

# COLORECTAL CANCER SCREENING PROGRAMME

Version 11. December 2024

Preparation:

Coordinating Centre of the  
Colorectal Cancer Screening  
Programme

Osakidetza General Directorate

The Basque Health Service

Isabel Portillo

Isabel Idigoras

Irene Sainz de Rozas

Nerea Lopez Mintegi

Beatriz Erro

Koldo López-Guridi

Marga Urrejola

Arantza Menchaca

Jon Koldobika Hurtado

[prevencionccr@osakidetza.eus](mailto:prevencionccr@osakidetza.eus)

This Programme, Version 11, December 2024, has been updated to enhance our knowledge of screening as an early detection method, at world, European and Basque level.

The procedures have been updated since version 10 of November 2023, so we present all those aspects that have been incorporated into the Screening Programme and that will allow us to continue improving our activities in order to offer both professionals and the public the available information based on scientific evidence and consensus. This version has been written and edited by the work team of the Screening Programme Coordinating Centre.

Since its launch in 2009, changes have been made and new protocols have been introduced to facilitate the standardisation of procedures and improve results.

This document is dynamic and open to suggestions. Indeed, it would not have been possible without the invaluable help of the individuals and professionals who have contributed ideas during this time.

We would like to take this opportunity to thank each and every one of the individuals who have made contributions from all areas and knowledge to improve this version 10.

Coordinating Centre of the Colorectal Cancer Screening Programme

Subdirectorate of Hospital Coordination

Osakidetza General Directorate

Gran Vía, 62 – 4<sup>a</sup> Planta

48011 Bilbao

prevencionccr@osakidetza.eus

900 840 070

<https://www.osakidetza.BasqueCountry.eus/programa-de-prevencion-del-cancer-colorrectal/webosk00-os-kenf/es/>

## TABLE OF CONTENTS

<b><u>1. ABBREVIATIONS</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>2. INTRODUCTION</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>3. COLORECTAL CANCER SCREENING PROGRAMME (CCSP) IN BASQUE COUNTRY</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>4. RATIONALE FOR COLORECTAL CANCER SCREENING (CRC)</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>5. OBJECTIVES OF THE CRC SCREENING PROGRAMME 2023-2025</u></b> .....	<b>14</b>
<b><u>6. SCOPE OF ACTION</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>7. INFORMATION, MONITORING AND EVALUATION SYSTEM</u></b> .....	<b>17</b>
<b><u>8. SCREENING PROGRAMME MANAGEMENT CYCLE</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>ANNEX I CRITERIA FOR SELECTING THE POPULATION AND OBTAINING PROGRAMME INDICATORS</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>ANNEX II INVITATION PROCEDURE</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>ANNEX III SAMPLES: DELIVERY AND PROCESSING</u></b> .....	<b>28</b>
<b><u>ANNEX IV FIT RESULTS MANAGEMENT</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>ANNEX V POSITIVE RESULTS MANAGEMENT</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>ANNEX VI COLONOSCOPY APPOINTMENT MANAGEMENT</u></b> .....	<b>33</b>
<b><u>ANNEX VII COLONOSCOPY RESULTS MANAGEMENT</u></b> .....	<b>35</b>
<b><u>ANNEX VIII OSAKIDETZA COLONOSCOPIES PRIORITISATION PROPOSAL</u></b> .....	<b>41</b>
<b><u>ANNEX IX STRATIFICATION CRITERIA</u></b> .....	<b>45</b>
<b><u>ANNEX X PROGRAMME VARIABLES</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>ANNEX XI PROGRAMME QUALITY CRITERIA (EUROPEAN COMMISSION, 2010)</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>ANNEX XII AWARENESS-RAISING AND TRAINING PROCEDURE</u></b> .....	<i>¡Error! Marcador no definido.</i>
<b><u>ANNEX XIII LETTERS / SMS</u></b> .....	<b>588</b>
<b><u>ANNEX XIV INVITATION OF PERSONS WITHOUT AN IHC</u></b> .....	<b>61</b>
<b><u>ANNEX XV PATHOLOGICAL ANATOMY</u></b> .....	<i>¡Error! Marcador no definido.</i>

