

ROADMAP FOR

COLORECTAL CANCER SCREENING



FOREWORD

Across Europe, many people are still dying from a very common yet avoidable disease: colorectal cancer. It is the second deadliest cancer in Europe with 170,000 people dying from it in the European Union every year and yet, despite abundant evidence that they are both medically effective and cost-effective, only a few EU Member States have nationwide population-based screening programmes. Lives are being needlessly lost and money wasted.

Setting up a colorectal cancer screening programme is complex, and detailed clinical and organisational systems, requiring a broad range of skills, need to be developed. The success of such a programme depends not only on organisational effectiveness and high clinical quality but on motivating citizens to participate when they have no apparent symptoms. Success will depend on committed and skilled managers working with a network of general practitioners, endoscopists, nurses, oncologists, clinical biochemists, histologists, epidemiologists and information scientists with access to high quality clinical and laboratory facilities and a commitment to clinical excellence. The whole process will also require continuous education, performance review and accreditation, as well as frequent feedback and updates.

In the process of developing this roadmap or blueprint for screening programmes, we looked at the literature on the subject, and we invited specialists and representatives from countries with good screening performance to come and explain their success factors. We had a brainstorming session with them to understand what the barriers and drivers of change were, and how to overcome them.

The most successful programmes have demonstrated that it takes time to build robust foundations and to develop sound plans, systems and structures with supportive political and clinical alliances; all of which need to be in place before launching a new programme. It is advisable that screening agencies and other interested parties first evaluate existing best practice and determine how these might be applied locally. It may take five to ten years to develop such a programme, and will require political support and commitment, adequate funding and strong dynamic leadership.

We thank all those who participated in setting up this project, including experts from Slovenia, Spain and the Netherlands for the example they have set. We hope that many other countries will follow suit.

On the need for colorectal cancer screening

Colorectal cancer (CRC) is the second most common cause of cancer deaths in the European Union, with approximately 170,000 people dying every year, out of a diagnosed population of 370,000¹. The incidence of colorectal cancer is predicted to rise significantly in the next decade, due to an aging population, unhealthy diets, physical inactivity, obesity and use of tobacco and alcohol.

MORTALITY AND INCIDENCE IN THE EUROPEAN UNION			
	Incidence	Mortality	Current number of survivors (5 years after treatment)
Colon	242,987	117,257	
Rectum	125,260	52,924	
TOTAL	368,247	170,281	950,000

Yet colorectal cancer is easy to treat when detected at an early stage. A stage I diagnosis of colorectal cancer results in an overall 5-year survival rate of 90%, and this falls to 10% in the metastatic stage IV. Unfortunately, only 13-15% of patients are diagnosed at stage I². Recent studies in the UK (table below) Belgium⁴, Switzerland⁵ and Italy⁶, show figures within the same range, with around 15 to 16% in stage I and 20 to 25% in stage IV.

	Stage I	Stage II	Stage III	Stage IV
Chance of survival	90%	75%	70%	10%
Patients diagnosed per stage	13%	31%	32%	24%
Estimated Treatment cost	€4,000	€25,000	€30,000	€40,000

¹ Malvezzi, 2016. European cancer mortality predictions for the year 2016. *Ann Oncol*, p. 725–731.

² Figures from the US and the UK come to comparable results: American Cancer Society: Survival Rates for Colorectal Cancer, by Stage, 2018 and Bowel Cancer UK, Figures 2006

³ Source: Cancer.net

⁴ Cancer Burden In Belgium 2003-2014, Belgian Cancer Registry 2014

⁵ Feller, A., Schmidlin, K., Bordoni, A., Bouchardy, C., Bulliard, J., Camey, B., Oris, M. (2018). Socioeconomic and demographic inequalities in stage at diagnosis and survival among colorectal cancer patients: evidence from a Swiss population based study. *Cancer Medicine*, 7(4), 1498–1510. <http://doi.org/10.1002/cam4.1385>

⁶ Manuel Zorzi et alii: Characteristics of the colorectal cancers diagnosed in the early 2000s in Italy. *Epidemiology & Prevention*, 2015

Despite the high incidence of colorectal cancer, the identification of symptoms by the patient and diagnosis by a physician is not easy because many of the symptoms can be attributed to other, less severe and more common diseases. The median time between reporting the first symptoms to a GP and diagnosis is 128 days, with a range from 57 to 257days⁷.

The evidence supporting the effectiveness of screening programmes is based on major randomised control trials and has international support; the burden of colorectal cancer can be significantly reduced by adopting well-designed and organised screening programmes. Health economic assessment repeatedly demonstrates that such programmes are not just clinically as well as cost-effective but also cost-saving!⁸ The most comprehensive cost-effectiveness analysis was recently conducted in the Basque region of Spain⁹.

On 2 December 2003, the Health Ministers of the European Union unanimously recommended the adoption of cancer screening based on the “European Code Against Cancer” programme¹⁰. The Recommendation of the Council of the 10 European Union outlines the fundamental principles of best practices in early detection of cancer and invites EU Member to take common action to implement national cancer screening programmes with an organised, population-based approach and with appropriate quality assurance at all levels, taking into account European quality assurance guidelines for cancer screening, where they exist¹¹.

We refer to our **White Paper on Screening of Colorectal Cancer** in the European Union¹² for more details and policy recommendations. It is time to start putting words into practice.

Political Commitment and European Guidelines

The following text comes from the Introduction of the **European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnostics**:

“Colorectal cancer is the second most common newly diagnosed cancer and the second most common cause of cancer death in the EU. Many of these deaths, however, could be avoided through early detection, by making effective use of screening tests followed by appropriate treatment.

For this reason, the evidence-based European Code Against Cancer recommends that men and women from 50 years of age should participate in colorectal screening. This has been given effect within the EU by the 2003 Council Recommendation on cancer screening. Making this screening effective, in turn, depends on appropriate quality assurance at all levels.

That is the aim of the “European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis”. These guidelines, the result of tireless efforts over many years by a wide range of European experts, represent a major achievement, with the potential to add substantial value to the efforts of the Member States to improve control of colorectal cancer.

This, in turn, will save lives and help improve the quality of life of millions of EU citizens, their families and friends.”

⁷ Pablo Vega, Fátima Valentín, Joaquín Cubiella: “Colorectal cancer diagnosis: Pitfalls and opportunities”, in World Journal of Gastro-intestinal Oncology, 2017

⁸ Lansdorp-Vogelaar, Iris et al. “Cost-effectiveness of colorectal cancer screening” Epidemiologic reviews vol. 33,1 (2011): 88-100.

⁹ Arantzazu Arrospe et al. Cost-effectiveness and budget impact analyses of a colorectal cancer screening programme in a high adenoma prevalence scenario using MISCAN-Colon microsimulation model, BMC Cancer, 2018

¹⁰Council of the European Union, 2003

¹¹European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis, European Commission, 2010

Which populations to screen and why?

The European guidelines are clear: all citizens within the age group of 50 to 74 years old should participate in colorectal cancer screening programmes. The higher the screening participation, the higher the detection rate, and the better the cost-effectiveness of the programme.

Before screening is even contemplated, general practitioners should be sufficiently aware of what constitutes a risk population for colorectal cancer, and that includes asking patients about their family history of colorectal cancer. Patients with a parent or first-degree relative who suffered from colorectal cancer should undergo colonoscopy as a standard measure at the age of 40, or ten years before the sibling was diagnosed¹³.

