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Against Cancer

IMPROVEMENT OF QUALITY OF THE NATIONAL CANCER SCREENING PROGRAMMES IMPLEMENTATION (CRO SCREENING)

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EU Guidelines for quality assurance in organization, implementation and monitoring of colorectal cancer screening programme

Jožica Maučec Zakotnik

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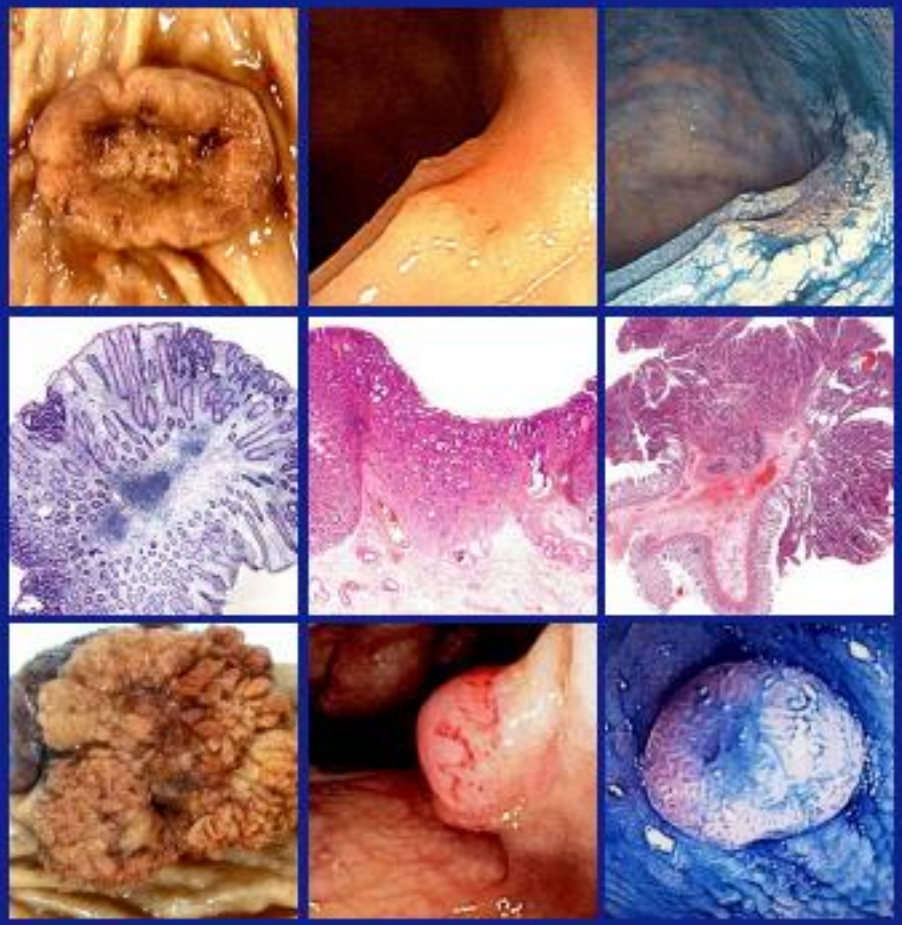
EU guidelines



European guidelines for quality assurance in colorectal cancer screening and diagnosis *First Edition*

European Commission

Directorate-General for Health & Consumers

Executive Agency for Health and Consumers

European guidelines for quality assurance in colorectal cancer screening and diagnosis

First Edition

Editors
N. Segnan
J. Patnick
L. von Karsa

Luxembourg 2010

EU guidelines - chapters

- Evidence for effectiveness of guaiac and immunochemical FOBT, endoscopy screening
- Organisation and participation
- Evaluation and interpretation of screening outcomes – indicators
- QA in endoscopy in colorectal cancer screening and diagnosis

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EU guidelines - chapters

- Professional requirements and training
- QA in pathology in colorectal cancer screening and diagnosis
- Management of lesions detected in colorectal cancer screening
- Colonoscopic surveillance following adenoma removal
- Communication

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Topics recommended to be improved in Croatia

AREAS OF RECOMMENDATIONS

- Legal framework
- Governance
- Organisation
- Implementation of the Programme
- Information system – data provision
- Quality assurance
- Financing

LEGAL FRAMEWORK

- There is a need for a stronger **„legal framework„** to support the Programme organisation, management and implementation.
- It should clearly define:
  - legal establishment of the Programme,
  - appointment of the responsible authority of the Programme, other stakeholders and providers of the programme and the relationships among them
  - financial framework
  - screening registry and the responsible holder of the screening registry
- **Protocols and guidelines,** supporting the organisation, implementation, evaluation, surveillance and monitoring, shall be defined in a **form of regulation, adopted by Ministry of Health.**

EU recommendation

- Appropriate political and financial support are crucial to the successful implementation of any screening programme.
- Council Recommendation on Cancer Screening of 2 December 2003 spells out fundamental principles of best practice in early detection of cancer and invites EU Member States to take common action to implement cancer screening programmes with an organised, population-based approach and with appropriate quality assurance at all levels

GOVERNANCE

- **Legally authorized institution/body** (existing or to create new) should be **responsible for organization, management and implementation** of the Programme.
- It should **employ enough competent staff, to assure** all the necessary activities of excellent **governance** of the Programme:
  - Provision of appropriate **organization of** the Programme
  - **Planning and Coordination** of
    - detailed budgeting scheme
    - Implementation of the Programme
    - professional guidelines development and implementation
    - professional training
    - quality control
    - monitoring and evaluation

EU recommendation

- A colorectal cancer screening programme is a multidisciplinary undertaking. The objective is to:
  - *reduce mortality from and possibly incidence of colorectal cancer* WITHOUT adversely affecting the health status of those who participate in screening.
  - The effectiveness is a function of the quality of the individual components of the process.
- The public health perspective in the planning and provision of screening services requires commitment to ensuring equity of access and sustainability of the programme over time.

ORGANISATION FOR BETTER QUALITY ASSURANCE

- **Centrally organized and centrally managed** CRC screening program is recommended to assure high Quality of the Programme
- **Centralization of some procedures** of the Programme should be considered:
  - The **use of immunochemical fecal occult blood** (iFOBT) test
  - **Central laboratory for iFOBT test readings**
  - Greater **centralization of pathohistological laboratory** diagnostics

EU recommendation

Which strategy for screening to choose? What we have to take into account, when designig and implementing the screening programme and choosing the screening strategy?

