QUALITY MANUAL FOR COLORECTAL CANCER SCREENING

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1. SUMMARY

Colorectal cancer is the second most common cancer in men and women in Finland. Screening seeks to detect colorectal cancer at the precancerous and early stages. The aim is to reduce the number of deaths from colorectal cancer. The EU recommends screening for colorectal cancer with a faecal occult blood test, which has been shown to reduce colorectal cancer mortality among those screened by almost a third.

The colorectal cancer screening programme using the faecal immunochemical test started in Finland in January 2022 and will expand to men and women aged 56–74 by 2031. Screening will be carried out every two years for the selected age groups. A screening test kit is sent to the target population by post to their homes, where a stool sample is taken and then sent to a laboratory for analysis. If the stool sample contains blood above the test limit, the person is invited for a colonoscopy.

The organisation of screening for colorectal cancer is the responsibility of wellbeing services counties. It may carry out the screening itself, in cooperation with other wellbeing services counties or as a purchased service. The screening must comply with the Government Decree on Screenings and cover all stages of the screening process (Figure 1). The wellbeing services county is responsible for the quality of the screening from the invitation to specialised healthcare. It must also submit individual-specific data on screening to the Mass Screening Registry of the Finnish Cancer Registry.

This manual describes the stages of the colorectal cancer screening process and provides guidance on national best practices for high-quality screening.

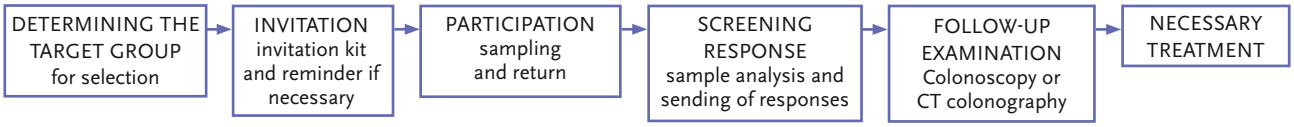

Figure 1. Stages in the screening process

2. TERMINOLOGY AND ABBREVIATIONS

The terms colorectal cancer and colorectal cancer screening are used in the manual, in accordance with the Government Decree on Screenings. The national care guidelines for colorectal cancer uses the terms colorectal cancer, bowel cancer and colon cancer. When referring specifically to colon cancer, the term refers to cancers of the large bowel that are not in the rectum. The endoscopic examination of the large bowel is referred to as colonoscopy in this quality manual.

The survival of colorectal cancer patients is described by relative survival. Relative survival is the probability of survival assuming that cancer is the only possible cause of death. It is calculated statistically by comparing the mortality of patients with the mortality rates of a similar population group.

ABBREVIATIONS

TA tubular adenoma
TVA tubulovillous adenoma
VA villous adenoma
HP hyperplastic polyp
SSL sessile serrated lesion
TSA traditional serrated adenoma

3. INTRODUCTION

This Quality Manual for Colorectal Cancer Screening is intended to support decision-making and activity by those responsible for the organisation and practical implementation of colorectal cancer screening. It provides recommendations, based on research evidence and practical experience, for implementing an effective and cost-efficient organised screening programme to prevent colorectal cancer mortality. Colorectal cancer care is extensively covered in the 2022 national care guidelines for colorectal cancer 1, which is why treatment is largely excluded from the scope of this manual. Scientific research on colorectal cancer screening is active and this quality manual will be regularly updated in the light of the accumulating research evidence.

4. BACKGROUND

4.1 EPIDEMIOLOGY OF COLORECTAL CANCER

Colorectal cancer is the second most common cancer in men and women. In 2019, around 3,800 new cases of colorectal cancer and around 1,400 deaths due to colorectal cancer were diagnosed in Finland[2]. The incidence of the disease has been increasing since the 1960s. It is estimated that 5.6% of men and 5.0% of women in Finland will develop colorectal cancer in their lifetime. The majority of cancers are diagnosed in people over 50 years of age [2].Fewer women than men are diagnosed with colorectal cancer – 2,108 men and 1,717 women were diagnosed with colorectal cancer in Finland in 2021[2].

The relative five-year survival rate for colorectal cancer in Finland at the end of follow-up in 2020 was 68%[2]. Survival rates are influenced by factors such as cancer stage, gender and age at diagnosis. For local, non-spreading cancers, the five-year survival rate is over 90% (Table 1: Bowel cancer stage and five-year prognosis by stage according to American Cancer Society (ACS) data 2013-18)[7]. In Finland, the five-year relative survival rate for men and women was 66% and 70%, respectively, in the follow-up period ending in 2020. Age-specific survival rates in Finland have ranged from 64% (over 75 years) to 76% (under 55 years)[2].

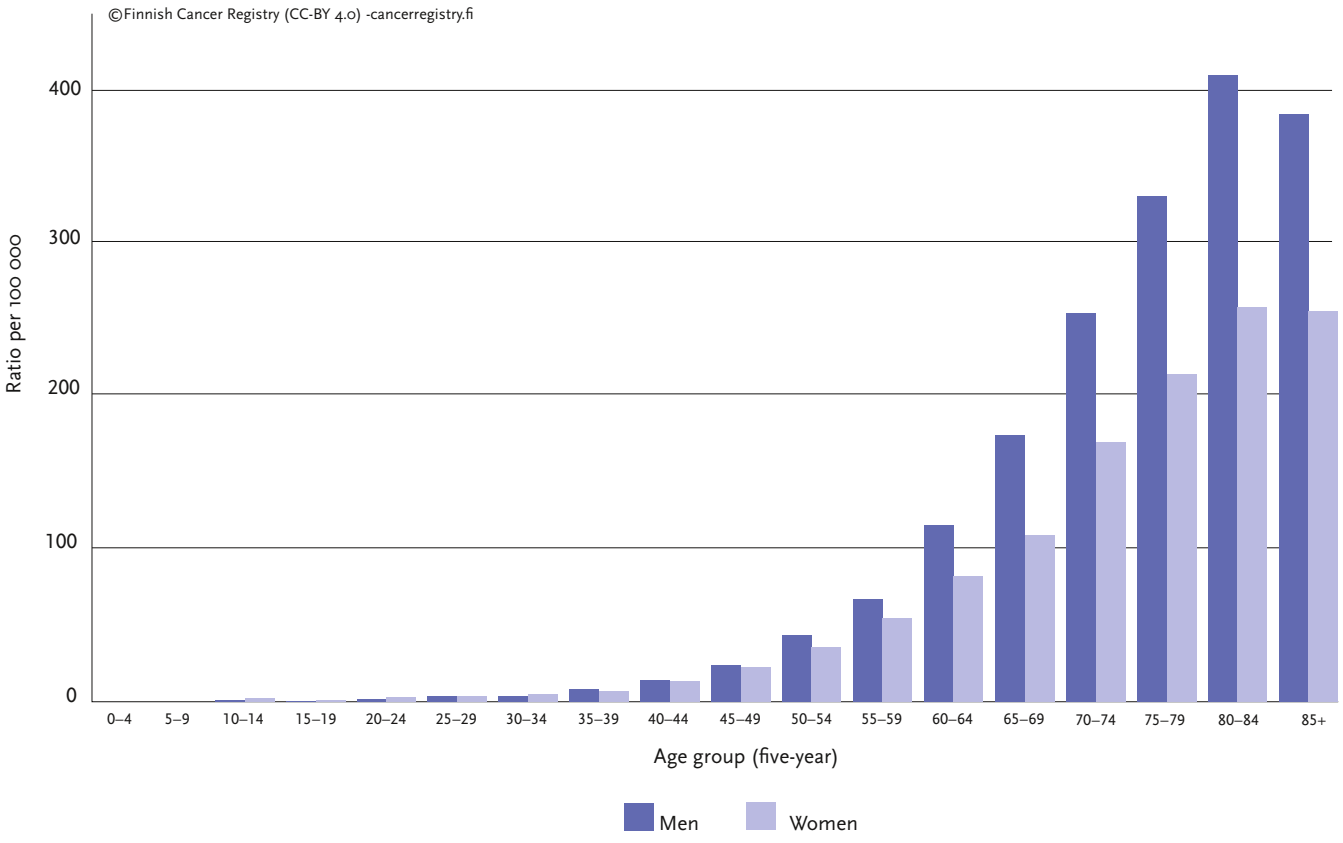

Figure 2 Incidence of colorectal cancer (colorectal cancers per 100 000 person-years) in Finland by five-year age groups in 2017-2021

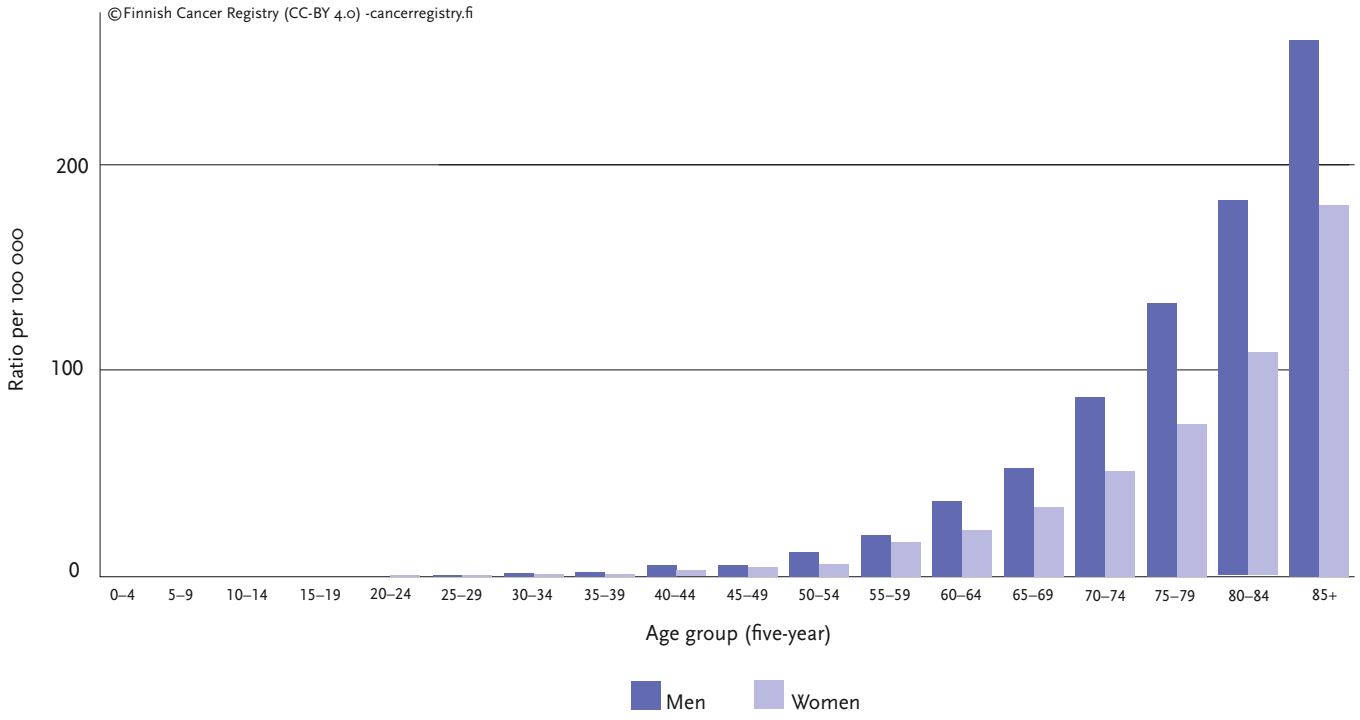

Figure 3. Colorectal cancer mortality (deaths per 100 000 person-years) in Finland by 5-year age group in 2017-2021.

