(Territory of Slovakia is divided into 8 main administrative units - counties and into 79 smaller units-districts).

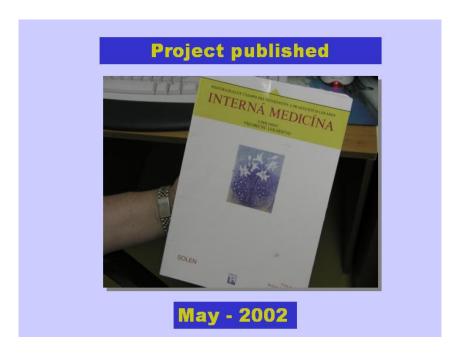


Figure 10.

During May and June of 2002, we met on workshops in 8 main slovak regions with the GPs. We presented our vision and tasks of the screening program. All meetings were very productive, because we had the opportunity to discuss with physicians experiencing everyday practical problems in their own regions. Only a 30% attendance of GPs on workshops was a little shadow on the whole project.



Figure 11.

During July of 2002, we organized a international competition for colonoscopic equipment. The winner was the OLYMPUS company and so, we purchased 42 colonoscopes and other necessary accessories.



Figure 12.

During August 2002, we prepared a international competition for the Haemoccult test. The winner was the OLYMPUS company and so, we purchased 300 000 tests in this first phase.

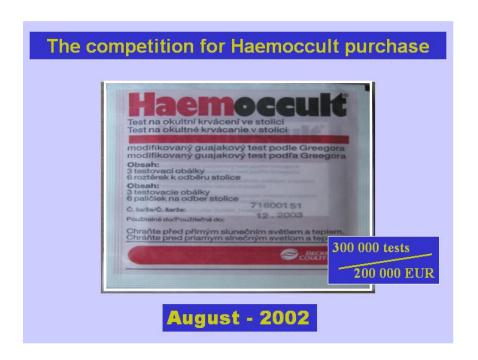


Figure 13. During August and September of 2002, we organized 2 live TV discussions, which had a very positive response from the general public.



Figure 14. In the Slovak radio broadcasting, we prepared 3 live discussions also with very positive response from the general public.



Figure 15.
From April to October of 2002, we prepared a lot of posters, leaflets and educational materials for the general public on the CRC issue. To every GP's ambulance, there was a big poster sent, in which we tried to explain all the problems and obstacles connected with the screening of CRC in a general public in a easy form.



Figure 16.

During September 2002, Haemoccult tests were distributed for free to all GP's ambulances together with F1 forms and a database of all gastroenterologists attending on the screening program in a electronic form. This very pretentious logistic problem we successfully solved with the help of the Olympus company.

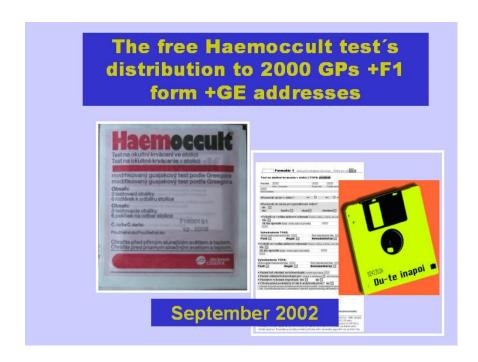
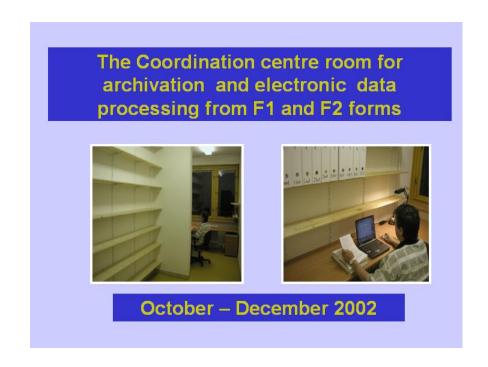


Figure 17.
From January to October of 2003, we created a original computer software for processing, and statistical analysing of F1 and F2 forms sent by GPs resp. gastroenterologists to the coordination center.