- The costs of screening organisation (including infrastructure, information technology, screening promotion, training and quality assurance),
- The occurrence of adverse effects and
- *The likelihood that patients will actually complete the tests*

Age & Sex – Uptake

FIT
gFOBt

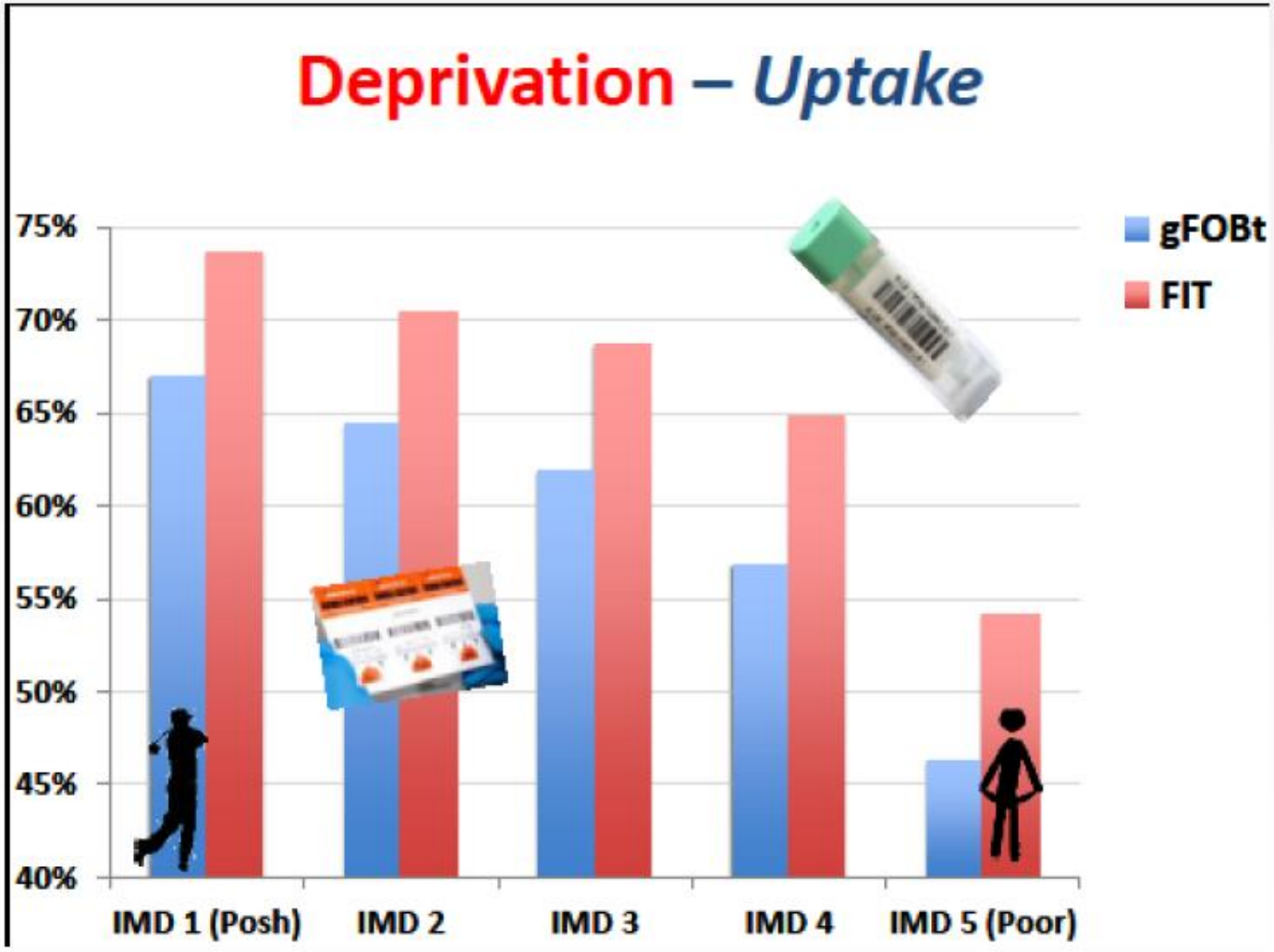
70-74
65-69
60-64
All Age

70-74
65-69
60-64
All Age

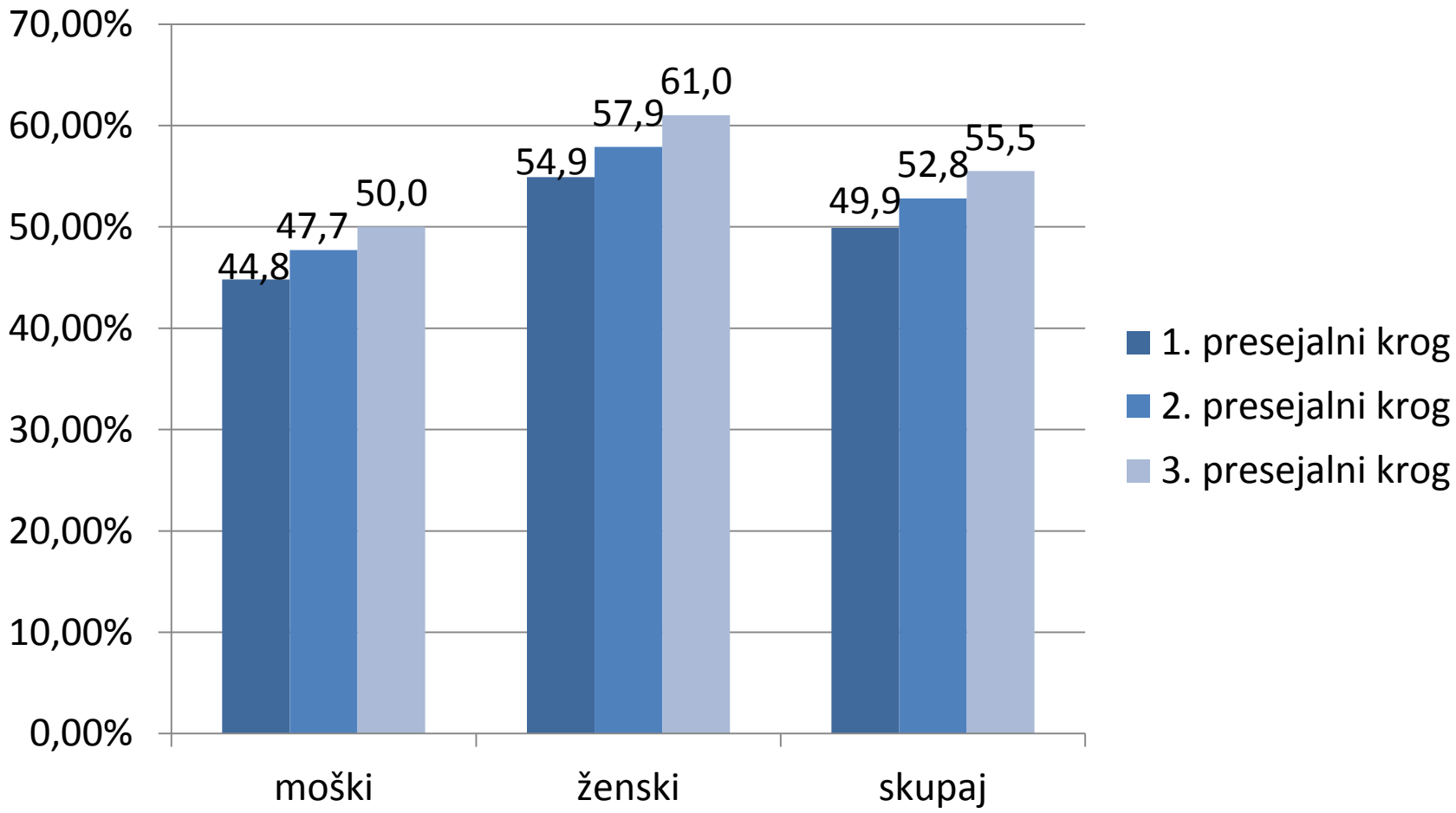
10.6%

45% 50% 55% 60% 65% 70% 75%

Uptake of FIT vs gFOBT in England



Screened population (screenig uptake) regarding sex and screening round in Programme Svit