In the United States, the American Cancer Society recently recommended lowering its colorectal cancer screening age to 45 years old, because studies have demonstrated rising incidence in young people, possibly due to obesity¹⁴.

What can screening achieve?

The illustration below describes the stages of colorectal cancer, from pre-cancerous adenomas to late-stage colon cancer. The progression from one stage to the other is relatively slow in colorectal cancer and can take several years. The removal of the pre-cancerous adenomas is usually relatively easy and with little cost. In Europe, on average, only 13 to 15% of patients are diagnosed in the early stages (pre-cancerous to Stage I), and more than 24% of patients are still diagnosed in the late Stage IV, or more than 55% in stages III & IV, when chances of overall survival are the lowest. Unlike many other cancers, this cancer's most effective diagnostic — colonoscopy — is also a preventive treatment. Polyps and precancerous lesions are removed during the test and the patient may then avoid a diagnosis of cancer.



Good screening programmes lead to immediate results. In the Netherlands, 48% of all identified colorectal cancers are diagnosed at stage I, compared to 17% before implementing the programme, thus significantly reducing the late-stage diagnoses¹⁵.

Taking this demonstrated achievement as a reference, a good screening in the European Union can increase the number of patients diagnosed in Stage I from 50,000 to 180,000 patients. That is an additional 130,000 patients every year who would benefit from a chance of survival of 90%.

In the United States, studies have shown that screening programmes reduced the mortality from colorectal cancer between 37%¹⁶ to 53%¹⁷.

¹³ Winawer S, Fletcher R, Rex D, Bond J, Burt R, et al. Colorectal Cancer Screening and Surveillance: Clinical Guidelines and Rationale-Update Based on New Evidence. *Gastroenterology* 2003;124:544-560

¹⁴ American Cancer Society, May 2018 - <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html>

¹⁵ Dutch Ministry of Public Health, 18 January 2019 - <https://www.rivm.nl/bevolkingsonderzoek-darmkanker-voor-professionals/achtergrond-en-ontwikkelingen/feiten-en-cijfers>

¹⁶ Surveillance, Epidemiology, and End Results Program. SEER Stat Fact Sheets: Colon and Rectum Cancer: Centers for Disease Control; 2014

¹⁷ Zauber AG, Winawer SJ, O'Brien MJ, Lansdorf-Vogelaar I, van Ballegooijen M, Hankey BF, Shi W, Bond JH, Schapiro M, Panish JF, et al. Colonoscopic polypectomy and long-term prevention of colorectal-cancer deaths. *N Engl J Med*. 2012

Setting up a screening programme

There is no one-size-fits-all solution. In every member state the set-up of the healthcare system, its organisation and reimbursement systems, are different. There are cultural differences among the citizens, so it is important to assess all these unique characteristics when establishing a screening programme.

The screening agency and the participating partners will need to take into account their current screening programme, past failures, resources (finances, organisational structures, available trained staff, IT systems), communication, personal data access and associated legal constraints, cancer registry systems and access, reliable lists of people and addresses, laws associated with access to individuals, privacy issues, etc. It is a complex task and thus requires robust preparations.

1. Time frame

It will take several years of preparation to launch a high-quality screening programme, and should not be rushed. Because of the nature and the scale of the programme, preparation is key, and that includes generating insights into potential levers and barriers, and setting up pilot projects before officially launching the real programme. Involving professional staff and patient associations in the planning demonstrably contributes to better performance and future success.

2. Testing and diagnostic technology

There are currently several types of approaches and tests used.

The fecal immunochemical test (FIT) is the test currently considered appropriate. FIT is a simple test which can be done quickly and easily, and has a good degree of success. FIT requires only one stool sample, which increases participation rates over the older guaiac FOBT test. The accuracy of quantitative FIT for detection of colorectal cancer will depend on various clinical and logistic issues. The FIT test has performance characteristics of 79% sensitivity and 94% accuracy¹⁸. FIT has been widely adopted and is generally applied to 50 to 74-year old with biennial (every two years) screening.

Blood tests have been in development for many years and if they were to prove successful they would make testing even easier. Both the US and Switzerland have already approved blood tests for colon cancer, but these tests are not currently as effective as the stool FIT tests.

In the United States and Germany, citizens in the target population are directly invited for a colonoscopy, but Germany is now shifting to FIT tests too.

Flexible sigmoidoscopy is a simpler and more attractive primary screening modality to that of colonoscopy and its effectiveness has been confirmed by four randomised clinical trials¹⁹. It uses a small flexible scope to view the lower part of the colon. Because the test only looks at the last one third of the large intestine (colon), it will miss some cancers that are higher in the large intestine. It is unclear whether it is significantly better than a FIT test.

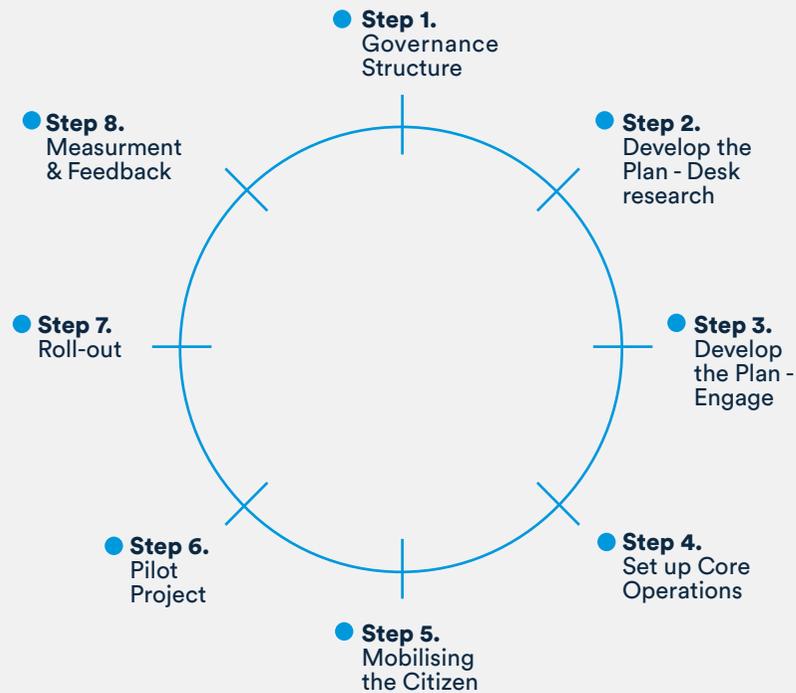
Citizens with a positive FIT or other test should undergo a colonoscopy for a full diagnostic. The capacity for colonoscopy is a critical issue in any screening programme, and citizens with a positive test should be able to have their colonoscopy within a month after receiving their test results. Ensuring this capacity for colonoscopy is essential to the success of the programme.

¹⁸ Lee, Jeffrey K et al. "Accuracy of fecal immunochemical tests for colorectal cancer: systematic review and meta-analysis" *Annals of internal medicine* vol. 160,3 (2014)

¹⁹ Holme, Øyvind et al. "Effectiveness of flexible sigmoidoscopy screening in men and women and different age groups: pooled analysis of randomised trials" *BMJ (Clinical research ed.)* vol. 356 i6673. 13 Jan. 2017, doi:10.1136/bmj.i6673

How to set up a successful screening programme

Based on the experience of several successful programmes previously implemented, a screening programme can be developed using the following eight major steps.



A screening programme is complex, and it requires the input from many experts from different backgrounds.