Figure 18.

During October and December 2003, we built up the coordination center room for collecting and processing electronic data from F1 and F2 forms. The centre was equipped with basic computer equipment.



Results of screening program during the 51 months

Figure 19.

During the 51 months of the CRC screening program, we analysed 60 942 F1 forms form GPs. By statistical analysis, we can inform about more than 30 parameters.

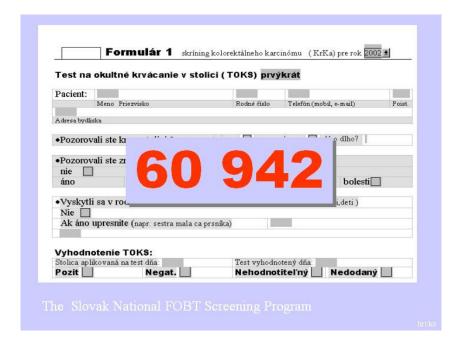


Figure 20.

During the 51 months of the CRC screening program, we analysed 2 797 F2 forms, which represented colonoscopies of FOBT positive patients sent to gastroenterologists from GPs. By statistical analysis, we can inform about more than 60 parameters.

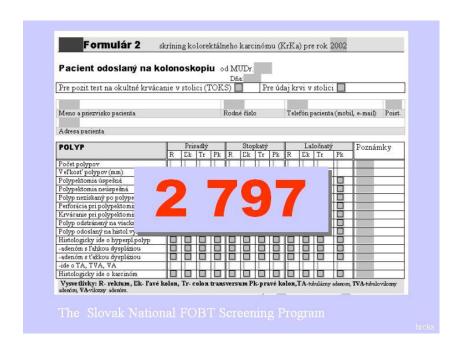


Figure 21.

805 GPs and 58 gastroenterology units sent F1 resp. F2 forms during 51 months to the centre for analysis. This represents 38% GPs and 60% gastroenterologists. We have information that nearly 70% of GPs and 90% gastroenterologists were attending the screening program. It is a pity that so many F1 and F2 forms were not sent to the centre for analysis, despite of the work, which was done. That is the reason why we are not able to work with the true reality and our approximations are not 100% correct.

How many GPs and GEs were sending F1 resp.F2 forms from the Oct. 02 to Jan 07?
$$805 \text{ GPs} = 38\%$$

$$58 \text{ GE units} = 60\%$$

Figure 22.

FOBT positivity in our screening was 10%. This is three times higher than reality. Main reason is the unwillingness of GPs to sent all F1 forms to the centre. GPs prefer to sent mainly FOBT positive forms to the centre. In this way, the concentration of FOBT positive F1 forms is three times higher than reality. However, we called for attention to this problem many times, the response from GPs was mainly insufficient. The analysis of the reasons of insufficient feedback information is very complex and is beyond of the topic of this short report.

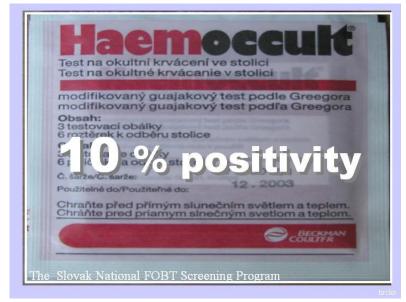


Figure 23.

With the limitations mentioned above, we can document 201 CRC, (75% in stadium Duke's A and B) during 51 months of the screening. We suppose, that the real number of revealed carcinomas was three times higher.



Figure 24. We can document 454 people with dysplastic adenomas bigger than 10mm. As we mentioned above, the real number of polypectomized adenomas is probably three times higher.