## 1. ABBREVIATIONS

**AAR:** Age-adjusted rates

**ACBC:** Autonomous Community of the Basque Country

**AL:** Advanced Lesion (AMR + AAR)

**AN:** Advanced Neoplasia

**ASA:** Classification criteria of the American Society of Anaesthesiologists

**BPD:** Basic Patient Data in Primary Care

**CCSP:** Colorectal Cancer Screening Programme

**CH:** Clinical History

**CIC:** Corporate Identification Code

**CLINIC/Osabide Integra:** Access to Clinical Data of Basque Country Patients

**CRC:** Colorectal Cancer

**CSA:** Customer Service Area

**DB:** Database

**EUSTAT:** Basque Institute of Statistics

**FIT:** Faecal Immunochemical test.

**FOB:** Faecal occult blood

**FOBT:** Faecal Occult Blood Test

**GestLab:** Laboratory test management programme

**HC:** Health Centre

**HGD:** High Grade Dysplasia

**HPCU:** Head of Primary Care Unit

**HRA:** High Risk Adenoma

**HTR:** Hospital Tumour Registry

**IC:** Informed Consent

**IHC:** Individual Health Card

**IHO:** Integrated Health Organisation

**INDEF:** National Death Index

**LGD:** Low Grade Dysplasia

**LOPD:** Organic Law on Data Protection

**LRA:** Low Risk Adenoma

**MHDD-Altas:** Minimum Hospital Discharge Data Set

**MIA:** Medium or Intermediate Risk Adenoma

**NHS:** National Health System

**OGP:** Osabide Global Primaria

**OSABIDE:** Patient and clinical documentation management programme. Basque Country Clinical History.

**OSAKIDETZA:** Basque Health Service

**PAC:** Percentage of annual change

**PoCC:** Point of Continuous Care

**PCC:** Programme Coordinating Centre

**PCP:** Primary Care Physician

**PCU:** Primary Care Unit

**PTR:** Population-based Tumour Registry

**QALY:** Acronym for quality-adjusted life years

**RS:** Relative survival

## 2. INTRODUCTION

### Global Colorectal Cancer Data

Colorectal cancer (CRC) is the third most common cancer in men and women worldwide. According to the most recent GLOBOCAN estimates (IARC, 2022)<sup>1</sup>, 1.069.446 new cases were estimated in men and 856.979 in women in 2022. CRC accounted for more than 10% of the global cancer burden; the proportions were higher only for lung and prostate cancers (in men) and breast and lung cancer (in women).

In 2020, the overall age-standardised incidence rate (ASR) for CRC was 21.9 per 100 000 in men and 15.2 per 100 000 in women.

### Risk factors in colorectal cancer.

The main risk factor for developing colorectal cancer is age, with the risk of onset increasing above the age of 50. People with a personal or family history of CRC, colorectal polyps or hereditary syndromes also have a higher risk of developing this type of cancer. These factors are not modifiable, however, there are other modifiable risk factors that are associated with colorectal cancer.

Modifiable risk factors associated with colorectal cancer include a diet high in red or processed meat, tobacco and alcohol consumption and physical inactivity, among others.

### Framework of the Colorectal Cancer Screening Programme of the Basque Country.

The score card of the Basque Country 2030 Health Plan includes coverage of CRC screening as part of the objective of improving health and reducing morbidity and mortality and tackling the disease and disability that causes the greatest loss of DALYs (disability adjusted life years) using criteria of equity, quality and efficiency.

The Basque Country Cancer Plan 2018-2023 describes the data on anal and CRC cancer. The goals of the Screening Programme, included in this Oncology Plan, are: to increase the effective coverage rates of the colorectal cancer screening programme (to reach at least 90% of the theoretical target population) and to make progress in improving and implementing this screening.

## 3. COLORECTAL CANCER SCREENING PROGRAMME (CCSP) IN BASQUE COUNTRY

Approved by the Basque Parliament in 2008, it was launched in 2009.

- a) Population. Aimed at women and men between 50 and 74 years of age (778,359 persons: 400,181 women and 378,178 men - *Eustat 2023*).
- b) Biennial. Quantitative Immunochemical Test (FIT). Cut-off point 20µg Hb/g stool. 1 single sample
- c) Colonoscopy under sedation in all positive cases
- d) Primary Care involvement
- e) Inter-operative information system with the clinical history and clinical databases (registration of procedures, hospital discharges, hospital and population tumour registers and mortality).

- f) Centralized coordination through a working team: 1 doctor coordinating the Programme, 3 technicians and 4 administrative staff shared with the Prenatal Screening Programme.
- g) Quality system for processes and results that allows for systematic and continuous monitoring and evaluation of pre-established indicators in accordance with the Clinical Practice Guidelines and the implementation of improvements.
- h) Participation in projects and initiatives at Autonomous Community, State and International level to share knowledge and common strategies.

### **3.1. Main results**

#### 3.1.1. Coverage

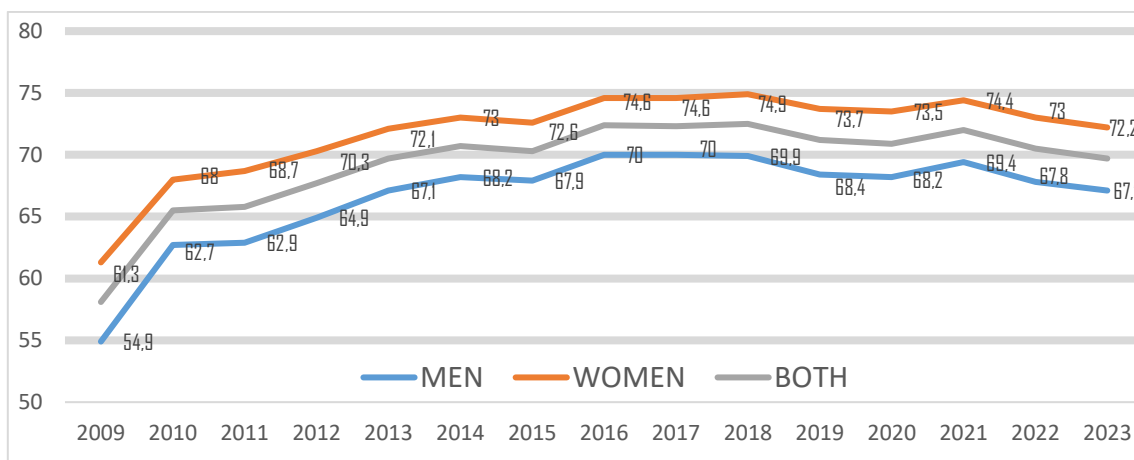
CCSP coverage on the first invitation of approximately 100% of the target population. This was achieved in the first quarter of 2014, being the first Autonomous Community to achieve this. This required a significant investment in resources, mainly in the endoscopy department, the cornerstone of all CRC screening programmes.