4.2 DEVELOPMENT OF COLORECTAL CANCER

Colorectal cancer usually develops from adenoma or serrated precancerous lesions, which lead to the development of cancer through genetic mutations[3]. Precancerous lesions of the colon are estimated to occur in 10–40% of the adult population.

About two-thirds of colorectal cancers are on the left side of the colon, one-third in the rectum and about half of those in the lower rectum[4] (Figure 4). There are gender differences in the type and location of colorectal tumours. For example, a higher proportion of women than men have been found to have serrated and right-sided colorectal tumours[5,6].

	Five-year prognosis (%), relative survival	
Stage	Colon	Rectum
Local	91	90
Spread	72	74
Metastasised	13	17
Total	63	68

Table 1. Prevalence and five-year prognosis of colorectal cancer by stage in the American Cancer Society (ACS) data 2013-18[7].

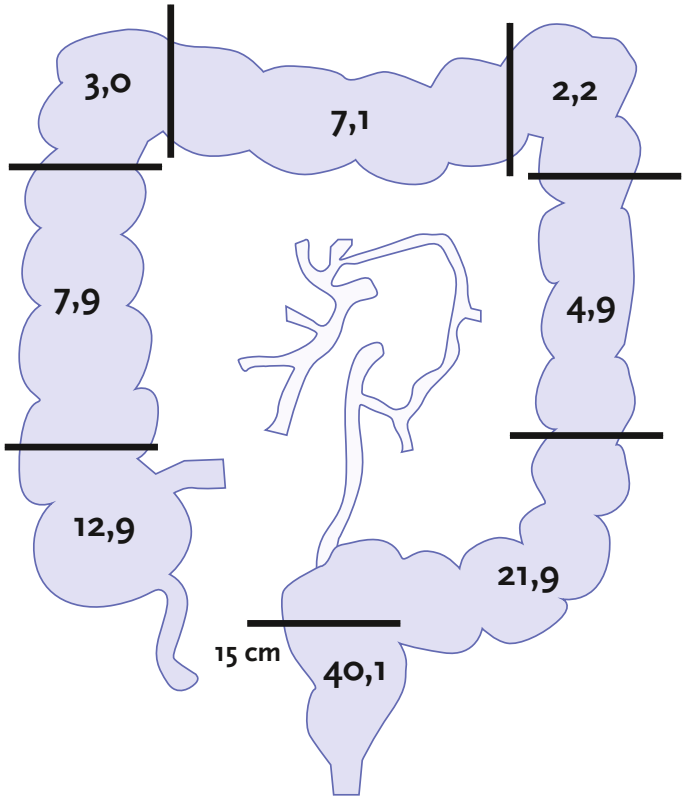

Figure 4. Location of cancerous tumours in the colon and rectum (% of all).

The Western lifestyle, involving a low-fibre diet rich in red meat, high alcohol consumption, smoking and obesity, has been shown to increase the risk of colorectal cancer[5,6,8]. On the other hand, a healthy lifestyle, involving a high level of physical activity[9,10], has been found to reduce the risk. Calcium supplementation, a high-fibre diet, vitamin D supplementation and regular use of non-steroidal anti-inflammatory drugs (NSAIDs) may also protect against colorectal cancer[11].

Inflammatory bowel diseases, ulcerative colitis and Crohn's disease of the colon increase the risk of colorectal cancer[12,13]. The risk is particularly high in patients with chronically active inflammatory bowel disease, those diagnosed at a young age (≤ 16 years), and those with inflammation of the whole colon or primary sclerosing cholangitis (chronic inflammatory biliary disease). These patients should be monitored for cancer risk outside the screening programme[12].

4.3 SCREENING

- Colorectal cancer can be screened by endoscopy (sigmoidoscopy, colonoscopy) and primary tests based on guaiac faecal occult blood testing or faecal immunochemical testing (gFOBT or FIT).
- In screening based on faecal occult blood testing, positive primary samples are confirmed by endoscopic examination.
- In Finland, screening is based on faecal immunochemical testing (FIT).

4.3.1 Principles of screening

Cancer screening is the systematic search for precancerous or early stages of cancer in the population. The aim is to reduce the number of deaths caused by screened cancers.

Colorectal cancer is most typically screened by faecal blood tests and colonoscopy. The types of endoscopy used for screening are sigmoidoscopy and colonoscopy. Faecal occult blood tests include the guaiac FOB (gFOB test) and the FIT. Faecal occult blood tests are used to look for occult blood and identify those at the highest risk, which are subsequently targeted for screening resources. A colonoscopy is used to look closely at changes in a completely empty colon using a camera attached to the tip of a flexible tube. At the same time, samples can be taken for further diagnostic work by a pathologist and polyps can be removed.

In a randomised setting, sigmoidoscopies have been shown to reduce colorectal cancer mortality by 43%[14]. The evidence on the effectiveness of colonoscopy screening is largely based on cohort and case-control studies 15. In case-control studies, colonoscopy has been found to reduce colorectal cancer mortality by 50 – 68%[16,17]. On the other hand, a recently published randomised trial in Poland, Norway and Sweden found no statistically significant difference in colorectal cancer mortality between the control group and the group referred for colonoscopy screening at ten years follow-up[18].

The first randomised controlled trial evidence of the effectiveness of faecal occult blood testing in reducing colorectal cancer mortality was obtained in the Minnesota trial, which began in 1975, where annual screening with gFOB reduced mortality by 33% over a 13-year period[19]. The use of the FIT has been shown to be more sensitive than the gFOB test, reducing the incidence of colorectal cancer by 10% and mortality by 27%[20] with a longer two-year screening interval. In addition, the gFOB test requires dietary restrictions (e.g. avoidance of red meat) prior to testing, whereas the FIT, which is specific to human blood, does not. The guaiac test produces binary (positive/negative) results, which are interpreted visually by inspection of the sample slide. FIT tests are performed with an analyser that displays the haemoglobin concentration measured in the sample on a continuous numerical scale. Concentrations at or above a specifically agreed threshold are interpreted as test positive. The sensitivity and accuracy of FIT-based tests to detect advanced adenoma or cancer depends on the sex of the subject and the Hb level used to interpret the test as positive. At the cut-off value (25µg/g), the sensitivity of the test for detecting advanced adenomas and colorectal cancer ranges from 20–26% and the accuracy from 89–93%.[21] The prevalence of advanced adenomas in the intestine is significantly higher than that of cancers, which overestimates the sensitivity for adenomas in the above figure. At a cut-off value of 20 µg/g, sensitivity for cancer tumours has been reported to be 61–86% and for advanced adenomas 20–31% (95% confidence interval of the meta-analysis)[22]. The likelihood of false-negative results is increased by male sex, family history of colorectal cancer, obesity, hypertension and smoking[23].

4.3.2 Colorectal cancer screening in Finland

The European Union has recommended colorectal cancer screening based on faecal occult blood tests to its member states since 2003[24]. At that time, screening was carried out using the gFOBT. In Finland, a gFOB-based colorectal cancer screening programme in a randomised trial setting was launched

in 2004. Half of the residents aged 60–69 years in the municipalities included in the study were invited for screening every two years. However, there was no reduction in colorectal cancer mortality among those invited to the programme after an average follow-up period of 4–5 years, and an increase in colorectal cancer mortality among women was even observed. The screening programme was discontinued in 2016[25,26].

A FIT-based colorectal cancer screening pilot was launched in nine municipalities in Finland in 2019[27]. Due to sex differences in tumour types, tumour location, bowel transit time and haemoglobin levels in the blood, the threshold for the screening test was set lower for women than for men[28,29]. In 2020, the test thresholds were lowered further[30].

In 2021, a modelling study based on the results of the screening pilot and the register data was carried out together with Erasmus University[31]. The aim was to identify a cost-effective and affordable implementation modality for the future national programme. Based on the results, the target population was defined as people aged 56–74. The screening interval was set at two years and the test cut-off at 25 µg Hb/g faeces for both sexes.

5. LEGISLATION AND GUIDANCE

- The organisation of screening is laid down in the Government Decree on Screening.
- The wellbeing services counties and the City of Helsinki are responsible for organising the screening programme.
- Screening for colorectal cancer is provided under the screening decree for 56–74-year-olds, with a gradual expansion. Screening is carried out every two years for the selected age group.
- The implementation and development of screening is guided by the National Cancer Screening Steering Group, part of the Finnish Cancer Centre (FICAN).

5.1.LEGISLATION

According to the Health Care Act (1326/2010), wellbeing services counties must organise screenings in accordance with the national screening programme. Cancer screening is regulated in more detail in the Government Decree on Screening (339/2011 and amendments 908/2011, 752/2021 and 1243/2022). The 2021 screening decree was updated to include a gradual expansion of screening for colorectal cancer for 56–74-year-olds, starting in January 2022[32], based on biennial faecal occult blood testing. This expansion is also described in the 2021 amendment to the screening decree.