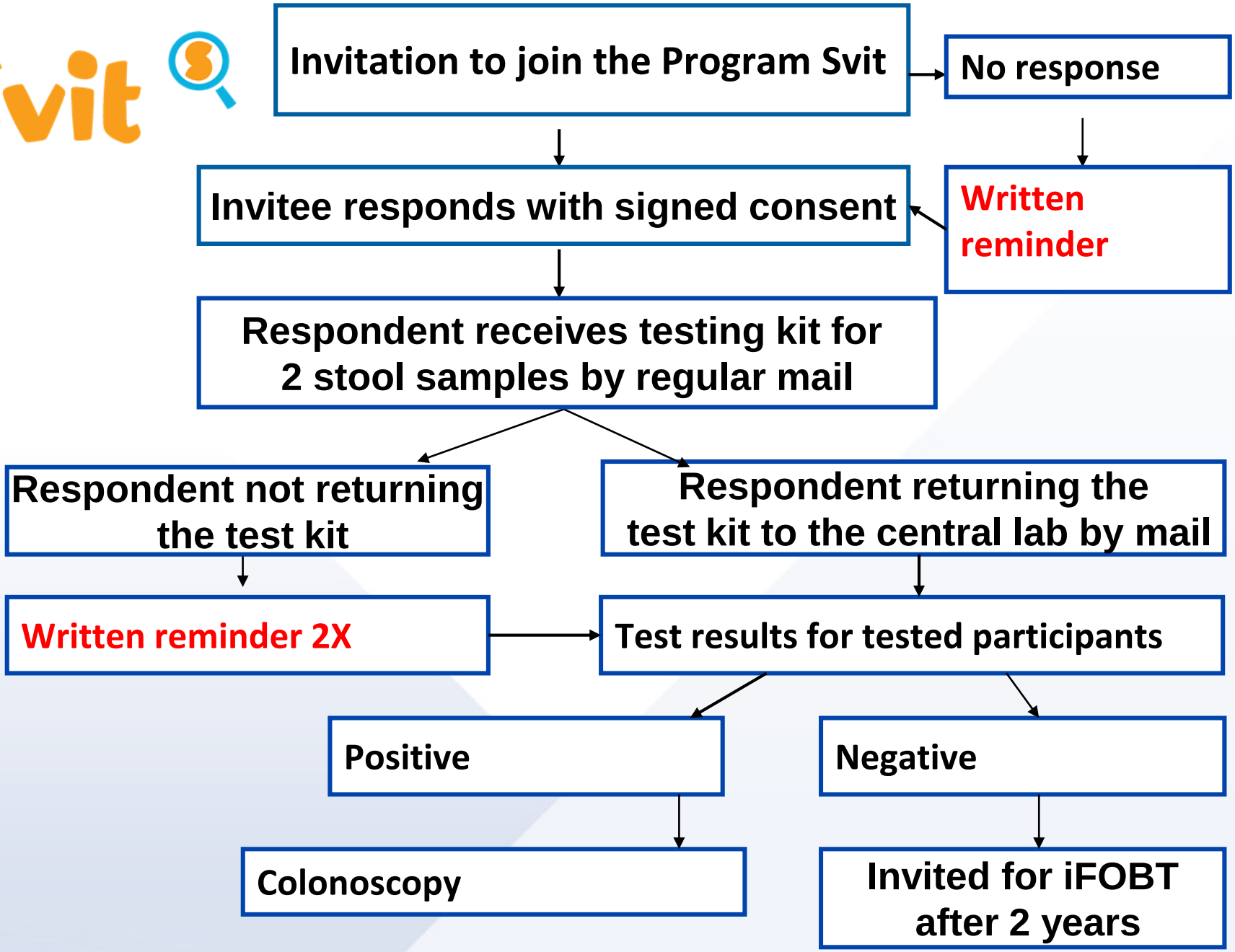
Examples of programme performance

Screening test	Country	% Adherence	Reference
gFOBT			
	Finland	72.0	Artama M, Acta Oncol 2016
	England	56.0	Halloran S, Gut 2016
	Scotland	55.3	Steel RJ, Gut 2012
	France	52.8	Hamza M, Dig Liv Dis 2014
FIT (iFOBT)			
	Netherlands	71.3	Toes-Zoutendijk M, submitted
	Italy	47.1	Zorzi M, Epidemiol Prev 2015
	Spain	43.8	Salas Trejo D, EU J Can Prev 2016
	Spain (Basque)	68.5	Portillo I, WEO Meeting 2015
	Slovenia	59.7	Zakotnik J, ISIS 2016

IMPLEMENTATION

Increasing the response rate of the target population **to at least 45 %** should be achieved by:

- **Systematic and planned promotion** based on identified obstacles and written communication strategy
- **Introducing the call/recall (reminder) system**
- Stronger **involvement of family medicine doctors** and **district nurses** in recruitment of non-responders
- **Payment** of additional work could be connected to the **level of the response rate** of the individual family doctor's list of patients
- Stronger **involvement of civil society** (NGO, opinion leaders, ambassadors) in the Program promotion
- Stronger **involvement of PH proffesionals** at county level in targeted community promotion of CRC screenig peogramme to influence responce rate in the programme


Svit
Invitation to join the Program Svit
No response
Invitee responds with signed consent
Written reminder
Respondent receives testing kit for 2 stool samples by regular mail
Respondent not returning the test kit
Respondent returning the test kit to the central lab by mail
Written reminder 2X
Test results for tested participants
Positive
Negative
Colonoscopy
Invited for iFOBT after 2 years

PATIENT CENTERED PROGRAMME

Higher response rate of the target population could be achieved trough using **patient friendly procedures and solutions:**

- Simple manuals, use of social networks and support, clear messages
- Using user friendly test kit
- Colonoscopy without pain or with less pain
- Treating minor lesions (polyps) inside the first screening colonoscopy
- Needs of disabled people and language/ethnic minorities should be detected and fulfilled

EU recommendation

- Taking into account the perspective of the individual requires commitment to promoting informed participation and to providing a high quality, safe service.

INFORMATION SYSTEM – DATA PROVISION

Appropriate IT system should **support all steps** of the Programme implementation and management through:

- **Governance of CRC screening registry** by authorized institution
- **Reliable data sources** for identification and inclusion of the target population in the Program
- Enabling **different providers to connect to the unified Programme IT system** according to their role
- **Connection of the screening registry** to the national **cancer registry** and **regular refreshment** of the data
- Enabling **the access to micro data** of the Programme for analytical and research purposes

EU recommendation

Complete and accurate recording of all relevant data on each individual and every screening test performed,

- including the test results,
- the decision made as a consequence,
- diagnostic and treatment procedures and
- the subsequent outcome, including cause of death, should be ensured.

This monitoring process is of fundamental importance.

QUALITY ASSURANCE

Assurance of high quality system at all levels of the Programme is a prerequisite of any screening program.

Therefore the **authorized institution/body,** responsible for the Programme **should develop and implement :**

- CRC screening **programme guidelines**
- Clear **inclusion criteria** for the target population
- **Standard procedures**
- **Quality indicators**
- **Accreditation system** and entering criteria for Programme providers
- Auditing / **Quality control** of Programme providers
- **Education and training** for all professional groups of Programme providers

FINANCING

The prerequisite of successful and efficient implementation of the Programme is **stable and sufficient financing**.