#### 3.1.2. Participation

Participation rates in the Programme have seen a positive trend throughout the period 2009-2023, although significantly lower in men vs. women, in both cases; and since 2011 it has been observed that in both cases it is higher than those recommended in the Clinical Practice Guidelines (2010) and the Strategy against Cancer 2021 (desirable 65%).

GRAPH 1. Evolution of the participation rate in the colorectal cancer screening programme. CAE.

Years 2009-2023



Despite this high participation rate, superior to the recommendations of the European Guidelines (65%) and similar programmes<sup>1-2-3-4</sup>, it should be noted that significant gender differences have been found as in other CRC population-based screening programmes<sup>5-6</sup>. Differences were also found by the Integrated Health Organisation (IHO), Primary Care Unit (PCU) and Health Centre (HC), with lower participation in people with a high deprivation index, as observed in the UK National Health System Programme (NHS)<sup>7,8,9,10</sup>

1 Bakker CK, Jonkers D, Smits K, Mesters I, Masclee A, Stockbrügger R. Participation in colorectal cancer screening trials after first-time invitation: a systematic review. *Endoscopy* 2011; 43:1059-1086.

2 Clarke N, Sharp L, Osborne A, Kearney PM. Comparison of Uptake of Colorectal Cancer Screening Based on Faecal Immunochemical Testing (FIT) in Males and Females: A Systematic Review and Meta-analysis. *Cancer Epidemiol Biomarkers Prev*. 2015;24;1:39-47

3 Lo SH, Halloran S, Snowball J, Seaman H, Wardle J, von Wagner C. Colorectal cancer screening uptake over three biennial invitation rounds in the English bowel cancer screening programme. *Gut*. 2015; 64;2:282-91.

4 Kapidzic A, Grobbee EJ, Hol L, van Roon AH, van Vuuren AJ, Spijker W, et al. Attendance and Yield Over Three Rounds of Population-Based Fecal Immunochemical Test Screening. *The American Journal of Gastroenterology*. 2014;109;8:1257-64

5 Portillo I, Idigoras I, Ojembarrena E, Arana E, Zubero MB, Pijoán JI et al. Principales resultados del programa de cribado de cáncer colorrectal en el País Vasco. *Gac Sanit*. 2013; 27; 4: 358-361

6 Clarke N, Sharp L, Osborne A, et al. Comparison of uptake of colorectal cancer screening based on fecal immunochemical testing (FIT) in males and females: a systematic review and meta-analysis. *Cancer Epidemiol Biomarkers Prev* 2015;24:39-47.

7 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.

8 Christian von Wagner et al. Inequalities in Participation in an Organized National Colorectal Cancer Screening Programme: Results from the First 2.6 Million Invitations in England. *International Journal of Epidemiology*. 2011; 40; 3: 712-18, doi:10.1093/ije/dyr008

9 Unanue-Arza, S.; Idigoras-Rubio, I.; Fernández-Landa, M.J.; Bilbao-Iturrabarria, I.; Bujanda, L.; Portillo, I. Analysis of Post-Colonoscopy Colorectal Cancer and Its Subtypes in a Screening Programme. *Cancers* 2021, 13, 5105.

10 Solís-Ibinagaitia M, Unanue-Arza S, Díaz-Seoane M, Martínez-Indart L, Lebeña-Maluf A, Idigoras I, Bilbao I and Portillo I (2020) Factors Related to Non-participation in the Basque Country Colorectal Cancer Screening Programme. *Front. Public Health* 8:604385. doi: 10.3389/fpubh.2020.604385

### 3.1.3. Benefits of the Programme

To date, the results of the Programme are aligned with the recommendations of the European Clinical Practice Guideline and published studies on population-based screening programmes (Table 1)<sup>11-12</sup>. In addition, there is no clear relationship between social class or educational attainment and prevalence of participation<sup>13</sup>.

Thus, this participation shows higher rates and no inequalities in terms of socio-economic and educational level, in contrast to the Programme's records<sup>8</sup>. This may be due to the fact that screening is offered in other systems (private, public).

On the other hand, compared to other national and international programmes, the high participation rate is possibly related to the organisation of the programme (sending the kit to homes) and the involvement of primary care<sup>21,14</sup>.