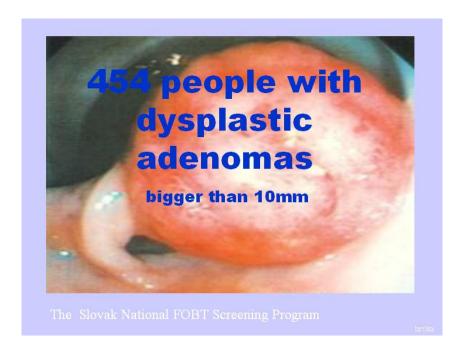


Figure 25.

It is sad, that screening program in Slovakia is still in a beggar position. In the very beginning, the Ministry of Health supported the screening program with finances for the purchase of colonoscopes and Haemocult tests, but during the period of 51 months, we had to bag for support from sponsors, despite of the fact, that the national screening program should be supported from state budget.

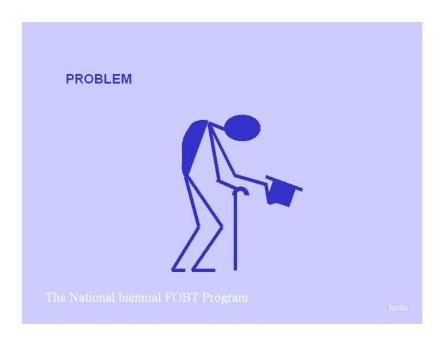


Figure 26.

It seems that the biggest problem of screening program in our country is the unwillingness of GPs and gastroenterologists to fill and sent F1 a F2 forms to the center. We did not anticipate that only 38% of the doctors wil be willing to cooperate with centre successfully. We are preparing legislative changes, which could compell the GPs and gastroenterologists for better collaboration with the coordination center, because the feedback is the essential part of this process.

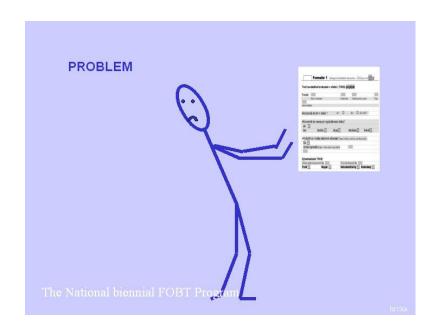


Figure 27.

After 51 months period of the CRC screening, it is clear that the participation of 60% of the gastroenterologists and 38% of the GPs on program was excellent. Unfortunately the data obtained from them about our program, are only a visible tip of the iceberg. We suppose, that the data from 70% of screened persons are not available for many more reasons than we've mentioned.

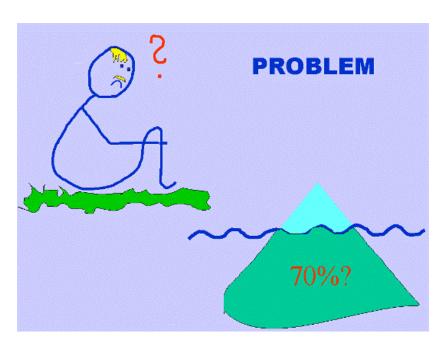


Figure 28.

Despite of the facts that the information on t

Despite of the facts that the information on the screening program are reduced, we can say that at least 655 persons are still alive thanks to this screening program. If we had the proper financial support for the program during the whole screening period, we could be sure, that the number of saved lives could be three times higher

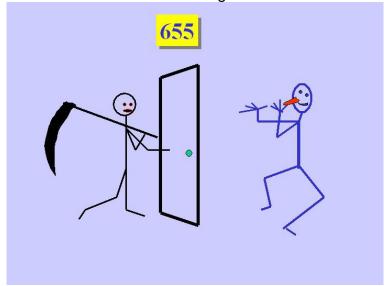


Figure 29.

The perspective of the Slovak CRC screening program will depend on two basic conditions. The first one is the financial support for a big nationwide awareness campaign. A second one is an acceptance of the new legislative reforms, which enable to facilitate the GPs and the gastroenterologists to participate on the screening program with higher responsibility. Despite of the financial shortages, we taught all the GP's and gastroenterologists during the screening period, what is the CRC screening, why is this screening so important and how to manage endangered population. We hope, that in a short time, we will be able to fulfill the conditions mentioned above and the Slovak CRC. Screening program will fulfill the expectations **e.g. lowering the CRC mortality in Slovakia substantially.**



Acknowledgement

We would like to acknowledge to EUROCHIP - 2 project for support by the creation of this short report.