The coordinating authority should prepare **detailed budgeting scheme and** state should provide **stable and sufficient financing for**

- **Management cost** – sufficient staff and material cost for organization, coordination, IT system, promotion of the Programme, monitoring, evaluation, quality control
- **Implementation costs (**invitation, testing, colonoscopy, PH,…)

- Recalculation and definition of appropriate **colonoscopy prices** to assure high quality procedures
- **Incentives for family doctors** according to response rate

EU recommendations

- The programme needs political support with sustainable funding to succeed.
- Provisions should be made for the financing of the programme, including evaluation costs.

DISCUSSION
Worksheet 2

Please discuss the questions:

a) What are to your opinion the reasons why people in Croatia respond to invitation only in approximately 20%?.

   Please focus on peoples' individual reasons.

Please rang them according to impotrance from 1 to 10.

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DISCUSSION

Worksheet 2

Please discuss the questions in pairs:

- Is quality assurance important for you when working in screening programme? Rang it from 1 to 10 (1 is not important, 10 is very important).
- Do you know which data/indicators represents quality in your screening work?
- Do you report and folow this data in screening programme? Which ones?

Write a list of quality indicators concerning your work in CRC screening programme on flipchart paper.

Reasons for non response in Slovenia

Reasons for nonresponse among nonresponders - Field interview survey in 2014			
Believe they are healthy	30,5%	Forgotten	6,0%
Lack of time and preoccupied	22,2%	Screening is not important	6,0%
Fear of cancer to be discovered	18,6%	Lack of information	4,2%
Already performed colonoscopy	15,0%	Fear of expences	3,6%
Negative attitute towards health sistem	14,4%	Confused an invitation with advertising	3,6%
Ill from other serious disease	13,8%	Not know to be tested every 2 years	3,6%
No need for subsequent testing after neg. test	8,4%	Misplaced	3,0%
Postponing	7,8%	Not familiar with Svit programme brand	3,0%
Did not get / noticed the inviation	7,8%	Convinced that health cannot be influenced	2,4%
Fear of colonoscopy	6,6%	Problematic procedure of test sampling	2,4%
		Other	1,8%

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EU Guidelines and Screening Programme Quality Indicators

Jožica Maučec Zakotnik

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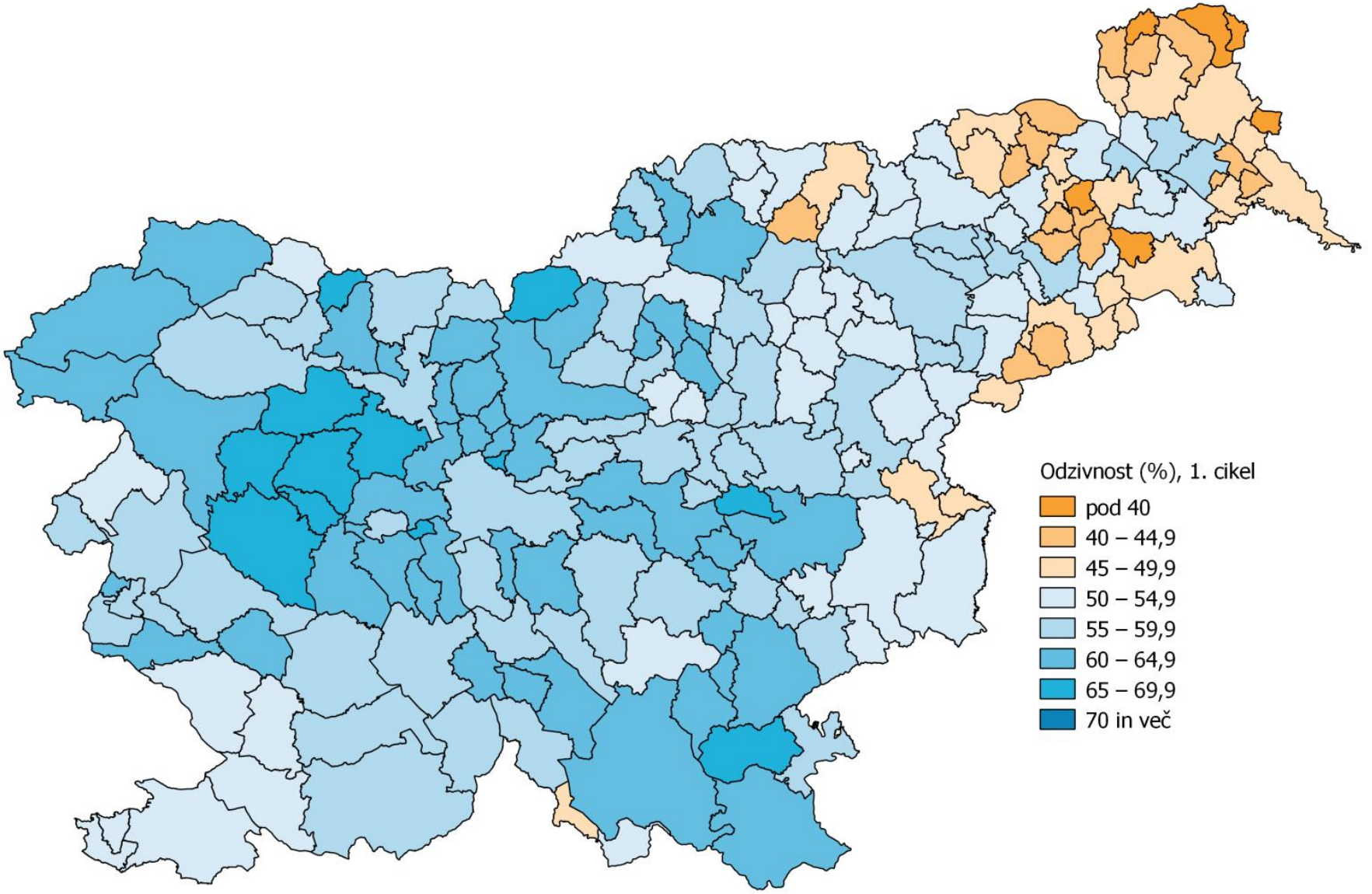
Quality indicators in CRC screening Programme organisation, implementation and management

- **Programme performance indicators – organization**
  - Coverage by invitation
  - Invitation response rate
  - Unreturned fit rate
  - Time interval between completion of test and issuing of results
  - Referral to follow-up colonoscopy after fit
  - Time interval between referral after positive test and performed colonoscopy
  - Colonoscopy compliance rate
  - Time interval between laboratory receipt and histological result
  - Time interval between diagnosis of screen-detected cancer and start of definitive treatment
- **Programme performance indicators – outcome results (diagnosis)**
  - Inadecvate fit rate
  - Positive fit rate
  - Colonoscopy after positive fit rate
  - Caecal intubation rate
  - Rate of high-grade neoplasia reported
  - Proportion of cancer cases not requiring surgery
  - Endoscopic complications rate
  - 30-day colonoscopy specific mortality
  - Positive predictive value for detection of lesions/adenoma/advanced adenoma/cancer)
- **Early performance indicators – impact to population health**
  - Uptake/participation rate
  - Stage of screen-detected cancers
  - Interval cancers