**TABLE 1.** *Indicators of positivity, colonoscopy acceptance and detection rates*

Rates	Basque Country 2009-2023			European Guide
	Men	Women	Both sexes	Both sexes
<b>PARTICIPATION RATE</b> (% of valid invitations)	67.78%	72.85%	<b>70.40%</b>	>65%
<b>POSITIVE RATE</b> (% of participants)	6.34%	4.10%	<b>5.14%</b>	4-11%
<b>ADHERENCE TO CONFIRMATORY COLONOSCOPY WITH DEFINITIVE DIAGNOSIS</b> (% of positives)	94.55%	94.82%	<b>94.66%</b>	90-95
<b>LOW-RISK ADENOMA DETECTION RATE</b> x 1,000 participants	11.541‰	7.173‰	<b>9.20‰</b>	–
<b>INVASIVE CANCER SCREENING RATE (CRC) ≥pT1</b> x 1,000 participants	2.84‰	1.43‰	<b>2.09‰</b>	1.3-9.5‰
<b>ADVANCED LESION DETECTION RATE (AL=AAR + AMR+Lx)</b> x 1,000 participants (1-3 Adenomas and/or 1 ≥ 10mm and/or 25% villous and/or high-grade dysplasia)	27.058‰	10.87‰	<b>18.38‰</b>	–

11 Kapidzic A, van de Meulen P, van Roon AH, Looman CW, Lansdorp- Vogelaar I, van Ballegooijen M, et al: Gender differences in fecal immunochemical test performance for early detection of colorectal neoplasia. Clin Gastroenterol Hepatol 2015; pii: S1542-3565;15;00162-7

12 Portillo I, Arana-Arri E, Idigoras I, Espinás JA, Pérez-Riquelme F, de la Vega M, González A, Oceja E, Vanaclocha M, Ibañez J, Salas D y Grupo CRIBEA. Proyecto CRIBEA: Lesiones detectadas en seis Programas Poblacionales de Cribado de Cáncer Colorrectal en España. Rev Esp Salud Pública 2017; 91; 20 February e1-e10.

13 Encuesta de Salud del País Vasco. Año 2018 (ESCAV 2018). Capítulo 6: Servicios de salud y de cuidados. Programas de cribado de cáncer.

14 Unanue-Arza S, Arana-Arri E, Portillo I, Arostegui I. Implicación de los profesionales de atención primaria en el programa de detección precoz de cáncer colorrectal del País Vasco. Rev Esp Salud Pública. 2021; Vol. 95: 26 January e1-11.

<b>ADVANCED NEOPLASIA DETECTION RATE (AN) = AA+CRC</b> x 1,000 participants	29.90‰	12.30‰	<b>20.47‰</b>	–
<b>POSITIVE PREDICTIVE VALUE CRC</b>	4.49%	3.51%	<b>4.07%</b>	4.5-8.6%
<b>POSITIVE PREDICTIVE VALUE AL</b>	42.67%	26.5%	<b>35.76%</b>	–
<b>POSITIVE PREDICTIVE VALUE AN</b>	42.74%	26.35%	<b>35.77%</b>	–

Source: Prepared by the authors (data from the Basque Country colorectal cancer screening programme; European CPG 2010).

The following table (Table 2) shows the data by stages of the cancers detected by the Programme for the years 2009-2023

**TABLE 2. Invasive cancers detected by the Programme 2009-2023, by gender**

INVASIVE CANCERS	Basque Country 2009-2023			Sig.
	Men (N; %)	Women (N; %)	% Difference (IC 95%)	
INITIAL STAGE I and II	2,041 (72)	1,118 (67.6)	4.43 (1.59 – 7.27)	0.001
ADVANCED STAGE III and IV	768 (27.1)	514 (31.1)	-3.96 (-1.14 – -6.78)	0.003
STAGE UNKNOWN	24	21	-	-
<b>TOTAL INVASIVE CANCERS DETECTED BY THE PROGRAMME</b>	<b>2,809</b>	<b>1,632</b>	-	-

### 3.1.4. Adverse effects of the Programme

The main adverse effects of the Programme are:

- **False positives:** After a positive test result, no Advanced Adenomas and/or Colorectal Cancer are found at colonoscopy.
- **False negatives**, (interval cancer) which are of 2 types:
  - o **Interval cancer FIT:** with FIT result (-) and CRC diagnosis before the next invitation.
  - o **Colonoscopy Interval cancer:** CRC diagnosed before the recommended follow-up after a diagnostic confirmation colonoscopy at FIT (+)
- **Post-colonoscopy complications:** complications occurring 0-30 days post-colonoscopy<sup>15,16</sup>.

These effects are systematically monitored in order to establish guidelines for minimising them. The false positive rate has been increasing as screening rounds increase, being higher in women than in men, although no effective and efficient method to minimise it has yet been found<sup>17,18</sup>.

Serious complications (lower gastrointestinal bleeding with transfusion, perforation with conservative or surgical treatment, post-polypectomy syndrome, sedation problems requiring hospitalisation and death) recorded up to 31 December 2023 were 395 out of 60,277 (6.5‰) in men and 272 out of 43,707 in women. (6.2‰).

With regard to Interval Cancers, it was observed that both their location, stage and survival differed significantly from those detected by the Program, with a less favourable prognosis<sup>19, 21</sup>

---

<sup>15</sup> Arana-Arri E, Imaz-Ayo N, MJ, Idigoras I, Bilbao I, Bujanda L, et al. Screening colonoscopy and risk of adverse events among individuals undergoing fecal immunochemical testing in a population-based program: A nested case-control study. *United European Gastroenterol J.* 2018 Jun; 6(5): 755–764. doi: 10.1177/2050640618756105