Form 1	Colorectal carcinoma screening	g (CRCa) for year	ar 2002	
Fecal Occ	cult Blood Test (FOBT) fir	st		
Patient:	First name Surname	Date of Birth	Telephone (mobil, e- mail)	Insured in
		Address		
•Have you	u ever seen the blood in y stool ?	our no	ye How s long?	
•My stool h	nabit had changed diarrhoea obsti	pation cha	nge pain	
No If yes who	e of malignant disease in your ? (for example. My sister had bre ult: application on test: Negat.		aluation:	
 Patient wa Patient re Did pacie Did patien Informed neither If necessary gas 	as sent to colonoscopy: (name of fused colonoscopy for : colono nt undergo irigoscopy? yes nt ingest last 10 day acetylosar to ingest acetylosalycilic acid nor any ar troenterologist makes decision about disc	f colonoscopist) phobia anothe no phobia rocilic acid nothe	rdisease another reason another reason If yes patie one week before colonoscopy	eons nt should by
polypectomy.		signature and sta	nmp of physician	
		(name of physici	an when e-mail is used)	
Dear colleag	ue, sent please filled form to a	ddress MUDr.Hrč	ka Rudolf CSc. GEK-S	SZU,S NsP

Dear colleague, sent please filled form to address MUDr.Hrčka Rudolf CSc. GEK-SZU,S NsP Bratislava-Petržalka, Antolská 11, 85107 Bratislava. You can use fax 63811218 or e-mail (hrcka@npba.sk). Telefon contact: 02 68672327 or to secretary of clinic 02 68672012. **Form 1** is possible to filled by pen, typewriter, computer (we can distribute form by disc or by e-mail). Forms are possible to sent to the center continually or collected in envelope minimaly one for 3 months.

Form 2 Screening of colorectal carcinoma (CRCa) year 2002																			
Patient sent to colonoscopy from (name of physician). Date:																			
For FOBT positivity (FOBT)											Fo	or vi	sible	e blo	od	in	sto	ol	
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Name and Surname of patient		Birth date Patient's Telefon (mobil, e-mail)											i1)	Insured in .					
Patient's address																			
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Polyps size(mm)																			
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Polypectomy was not successful		Ī]				Ī												
Polyp was lost after polypectomy]							П									
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Bleeding after polypectomy																			
Necessary peacemeel polypectomy																			
Polyp sent to histology																			
Histology- hyperplastic polyp																			
-adenoma with LGD																			
-adenoma with HGD]														[
- carcinoma																			
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•Patient suffers from M.Crohn? Yes No																			
• Patient suffers from FAP? Yes \(\sum \) No \(\sum \)																			
•Was patient operated on for colorectal carcinoma? Yes No																			
•Was she operated on for breast cancer? Yes																			
 Did you know about existence of CRCa in your young family members without polyposis? (Lynch I) Yes ☐ No ☐ 																			
• Did you know about existence of CRCa in your young family members without polyposis and together with another malignacies? (stomach, pancreas, endometrium, urinary blader, skin) (Lynch II) Yes No																			
signature and stamp of examinator (The name of examinator by e-malil contact)																			

Dear colleague! After obtaining a histology sent please Form 2 to address MUDr.Hrčka Rudolf CSc., GEK-SZU, FNsP. Bratislava-Petržalka Antolská 11 851 07 Bratislava You can use fax 63811218 or e-mail (hrcka@npba.sk). Telephone contact: 02 68672327 or to secretary of clinic 02 68672012. Form is possible to fill by pen, typewriter, computer (we can distribute form to you by disc or by e-mail). Forms are possible to sent to the center continually or collected in envelope minimaly one for 3 months.

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