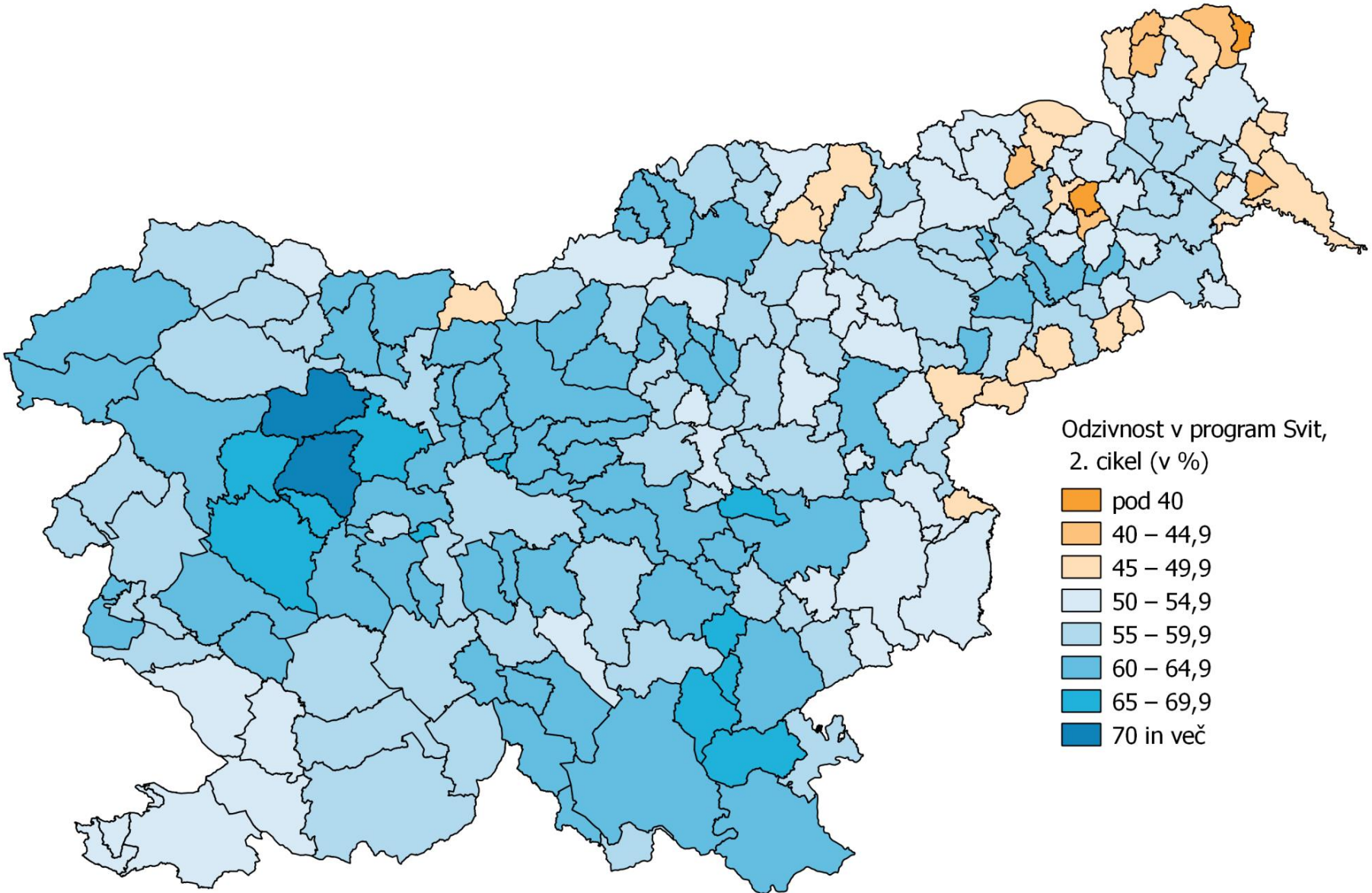
First 3 screening round of Program Svit results

	1. screeming round		2.screening round		3.screening round	
	number	%	number	%	number	%
People invited	536.709	*95,4%*	502.488	*95,3%*	501.300	*95,6%*
Delivered invitations	533.040	*99,3%*	500.516	*99,6%*	499.279	*99,6%*
Responded to invitation (signed consent returned to Program Svit	303.343	***56,9%***	289.070	***57,8%***	298.291	***59,7%***
Patients not eligible for screening (history of colorectal condition)	38.017	*12,5%*	22.425	*7,7%*	16.316	*5,5%*
Persons not wanted to participate but responded	1.354	*0,3%*	1.457	*0,3%*	676	*0,2%*
Persons received test kit	265.319	*87,5%*	266.649	*92,3%*	281.971	*94,2%*
Participated – returned test kit	246.916	***49,9%***	252.653	***52,8%***	268.183	***55,5%***
- persons returned test kit appropriate for the analysis	245.714	*99,5%*	251.948	*99,7%*	267.679	*99,8%*
• positive test	15.310	***6,2%***	15.147	***6,0%***	16.024	***6,0%***
• negative test	230.404	*93,8%*	236.801	*94,0%*	251.655	*94,0%*
- persons returned only inappropriate test kits	1.202	*0,5%*	705	*0,3%*	505	*0,2%*
N of people with clonoskopy performed	13.919	***90,9%***	13.969	***92,2%***	14.883	***92,8%***

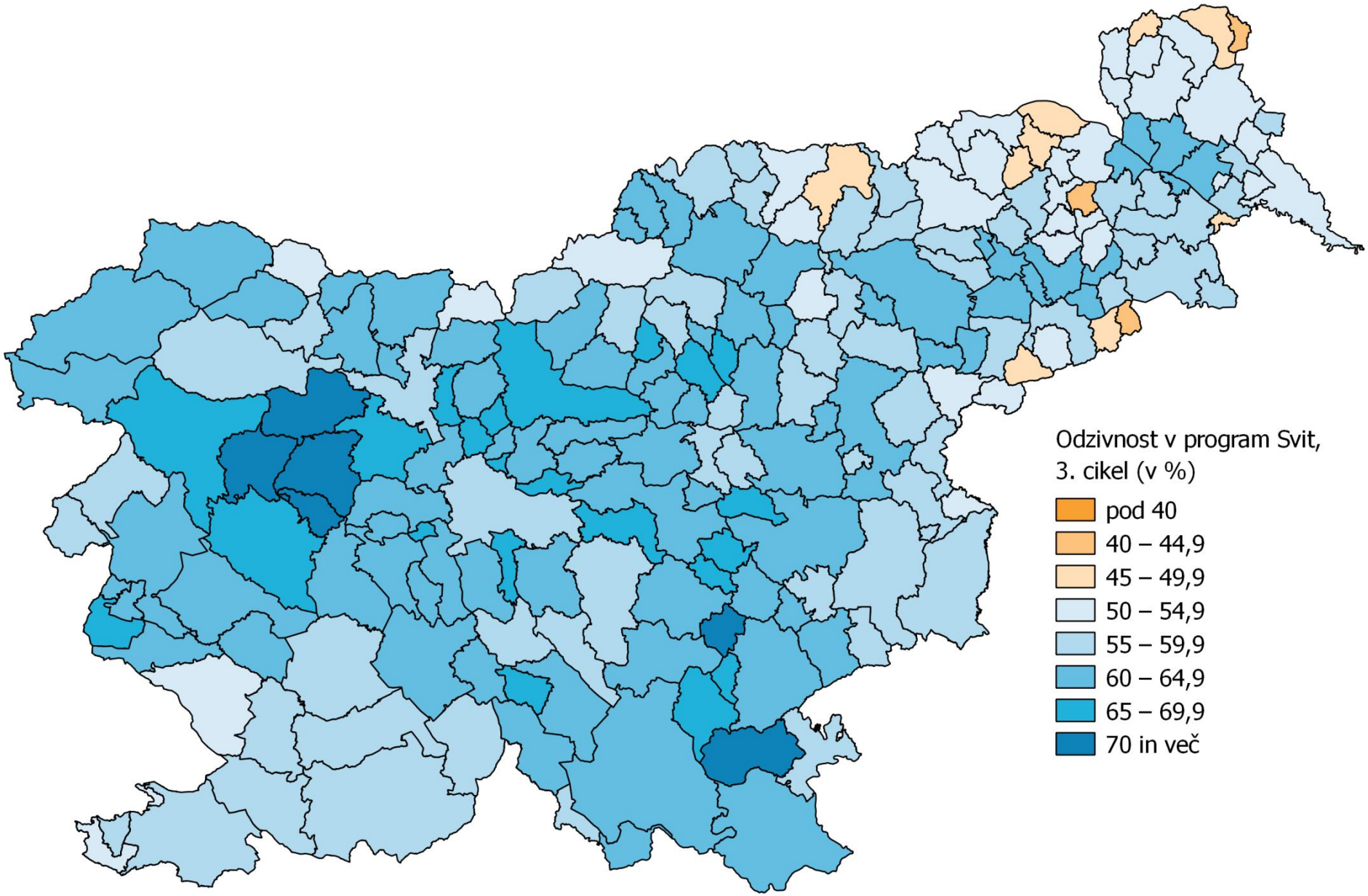
Invitation responce rate regarding communities, 1.screening round (april 2009 – marec 2011)