It requires the involvement of the key stakeholders: ministries of health, gastroenterologists and surgeons, oncologists, nurses and hospitals, but it also requires tight collaboration between database managers, clinical laboratories, individual citizens, primary care professionals and the screening agency. It will need expertise in areas as diverse as IT management, medical research, psychology, epidemiology. We will examine each of these steps in more detail. Furthermore, it also requires the tight collaboration of the key partners such as the cancer registry, specialists and hospitals to agree on a common classification of lesions, to allow for effective monitoring and effectiveness measurement once the programme is in place.

Step 1 Governance Structure

Steering Committee

- Ministry of Public Health (national, regional)
- Screening agency
- Oncologists/endoscopists
- GP association
- Hospitals
- Cancer Registry
- Patient organisation
- Insurance companies/sick funds

Operations Committee

- Information technology/databases
- Finance
- Research
- Legal
- Testing
- Laboratory engagement and analysis
- Quality Assurance
- Training
- Awareness building
- Patient Communication

Step 1 – The Governance

A good screening programme needs the involvement of all the relevant stakeholders: the screening agency (or agencies), the cancer registry, the different political levels of health (local, regional, national), the relevant patient organisations, oncologists and colonoscopists, hospitals, GPs, diagnostic laboratories, pathology labs, insurance companies and sick funds.

There is no one-size-fits-all approach to governance. This will depend on the way the healthcare system is set up nationally or regionally, yet successful programmes have testified to thorough involvement of all stakeholders from the start.

Some countries set up a Steering Committee that will develop the broad plan for the programme and that will supervise its execution. Typically, the Screening Agency acts as the coordination office of the Steering Committee.

The Steering committee will supervise the activities of the Operations Committee responsible for all operational aspects of running the screening programme. They include the IT and database management experts, legal and financial expertise, research, communications, lab testing experts, etc.

If possible, a third Expert Committee could be set up, with identified specialists in epidemiology, international screening, health psychology, marketing or health economics.

The Steering Committee will determine the meetings cycle, the finance and the engagement with other stakeholders and with the political sponsors.

Sustained funding is critical, as well as a clear discussion among the regional and national authorities about the benefits of investments and the value of savings. The initial set-up of a screening programme will possibly require a higher investment than in subsequent years. Since screening programmes may take more than five years to fully develop, it requires a strong political commitment to invest without having results in the same political term. From this perspective, it makes sense to involve all political parties to participate, and to obtain government approval even in case of political changes. A population-based screening programme can only be cost-effective when the participation rate among the population is high. Therefore, excellent governance and sufficient funding is critical. Screening programmes with insufficient power risk missing the objective of saving lives and money. Social inequalities should be taken into account in order to decrease any participation barriers related to income and religion.

Step 2

Develop The Plan - Desk Research

Design the ideal screening programme

- Number of patients
- Capacity for laboratories
- Capacity for colonoscopy
- Capacity for treatment
- Best practices other countries

Map current situation

- Capacity for laboratories
- Capacity for colonoscopy
- Capacity for treatment

Identify all stakeholders and how they can contribute

- GPs
- Oncologists
- Endoscopists
- Hospitals
- Local primary care centers
- Patient organisations
- Minority associations
- Religious groups
- Employers
- Unions

Draft Plan

- Set realistic objectives and expected outcomes
- Determine financial investments in capacity
- Determine financial investments in awareness and screening campaign
- Determine time frame and milestones
- Establish dashboard
- Set scientific and research goals

Step 2 – Develop The Plan

Step 2 sets out the broad framework of the plan. It looks at the total patient population to be screened, where they are located, how they are stratified (geographically, socially). It assesses what would be necessary to screen all patients on the assumption of a high participation rate. It measures the existing capacity for laboratories to perform the tests and offer results within an acceptable time frame. It evaluates the required and existing capacity for colonoscopy, and for treatment, based on simulations of the expected number of patients to be identified.

This step is critical because it will show the gap between the current and the desired situation, and where additional funding is needed to increase screening capacity. The cost-effectiveness of colorectal cancer screening programmes increases with the participation level, thereby justifying the investment.

The capacity needs to be adequate to meet the response, it can be increased to meet anticipated needs and the referral rate from FIT can feed the growing available capacity.

All colonoscopies need to be undertaken by accredited colonoscopists who have their Adenoma Detection Rate (ADR - a quality standard), withdrawal rates, caecal intubation rate and interval cancer rates monitored and reviewed (for screening activity). Histology services need appropriate quality assurance monitoring and referral facilities must be available for difficult cases. All this needs to be assessed in advance, and - if necessary - investments in training, certification and infrastructure need to be made.

The quality of CRC surgery needs to be known and monitored. The European Cancer Organisation (ECCO) has developed clinical guidelines for the “Essential Requirements for Quality Cancer Care in Colorectal Cancer”²⁰. The ECCO expert group recommends that “for a hospital to be considered as a CRC centre it should manage at least 100 new CRC cases a year”. Because there is a clear link between overall survival and the specialisation of the hospital, we would recommend all patients be treated in specialised CRC centres.

It is also important to identify and involve the different citizen groups that might be relevant to provide insights and to share the importance of screening: religious organisations, employers and unions, social centres, minority groups, etc. The selection and choice of these stakeholders will vary from country to country.

As a following preparatory step, the broad framework can be summarised as: what are the milestones, what should be achieved when, and what scientific and medical research goals should we add to this programme?

²⁰ ECCO essential requirements for quality cancer care: Oesophageal and gastric cancer, Critical Reviews in Oncology/Hematology, Volume 122, 2018

Step 3

Develop The Plan - Engage

Engage with key stakeholders

Roundtable/Congress on screening

- Present core plan
- Identify potential barriers
- Identify key drivers of success
- Determine the role and importance of each stakeholder

Identify and recruit external partners

- Health psychology expertise
- Advertising agency
- Social media agency
- External laboratories

Final Plan

Adjust existing plan where needed based on insights from the above interactions

Contingency Plan

Ensure that there is crisis management plan if things go wrong (start from worst case scenario)

Step 3 – The Plan

As a next step, the external partners should be involved. All identified stakeholders should be invited to a large round table meeting in order to have in-depth discussions about the plan.

It is important to discuss barriers and drivers because they will be critical in obtaining success for the programme. The more insights, the better the outcomes. Furthermore, it helps to mobilise all stakeholders behind the project. Based on an initial analysis, the major barriers for screening success are at the level of the government and the citizen, and to a lesser extent, the general practitioner.

Potential barriers at the government level

- **Regional/national responsibilities:** prevention is a regional responsibility in several Member States with regional funding, and the potential savings in the healthcare system of a good screening programme are made at the national level in the “curative” healthcare budget. This lack of coherence is possibly the single most important barrier to implement screening in many EU member states. So it is critical to make a clear national “business case” for screening so that all authorities see the value of investments and collaborate and, if needed, co-invest in screening programmes.
- **Capacity:** conducting a massive screening programme among all people older than 50 requires sufficient follow-up capacity to conduct colonoscopies to deal with the positive tests, and then later with sufficient capacity for surgery and treatment. A multi-stakeholder dialogue and a political willingness are needed to make this work. Based on existing epidemiological data, any country can easily calculate the capacity needed to detect and treat patients, and organise for it.