In order to organise screening programmes that are not included in the Government decree on screening (for example, when expanding the age groups for screening), wellbeing services counties must assess the requirements and impact of screening on the health care service system before starting screening.

5.2.STEERING GROUP AND EXPERT GROUP

The National Cancer Screening Steering Group, which is part of Finnish Cancer Centre (FICAN), provides guidance and monitoring of the initiation, implementation and development of cancer screening, and makes proposals and provides expertise to the Ministry of Social Affairs and Health in the preparation of laws and decrees related to cancer screening. The Steering Group consists of expert members from FICAN, the five regional cancer centres, the Finnish Cancer Registry and a representative of the Ministry of Social Affairs and Health. The Steering Group has also appointed an Expert Group for each cancer screening programme to provide more detailed guidance on the implementation of screening.

A quality manual drawn up by the Expert Group gives more detailed guidance to the wellbeing services counties on how to implement the screening programme. The wellbeing services counties are responsible for implementing these guidelines.

The main responsibility for monitoring the screening programme lies with the wellbeing services counties. The Regional State Administrative Agencies and the National Supervisory Authority for Welfare and Health (Valvira), as supervisory authorities, are also responsible for monitoring the screening organised by the wellbeing services counties in the same way as other health care services, in line with their mutual division of labour.

6. SCREENING PROTOCOL

The screening laboratory will send a FIT kit to those invited for screening and, if necessary, a reminder six weeks after the initial test kit is sent. If blood in stool is below the specified threshold (negative test result), the person will be invited for screening after two years. Those above the cut-off point (with a positive test result) will have a follow-up examination assessment with a recommendation for a colonoscopy or a replacement test (CT colonography), or exclusion from the screening population, either for a limited period of time or completely, on the basis of certain factors.

Screening colonoscopy is not recommended for people who are under regular colonoscopy surveillance for inflammatory bowel disease (IBD)[8] or people who have had a colectomy i.e. removal of the target organ.

A single negative FIT result does not rule out the presence of precancerous colorectal lesions, which is why repeated faecal occult blood testing is necessary. After a negative FIT result, the screening is repeated after two years, up to the age of 74.

The screening protocol is also described in the Protocol for Colorectal Cancer Screening[33], developed by the Expert Group on Colorectal Cancer Screening. The names of the authors of the protocol can be found in the document, which will be updated as necessary.

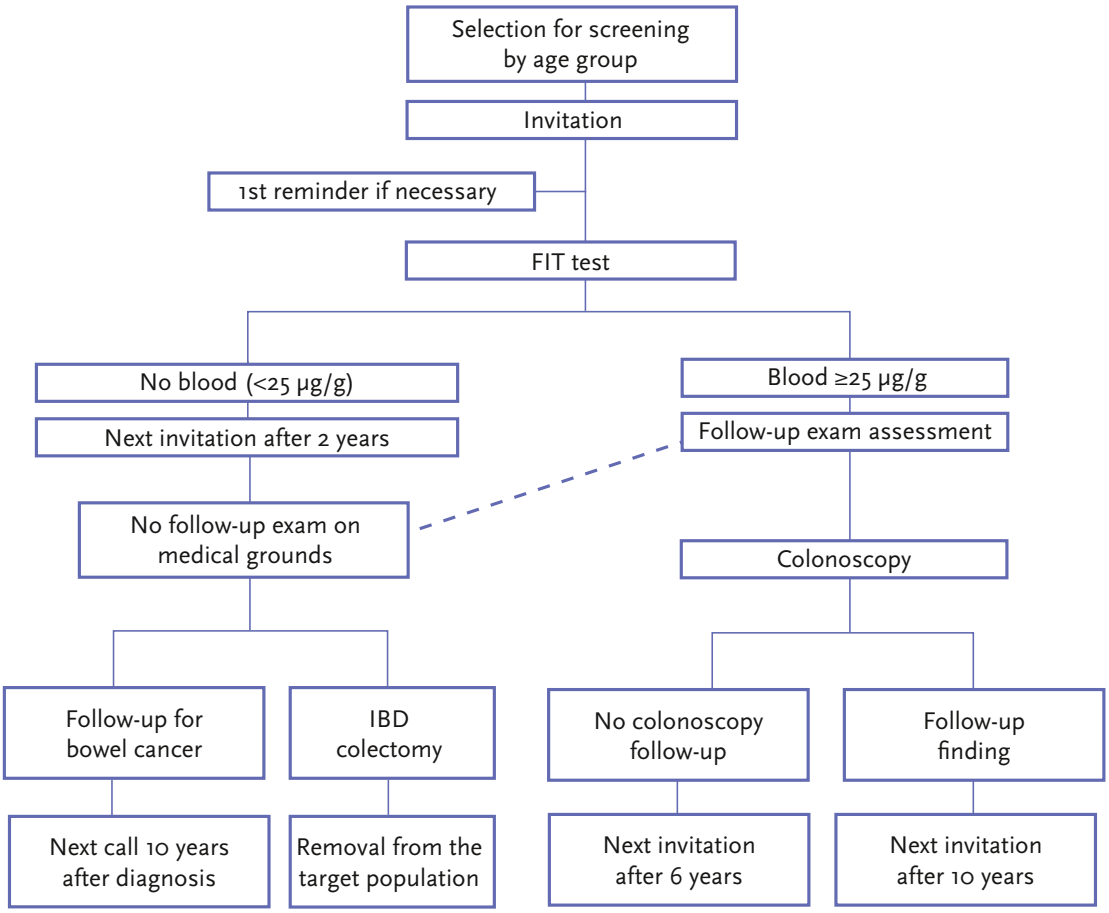

Figure 5. Screening protocol/algorithm of the colorectal cancer screening programme.

7. TARGET POPULATION FOR SCREENING

- The target population for screening will gradually expand to people aged between 56 and 74 by 2031.
- In order to avoid unnecessary examinations and to save resources, restrictions to the target population will be made as the programme progresses.

7.1. AGE GROUPS TO BE SCREENED

In 2022, screening for colorectal cancer started with 60–68-year-olds and will be extended by age groups to cover the entire target population, i.e. all 56–74-year-olds, from 2031. During the expansion phase, the matrix (Annex, Table 7) for the annual age groups to be invited for screening. The selection of age groups is based on cost-effectiveness modelling calibrated to the Finnish colorectal cancer incidence rate 31. The effectiveness and cost-effectiveness of the screening programme in different age groups will be continuously evaluated on the basis of the data collected in the mass screening register. The Finnish Cancer Registry selects those eligible for screening annually from the Digital and Population Data Services Agency (DVV) on the basis of age group.

7.2.EXCEPTIONS TO POPULATION-BASED RECOMMENDATIONS

High-quality endoscopy protects against colorectal cancer for at least six years 34,35. If no findings requiring follow-up are found in follow-up examinations, the person is recommended to be screened after six years. Patients with colorectal cancer are typically followed up with screening five years after cancer. If a person with a positive test result is less than 10 years from the diagnosis of colorectal cancer, screening is recommended in the year following the 10th anniversary of the date of diagnosis instead of a colonoscopy. People who are under regular colonoscopy surveillance for inflammatory bowel disease (IBD)[8] or persons who have had a colectomy, i.e. removal of the target organ, are not referred for colonoscopy after a positive test according to the screening protocol.

In these cases, the test positive persons should be instructed to contact the health care unit to ensure that the need for colonoscopy examination is evaluated as a part of the IBD surveillance programme. If the health care unit responsible for the IBD surveillance is unknown, the person should be guided to contact primary health care services to participate in a proper IBD surveillance protocol and possible colonoscopy.

8. APPROVED TESTS

- There are currently three different options for screening tests.
- The list will be updated as necessary in the light of new research.

In Finland, the main screening tests used in the colorectal cancer screening programme are the faecal immunochemical blood tests (FIT), which have been validated and used in European screening programmes over several rounds of screening[36–38].

The tests should be quantitative, with an automatically adjustable sensitivity level. The sensitivity level of the screening programme is based on research evidence and has been set at 25 µg Hb/g of faeces for both sexes in 2022.[31,39,40]. The threshold will be updated based on the proportion of positives, the need for colonoscopy and the accumulation of research data. The performance of the test method and the accuracy of the result should be ensured by daily laboratory work and demonstrated by inter-laboratory comparisons[41].

Using these criteria, the screening protocol has validated the FIT tests for men and women aged 56–74 years in the screening protocol:

- FOB Gold NG, Sentinel CH. SpA, Italy
- OC-Sensor Diana, Eiken Chemical Co. Ltd, Japan
- OC-Sensor Pledia, Eiken Chemical Co. Ltd, Japan

The expert group will update the list as necessary in light of new research.

9. ORGANISATION OF SCREENING

- The wellbeing services county is responsible for organising the screening.
- A wellbeing services county can carry out the primary and follow-up testing of the screening programme either on its own, in cooperation with another wellbeing services county or by purchasing it.
- The specific features and quality criteria of screening should also be taken into account when purchasing the service.

9.1. WELLBEING SERVICES COUNTIES

At the beginning of 2023, the responsibility for organising screenings was transferred from municipalities to the 21 wellbeing services counties and the City of Helsinki. In addition, the province of Åland is responsible for organising screening in its territory. Screening is organised according to a programme decided in advance by the wellbeing services county, which must appoint a person responsible for each screening programme. The wellbeing services counties can either carry out the screening themselves, in cooperation with their counterparts or outsource the screening to a service provider of their choice. The most common practice is for the wellbeing services county to contract a screening laboratory to carry out the primary phase of the screening (invitations, tests and their analysis, responses) and to be responsible for organising the follow-up screening and specialised healthcare.

The wellbeing services counties are responsible for establishing a screening programme that includes an appropriate quality management and quality assurance procedure[42]. The wellbeing services county shall regularly monitor and evaluate the quality of the whole screening process and the reliability of the screening tests. In addition, the wellbeing services county must submit individual-level data on screening to the mass screening register maintained by the Finnish Cancer Registry, which will allow the quality and effectiveness of screening to be assessed at the national level. The National Institute for Health and Welfare (THL) has commissioned the Finnish Cancer Registry to monitor and evaluate, in cooperation with other actors in the field, ongoing screening programmes and the methods used in them.