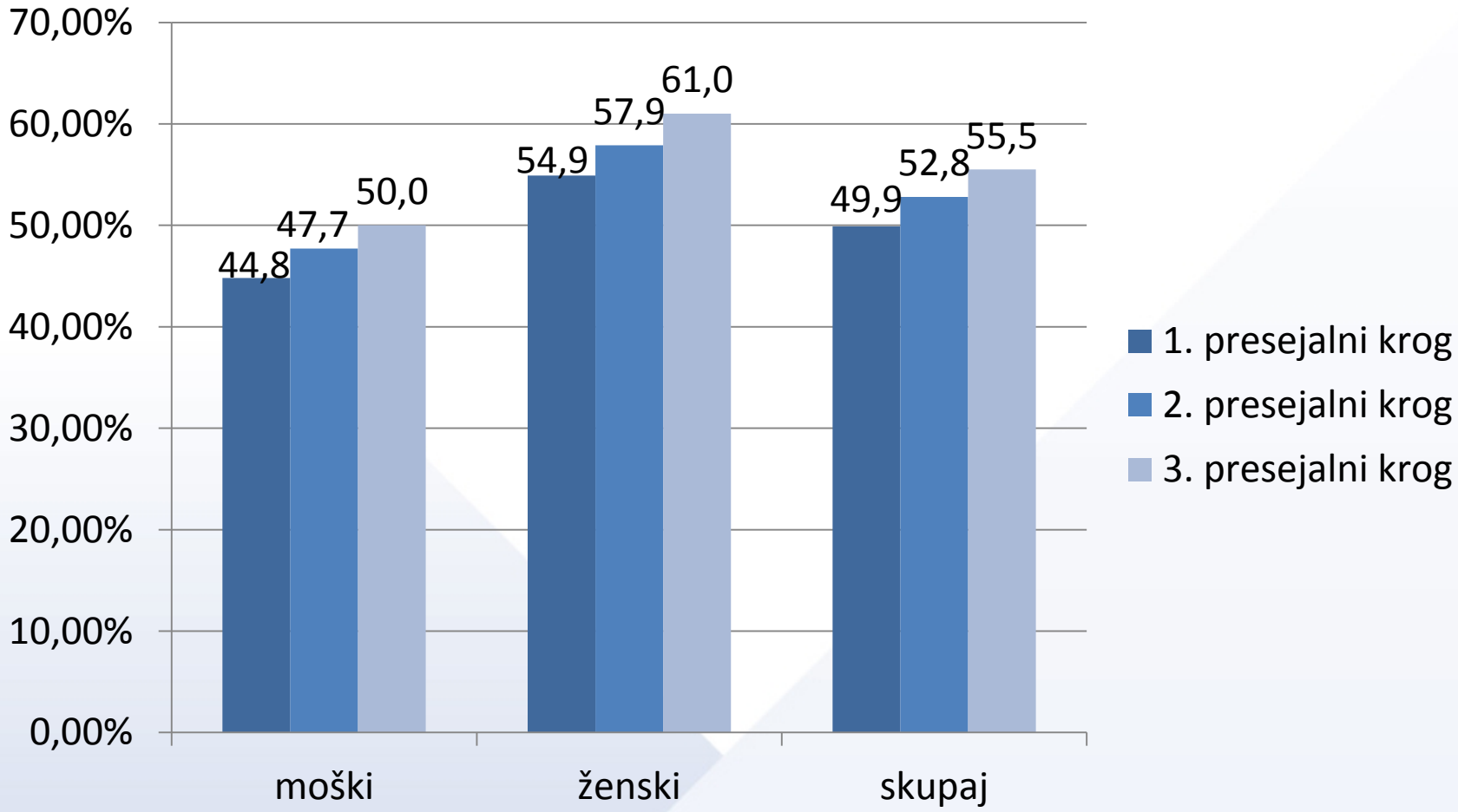
Invitation responce rate regarding communities, 2.screening round (april 2011 – december 2012)



Invitation responce rate regarding communities, 3.screening round (januar 2013 – december 2014)