<sup>16</sup> Mercedes Vanaclocha-Espia, Josefa Ibáñez B, Ana Molina-Barceló, María José Valverde-Roig, Elena Pérez, Andreu Nolasco, Mariola de la Vegad, Isabel Diez de la Lastra-Bosch, María Elena Ocejae, Josep Alfons Espinàs, g, Rebeca Font, g, Francisco Pérez-Riquelme, i, Eunat Arana-Arri, Isabel Portillo, Dolores Salasa, b, \*, CRIBEA Group. Risk factors for severe complications of colonoscopy in screening programs. <https://doi.org/10.1016/j.yjmed.2018.11.010>

<sup>17</sup> Cristina Alvarez-Urturi, Montserrat Andreu, Cristina Hernandez, Francisco Perez-Riquelme, Fernando Carballo, Akiko Ono et al. Impact of age and gender-specific cut-off values for the fecal immunochemical test for haemoglobin in colorectal cancer screening. *Digestive and Liver Disease* 2016. DOI.org/10.1016/j.dld.2016.02.001

<sup>18</sup> Arana-Arri E, Idigoras I, Uranga B, Perez R, Irurzun A, Gutierrez-Ibarluzea I, Fraser C, Portillo I, EUSKOLON group. Population-based colorectal cancer screening programmes using a faecal immunochemical test: should faecal haemoglobin cut-offs differ by age and sex? *BMC Cancer* DOI 10.1186/S12885-017-3555-3

<sup>19</sup> Portillo I, Arana-Arri E, Idigoras I, Bilbao I, Martínez-Indart L, Bujanda L, Gutierrez-Ibarluzea I. Colorectal and interval cancers of the colorectal cancer screening program in the Basque Country (Spain). *World Gastroenterol* 2017; 23; 15: 2731-2742.

### 3.1.5. Impact of the Programme

Measuring the impact of health programmes is essential for ascertaining the extent of their benefits at population level. In our case, we have population-based incidence and mortality registers that allow us to carry out a pre- and post-intervention evaluation.

By analysing all CRC cases detected and not detected by the Programme as of 31/12/2023, these were the main results we obtained for the quantitative immunochemical test (Table 3):

**TABLE 3.** *Sensitivity and specificity of FIT (2009-2023)*

CCSP	MEN	WOMEN	<i>p</i> value
Sensitivity	83.8% IC 95% (0.82-0.85)	78.8% IC 95% (0.77-0.80)	<0.05
Specificity	94.2% IC 95% (0.942-0.943)	96.0% IC 95% (0.096-0.097)	<0.05

Although the effectiveness data are superior to those found in the literature for this type of test, it is necessary to continue monitoring them systematically with cancer and mortality registries to identify areas for improvement (reduction of adverse effects).

## 4. RATIONALE FOR COLORECTAL CANCER SCREENING

### 4.1. Necessary conditions for colorectal cancer screening

It should be borne in mind that a screening programme is not merely a series of tests, but also a set of coordinated multidisciplinary activities continued over time and aimed at achieving common objectives. It is based on established quality criteria and standards, supported by scientific evidence which guarantee the benefits and reduce the risks, i.e. effectiveness and cost-effectiveness studies have been conducted to implement it, given the involvement of the Health Systems involved.

We know from the natural history of CRC that in 70-80% of cases it originates from an intestinal polyp (adenoma) that undergoes malignant transformation (carcinoma). The average time in which an adenoma can develop into cancer is estimated at 10 years<sup>20</sup>. Most cases (70%) are sporadic, with no family history.

Initially, this type of lesion presents few or no symptoms, and the following schematic sequence shows how it can progress from an adenoma to a localised carcinoma (Stage I) and then to metastasis (Stage IV).

The next factor to consider for a screening programme is the existence of a suitable test or examination and, in the case of CRC, the following are considered to be effective tests: colonoscopy, sigmoidoscopy and faecal occult blood -FOB- (European Guidelines, 2010 subsequently updated in the IARC Handbook<sup>34</sup>).

The new European screening recommendation (2021) recommends the use of the quantitative immunochemical test for FIT, instead of screening with a faecal occult blood test (guaiac test) , for colorectal cancer screening in persons aged 50-74 years, with a follow-up colonoscopy.

In Basque Country, the method chosen was the quantitative immunological FIT, comparing the available validated methods: Sentinel® and OC-Sensor® in 2009-2010<sup>21</sup>. From the second half of 2010 OC-Sensor® is used, with a cut-off value of 20µHb/g faeces, equivalent to 100 ngHb/ml buffer.

The diagnostic test and "gold standard" for this screening is full optical colonoscopy (visualising the caecum) under sedation.

In the context of the CRC screening programme, this colonoscopy has special connotations, as it not only allows confirmation of the diagnosis but also the removal of pre-neoplastic lesions, thus will reducing the incidence and mortality from colorectal cancer in the population in the medium to long term.

---

20 Bonelli L. Epidemiology and screening: what's new? *Colorectal Dis.* 2015;17:10–4. Accessible at: <http://onlinelibrary.wiley.com/doi/10.1111/codi.12815/abstract>

21 Zubero MB, Arana-Arri, E, Pijoan JI, Portillo I, Idigoras I et cols. Population-based colorectal cancer screening: comparison of two faecal occult blood test. *Frontiers in Pharmacology* 2014; 4; 175; 1-8

## 5. OBJECTIVES OF THE CRC SCREENING PROGRAMME 2023-2025

### 5.1. General Objective

Early detection and treatment of premalignant and malignant lesions to reduce colorectal cancer incidence and mortality.