The wellbeing services counties must appoint screening nurses to act as liaison persons for those who are screened and to be responsible for the counselling of those who test positive. For a more detailed description of the organisation of screening and the role of the wellbeing services county, see the guide to organising screening for colorectal cancer[43].

9.2.SCREENING LABORATORY

The screening centre is typically the screening laboratory, which is responsible for sending out invitation packs and reminders, analysing samples and communicating results to the screening participant. The screening laboratory must be accredited and have suitable facilities, equipment and staff to send out screening invitations and reminders and analyse samples. It is recommended that the screening method be included in the scope of the laboratory's accreditation.

The laboratory is staffed by a hospital chemist responsible for the performance of the colorectal cancer screening test method and health professionals who assess the suitability of samples for analysis and analyse the samples. Some of these professionals must be trained to be responsible persons, who supervise the maintenance of the analytical equipment and the adequacy of reagents and consumables. The staff must have the appropriate training and be familiarised with their tasks.

The screening laboratory provides the individual-level data of the screening chain (Figure 1: Steps in the screening process: invitations, tests and their results, follow-up examinations and their results, specialised healthcare and its results) to the Mass Screening Registry of the Finnish Cancer Registry[32].

To this end, the laboratory must have an information system that collects and transmits the data in accordance with the data model and parameters defined by the Finnish Cancer Registry[44]. The data flow in the screening programme is shown in the figure (Figure 6: Information flow between the screening centre and other actors.). The screening nurses in the well-being services county and other health professionals involved in the follow-up phase are responsible for reporting the data in the screening chain to the screening laboratory's information system.

The organisation of screening and the role of the screening laboratory (screening provider/screening centre in the guide) are also described in the guide to the organisation of screening for colorectal cancer[43].

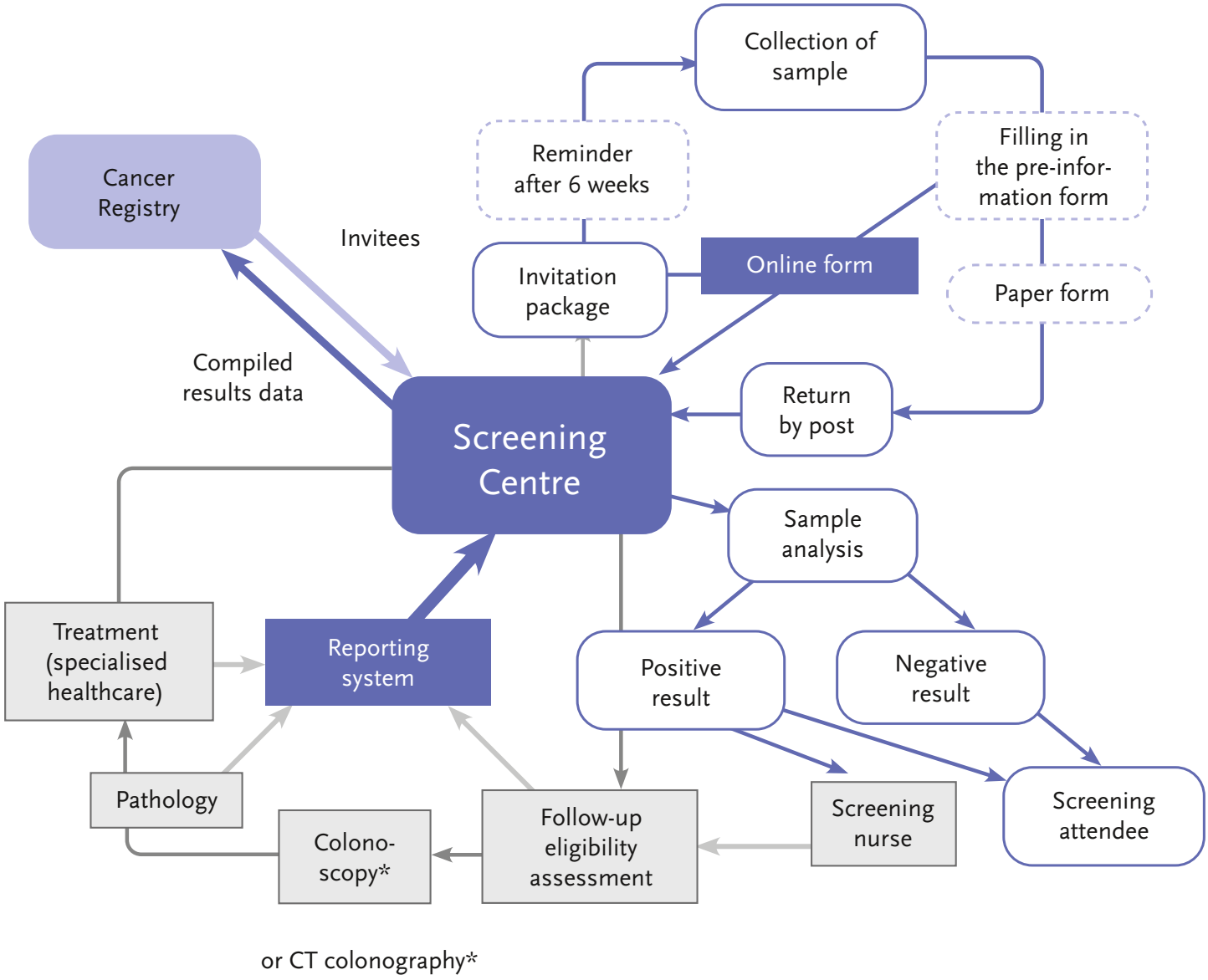

Figure 6. Information flow between the screening centre and other actors.

9.3.ORGANISATION OF ENDOSCOPIC ACTIVITY

Wellbeing services counties responsible for the colorectal cancer screening programme are also responsible for organising and both ensuring and monitoring the quality of colonoscopy activity. This may be done by a wellbeing services county as its own activity, as a outsourced service or as a combination of the two. In all cases, the availability of sufficient capacity and the quality of the colonoscopies must be ensured.

Competitive tendering and the organisation of endoscopies should take into account the high number of findings typical in screening programme, and the increased need for demanding polypectomies. Colonoscopy quality should be good enough to minimise the need for repeated colonoscopies and/or other additional examinations. If parts of the colonoscopies are bought using service vouchers, it is advisable to issue the voucher through the screening colonoscopy unit rather than through primary healthcare to ensure efficient use of resources.

When tendering and selecting the unit that will perform the endoscopic screening, the following should be taken into account:

- Staff are adequately trained and continuous training is ensured
- The endoscopy unit meets the quality criteria (ASGE – Quality indicators for gastrointestinal endoscopy units[45])
- Patient preparation (bowel clearance) is appropriately instructed and the unit has the possibility to use intravenous pre-medication with appropriate follow-up
- The endoscopic findings and the progress of the examination must be recorded in a structured electronic endoscopy report
- The unit should have the possibility to document the findings with images/video
- Prospective, systematic follow-up of colonoscopy complications
- Methods for measuring patient satisfaction

The physician involved in screening requires:

- At least 3 years of post-graduation experience in colonoscopies
- Annual number of colonoscopies performed ≥200, experience of at least 500 colonoscopies
- Experience in polypectomies ≥50/year
- Cecum intubation rate >90%
- Capability to provide treatment and follow-up advice based on findings
- To have completed a course in endoscopic screening (for details, see Endoscopists

The factors related to the quality of colonoscopies and their follow-up are described in more detail in the section where the patient's stool sample would have been analysed in the old welfare area. The screening nurse should instruct the person being screened to contact the screening nurse/screening laboratory in their new municipality of residence to arrange this. Screening centres may, if they wish, refer the person to the screening centre in the new municipality after being informed of the person's change of residence.

10. INVITATION

- Persons to be invited are extracted from the Population Information System (DVV). Persons in a special situation (e.g. people subject to non-disclosure for personal safety reasons) should be offered the opportunity to participate in the screening, even if they are not included in this selection.
- The invitation package should contain sufficient information about the screening programme. The Cancer Registry provides materials for this purpose.
- The invitation packages should be sent in a schedule allowing the samples to be analysed by the end of March that follows the screening year.

10.1.COLLECTING A COHORT OF INVITEES

The cohorts based on year of birth to be invited to the screening are extracted from the up-to-date Population Information System (DVV) on the basis of the screening regulation. This ensures that those eligible for screening receive an invitation to screening in the correct year. A list of personal identification numbers is sent to the screening laboratories at the beginning of each calendar year. To facilitate the organisation of screenings, the Finnish Cancer Registry provides an invitation service, which includes the extraction of contact details of those invited for screening from the Population Information System.

Persons subject to non-disclosure for personal safety reasons will not be included in this selection. They should be offered the opportunity to contact the screening centre either to collect an invitation pack or to provide an address to which an invitation pack can be sent.

Information on the invitations sent is submitted to the Mass Screening Registry of the Finnish Cancer Registry as part of the reporting aggregate for quality assurance.

10.2.INVITATION

10.2.1 Contents of the invitation package

The invitation package should include:

- Invitation letter
- Sampling kit
- Clear, illustrated sampling instructions
- Return envelope with prepaid postage
- A questionnaire form to collect the background information designated by the expert group.

10.2.2 Language of the invitation letter

The invitation letter must be in writing and personally addressed to the person invited for screening. The invitation letter should be either bilingual or in the invitee's mother tongue if Finnish or Swedish is the mother tongue. If there are significant linguistic minorities in the wellbeing services county, consideration should be given to translating the invitation into other languages.

10.2.3 Information contained in the invitation letter

For invitees to make a decision on participation in screening, the invitation letter must contain the following information:

- The purpose of screening
- On how to carry out a screening test
- The importance of early detection of disease (of cancer or pre-cancerous lesions)
- The benefits and harms of screening
- On follow-up examinations, what they involve and their importance

The letter must also include:

- Information on how the participant will be informed of the screening test result
- Information on how quickly the screening test result will be delivered (recommendation: within one month)
- Contact details for further information
- Notification of the source of the invitee's address (the DVV Population Information System)

There are invitation letter templates produced and maintained by the Finnish Cancer Registry, which can be used as a basis or as an invitation letter in their own right. There are versions of the invitation and reply letters in Finnish, Swedish, English, Northern Sami and Russian. There are Finnish, Swedish and English versions of the pre-information form which are freely available. All materials can be found on the website of the Finnish Cancer Registry: https://cancerregistry.fi/screening/organising-cancer-screening/

10.3.PRE-INFORMATION FORM

The questionnaire form collects information on factors affecting the risk of colorectal cancer and the success of faecal immunochemical testing. Known risk factors for colorectal cancer include smoking, family history of cancer, alcohol consumption and obesity[5,6,46]. There is also research evidence that the use of certain drugs is associated with the sensitivity and accuracy of immunochemical blood testing of stool samples[47].