Screened population regarding sex and screening round



Shift in cancer stages detected in the SLO screening

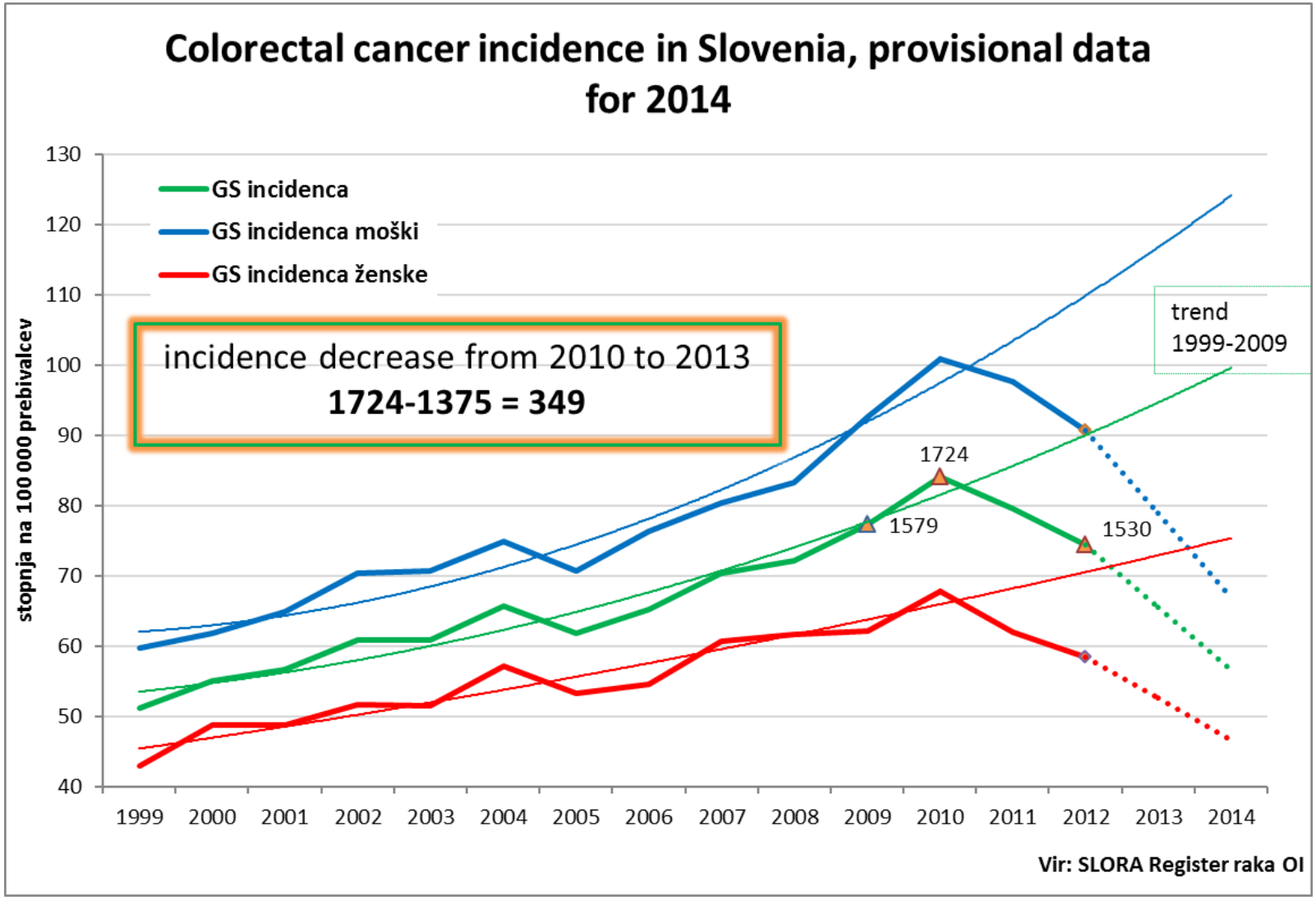
Stage	1. round 2009-10		2. round 2011-12		Cancer register in 2008 (limited)	
	number	share	number	share		
I. stage T1Nx (T1 Nx Mx) *	196	21,9%	117	23,4%		13,5%
I. stage (T1/2 N0 M0)	238	26,7%	140	27,9%		
II. stage (T3/4 N0 M0)	191	21,4%	99	19,8%		
III. stage (any T N1/2 M0)	211	23,6%	105	21,0%		
IV. stage (any T N1/2 M1)	57	6,4%	40	8,0%		
total with stage	893	100,0%	501	100,0%		
no data	15					
Total cancers	908		501			

Endoscopic removal

Early phase of detection (I. in II. stage): 70,0 % in 71 %

Effects of CRC screening in Slovenia

www.program-svit.si



Programme performance indicators - organization

1. Coverage by invitation

Share of people to whom the invitation was delivered by mail according to number of target population eligible for screening (permanent, temporary residents, insured ?...)

Acceptable	Target	Program Svit
95%	>=95%	99,6% in 2.round

2. Invitation response rate

Share of people who responded to the invitation according to the number of target population who received the invitation.

Acceptable	Target	Program Svit
> =45%	>=75%	57,8% in 2.round

3. Unreturned fit rate

Share of people who did not returned the stool test kit among people to whom the test kit was sent.

Acceptable	Target	Program Svit
< 10%	< 5%	5,2% in 2.round

Programme performance indicators - organization

4. Time interval between completion of test and issuing of results

Share of people who received the test result in 15?, 10? days. Sending the results to people with negative test should be included in the program algorithm.

Acceptable	Target	Program Svit
> 90% in 15 days		100%

5. Referral to follow-up colonoscopy after fit

Share of people appointed to colonoscopy among people with positive FOBT result. Different reasons for not being appointed should be monitored.

Acceptable	Target	Program Svit
90%	> 95%	93,2% in 2.round

6. Time interval between referral after positive test and performed colonoscopy

Share of people with the first colonoscopy performed in 31 days (42 days?) after the day of appointing to the colonoscopy.

Acceptable	Target	Program Svit
> 90% in 31 days	> 95% in 31 days	74,6 % in 2.round

Programme performance indicators - organization

7. Colonoscopy compliance rate

Share of people with at least one colonoscopy in the programme among people who were after positive FOBT appointed for colonoscopy

Acceptable	Target	Program Svit
> 85%	> 90%	98,9% in 2.round

8. Time interval between laboratory receipt and histological result

Share of colonoscopies where result of histopathology diagnostics was available (send in paper form or entered to information system) in 5 or 10 working days.

Acceptable	Target	Program Svit
> 95% in 5 days > 98% in 10 days (entered in information system)	> 95% in 5 days > 98% in 10 days (entered in information system)	67,9% in 5 days in 2.round 95,8% in 10 days in 2.round

9. Time interval between diagnosis of screen-detected cancer and start of definitive treatment

Share of people with colorectal cancer who received definitive treatment in 31 calendar days after histopathology diagnosis of cancer among people who need additional treatment (surgery).

Acceptable	Target	Program Svit
> 90% in 31 days	> 95%	

Programme performance indicators – outcome results (diagnosis)

10. Inadequate fit rate

Share of people with at least one inadequate fit test, who did not manage to receive test result (positive or negative) among screened (sent stool samples).

Acceptable	Target	Program Svit
< 3%	<1%	0,3% in 2.round

11. Positive fit rate

Share of people with positive test result among people with test result.

Acceptable	Target	Program Svit
international standards not clearly defined		6,0% in 2.round

12. Colonoscopy after positive fit rate

Share of people with at least one colonoscopy in the programme among people with a positive FOBT test result.

Acceptable	Target	Program Svit
no standard	>85%	92,2% in 2.round

Programme performance indicators – outcome results (diagnosis)

13. Caecal intubation rate

a. Share of total colonoscopies among all performed colonoscopies.

b. Share of total colonoscopies according to the number of people with at least one colonoscopy.

Acceptable	Target	Program Svit
> 90%	>=95%	98,8 % in 2. round

14. Rate of high-grade neoplasia reported

Share of findings which histopathologists classified as high-grade displasia among all findings with histopathology diagnose.

Acceptable	Target	Program Svit
< 10%		6,6 % in 2. round

15. Proportion of cancer cases not requiring surgery

Share of people with colorectal cancer detected who did not need surgery, because cancer was removed at endoscopy among people with colorectal cancer as the worst finding detected at colonoscopy.

Acceptable	Target	Program Svit
reference standard not clearly defined	no standard	24,30 % in 2. round

Programme performance indicators – outcome results (diagnosis)

16. Proportion of adenoma cases referred for surgery

Share of people with adenoma as the worst finding who were referred to surgery, among people with adenoma as the worst finding at colonoscopy.

Acceptable	Target	Program Svit
no generally accepted standard	no standard	2,4% 1.round

17. Surgery compliance rate

Share of people referred to surgery with the procedure performed, according to all people referred to surgery.