Potential barriers at the citizen level. Among citizens, many factors play a role in not participating in screening programmes

- **Psychological** - ranging from the completely self-assured sense of invincibility (“I have no symptoms, and I feel good, so why would I do all this?”) to the ostrich-strategy (“what I don’t know, I don’t have to fear”). Apart from those attitudes of denial, the major barriers are feelings of distaste associated with the requirements of providing stool samples, the misguided fear of the colonoscopy (painful, uncomfortable, embarrassing ...).
- **Comorbidities** - citizens suffering from other disabilities and diseases, some associated with age, some associated with previous gastrointestinal surgery“
- **Socio-economic** - costs related to treatment, religion, ethnicity-related taboos
- **Practical** - reactions such as “this is not the right moment”, access to services (transport, screening appointment, etc).

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Potential barriers at the GP level

GPs are essential to the success of the programme, and they play a major role in raising awareness of the screening tests. They still need to make time with the patient to discuss the risks of colorectal cancer, especially in countries with no formal population-based screening, GPs should play a role in encouraging every patient older than 50 to carry out a CRC test. GPs should be kept informed, provide encouragement and support. Patients often use their GP as the only reference with regard to their health, so “since my GP did not bring up the need for screening, I assumed it was not really important”, is also used as an excuse not to undergo screening. Obviously, GPs play an important role in prevention, by highlighting the risk factors related to lifestyle choices such as smoking, physical inactivity and alcohol consumption.

Identify and recruit external partners

Because of the size and the required expertise of such a project, it is essential to work with qualified external partners to help set up the programme: database management companies, advertising agencies, social media specialists, health psychology experts, direct mail companies, etc. As the selection, procurement and contracting process can be very long, it is essential to start in good time.

Step 4 Set up Core Operations

Operational Center

- Programme fully financed
- Operational staff
- Database
- Quality assurance system
- Test (dry run) the functioning of all logistics

Step 5 Mobilizing The Citizen

Focus group sessions

- Citizens (men/women)
- Minority groups
- GPs/primary care

... in preparation to understand practical and psychological drivers and barriers. Is needed as input for communication agencies.

Communications campaign

- Broad advertising campaign on the importance of participating in the screening campaign
- Website with call centers for further information
- Posters and leaflets are primary care centers
- Test tone and style of invitation letters with citizen panel
- Test tone and style of positive result test with citizen panel

Step 4 – Set up of Core Operations

Once the plan has been approved, the operational backbone should be put in place and thoroughly tested. The setting up of pilots is important. The programme must run smoothly before embarking on a recruitment campaign. Ensure that there is sufficient clinical capacity before actual recruitment and ensure there is a good approach to citizen participation and the legal requirements of 'Informed Consent'. Health literacy evaluation criteria should be included in the programme's communication plan.

Step 5 – Mobilising The Citizen

Setting up a population-wide awareness campaign needs an appropriate amount of investment and understanding of what will mobilise citizens to participate in screening. People who feel no symptoms may not feel sufficiently motivated to participate, even if they are in the at-risk population. Consequently the campaign imagery and messages should be sufficiently emotionally appealing and rationally persuasive to impel citizens to act. We would recommend organising focus group sessions with various sub-sets of the population to understand their different perspectives, and to tailor messages to them.

The communications campaign will also need to rely on multipliers and amplifiers: institutions and individuals who can share the core information with their members and followers. These can include patient organisations, health institutions, sick funds, unions, employers, bloggers, vloggers, and celebrities.

Communication materials may include video, social media content, media relations, infographics, posters and fact sheets to be displayed at the GP office, postcards, podcasts, blogs, a quiz, etc. The best campaigns form an integrated and coherent set of motivational, fun, and informative messages.

Not only the campaign message needs to be tested, but also the tone and style of the letters that the citizens will receive at home. This will include the letter that is sent to confirm a positive test, inviting the recipient to participate in a colonoscopy. In some countries, more than 20% of patients with a positive test do not take the further step for a colonoscopy, possibly because the letter is not alarming enough. Other reasons are sedation or the practical difficulty of making an appointment.

It is also critical to test if/how many repeat letters would work, and how the local GP can be integrated in the contact of the citizen. This should also be looked at from a legal perspective. Too many repeat letters may be counterproductive too and even be considered as bullying. In Canada, tests have been made with telephone follow-up, which demonstrated better results than by letter, but obviously at a higher cost²⁰.

Step 5 Mobilizing The Citizen

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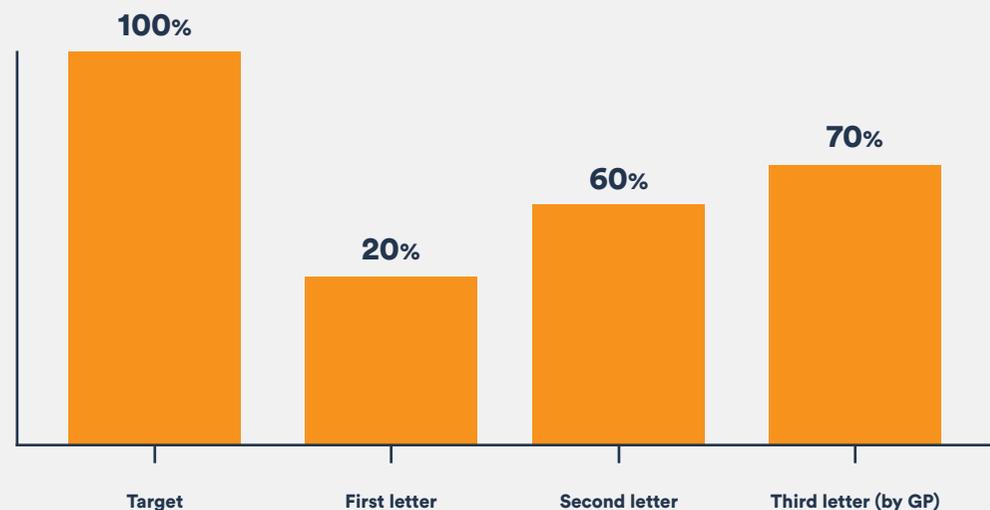
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The role of the GP and Patient Organisations

Even if most screening programmes communicate directly from the Ministry of Health to the individual citizen, all GPs should be aware of the initiative and fully endorse its objective and process. The number of steps between the reception of the screening kit, and the completion of the test should be as short as possible and preferably done the same day. In some countries, the central invitation letter is sent on behalf of the citizen's GP, which results in a higher participation because of the familiarity with the sender. This can of course only be done in countries where the government is aware of which GP treats which citizen, and when the GP is in agreement for his or her name to be used.

Apart from the GP, other healthcare stakeholders could be mobilised, and those include patient organisations, who increasingly act as “patient navigators”, to help patients navigate the healthcare system. Total patient support, which can include patient navigation, has emerged as an important component of many CRC screening efforts. The most successful programmes use patient navigators to reduce logistics barriers, address cultural issues, and encourage participants to undergo screening^{22,23}. These services can be offered by local colorectal cancer patient organisations.

Participation rate



Make sure GP is kept informed on the results of her/his patients, so that she/he can follow-up with patient.

Notifying the GP that some citizens have not responded is not needed. The GP can identify which of his patients in the target population she has not been copied in the results.

Alternatives are telephone calls by a call center. This is highly effective but also more expensive.