10.4.RETURNING A SAMPLE

The Post Office has defined the criteria for returning a sample taken at home for colorectal cancer screening. If another carrier is used instead of the Post Office, the requirements for sending samples must be agreed with that carrier. The current screening invitation package includes a hard-cover envelope, which can be white, for example. The envelope does not need to be marked to indicate that it contains the screening sample. The sample tube is packed inside the envelope in a plastic bag with an absorbent pad. The screening participant can drop the envelope in the nearest Post Office post box. For example, a sample post box at a health centre or laboratory can also be used to mail samples.

10.5.REMINDER LETTER

If the person invited to the screening has not returned the sample within six weeks of the first invitation, a reminder letter will be sent, as specified in the protocol[33]. The reminder will include instructions for ordering a new sampling device at no charge.
A model reminder letter is available in Finnish, Swedish and English on the Cancer Registry website, as are other invitation and response letter templates for colorectal cancer screening[48]. The reminder letter can also be submitted electronically using the suomi.fi service or a similar strong authentication channel adopted by the person being screened.

10.6.CHANGE OF WELLBEING SERVICES COUNTY BY SCREENING INVITEE

If a person relocates to another wellbeing services county before participating in the screening, they can ask for a new screening pack at the screening centre in their new wellbeing services county. The wellbeing services county to which the person has moved is obliged to arrange for screening, regardless of whether the person was living in the wellbeing services county at the time of selection for invitation. Screening-positive persons will become clients of their new wellbeing services county in the same way that their health services are transferred to it.

11. SAMPLE ANALYSIS AND COMMUNICATION OF RESULTS

- Samples are analysed in screening laboratories in line with best laboratory practices.
- A positive test result is communicated to the person screened, providing sufficient information about the significance of the result and the possibility of contacting the screening nurse.
- A negative test result can be reported by SMS.

11.1. ANALYSIS

Screening samples returned to the laboratory are analysed as soon as possible and within their storage life in aline with the analysis process described in writing. The operational condition of the analytical equipment shall be monitored and maintained by the user and periodic maintenance according to the manufacturer's instructions. Maintenance and error reports should be documented.

The performance of the analysis method is verified by at least two control samples of known concentration before analysing the screening samples. The result levels of the control samples shall be within the predefined acceptance limits. Performance should also be monitored by inter-laboratory comparisons (external quality assessment, e.g. Labquality).

The eligibility of the screening sample for analysis is checked according to written instructions, e.g. regarding the storage life of the sample. Screening samples arriving at the laboratory must be identified throughout the laboratory process. Incompletely identified samples must not be analysed.

Ineligible samples will be rejected, and a new screening sample will be requested. At the same time, the reason why the first sample could not be analysed will be communicated to the subject. Samples exceeding the storage life specified by the manufacturer will also be analysed: if the haemoglobin concentration measured exceeds the screening limit, the result is positive. If the measured concentration is below the screening limit, a new sample is requested from the subject.

Each result must be traceable to the reagent used in the analysis and to control results that have been used to verify the performance of the method. The analyser sends the analytical result together with the sample identification data to the laboratory information system. The result, the time of analysis and the equipment used for analysis must be traceable in the laboratory's computer systems.

If a resubmission from the person being screened has to be rejected because of non-successful sample collection, the laboratory is advised to inform the screening nurse of the municipality concerned, who can then contact the person to be screened and instruct them on how to take the sample.

11.2. NOTIFICATION OF TEST RESULTS

11.2.1. Positive test result

The screening laboratory submits reports of test-positive screeners to the screening nurses appointed by the wellbeing services counties. The screening nurses will contact those who test positive by telephone. A letter is sent to those who test positive with a two-week delay after the list of test-positive individuals has been provided to the screening nurse. This is to ensure that the screening nurse is informed in a timely manner of those who have tested positive in their municipality.

Anyone who tests positive should receive instructions on how to contact the screening nurse. The letter should also include the following information:

- What does a positive result mean, i.e. blood was found in the stool sample.
- A positive result does not indicate cancer, as bleeding is often due to another cause
- It is important to investigate the cause of bleeding
- To arrange a follow-up, contact the screening nurse (direct contact details or instructions for contact details are to be included in the letter)

If the person who has tested positive does not contact the screening nurse within about two weeks, the screening nurse should call them.

11.2.2. Negative test result

A negative test result can be communicated by letter or SMS. In both cases, the message informing the subject of the negative test result must contain the following information:

- What a negative result means, i.e. no occult blood found in the sample
- Nevertheless, if symptoms do occur, the subject should still contact their healthcare provider
- The next invitation will come every two years until the age of 74

When using SMS, the laboratory must ensure that consent is given for its use and that the telephone number is up-to-date and correct during the relevant screening round. For data security reasons, the SMS message should not contain personal information.

11.3. CHANGE OF MUNICIPALITY OF RESIDENCE

If a person moves to a different wellbeing services county before participating in the screening, the follow-up screening will be carried out in the new wellbeing services county of the person being screened. This is done even if the patient's stool sample was analysed in the previous wellbeing services county of residence. The screening nurse should instruct the screened person to contact the screening nurse/screening laboratory in the new wellbeing services county to arrange this. Screening centres may, if they wish, refer the person to the screening centre in the new municipality after being informed of the person's change of residence.

If a person moves to another screening centre after a positive test, but before attending further screening, their screening chain is broken. Currently, screening data for an individual cannot be reported under the same screening identity code from more than one screening laboratory.

12. CARRYING OUT FOLLOW-UP EXAMINATIONS

- The person screened will agree on follow-up examinations with the screening nurse.
- Colonoscopies are the primary follow-up method, and their quality is monitored through quality indicators both nationally and in the wellbeing services county.
- Colonoscopy should be performed within one month of a positive test result.

12.1.RESPONSIBILITY FOR IMPLEMENTATION

Follow-up examinations can be carried out by the wellbeing services county itself or by a service provider chosen by the wellbeing services county. In the event of competitive tendering, the wellbeing services county must require and monitor that the provider of follow-up examinations complies with the quality criteria and reports all data in the screening chain to the mass screening register of the Finnish Cancer Registry.

A positive screening test result will lead to an agreement with the screening nurse for a follow-up examination. A positive screening result indicates that cancer is suspected and the need for an urgent referral for a follow-up examination. The primary follow-up examination is a colonoscopy with samples.

The wellbeing services county is responsible for the implementation and quality of the whole screening process. This includes ensuring that examinations are conducted according to quality criteria and that all data generated is recorded and reported.

12.2.COLONOSCOPY

High-quality colonoscopies are a prerequisite for an effective screening programme. Several treatment recommendations have been published on the quality of colonoscopies, the screening of colorectal cancer, the capacity of the units performing them and the monitoring of the quality of colonoscopies[49–51]. The published recommendations on quality assurance are highly consistent, covering indications for the examination, patient preparation, pre-medication, success of the examination (access to the cecum), detection rate of polyps (adenomas), proportion of polyps removed and removal technique, complications, patient experience of the endoscopy and post-operative follow-up.

Tables 2 and 3 show the main quality criteria and their target values, as recommended by the European Society of Gastrointestinal Endoscopy (ESGE). 49. The implementation of the quality criteria for colonoscopy is monitored nationally on the basis of data submitted to the Mass Screening Registry The colonoscopy indicators to be submitted to the registry are summarised in Table 2.

INDICATOR	MINIMUM LEVEL	TARGET LEVEL
Adequate bowel preparation for the examination (%)	90 %	>95 %
Cecum intubation (%)	90 %	>97 %
At least one adenoma found on colonoscopy (%)	30 %	> 40 %
Withdrawal time over 6 minutes (%)	90 %	> 95 %
Incidence of perforations	<1 %	
Bleeding after polypectomy	<1 %	

Table 2. Quality criteria for colonoscopy monitored nationally through the Mass Screening Registry

INDICATOR	MINIMUM LEVEL	TARGET LEVEL
Mucosal, pedunculated polyps and sessile polyps < 2 cm in size must be endoscopically removed or endoscopically incomplete removal must be convincingly documented	100 %	100 %
Timing of follow-up polypectomy colonoscopy determined on the basis of histological results	95 %	
Non-operative treatment of post-polypectomy bleeding	90 %	
Documentation of patient discomfort, with scoring		100% documentation

Table 3. Other quality criteria that should be monitored.

In addition to national monitoring, the implementation of the criteria should be monitored as part of the activities of the colonoscopy units themselves (Table 3).

In addition, the incidence of post-colonoscopy colorectal cancer (PCC) is used as one of the quality indicators for screening copies[52]. The number of polyps detected has been shown to correlate with the effectiveness of screening and the incidence of colorectal cancer 52. The rates of intermediate cancers are monitored nationally using data from the mass screening registry and the cancer registry.

12.3.COMPUTED TOMOGRAPHY (CT) COLONOSCOPY

The primary follow-up examination to screening is colonoscopy, but if this cannot be done due to contraindications, CT colonoscopy can be used as a secondary replacement. Clinical indications for CT colonography are discussed in recommendations such as those of the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastrointestinal and Abdominal Radiology (ESGAR)[53].

Modern CT colonography has a sensitivity almost equivalent (96%) to colonoscopy, but only in detecting polyps larger than 10 mm. However, for polyps smaller than 10 mm and for flat polyps, its sensitivity is clearly inferior to that of colonoscopy. CT colonography cannot take biopsies or remove small polyps and therefore leads to colonoscopy in about 30% of cases[53,54].

13. PATHOLOGY

- Screening pathology has certain specific characteristics, which are presented in this chapter.
- The recording of pathology data in tabular form is also recommended.
- At least 90% of screening samples should be responded to within one week of arrival at the laboratory.