Acceptable	Target	Program Svit
> 90%	> 95%	87 % in 2. round

Programme performance indicators – outcome results (diagnosis)

19. Endoscopic complications rate

Share of screening or therapeutic colonoscopies with complications among all colonoscopies. Type of serious complications should be identified and reported from all colonoscopy providers inside the programme.

Acceptable	Target	Program Svit
< 0,5% diagnostic colonoscopy < 2,5% therapeutic colonoscopy < 1/1000 perforations requiring surgery < 1/1000 immediate or delayed bleeding requiring surgery	no standard	0,3% during diagnostic colonoscopy 0,81% during therapeutic colonoscopy 0,02% serious complications, diagnostic colonoscopy 0,24% serious complications, therapeutic colonoscopy

20. 30-day colonoscopy specific mortality

Share of people who died in 30 days after colonoscopy because of colonoscopy complications, among all people with at least one colonoscopy.

Acceptable	Target	Program Svit
no standard	0%	0,00007% in 2.round

Programme performance indicators – outcome results (diagnosis)

18. Positive predictive value for detection of lesions/adenoma/advanced adenoma/cancer)

- a. Positive predictive value of colonoscopy

Share of people with at least one lesion /one adenoma/one advanced adenoma/one carcinoma counting the worst finding, among people at least one colonoscopy performed.

PPV for advanced adenoma and carcinoma at colonoscopy

Acceptable	Target	Program Svit
First test>25% Next test>15%	First test>30% Next test>20%	43,3% in 1. round

- b. Positive predictive value of FOBT test

Share of people with at least one lesion /one adenoma/one advanced adenoma/one carcinoma counting the worst finding, among people with positive FOBT test result.

Acceptable	Target	Program Svit
First test>25% Next test>15%	First test>30% Next test>20%	39,3% in 1. round

Early performance indicators – impact to population health

21. Uptake/participation rate

Share of people with returned test kit (suitable for testing or not) among all people delivered the invitation minus people excluded because of previous bowel cancer or bowel decease

Acceptable	Target	Program Svit
> 45%	>65%	55,5% in 3. round

22. Lesions/adenoma/advanced adenoma/cancer detection rate of FOBT

Share of people with at least one lesion /one adenoma/one advanced adenoma/one carcinoma counting the worst finding, among people with FOBT test result (positive and negative).

Acceptable	Target	Program Svit
CRC: >2/1000 in 1.round, >1/1000 in subsequent Advanced adenoma: >7,5/1000 in 1.round, >5/1000 in subsequent	CRC: >2,5/1000 in 1.round, >1,5/1000 in subsequent Advanced adenoma: >10/1000 in 1.round, >7,5/1000 in subsequent	CRC: 3,5/1000 in 1. round, 2/1000 in 2.round Advanced adenoma: 21/1000 in 1. round, 17/1000 in 2.round

Early performance indicators – impact to population health

23. Stage of screen-detected cancers

Share of people with different cancer stage among all people with cancer diagnosed inside screening programme, counting the worst finding. TNM (I, II, III, IV) classification is used.

Acceptable	Target	Program Svit
stage 3 or higher <30%	stage 3 or higher <20%	29,8% in 1. round

24. Interval cancers

Share of people with interval cancer (primary colorectal cancer) diagnosed before next planed FOBT or planed colonoscopy control, among people with FOBT test result or people with colonoscopy performed. For this definition strict rules of time period of repeated invitation to next screening round must be followed by screening managing institution.

Acceptable	Target	Program Svit
no generally accepted reference standard		

Quality of colonoscopy indicators

25. Colonoscopists with sufficient number of conducted colonoscopies

Share of colonoscopists who performed at least 200 colonoscopies per year inside and outside the programme among all colonoscopists in the programme.

Acceptable	Target	Program Svit
85% >= 200	100% > 200	

26. Bowel cleansing, quality of colonoscopy preparation

Share of colonoscopies with good cleansing among all performed colonoscopies.

Acceptable	Target	Program Svit
> 90%	>=95%	96,9% in 2. round

Quality of colonoscopy indicators

27. Colonoscopy withdrawal time

Share of colonoscopies without polypectomy or biopsy with at least 6 minutes withdrawal time among all colonoscopies without polypectomy or biopsy.

Acceptable	Target	Program Svit
>= 90% 6 min		

28. Adenoma detection rate (ADR) of first colonoscopy

Share of first colonoscopies with detected at least one adenoma among all first colonoscopies

Acceptable	Target	Program Svit
men>=50% women>=30%	men>=60% women>=40%	men>=61,3% in 2. round women>=39,6% in 2. round

Quality of colonoscopy indicators

29. Left and right colon adenoma detection proportion

Share of adenomas detected in left/ right colon among all adenomas detected in entire colon. Right hemicolon includes flexura lienalis, colon transversum flexura hepatica, colon ascendens, and cecum. Left hemicolon includes anus, rectum, colon sigmoideum and colon descendens.

Acceptable	Target	Program Svit
Left/right colon proportion 65% / 35%	Left colon < 60 % Right colon > 40%	Left colon < 63,4% in 2.round Right colon > 36,6% in 2.round

30. Sessile serrated lesion in right colon detection rate –(SSLR)

Share of first colonoscopies with at least one detected sessile serrated lesion in right hemicolon among number of all first colonoscopies.

Acceptable	Target	Program Svit
> 4%		men: 1,4% in 2. round women: 1,7% in 2. round

Quality of colonoscopy indicators

31. Mean adenomas per procedure – map),

(Mean adenomas per positive procedure – map+)

Share of all adenomas detected in first colonoscopies among number of all first colonoscopies (map) or among number of all first colonoscopies with at least one adenoma detected (map+)

Acceptable	Target	Program Svit
no standard	no standard	MAP (2.round) 1,05 aden/colon MAP+ (2.round) 2,02 aden/+colon

32. Referral to surgery or tertiary endoscopy in the same or another facility

Share of people referred to surgery or additional colonoscopy for polypectomy among number of people with findings at colonoscopy.

Acceptable	Target	Program Svit
	< 5 %	

DISCUSSION

Worksheet 3- group A

Quality assurance in organization and management to achieve adequate response rate of target population.

- *45% response rate is the bottom target agreed in EU guidelines if the screening programme goals in improving population health are to be reached.*
- Professionally mixed group discuss and answer the questions:

a) Is the current organization of the screening programme optimal to achieve this target response rate in Croatia? How it can be improved?

b) Which are the fields where do you see the necessary development of the coordinating institution HZJZ (NIPH) and county public health institutes if you have in mind how to achieve 45% response rate?

- Rapporteur of the group will have to report to coordinator and to other groups.

DISCUSSION

Worksheet 3- group B

"EU guidelines for quality assurance in CRC screening programme" define quality indicators in all steps of organisation, management, implementation and evaluation as a prerequisite to run an organized, population based screening programme.

- Professionally mixed group discuss and answer the questions:

a) What are the main challenges to be improved for quality assurance of CRO colorectal cancer screening programme in organisation, management and implementation, and evaluation?

b) Where changes are most needed? What should be done first, what next? Rang them in importance.

c) Which changes are the easiest to implement and which most difficult?? Please rang them from the easiest to introduce to the more complicated.

- Rapporteur of the group will have to report to coordinator and to other groups. Use flipchart paper to colect important masages to be reorted.