²¹ <https://www.jabfm.org/content/31/6/857>

²² Myers RE, Bittner-Fagan H, Daskalakis C, Sifri R, Vernon SW, Cocroft J, Dicarolo M, Katurakes N, Andrel J. A randomized controlled trial of a tailored navigation and a standard intervention in colorectal cancer screening. *Cancer Epidemiol Biomarkers Prev.* 2013;22:109–117

²³ Ritvo PG, Myers RE, Paszat LF, Tinmouth JM, McColeman J, Mitchell B, Serenity M, Rabeneck L. Personal navigation increases colorectal cancer screening uptake. *Cancer Epidemiol Biomarkers Prev.* 2015;24:506–511

Step 6 Pilot Project

Start in a few municipalities

- Check the interaction between information systems, databases, letters and participation rates, interaction with GPs, problems at lab level, etc.
- Check communication materials, interactions with website and call center
- Adjust programme based on learnings

Step 7 Roll-out

Important steps

- A slow, phased roll-out to identify start-up problems
- Invite a mixed age group
- Monitor key indicators on a short-cycle basis

Step 6 – The need for pilot projects

Because of the nature of such a large and intricate programme, it is critical that all the various aspects are duly tested before the official launch. All the systems and that includes the interaction between the database system, the citizen response, the logistics aspect of sending back the sample, the lab tests and analysis, the response letter to the citizen, and his/her follow-up with data capture and storage in every step of the process, whilst keeping the GP and the cancer registry involved. This is by no means an easy task. Pilots may seem to delay the process, but at least they will guarantee that the project is suitable to be launched nationwide.

This also includes testing helpline services to help address questions and problems encountered by invited subjects, especially after following the diagnosis of a high-risk adenoma or cancer. Many patients are lost between a positive test and the colonoscopy. It is critical that call centre staff are prepared for the most basic type of questions and that simulations are conducted to test readiness and responses.

Step 7 – Roll-out

Some countries prefer to have a staggered roll-out, expanding geographically or by age group, adding groups of citizens as the programme progresses.

Step 8 Measurement & Feedback

Measurements

- Keep track of participation rates
- Monitor referrals for colonoscopy
- Measure effective colonoscopies

Feedback

- Capture citizen insights
- Follow-up with key stakeholders to understand possible improvements in the process
- Track operational fluidity and adjust where needed

Step 8 – Measurement and feedback

Successful programmes have a good system of process monitoring and outcome capture. Since GPs get the results of all their patients who participated in a screening programme, they can infer from this information who among their patient base never submitted their test, and have a conversation with them during their next visit.

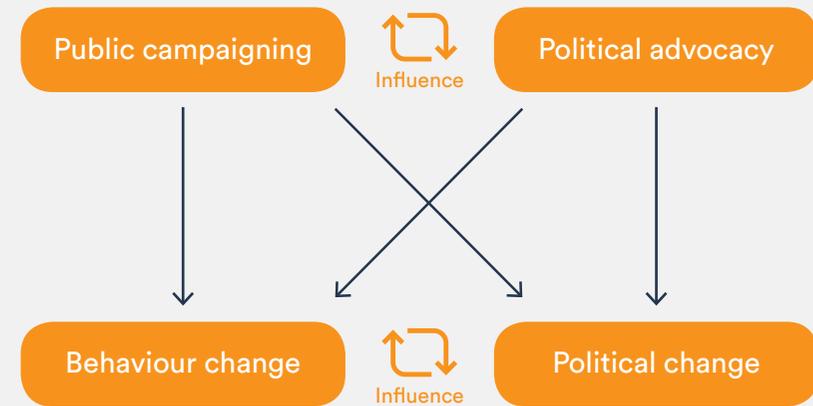
Best Practices

Lessons from breast cancer screening campaigns

Breast cancer screening campaigns have been quite successful in the past decade because of a high level of participation. Even though some now question the relevance of the campaigns, it is the actual mobilisation power in which we are interested. The following overview demonstrates the impact and importance of having a combined public and political campaign. The public campaign will raise awareness of the issue, ensure its relevance to the target audience and make it a frequent topic of conversation. The “political advocacy” will make sure that it also reaches the political agenda and the promises on paper also become a fact in the real world. Behavioural change requires removing emotional barriers and increasing internal motivation for cancer screening. These complex, interrelated goals have been achieved by breast cancer campaigners, who have persuaded significant numbers of women to undergo an “unpleasant” screening process. laboratories, individual citizens, primary care professionals and the screening agency. It will need expertise in areas as diverse as IT management, medical research, psychology, epidemiology. We will examine each of these steps in more detail. Furthermore, it also requires the tight collaboration of the key partners such as the cancer registry, specialists and hospitals to agree on a common classification of lesions, to allow for effective monitoring and effectiveness measurement once the programme is in place.

Campaign principles: Public campaigning and behavioural change

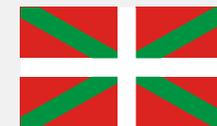
- Have a non-medical narrative and build a social movement (socio-demographic & communication barrier)
- Education is a pitfall (motivational barrier) - people have to understand and they have to be reached through mainstream media channels that are not always accessed by some groups in society
- Enablement of personal interaction (psycho-social barrier) - make sure there is the possibility to discuss face-to-face (doctor, nurse, ...) or to have a conversation over the phone or via social media
- Find the injustice (empathy barrier) - the breast cancer campaigners used their “feminine” community as having a “right to screening”.



- Celebrity catalysts (psycho-social barrier) - the use of celebrities worked very well, but appears to be more difficult for the taboo context of colorectal cancer
- Broader business support (barriers of scale, as well as resources) - some companies put their marketing weight and international presence behind a campaign for women’s rights for screening.
- Cumulative effect (backfire effect, health literacy & educational barriers)
- US to UK to EU - the breast cancer campaign started in the United States, then moved to the UK and then to mainland Europe.
- “Campaign before system” vs “system before campaigning” (credibility & consistency barriers) - this is a topic of debate. The conclusion is that it is better to raise awareness of the issue and the need for screening well before the system is in place. To be high on the public agenda will only increase the resources and the seriousness with which a screening campaign is able to be organised and implemented.

Campaign principles: Political advocacy and political change

- Have an academic community advocate with you (practical and credibility barrier) - medical insights and benefits are critical to persuade the political world
 - Make science accessible & understandable (communication barrier) - turn complex scientific publications into digestible communication messages
 - Confront political barriers through activity - organise events which are visible and at places that will generate public and media attention. These can also serve as fundraisers at the same time.
 - Be ready to act politically when you ignite an issue (organisational barrier) - once in public, know what you want, and how to ask for it, and how you will organise for it.
 - Activate a sub-set of the community (media-cycle barrier) - use a small but vocal group to start sharing their information and the need for political change through social and other media.
- Unblock the number-crunchers (barrier of political risk) - build your business case, make sure you can demonstrate how society will benefit from it, and not only medically
 - Go grand (resource and access barrier) - make it a big project in line with the severity of the issue.
 - Build a system, not just a single voice (organisational barrier) - make sure people across different communities are mobilised. The issue affects society, not only little groups here and there.



The case of the Basque region of Spain

Key Facts

Population: region-wide (586,700 people)

Target group: 50 to 69 year old

Test used: quantitative FIT

Participation Rate: 72.3%

Colonoscopy Rate: 95%

Roll-out commenced/complete: 2009/2014

General Description

The Basque region of Spain has shown amazing progress over the past decade, increasing the participation rate of its citizens to 72%, which is one of the best achievements in the world.

This can be explained by the involvement of all primary care professionals and the trust of the population in the Basque public health system, but should also be attributed to the strong commitment from the team behind the programme, and the way it was thought through and set up. From the start all stakeholders were involved, and the citizen databases were linked with medical databases and the cancer and mortality registries, allowing for the better identification of the eligible population and obtaining follow-up data.