### 5.2. Specific Objectives

- 99% coverage of persons resident in Basque Country, regardless of their insurance status.
- Contribute to the reduction of social inequalities by increasing access for vulnerable individuals.
- Increase the participation of men across all age groups.
- Decrease screening test errors by < 1%.
- Ensure follow-up of all screened positive individuals with a miss rate of < 5%.
- Monitor and minimise adverse effects of screening (haemorrhage, perforation, respiratory depression and death).
  - Incidence of perforation  $\leq 1: 1,000$  diagnostic or therapeutic colonoscopies;  $\leq 1: 500$  colonoscopies with polypectomy.
  - Incidence of post-polypectomy bleeding  $\leq 1: 1:100$  colonoscopies with polypectomy
- Decrease the rescheduling rate due to inadequate preparation to 2% to improve safety and reduce costs.
- Monitor the performance of colonoscopies in positive cases to decrease wait times to less than 30 days post-visit by Primary Care Physicians in coordination with Service Organisations.
- Monitor false positive and false negative rates (interval cancer) to put in place measures that improve the Programme's effectiveness and efficiency.
- Design interventions to reduce inequalities and monitor their impact.
- Improve communication at all levels, professional, community and general public through campaigns, websites and social media.

## 6. SCOPE OF ACTION AND GENERAL SCREENING PROCEDURE

The aim of the screening programme is to systematically and periodically cover all persons resident in Basque Country who form part of the target population.

Persons whose provider is Osakidetza and individuals who have another provider (Mutual insurance societies and other insurance companies) will be invited in order to guarantee equity.

Groups facing difficulties in accessing the Programme will be taken into account (institutionalised individuals, ethnic groups, religious communities and those with a low socio-economic level).

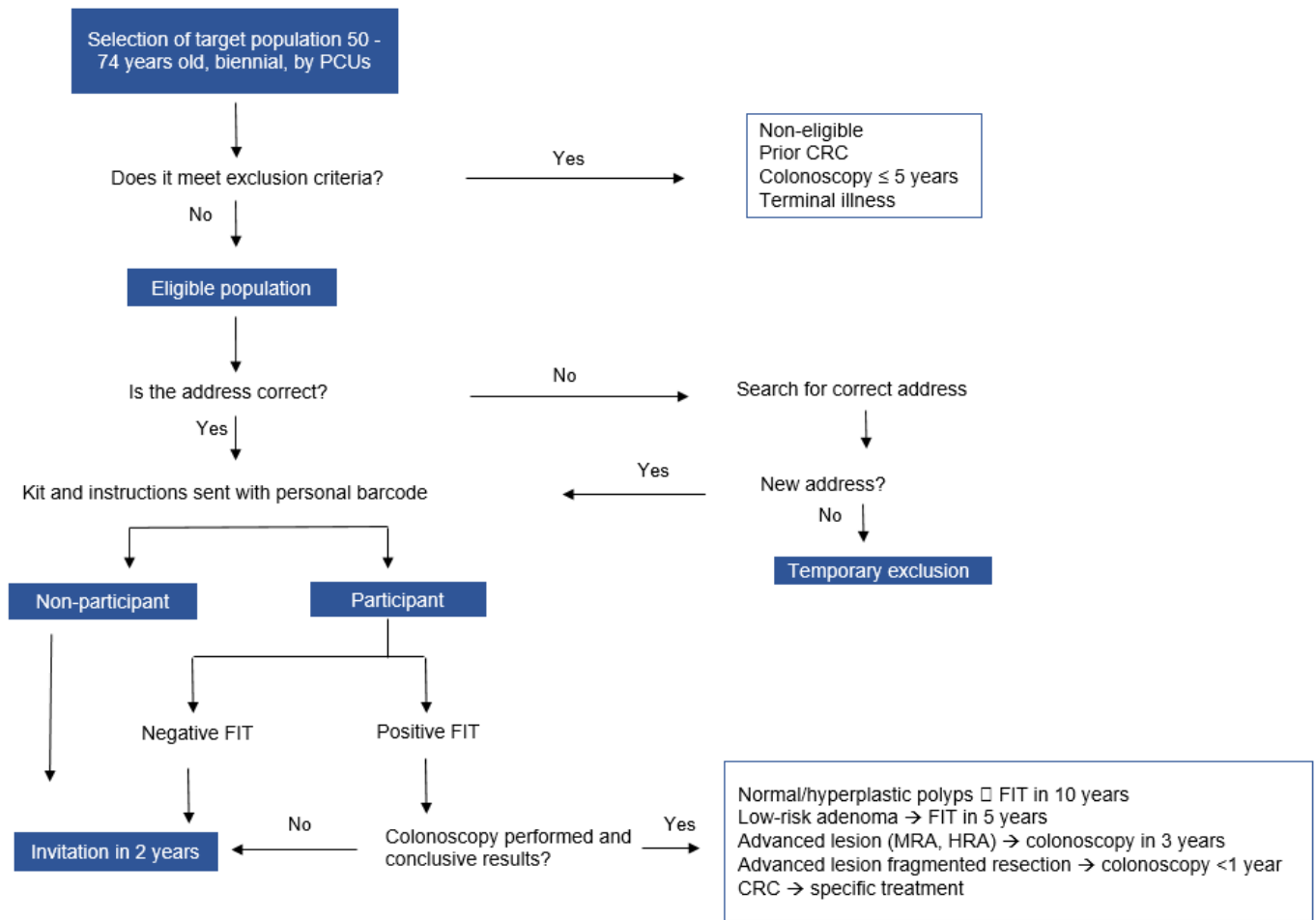
Annexes I and II set out in detail the criteria for the selection of the population, the procedures for invitation and management of the FIT result and colonoscopy, where indicated.