13.1.TYPICAL SAMPLES AND FINDINGS

Screening colonoscopy samples are almost invariably mucosal biopsies or endoscopically removed polyps. Some of those screened have endoscopic mucosal resection or surgical bowel resection as follow-up procedures. The management and diagnostics concerning colorectal cancer resections are covered in the National Treatment Guidelines for Colorectal Cancer[1].

The most common findings on screening colonoscopy are classical adenomas or serous changes, and other benign changes and malignant findings in a minority. A higher proportion of cancers found at screening are early-stage (pT1) cancers compared to those found in patients who present for screening on the basis of symptoms. Early-stage cancers have a better prognosis and some can be treated endoscopically with local excision.

13.2.REFERRAL INFORMATION AND SAMPLE HANDLING IN THE PATHOLOGY LABORATORY

The colonoscopy referral should include a brief description of the endoscopic finding (polyp or flat (or sessile) lesion or e.g. suspected cancer), the sampling site and the endoscopic size of the change. Each separate lesion should be sent for examination in its own sample container with the exception of multiple small (up to 5 mm) hyperplastic lesions of the rectum. It is nationally agreed that the endoscopic diameter is used for the size of the polyp. In addition, the pathology laboratory measures the size of the polyp after formalin fixation, preferably at the time of start-up. If there is a significant difference between the endoscopic measurement and the pathological measurement, the pathologist should report this in their statement.

Samples arrive at the pathology laboratory prepared in formalin and are processed in the same way as other endoscopic intestinal biopsy samples. In general, polyps and mucosectomy specimens are fully prepared. If necessary, resection margins can be marked (silver or ink) before dissection, but often the coagulation artefact from the endoscopic excision is sufficient to assess this. Very small polyps (<5 mm) can be started as such. For those larger than this, the maximum diameter is recorded at the start-up and the polyps are either halved or sliced longitudinally to determine the strain and resection margin. The flat lesions removed by mucosal resection are sliced in parallel slices (approximately 2–3 mm apart) so that the shortest edge margin can be measured microscopically. The dissection planes are deepened if necessary and, in selected cases, additional staining may be used to indicate e.g. venous invasion. In the majority of small polyps, the resection margin cannot be assessed (orientation problem).

It is recommended that the pathology laboratory examining the screening samples be accredited.

13.3.FINDINGS AND THEIR HISTOPATHOLOGICAL DIAGNOSIS AND REPORTING

The British guidance[55] presents the distribution of non-invasive lesions (n= 816,323) in screening samples as follows:

- Over 70 % classical adenomas (57 % tubular adenoma, 14 % tubulovillous and 0,70 % villous adenoma).
- Over 20 % sessile serrated lesions.
- Other changes (less than 10 %) include inflammatory, Peutz-Jegherin and juvenile polyps and benign mesenchymal changes.

According to the above recommendation, at least 90% (target over 95%) of screening samples should

be responded to within one week of arrival at the laboratory. This should also apply in Finland.

13.4.SEVERE DYSPLASIA

Dysplasia is graded on a two-tiered scale from low to high grade. The diagnostic criteria for high-grade dysplasia are published in the WHO's 2019 classification[56]. High-grade dysplasia requires low-magnification structural changes (e.g. tightly packed glands or septate structures) and low-magnification cytological changes (severe stacking and polarity disturbance of nuclei, alteration of nucleus-cytoplasm ratio, hyperchromasia, prominent nucleoli, atypical mitoses). Approximately 5% of classical adenomas are expected to include high-grade dysplasia[55]. The diagnosis of severe dysplasia should not be used if such morphology is very sparse (in a few glandular structures), in reactive changes in the surface epithelium or in the area of a browning/coagulation artefact.

13.5.SERRATED LESIONS

About 20% of benign screening findings include serrated lesions[55]. The most common of these are hyperplastic (HP) (18%), sessile serrated lesions (SSL) (1.5%) and traditional serrated adenomas (TSA) (0.7%). Only about 6% of SSL lesions contain dysplasia[55], which is not graded because it is associated with a high risk of malignancy regardless of the morphology of the dysplasia. TSA, on the other hand, is always a dysplastic lesion and is graded as either low or high grade, as in conventional adenomas. Ectopic cryptic adenomas in TSA should not be diagnosed as severe dysplastic adenomas. Mixed polyps, unclassified polyps and polyposis are discussed in the references[55–57].

13.6.PT1-ADENOCARCINOMA

Diagnosis of colorectal cancer requires mucosal invasion (penetrating the muscularis mucosa into the submucosa)[1,56,58]. The diagnosis of in situ carcinoma is not used because of the very low probability of lymph node involvement. This is the best way to avoid confusing the diagnosis of in situ carcinoma with a diagnosis of adenocarcinoma requiring submucosal invasion. However, the invasion of Lamina propria should be mentioned in the opinion.

Often, the problem in making the diagnosis of adenocarcinoma is the absence of clear submucosal structures (nerves or large veins) on colonoscopic biopsies. Since intramucosal invasion rarely forms a strong desmoplastic stromal response, in the absence of submucosal structures, clear invasive glands and desmoplasia can be used to make the diagnosis of adenocarcinoma from colonoscopic biopsies. In the differential diagnosis, pseudoinvasion should be considered, where the histological structure and cytological features of the so-called displaced glands correspond to those of polyp glands, mostly surround the lamina propria and may contain mucinous accumulations and haemosiderin.[55,59]. Pseudoinvasion is most common in large sigmoid polyps.

Predictors of the likelihood of local recurrence or lymph node metastasis in pT1 adenocarcinoma:

- The resection margin of the base is < 1 mm (R1)
- Vein invasion (lymphatic or venous invasion)
- Neural invasion
- Certain histological subtypes
- High-grade differentiation
- Tumour budding
- Depth of invasion

The diagnosis of the above risk factors is discussed in the section on histopathological diagnosis of colorectal cancer in the national guidelines for the treatment of colorectal cancer[1]. For high-grade findings, differential diagnosis should include squamous cell carcinoma (basaloid subtype), neuroendocrine tumours and carcinomas, melanoma, lymphomas, mesenchymal neoplasms and metastases.

The recommendation is that pT1 cancers are given a double reading. In addition, all unusual findings,

dysplasia classification problems, suspected cancers and pseudoinvasions should be consulted. Microsatellite instability analysis is recommended for all cases of colorectal cancer [1,56,58].

13.7.CONSULTATION TABLE

The pathologist's opinion on screening colonoscopy specimens is accompanied by a table, an example of which is given below (HUS Diagnostic Centre, 10/2022). In the table, each box is ticked that applies to the findings.

* For patients with ≥ 10 mm polyps: diameter of the polyp as a rule from the endoscopy report. Applies to conventional adenomas (TA/TVA/VA) and all serrated lesions. Excludes inflammatory and reactive polyps (e.g. prolapse sdr.).

	No findings requiring follow-up
	High-grade dysplasia in any polyp
	≥ 10 mm polyp*
	Five or more adenomas
	Traditional serrated adenoma
	Sessile serrated lesion with dysplasia
	Polyposis (not inflammatory polyposis)
	polyp ≥ 20 mm in size removed in pieces
	Cancer or suspected cancer
	See report

Table 4. Pathology report chart.

14. FOLLOW-UP TREATMENT

- The table presented in this chapter is recommended as a basis for assessing the need for further treatment.
- The principles of colorectal cancer treatment are discussed in more detail in the National Treatment Guidelines for Colorectal Cancer.
- Follow-up examinations are performed as a matter of urgency to ensure that access to treatment is also urgent (30-day treatment guarantee).

14.1. BASIC PRINCIPLES

Follow-up treatment will be based on the findings of follow-up screening. If a screening colonoscopy reveals a significant polyposis finding (Table 5: Follow-up requirements for non-malignant screening findings.), the patient will proceed as usual to polyposis surveillance according to the agreed regional staging of care. Several international treatment recommendations have been published on polyp surveillance, with hospital district-specific recommendations, mostly based on the British recommendation[60] or ESGE[51]. If a polyp is found during endoscopy but removal is incomplete, the colonoscopy should be repeated within three months. If the polyp is completely removed, the timing of the follow-up colonoscopy is determined by the number and type of polyps (Table 5).

Patients who are found to have cancer or a large adenoma at endoscopy are referred to specialised healthcare for a multidisciplinary assessment. The place of follow-up for cancer treatment is determined according to the government decree on the division of tasks and centralisation of certain tasks in specialised healthcare[61]. The current wellbeing services counties have their own central hospitals where, depending on the local government co-management area agreements, colorectal cancer is treated. The treatment of colorectal cancer is centralised in university hospitals or larger central hospitals, where there are sufficient numbers of cases to treat.

Finding	Surveillance requirement
No polyps	Return to screening after six years
1-4 LGD adenomas, all less than 10 mm	
HP, size less than 10 mm	
SSL, size less than 10 mm	
Rectum and sigma HP, when their number is less than 20 and their size less than 10 mm	
Adenoma or serrated polyp 10 mm or larger	Check after three years
5 or more LGD adenomas	
Single HGD adenoma	
Single TSA	
Single dysplastic SSL (SSL-D)	
>= 20 mm polyp removed in pieces	Check after six months
Polyposis	Check after 1–2 years
Incompletely removed polyp	Repeat endoscopy after three months

Table 5. Surveillance requirement of non-malignant screening findings

With screening endoscopy, most polyps can be removed. However, submucosal invasion, or **pT1 adenocarcinoma**, is found in some polyps. These patients also need to be referred to specialist health care for multidisciplinary assessment.

14.2.STAGING AND OTHER EXAMINATIONS

According to the National Treatment Recommendation 1 all cancer patients should undergo a clinical and endoscopic examination, as well as a staging study; a body CT scan and, for colorectal tumours, a pelvic MRI scan. More detailed guidance on how to perform these tests is given in the National Treatment Guidelines. The radiologist's opinions should be structural[1]. The TNM staging of the disease at the time of diagnosis is an important prognostic factor. The patient's serum carcinoembryonic antigen (CEA) level should also be determined before treatment. Follow-up examinations are performed as a matter of urgency to ensure that access to treatment is also urgent (30-day treatment guarantee).