All citizens who receive a positive test are able to have a colonoscopy within 30 days after they receive their test results.

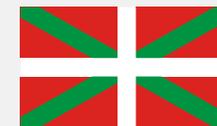
Key Points

- The process was well structured, with tight follow-up for quality assurance
- Robust and accredited training for all primary care staff (involving, convincing, informing about the results of previous invitations and established protocols), ensured that the whole programme also has impact within the medical community



- Participants deliver kits at the local primary care center without an appointment, and sent to laboratories for a result in 24 hours.
- Reminder letters are sent to non-participants within 45 days
- The high level results of the programme are published and widely communicated to healthcare professionals to ensure further collaboration and implication. One article²⁴ concludes that patients diagnosed thanks to the screening programme have a 90.1% survival rate as compared to 60.5% among patients diagnosed outside the screening programme.

²⁴ Idigoras Rubio, I. Arana-Arri, Portillo, I, E. Bilbao, Martínez-Indart L, I. Imaz-Ayo, N. et al. Participation in a population-based screening for colorectal cancer using the faecal immunochemical test decreases mortality in 5 years. I. Eur J Gastroenterol Hepatol. 2018 Dec 12. doi: 10.1097/MEG.0000000000001338.



- The non-participating part of the population is primarily from a deprived background²⁵, demonstrating again the difficulty to reach some parts of the community. Work has already begun on a project to try to reach them.

The cost-effectiveness analysis of the Basque programme was recently published. The economic evaluation showed a screening intervention with a major health gain that also produced net savings when a long follow-up was used to capture the late economic benefit²⁶.

	1-yr Survival	3-yr Survival	5-yr Survival	p-Value
Non-invited	87.6%	73.4%	66.9%	>0.001
Non-participants	83.1%	66.7%	60.5%	
Interval cancer	91.2%	79.0%	76.3%	
Screen detected	97.8%	93.4%	90.1%	

The significant 23.1% greater 5-year survival of the participants in the Basque colorectal cancer screening programme, suggests that the incidence and mortality rates of colorectal cancer will decrease in the near future. A high participation rate is essential to achieve health benefits, regardless of the type of participation.

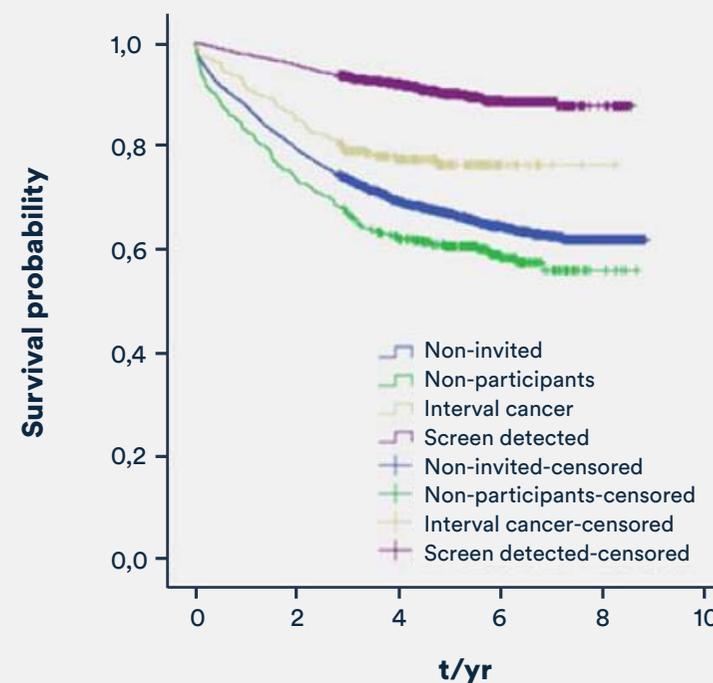


Figure 1 Kaplan – Meyer survival curve, comparison of survival rates between different colorectal cancer groups: non invited, non-participants, interval cancer and screen detected.

²⁵ Hurtado JL, Bacigalupe A, Calvo M, Esnaola S, Mendizabal N, Portillo I, Idigoras I, Millán E, Arana-Arri E, Social inequalities in a population based colorectal cancer screening programme in the Basque Country, BMC Public Health 2015. DOI:10.1186/s12889-015-2370-5

²⁶ Arantzazu Arrospide et alii. - Cost-effectiveness and budget impact analyses of a colorectal cancer screening programme in a high adenoma prevalence scenario using MISCANColon microsimulation model, BMC Cancer, 2018



The case of The Netherlands

Key Facts

Population: nationwide (4.2 million people)
Target population: all citizens between 55 and 75
Test used: FIT
Participation rate: 73%
Colonoscopy rate: 82,8% of patients with an unfavourable FIT test
Gradual roll-out between 2014 and 2019
Communications: designated website for citizens and segmented for all professionals with the inclusion of all protocols, contact addresses, education backgrounds, etc.

General Description

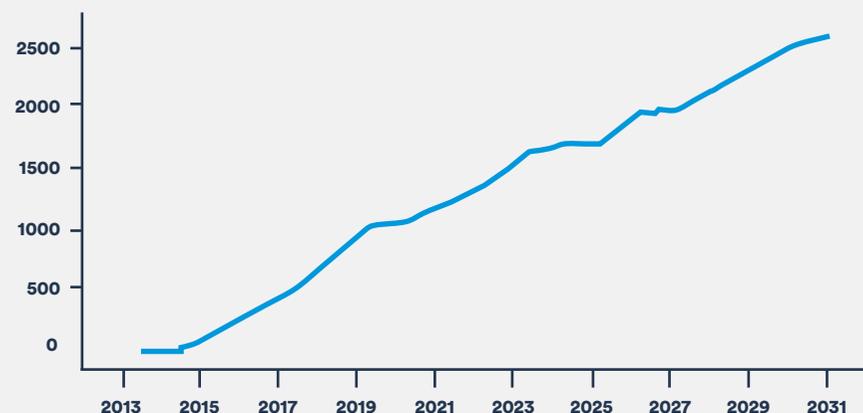
The Dutch Ministry of Health set up a very clear governance structure to ensure capacity and quality execution at every level. They also added a workstream on “Innovation & Science” with the objective to get better insights thanks to the screening programme but also the task of monitoring any new technology that might be of use for the screening programme. The whole process took a long time to set up, with the first pilot projects started in 2006, followed by a feasibility study in 2009, initial preparations in 2011 and the actual roll-out to achieve full population screening by 2019 started in 2014.

The Dutch government has also set clear goals. They expect their screening programme to result in 2,400 lives saved per year by 2031 as compared to today (see graph). They estimate the cost of the screening programme at 2,200€ per life year gained.

The invitation letter was sent to people in four languages, depending on how they were registered: Dutch, English, Arabic and Turkish.

More than 70% of citizens have participated in the screening test, which is the highest level globally for a nationwide programme. Before the screening programme, 17% of patients were detected in stage I, and thanks to the screening programme, this number has increased to 48%²⁷. This means that the lives of thousands of patients have been saved, and costly surgery and chemotherapy avoided. These are only initial results from the recently implemented programme.

It is also critical to have systematic monitoring and outcomes measurement so that the case for further screening can be made.