The programme circuit starts with a letter sent to the eligible population from the Coordinating Centre (50-74 years of age) with a kit and their identification code to give the opportunity to participate on the programme.

For the management of positive results, the recommendations of the Diagnosis and Prevention of colorectal cancer PCG (2018)<sup>32</sup> will be followed and updated with the consensus meetings of the Anatomical Pathology and Endoscopy groups (Annexes XVI and XVII).

A summary of all the steps of the general CRC screening procedure can be found in figure 1.

**FIGURE 1. Screening Program Flow gram**



PCUs: Primary Care Units; CRC: Colorectal Cancer; FIT: faecal immunochemical test; MRA: medium risk adenomas; HRA: high risk adenomas

## 7. INFORMATION, MONITORING AND EVALUATION SYSTEM

The Information System has been developed by the CCR in close collaboration with the Directorate General's IT Service and the heads of Osabide-PC, OsabideGlobal and OGP, Osabide Integra, GestLab, the Hospital Cancer Registry and the Population Cancer Registry. Interoperability with the Clinical Bases facilitates the traceability and monitoring of every case, with all activity recorded in Osabide.

Each person in the target population in the application has an individualised file which records: invitations, exclusions, participation/non-participation, FIT results, colonoscopy results and their quality (extension, preparation, complications), location, size and histology of the lesions, as well as TNM, stage and treatment of invasive cancers detected by the Programme, follow-up or interval cancers. All letters/SMS and variables are gathered in each invitation. Also, the research studies in which the person participates and their results.

The ultimate aim of the evaluation will be to assess the effectiveness of the screening programme. However, doing so immediately is not possible, as the decline in incidence and mortality is only observed in data sets that can be analysed in the medium term. From the outset, a continuous evaluation is maintained (byround of invitation, by Centres, by years, by age groups and sex) as the application developed (CCSP), owned by Osakidetza, allows both checklists and indicators to be obtained immediately after registration. It also allows mass exploitation for detailed statistical analysis.

This file is declared<sup>22</sup>, pursuant to the data protection regulations in force (article 31.2 of the PGDD<sup>23</sup> and article 13 of the GDPR<sup>24</sup>) in accordance with the safety regulations of Osakidetza.

Periodic evaluations are conducted by Primary Care Units, Integrated Services Organisations (IHO), as well as the State Screening Network in accordance with the European Guidelines (2010) and the network of Cancer Screening Programmes.<sup>25</sup>

Annexes VII and VIII set out in detail the variables and main indicators.

---

22 [https://www.osakidetza.Basque Country.eus/contenidos/informacion/osk\\_pro\\_dat\\_datatable/es\\_def/adjuntos/avisos/ci\\_PROGRAMA\\_CANCER\\_DE\\_COLON.pdf](https://www.osakidetza.Basque Country.eus/contenidos/informacion/osk_pro_dat_datatable/es_def/adjuntos/avisos/ci_PROGRAMA_CANCER_DE_COLON.pdf)

23 Organic Law 3/2018, 5 December pm Personal Data Protection and safeguarding of digital rights

24 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation)..

25 Cancer Screening Programmes Network. Available at [www.cribadocancer.com](http://www.cribadocancer.com)

## 8. SCREENING PROGRAMME MANAGEMENT CYCLE

The performance of this programme requires the participation of all levels of care in a multi-disciplinary manner. Each has specific roles in its achievement as detailed below:

### 8.1. Levels of responsibility

#### Programme Coordination Centre (PCC)

- Overall programme planning, organisation and implementation according to the objectives approved by the Directorate General and the Department of Health.
- Coordination of health professionals for the development and implementation of the programme.
- Preparation and updating of the programme's protocols and documents, as well as training, information and communication materials.
  - Invitation letters and SMS, notification of programme results.
  - Instructions for taking the FIT sample.
  - CRC information leaflets and posters.
  - Website contents
  - Videos and audiovisual materials
- Presentation of the Programme and results in the IHOs, PCUs prior to the invitations with updating of protocols according to the available evidence.
- Planning and tailoring of invitations in coordination with the Service Organisations and the Hospital Coordination Branch to avoid delays in the management of colonoscopies.
- Maintenance of updated databases and management of inclusions and exclusions according to invitations to be made in coordination with the General Directorate IT Service.
- Monitoring, management and evaluation of the invitation process, participation, positivity, quality of colonoscopy, registration and follow-up of all positive cases.
- Provision of monitoring data and results for the evaluation of the Health Plan, Oncological Plan, Strategic Plan, Contract-Programme, Annual Reports and requests from the IHOs and PCUs for management and improvement of the Programme.
- Implementation and participation in research studies, as well as publications related to the results and impact of the programme.
- Follow-up of positive cases
- Development and improvement of the Information System to ensure the quality of the whole process and procedures.
- Monitoring and evaluation of the Programme
- Elaboration of protocols for the improvement of processes with the different professionals, analysts, haematologists, anaesthesiologists, endoscopists, pathologists, primary care doctors and nurses, among others.