14.3.MULTIDISCIPLINARY ASSESSMENT

Every case of colorectal cancer – including pt1 adenocarcinomas and large adenomas – is treated treated in a multidisciplinary way. Treatment planning for colorectal cancer is based on clinical, radiological and histopathological assessment of the tumour, determination of disease spread, and the patient's condition. A multidisciplinary team (MDT) of specialists will make a risk assessment and individual treatment plan for each patient. The team includes a colorectal surgeon specialised in the operative treatment of colorectal cancer, an oncologist specialised in radiotherapy and anticancer therapy, a radiologist specialised in the interpretation of rectal MRI, a pathologist specialised in gastroenterology specimens and a nurse coordinating the implementation of the treatment decision. In addition, an assessment by a geriatric specialist of the patient's fitness to withstand the planned treatment is often required.

14.4.SURGICAL TREATMENT

The recommended treatment for **localised colorectal cancer** is the removal of the intestinal part of the tumour, which includes the intestinal lymph and blood vessels and lymph nodes feeding the tumour. Techniques for surgical treatment are discussed in the national guidelines for the treatment of colorectal cancer[1].

Localised rectal cancer should first be classified according to the prognosis of the disease: can the tumour be operated on directly or is preoperative treatment needed to reduce the risk of local recurrence or to shrink the tumour to improve the surgical outcome? Radiotherapy has been shown to reduce localised infiltration by about 50%, and the best benefit is achieved by administering radiotherapy before surgery[62,63]. After chemoradiotherapy and total anaesthetic adjuvant therapy, a pelvic MRI scan is performed before surgery to assess the response to treatment. Options for radiotherapy are discussed in the national guidelines for the treatment of colorectal cancer 1. In cases of very poor prognosis, preoperative body CT should be considered to rule out metastasis.

14.5.ADJUVANT CHEMOTHERAPY

After surgical treatment for radical colorectal cancer, adjuvant chemotherapy may be given. The purpose of adjuvant therapy is to reduce the risk of recurrence. The use of adjuvant chemotherapy for colorectal cancer has become widely used based on research evidence in colorectal cancer. However, research evidence on the benefit of adjuvant therapy in colorectal cancer patients who have not received neoadjuvant therapy is scarce. Adjuvant therapy should be started within eight weeks of surgery.

Adjuvant therapies are discussed in more detail in the national guidelines for the treatment of colorectal cancer[1].

14.6.TREATMENT OF DISSEMINATED DISEASE

Treatment of disseminated disease is addressed in the national guidelines for the treatment of colorectal cancer[1].

14.7. POST-TREATMENT SURVEILLANCE

The aim of the surveillance has been to detect relapses that are within the scope of curative treatment. Surveillance also increases the understanding of colorectal cancer clinicians of the disease and the factors that may influence the risk of recurrence and enables the unit to monitor treatment outcomes. It also allows for the management of late adverse side effects associated with the disease and the treatments required.

Surveillance methods include clinical examination, CEA determination, body CT scan and colorectal endoscopy of the colorectal junction and the remaining colon. Patients with a hereditary predisposition to colorectal cancer are screened for life-long cancer risk. 75% of recurrences are detected within the first two years. For patients diagnosed with bowel cancer at screening age or younger, a five-year follow-up after treatment is recommended as a rule.

15. STAFF AND TRAINING

- Screening nurses, endoscopists and pathologists undergo training to prepare them for the recording and specifics of screening.

15.1.SCREENING NURSES

Each wellbeing services county should have screening nurses who are in contact with people who test positive. The screening nurse advises and guides those undergoing screening and is the first point of contact for those who test positive. The screening nurse explains what a positive test result means, allay any concerns, explains follow-up examinations and ensures that suitability for follow-up examinations is assessed.

The screening nurse should be able to consult a doctor who performs colonoscopies.

The screening nurse collects and reports information on the screening process after a positive test result (including specialised healthcare and the private sector).

Each screening nurse attends an online training course organised by the Finnish Cancer Registry, which provides skills in counselling and guidance of screening participants and data collection. The training covers colorectal cancer screening in general, the different stages of the screening process, the role of the screening nurse in the screening process and data registration.

15.2.ENDOSCOPISTS

In many countries, there are clear criteria for endoscopists involved in screening based on previous experience and skills. They are also required to participate in training aimed at standardising endoscopy practices at the national level. These practices cover quality criteria, polypectomy, as well as documentation, reporting of findings and treatment and follow-up guidelines. In Finland, the training of specialists involved in screening endoscopy has been launched, following the Dutch model[6].

According to the criteria established by the Expert Group on Colorectal Cancer Screening, every endoscopist performing screening colonoscopies undergoes training organised jointly by the HUS Abdominal Centre and the University of Helsinki to ensure the documentation of findings and the quality of endoscopies. The selection criteria for the training are shown in Table 6. In addition, the training requires the ability to provide treatment and follow-up instructions based on the findings. Endoscopic screening findings are recorded by the Mass Screening Registry, which also enables the monitoring of the quality of the endoscopic work, such as the incidence of interval cancers[52,64]. Participation in screening is conditional on completion of a training course. The training is conducted online. It is essential in terms of the effectiveness and cost of

Criterion	Level
Experience with colonoscopies	> 3 years, > 500 colonoscopies performed
Annual number of colonoscopies	> 200
Annual polypectomies	> 50
Success rate of colonoscopies	> 90

Table 6. Criteria for a doctor participating in screening endoscopy training.

the screening activities that polyp surveillance is also based on current international treatment and monitoring recommendations[65,66].

15.3.PATHOLOGISTS

The healthcare professional who independently analyses the samples taken for further screening must have the privileges of a pathology specialist and sufficient experience in the diagnosis of intestinal biopsies (at least two years as a specialist and regular colonoscopic biopsies during that time). In addition, the person must have the possibility to consult a specialist in gastrointestinal (GI) pathology.

Pathologists should attend online training on colorectal cancer screening pathology and participate in national training courses in this field.

16. HARMS

- The screening programme is, by definition, an intervention for an asymptomatic population, which also has harms.
- The harms are monitored and minimised by the measures outlined in this chapter.
- Fecal occult blood testing is virtually harmless. Colonoscopy as a follow-up examination is also very safe.

16.1.GENERAL HARMS OF SCREENING PROGRAMMES

Screening targets an asymptomatic population, so harms are unavoidable. Harms that directly affect the person being screened are both physical and psychological. They can also be felt at a societal level, such as the additional costs of overdiagnosis.

In cancer screening, overdiagnosis is the detection of a cancer that would not have harmed a person in their lifetime even if it had not been diagnosed. Finding precancerous lesions that have never progressed to cancer can also be classified as overdiagnosis. At the time of detection, this classification cannot be made, but overdiagnosis is a population-level assessment of the harms of the screening programme. The harms of screening, as well as the benefits, should also be clearly communicated to the person being screened at the invitation stage.

16.2.HARMS OF COLORECTAL CANCER SCREENING

Faecal occult blood testing for colorectal cancer screening is non-invasive and there are no physical side effects associated with home sampling.

False positive screening results are harmful to the person being screened and also consume healthcare resources, especially colonoscopy capacity. Too frequent screening and too low test (FIT) cut-off value increase the number and proportion of false positive test results, and thus harms.

Adenoma findings require closer surveillance. Although not all precancerous lesions progress to cancer, the knowledge of an abnormal screening result may cause psychological distress to the person being screened. Waiting for test results and follow-up examinations is an essential part of the screening process. However, anxiety associated with colorectal cancer screening has been found to be relatively low in the research literature[67,68]. Adequate resourcing of follow-up examinations and rapid access to examinations help minimise harms.

Overtreatment is the treatment of precancerous lesions that would not have developed into cancer during the lifetime of the person being screened. Precancerous lesions in bowel cancer are asymptomatic and may only be detected by screening or by chance during another bowel test. Screening for colorectal cancer can lead to overtreatment due to false-positive results, misdiagnosis and overly conservative histological classification.

16.3.COLONOSCOPY SAFETY

A colonoscopy is a reasonably safe examination. In addition, the number of colonoscopies in faecal occult blood testing-based screening is lower than in colonoscopy-based screening, which contributes to reducing the harms of colonoscopy in the screening programme. The examination may be associated with stretching pain caused by both the balloon and the scope, which usually resolves quickly during the examination. If necessary, pre-medication may be used. If no intervention (biopsy or polypectomy) is performed during the procedure, the complication rate is 109 per 100 000 examinations and 218 per 100 000 if procedures (such as polypectomy) are performed. Serious complications such as leaks or perforations are much less frequent: 20/100 000 and 65/100 000 in the case of procedures . The vast majority of serious colonoscopy complications are related to polypectomy69. Complications, especially cardiovascular complications, increase with the age of the patient and the presence of comorbidities[70].

17. REGISTRATION OF SCREENING DATA

- Screening data from all stages of the screening chain, from referral to first treatment, are collected in the screening laboratory's data system.
- The screening laboratory sends the collected data to the mass screening registry of the Finnish Cancer Registry according to the defined data model and parameters.
- The data is collected by the screening nurse. Colonoscopy data is recorded by the colonoscopist.
- The effectiveness of the screening programme is monitored at national and regional level using relevant indicators.

17.1. DATA COLLECTION

Data from all stages of the screening process is collected in the screening laboratory's data system and submitted to the Mass Screening Registry of the Finnish Cancer Registry. The data flow is shown in Figure 6: Information flow between the screening centre and other actors. Screening laboratories or other screening providers have a legal right to process all screening data, including data for further investigation and specialist care. Likewise, follow-up and specialist care services have a statutory right to transmit this information to the screening provider. It is also essential in data collection that the different stages of the process (e.g. referral, testing, follow-up examinations) remain linked, i.e. that the data is retained in a coherent screening chain.

The development and quality of the process require the feedback of the identified findings from the specialist hospital to the screening nurse. To ensure smooth data collection, the screening laboratory must provide a data system for reporting follow-up and treatment data. The screening nurse shall collect and report information on the screening process after a positive test result (including specialist care and private sector) in accordance with Cancer Registry training. The treatment data is reported as the first treatment intervention.

The specialist performing the endoscopy reports the follow-up examination data to the screening centre's electronic reporting system according to quality criteria. Follow-up information includes details of the procedure, the findings of the endoscopy, the pathologist's opinion and follow-up instructions for treatment.

The controller of the patient data generated during the screening process is the wellbeing services county. This does not change even if the screening process is outsourced. Screening data is patient records and is confidential.