GRAPH - Targets: Number of lives to be saved by year of CRC screening (source: Dutch Ministry of Public Health)

²⁷ Dutch Ministry of Public Health, 18 January 2019 - <https://www.rivm.nl/bevolkingsonderzoek-darmkanker-voor-professionals/achtergrond-en-ontwikkelingen/feiten-en-cijfers>



Key Points Identified

It takes time to get all the stakeholders on board and to develop the pilot projects.

Of all the patients with a positive FIT test who wanted a follow-up discussion before deciding whether or not to accept a colonoscopy, 97.6% decided in favour, which emphasises the importance of having a conversation with patients.

The Netherlands team learnt from many existing programmes and visited many sites. They copied much of the programme in England but used FIT from the start. They had procurement issues for the test, but these were rapidly solved.

The Dutch system set up a clear governance structure. Under the supervision of the Ministry of Public Health, and the Institute of Public Health, a Programme Committee supervises the activities of six quality workstreams, which are responsible for: Quality Standards of Colonoscopy, Quality Standards of Pathology, Quality Standards of CT-colonography, Innovation & Science, Communications, and Quality, Capacity, Monitoring & Information Management.

Governance Structure Colorectal Screening



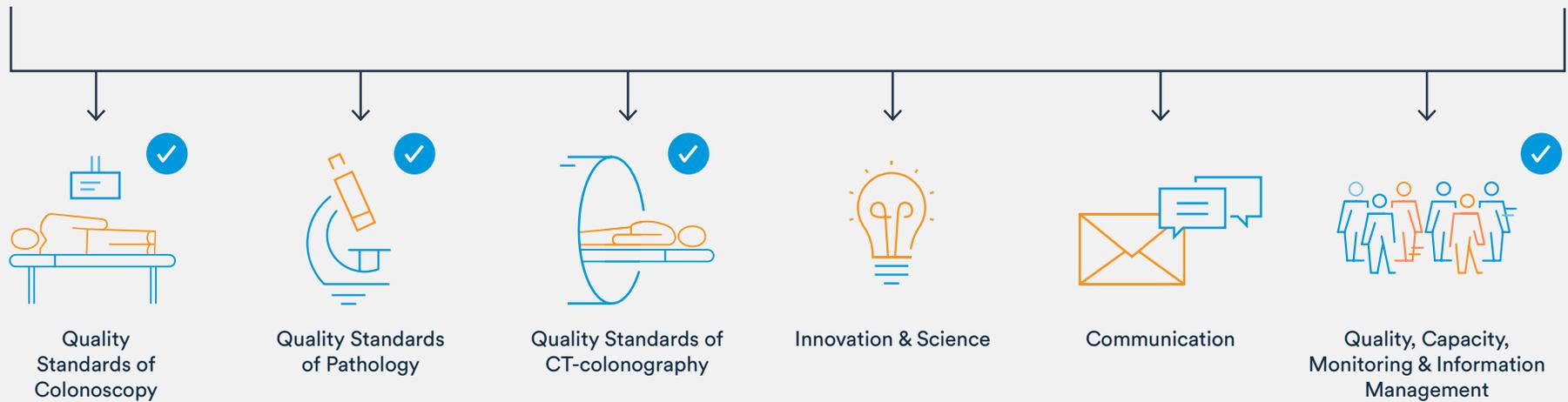
Ministry of Health, Well-Being and Sports



Institute for Public Health and Environment, Centre of Population Screening



Screening Programme



The case of Slovenia



Key Facts

Population: nationwide (600,000 in age group)
Target population: all citizens between 55 and 74
Test used: FoBT
Participation rate: 64,63%
Colonoscopy rate: 92%
Roll-out: since 2009
Communications: designated website for citizens

General Description

All persons aged between 50 and 74 years covered by compulsory health insurance in Slovenia have the right to free participation in the 'Svit' programme. Around 600,000 citizens are invited to participate, according to a pre-defined scheme, in the period of two years for each screening round.

All citizens are first invited to participate in the screening programme, and asked to complete and return a signed statement of participation to the central unit of the screening programme. A test kit for two faecal samples is sent by mail to the persons who responded. All faecal samples are analysed in one central laboratory thereby ensuring a simultaneous analysis of a large number of samples to a constant quality standard. The results of the analysis are sent by mail to the person tested and his/her general practitioner. Persons with a positive result are referred for colonoscopy. Colonoscopies are performed in accredited colonoscopy centres.

Information for citizens is very accessible and easy to understand. A central website has all the programme information, including in English. The system offers a call center in case of questions. Non-responding patients receive repeat messages and chemotherapy avoided.



Some key elements of the programme include:

- Standardised documents: invitation to screening, information material on colorectal cancer (booklet), instructions for collecting faecal samples, laboratory result of faecal samples analysis, pre-and post-colonoscopy questionnaire;
- Instructions for colonoscopists and histopathologists;
- Doctor's referral for histopathology and colonoscopy result;
- Information to general practitioners on their patients with positive and negative result of FOBT test, information to general practitioner on their patients who did not respond to the programme or did not return faecal samples or did not respond to the invitation to colonoscopy;
- Monitoring statistical results of target population response by health regions up to the municipal level twice a year;
- Annual professional quality audit in colonoscopy and histopathology centres;
- Review of all the procedures included in the treatment of patients who participated in the screening programme and were diagnosed with colorectal cancer;
- Central information system, legal basis for programme implementation;
- Regular professional trainings for programme providers.



The response

The screening programme achieved a 64,63% participation rate (59,38% men, 69,60% women), with 5,9% of citizens having a positive test result, of which 92% accepted a colonoscopy. Today, 49% of patients are identified in stage I, which is a major success.

Since 2011 the incidence of colorectal cancer in Slovenia starts to decrease. The assumption is that this is mainly influenced by extensive removal of precancerous lesions during screening colonoscopies. Earlier cancer diagnosis influenced the survival rates. Comparing period 2010-2014 to 2005-2009 there was significant improvement of five-year net survival of men diagnosed with colorectal cancer.

The challenge now, is to increase the overall response rate.

Template of invitation letter

_SO_NAAM
PO box _SO_POSTBUSNR
_SO_POSTBUSPOSTCODE _SO_POSTBUSPLAATS
t _SO_TEL
f _SO_FAX
_SO_WEBSITEADRES
_SO_EMAILADRES

> Return address: Kamerlingh Onneslaan 6, 8218 MA Lelystad

_CLIENT_NAAM
_CLIENT_ADRES
_CLIENT_POSTCODE _CLIENT_WOONPLAATS

Date of birth: _CLIENT_GEBOORTEDATUM
_SO_PLAATS, _DATUM_VANDAAG
Re: invitation bowel cancer screening programme

_CLIENT_AANHEF,

We would like to invite you to the bowel cancer screening programme.

The reason for the programme

Bowel cancer is a common disease and a serious one. Between 4 and 5 people out of every 100 will get bowel cancer at some point during their lifetime. Most people with bowel cancer are 55 years or older. Screening enables doctors to detect and treat cancer at an early stage, sometimes even before the disease has actually developed. In the longer term, this can help to prevent 2,400 deaths from bowel cancer each year.

The screening programme is for all men and women aged 55 to 75. They receive an invitation every two years.

You can carry out the procedure yourself at home. This envelope contains a leaflet about the bowel cancer screening programme, a reply form, a self-sampling test kit, a bag and a return envelope.

What happens during the screening?

The invitation is accompanied by a self-sampling test kit. The sampling tube has a green cap with a stool sampling stick attached. You take samples at four different places in your stool (poo). Only a tiny amount of stool material is needed to perform the test properly. The instructions include a step-by-step description of how to perform the self-sampling test properly.