17.2. SUBMISSION OF DATA TO THE FINNISH CANCER REGISTRY

Section 6c of the Screening Decree on the monitoring of cancer screening results obliges the screening provider to submit individual-level data on all stages of screening to the mass screening register of the Finnish Cancer Registry. These stages include sending invitations, taking and analysing samples, providing feedback, referral for follow-up examinations and specialised healthcare, and carrying out follow-up examinations and specialised healthcare.

According to the THL's administrative decision https://thl.fi/aiheet/tiedonhallinta-sosiaali-ja-terveysalalla/maaraykset-ja-maarittelyt/hallintopaatokset , the wellbeing services county must require the screening laboratory to submit the screening data for registration in the Mass Screening Registry in line with the instructions on the Finnish Cancer Register's Data Registration page 44. The data shall be submitted in accordance with the data model and parameters defined by the Cancer Registry. The results of screening are recommended to be submitted periodically as soon as they are generated. The whole screening (faecal blood testing, follow-up examinations, first treatment data) should be delivered to the Mass Screening Registry by the end of August following the screening year. The screening laboratory must have the IT capacity to collect, store and submit the data.

17.3.QUALITY ASSURANCE AND STATISTICS

The wellbeing services county is responsible for ensuring the quality of screening activities. The data systems of the colonoscopy units should also allow for reporting of the quality of endoscopies back to the individual endoscopy units performing them faster than is possible under the national Mass Screening Registry reporting of the screening programme.

Screening statistics and reports are produced annually from the individual-level data submitted to the Mass Screening Registry of the Finnish Cancer Registry. The key figures or indicators to be published are based on EU guidelines 71 and are similar to those used in other national cancer screening programmes. The indicators to be reported, with their recommended values, include:

1. **Invitation coverage**
   a.Invited/Target population (%) (> 99%)
2. **Active participation**
   a. Participants/invited (%) (>70%)
      i. First call
      ii. Reminder
      iii. Total
3. **Proportion of positive test results in screened participants**
   a. Test positive/participants (%) (5%)
4. **Data for the follow-up phase of the study**
   a.Proportion of colonoscopy referrals of test-positive patients (%) (>75%)
   b.Delays in performing a colonoscopy after a positive test result
   c. Quality indicators for colonoscopy (described in more detail in chapter Colonoscopy)
5. **Colonoscopy findings**
   a. Colonoscopy findings/test positives (%)
      i. normal finding
      ii. adenoma
      iii. advanced adenoma
      iv. cancer
6. **Surgical findings**
   a. Surgical findings/test positives
      i. normal finding
      ii. adenoma
      iii. advanced adenoma
      iv. cancer
         1.(pTNM, stage)

Screening indicators are reported at the national level and by the wellbeing services counties for the whole target population. They are also reported nationwide by two-year age group and by socio-economic status, level of education and mother tongue. The list of indicators will be updated and developed as necessary.

In addition to statistical indicators, the sensitivity, positive predictive value and accuracy of screening are monitored. They describe how well the screening test detects adenomas and cancers (sensitivity and positive predictive value) and identifies healthy ones (accuracy). Similar metrics can also be calculated for colonoscopy (sensitivity, positive predictive value and accuracy of the screening episode) and for all those invited for screening (sensitivity and accuracy of the screening programme).

The effectiveness of screening for colorectal cancer is assessed in a setting where the cancer incidence and mortality of age cohorts invited to screening are compared with those of cohorts not invited to screening. The assessment will also take into account the pre-screening period of those invited to screening at older ages, including cancer diagnoses and deaths. For the purpose of the estimation, screening data are combined with cancer data from the Finnish Cancer Registry, mortality data from the Digital and Population Data Services Agency (DVV) and cause of death data from Statistics Finland.

The follow-up period for mortality assessment should be long enough to allow the early diagnosis achieved by screening to have an impact on the distribution of colorectal cancer prevalence and cancer mortality. This means at least ten years of follow-up.

18. COMMUNICATION

- The aim of communicating the screening pro gramme is to provide a good understanding of the purpose, benefits, harms and process of screening.
- An important communication tool for screeners is the screening invitation pack. Communication should take into account special groups and people who have not participated in the screening.

18.1.THE AIM OF COMMUNICATION

Screening significantly reduces mortality from colorectal cancer. The benefits of screening have also been estimated to outweigh the harms. To ensure that screening continues to be effective, the programme should be communicated with the aim of achieving the highest possible screening uptake in the target population.

The communication should give a good understanding of the purpose of the screening and the screening process. It should also increase a sense of security at different stages of the screening chain. Good communication and information can minimise the potential psychological harm caused by screening.

Communication related to the screening is primarily the responsibility of the wellbeing services counties and the City of Helsinki. The well-being region must ensure that its residents have access to sufficient information about the objectives and effectiveness of screening, the possible risks associated with screening and the organisation of screening[42].

18.2.COMMUNICATION CONTENT

Good communication is needed at all stages of the screening chain: when receiving the home sampling package, when sending the screening response and at any follow-up examinations. Clear and accurate written information must be available to the person invited to the screening at all times.

Both summarised basic information and more detailed information on the different stages of screening should be available. Screening invitations and materials should contain the same information throughout the country to ensure regional parity. The Cancer Registry will provide and update (e.g. brochures, invitation letters, response letters) freely to screening providers. Materials are available in different languages[48].

Particular attention should be paid to those with an abnormal result in the information provided.

18.3.IMPROVING PARTICIPATION

Communication should also aim to reach people who have not participated in the screening programme. Reminders have been key to improving participation in the cervical cancer screening programme[72] and should also be used in colorectal cancer screening throughout Finland. In areas where screening uptake is lower than average, regional communication activities and campaigns can be implemented as appropriate.

Communication must emphasise the need for screening but in a way that does not compromise the right to self-determination and the possibility of opting out.

18.4.SPECIAL GROUPS

A major challenge in communicating about the screening programme is the variety of recipients of the information. Information material may need to be tailored to suit different audiences. For example, socioeconomic, linguistic and cultural differences need to be taken into account. Information should be available through different channels and in different languages and, where appropriate, cooperation can be established, for example with different ethnic communities[73].

The right to screening for other specific groups, such as people with reduced mobility, hearing and vision, and people with intellectual disabilities, must also be ensured through appropriate and accessible communication. Persons subject to non-disclosure for

personal safety reasons should not be automatically invited for screening. It is the responsibility of the wellbeing services county to inform special groups about their right to participate and to enable them to participate in screening.

18.5.INFORMATION AND COMMUNICATION CHANNELS

Wellbeing services counties should inform about any changes to the screening programme. This can be done through a press release, for example.

A person with an abnormal screening result should be allowed to contact the screening nurse in person. Contact details for this purpose may be given, for example, in the letter in response to the screening result. The healthcare professional should stress that a positive test result does not mean cancer or even a precancerous condition. Psychological support is available, for example, from the Cancer Society's advice service. The screening invitation letter and other communication practices for the individual are described in Chapter 10, Invitation.

Screening nurses are in direct contact with the people being screened, so they should also be trained in communication. Screening nurses can answer questions from screeners or tell them where more information is available. This will increase confidence in the screening programme.

Comprehensive and up-to-date information is also available on the internet, for example on the following websites:

Health Village (In Finnish):
https://www.terveyskyla.fi/tutkimukseen/laboratoriotutkimuksia/seulontatutkimukset/suolistosyovan-seulonta

Cancer Society of Finland:
https://www.freefromcancer.fi/check-your-body/colorectal-cancer-screening/

National treatment guidelines for colorectal cancer (in Finnish):
https://www.terveysportti.fi/apps/ltk/article/hsu00007

19. THE FUTURE OF COLORECTAL CANCER SCREENING

The colorectal cancer screening programme in Finland was expanded to a nationwide programme in 2022. One of the clearest goals for the new screening programme in the coming years is to consolidate the programme's activities in line with the guidelines in this quality manual. The first monitoring data and reports on the national programme will be available in 2024, after which areas for particular improvement can be analysed.

The screening programme will expand to its full age range (56–74) by 2031. As the population to be screened grows, the challenge in the coming years will be to ensure that there are adequate colonoscopy resources.

Screening for colorectal cancer is the subject of ongoing active research both in Finland and internationally. Currently, topics of interest on the research front include, in particular, targeting screening based on background risk, taking into account, for example, the previous test results of those screened. By optimising screening through the use of screening history, it would be possible in the future to better target screening to those who need it most and to reduce the amount of screening in the part of the population that would not benefit from screening to the same extent. Risk-based screening is still in the research stage. Concrete implementation at the national level requires not only research evidence but also national piloting.

The development of new screening tests will be continuously monitored and the test methods approved for the screening programme will be updated as necessary.

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21. ANNEX

	Calendar year										
Birthyear	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
1977	45	46	47	48	49	50	51	52	53	54	55
1976	46	47	48	49	50	51	52	53	54	55	56
1975	47	48	49	50	51	52	53	54	55	56	57
1974	48	49	50	51	52	53	54	55	56	57	58
1973	49	50	51	52	53	54	55	56	57	58	59
1972	50	51	52	53	54	55	56	57	58	59	60
1971	51	52	53	54	55	56	57	58	59	60	61
1970	52	53	54	55	56	57	58	59	60	61	62
1969	53	54	55	56	57	58	59	60	61	62	63
1968	54	55	56	57	58	59	60	61	62	63	64
1967	55	56	57	58	59	60	61	62	63	64	65
1966	56	57	58	59	60	61	62	63	64	65	66
1965	57	58	59	60	61	62	63	64	65	66	67
1964	58	59	60	61	62	63	64	65	66	67	68
1963	59	60	61	62	63	64	65	66	67	68	69
1962	60	61	62	63	64	65	66	67	68	69	70
1961	61	62	63	64	65	66	67	68	69	70	71
1960	62	63	64	65	66	67	68	69	70	71	72
1959	63	64	65	66	67	68	69	70	71	72	73
1958	64	65	66	67	68	69	70	71	72	73	74
1957	65	66	67	68	69	70	71	72	73	74	75
1956	66	67	68	69	70	71	72	73	74	75	76
1955	67	68	69	70	71	72	73	74	75	76	77
1954	68	69	70	71	72	73	74	75	76	77	78
1953	69	70	71	72	73	74	75	76	77	78	79

Table 7. Scaling-up matrix for the screening programme.