Send the tube and the complete questionnaire in the return envelope to the laboratory. There, your stool will be tested for traces of blood. These cannot usually be seen with the naked eye. Blood in your stool may be due to bowel cancer, but there are also a number of other possible causes. A follow-up examination (colonoscopy of the large intestines) is needed to establish this.

The results

You will receive a letter with the results sent to your home address within one to two weeks.

Costs

Participation in the screening programme is free of charge. The follow-up examination (intake interview and colonoscopy) is not part of the screening. The costs of these tests are covered by your health insurance. You may be obliged to pay the costs, or a part of them, yourself. This depends on your excess

amount and how much you have already used of this. For questions about this, please contact your health care insurer.

Whether you participate or not is for you to decide

Participation in the screening programme is voluntary. Whether you participate or not is for you to decide. The information in the leaflet can help you make a decision.

When is it better not to take part?

The leaflet explains when it would be better for you not to participate. This is something you can also discuss with your GP. Are you currently experiencing symptoms that might be related to bowel cancer? If so, first consult your GP. If you decide not to participate, we would still ask you to answer Question 1 and Questions 5 to 7 on the form and to send it back in the return envelope.

Sending your details online

You can also complete the questionnaire online. Go to _SO_WEBSITEADRES and click the button 'Mijn bevolkingsonderzoek'. To log in, you need your DigiD. You can also use 'Mijn bevolkingsonderzoek' to opt out of the screening programme.

Further information

The leaflet "Bowel Cancer Screening Programme" gives you more information about the screening programme. You can also read more on www.bevolkingsonderzoekdarmkanker.nl. This website also contains answers to Frequently Asked Questions and a short video called 'Bevolkingsonderzoek darmkanker'.

Do you have questions about your health? Please contact your GP. For answers to other questions, you can call the information line of the _SO_NAAM, _SO_TEL (Monday through Friday, from 9 a.m. to 5 p.m.). Our staff will be happy to help you.

Kind regards,



_SO_VTW_TITEL _SO_VTW_VOORLETTERS _SO_VTW_TUSSENVOEGSEL
_SO_VTW_ACHTERNAAM
_SO_VTW_FUNCIE

Attachments:

- leaflet 'Bowel cancer screening programme'
- instructions for use
- questionnaire
- tube
- bag
- return envelope

Template of positive test letter

_SO_NAAM
PO box: _SO_POSTBUSNR
_SO_POSTBUSPOSTCODE
_SO_POSTBUSPLAATS
t: _SO_TEL
f: _SO_FAX
_SO_WEBSITEADRES
_SO_EMAILADRES

> Return address: PO Box _SO_POSTBUSNR, _SO_POSTBUSPOSTCODE
_SO_POSTBUSPLAATS

_CLIENT_NAAM
_CLIENT_ADRES
_CLIENT_POSTCODE _CLIENT_WOONPLAATS

image: _CLIENT_KIX

_SO_PLAATS, _DATUM_VANDAAG
Re: result bowel cancer screening programme

Date of birth:
_CLIENT_GEBOORTEDATUM

_CLIENT_AANHEF,

You have recently taken part in the national bowel cancer screening programme.

What was the result?

Blood has been found in your stool.

What does this mean?

Blood in the stool does not necessarily mean that you have bowel cancer. It may be due to bowel cancer or polyps, but there are a number of other possible causes. This is not yet known. To find out if you have bowel cancer or polyps, you need to go to hospital for further examination. It is up to you to decide whether you want to have this follow-up examination.

What does the follow-up examination involve?

The follow-up examination consists of an internal surveillance examination, also known as a colonoscopy. You can read more about it in the enclosed leaflet 'If blood is found in your stool'. To see if a colonoscopy is appropriate and/or possible in your case, you will first be invited to an intake interview at the hospital. During the interview, you will be given more details about the examination.

What is the next step?

We have made the following appointment for your intake interview:

Date: _DATUM_INTAKE
Time: _TIJDSTIP_INTAKE hr
Place: _IL_NAAM, _IL_STRAATNAAM _IL_HUISNUMMER_TOEV, _IL_POSTCODE _IL_PLAATS
_IL_LOKATIE

6_0116

What do you need to bring with you to the hospital for the intake interview?

- this letter
- a letter from the GP containing medical history (if applicable)
- a valid form of identification (passport, driving licence, or ID card)
- your insurance details
- if you have previously been to this hospital: your medical ID card or patient ID card
- your medications or a list of the medications you are taking

Is this your first visit to this hospital? If so, please register at the patient registration desk prior to your intake interview.

Discuss with your GP which medical details you will have to bring to the intake interview. This involves information about your medication and medical history. Your GP is also available to discuss any other questions about the results and the screening programme.

Do you want to change your appointment?

During the scheduling of the intake interview, we have tried to take into account a reasonable travel distance and the availability of the hospital. Do you want to cancel or reschedule the appointment, or would you prefer to go to another hospital? If so, please let us know at least two working days before the scheduled appointment. You can do this in two ways:

- By calling the information line _SO_NAAM, telephone number _SO_TEL (Monday to Friday from 9 a.m. to 5 p.m.).
- Via the website _SO_NAAM. Go to _SO_WEBSITEADRES and click the button 'Mijn bevolkingsonderzoekdarmkanker'. To log in, you need your DigiD.

Costs

The follow-up examination (intake interview and colonoscopy) is not part of the screening. Your health insurance will reimburse the costs of this examination. You may be obliged to pay the costs, or a part of them, yourself. This depends on your excess amount and how much you have already used of this. For questions about this, please contact your health care insurer.

It is possible that your health insurance company may not have a contract with the colonoscopy centre to which we are referring you. In that case, your health care insurer will not reimburse all costs. Please check with your health care provider before you go to your appointment.

It is possible to change the appointment to another colonoscopy centre. See the section called 'Do you want to change your appointment?' for further details.

Do you have questions about the screening programme?

If you have any questions, you can call the _SO_NAAM, telephone number _SO_TEL (Monday to Friday from 9 a.m. to 5 p.m.).

The website www.bevolkingsonderzoekdarmkanker.nl also contains more information, including answers to Frequently Asked Questions. This website also contains the video 'from self-sampling test to colonoscopy'.

Kind regards,
on behalf of _SO_NAAM,

image: _SO_HANDTEKENING_RCMDL

_SO_RCMDL
Regional coordinating gastroenterologist

Appendix: leaflet 'If your stool has been found to contain blood'

6_0116

CONCLUSION

Setting up a colorectal cancer screening programme is complex, because it depends on the goodwill and participation of all parties concerned, including the active involvement of all citizens within a very large population group, some of whom are sometimes hard to reach, and some hard to persuade.

A multidisciplinary approach is critical to run a successful screening programme, including information systems, good monitoring and feedback.

There are no one-size-fits-all solutions, although there are some approaches which seem to consistently fail! This document provides guidance and ideas for programme developers. Success requires being well informed, learning from others, taking a long-sighted view, having an uncompromising view about service quality, overcoming funding challenges, professional and organisational barriers and engendering a collaborative approach with all stakeholders and a sense of pride in making a significant impact on CRC morbidity. The answers and possible solutions will hopefully become apparent in these discussions.

The three case-studies show what is possible, and they saved the lives of thousands of citizens.

We wish them the best of luck - the stakes are high. Remember that hundreds of thousands of lives can be saved every year... and **you** can make a difference!

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