- Follow-up of adverse effects: colonoscopy complications, false positive and false negatives (interval cancers).

### **Primary Care Units**

- Collaboration with the PCC in raising awareness, providing information and advice to the target population who receive the invitation to participate.
- Receiving FIT samples which are sent to the reference laboratory following the safety and traceability protocols of the process. Information from the health centres via email to the Coordinating Centre on errors (kit in poor condition, erroneous identification, etc.).
- Specific attention in consultation of positive FIT results.
  - Positives: Information on the significance of the FIT result and colonoscopy as a diagnostic confirmation test. Provision and signing of the informed consent form. Performance of the necessary tests prior to the colonoscopy with ASA risk criteria and specific risks of the participant, according to OSI protocol and the Osakidetza network.
- Management of the colonoscopy appointment
- Preparation prior to the colonoscopy.
  - Information for colonoscopy preparation and delivery of the preparation by the nurse 7 to 10 days before the test.
  - Advice and provision of preparation information sheets, diet and provision of informative videos.
  - Information, recommendations and advice to follow after colonoscopy.
- Follow-up of the results of the test in coordination with Endoscopy Units, informing people of the results and the follow-up to be carried out.

### **Specialised level of care**

#### **Biochemistry Service:**

- Sample reception system.
- Analysis and validation of the results of the FIT screening test.
- Dumping of the results in Osabide (quantitative and qualitative).
- Information on incidents and errors detected in the daily PCC (by email).
- Internal and external quality controls

### **Digestive Service:**

- Management of diagnostic confirmation colonoscopy appointments.
- Reception and filing of the informed consent form.
- Performance of colonoscopies in accordance with quality criteria.
- Diagnostic confirmation and treatment (removal of polyps).
- Follow-up of cases requiring new tests and/or extension studies.
- Referral to High-Risk Consultations in CRC and Advanced Lesions according to OSI protocols.
- Process follow-up.
- Issuance of a follow-up recommendation for PCP after evaluating the results of the Pathological Anatomy.
- Management of follow-up colonoscopies depending on the lesion found, the recommendations of the guidelines and the guideline established for the individual.

### **Pathological Anatomy Service:**

- Receipt and analysis of samples.
- Issuance of macroscopic and microscopic report on the endoscopy performed.
- Coordination with Endoscopy Units and Cancer Committees for follow-up and specific treatments.
- Performance of specific analyses in accordance with protocols.

## ANNEX I CRITERIA FOR SELECTING THE POPULATION AND OBTAINING PROGRAMME INDICATORS

### Target population:

Women and men resident in the Autonomous Community of the Basque Country (ACBC) aged between 50-74 years when invited and with Primary Care Physician (PCP) in the Primary Care Units (PCUs) where the Colorectal Cancer Screening Programme (CCSP) will be carried out.

The Osabide Database, which includes all persons who have had contact with the Health System in one way or another, will be used in the ACBC. It is more extensive than the IHC (Health Card) database, although in 7% of cases there are returns due to the address being unknown.

Since 2014, Population Screening has been extended to people without Osakidetza cover, who can access it through a specific procedure (see Annex XIV).

In 2017, people institutionalised in prisons began to be invited, and in 2020, people in medium and long-stay psychiatric centres, who despite having an Osakidetza cover have difficulties in participating, will be able to carry out the FIT through their doctors and nurses in charge.

It is estimated that the target population registered in Osabide is over 97% of the census target population.

### Eligible population:

Women and men in the target population **eligible for effective invitation** to participate in the screening programme. In other words, they would be individuals who do not have any temporary, total or definitive exclusion criteria at the time of the invitation.

### Non-eligible population:

Women and men in the target population who meet any exclusion criteria at the time of invitation:

- Death: This will be automatically detected in the OSABIDE upload. In addition, the files will be cross-referenced with INDEF. It will also be detected from the information of professionals/users. **Total exclusion.**
- CRC diagnosed: - It will be automatically detected in the AS400 upload (persons who in primary or secondary diagnosis have codes 1530-1548. Hospital and/or Population-based cancer registry codes C18.1-C20.9 M %%%3 and M %%%6. It will also be detected from the information of professionals/users. **Total exclusion.**
- Illness at the present time. It will be detected from the information of professionals/users. **Temporary exclusion**

- Participants with a colonoscopy/sigmoidoscopy performed in the last 4 years. This will be automatically detected in the OSABIDE Db. The date must be stated. It will also be detected from the information of professionals/users. The date must be stated. *Temporary exclusion*
- Participants undergoing colonoscopy follow-up by the Programme. *Temporary/total exclusion in accordance with findings.*
- Participants who have undergone a FIT for the Programme with a negative result < 18 months. The date must be stated. *Temporary exclusion*
- Change of address outside the ACBC. *Total exclusion.*
- Health relocations in the ACBC. *Temporary exclusion*

### **Eligible and ineligible population:**

Eligible population that can be located for invitation. If the letter with the kit is returned, another second address is searched in EUSTAT and if this letter is also returned, it is excluded as address unknown and becomes ineligible population. *Temporary exclusion*

Neither is the following population eligible:

- Change of address outside the ACBC. *Total exclusion.*
- Health relocations in the ACBC. *Temporary exclusion* (they will be invited when appropriate depending on the area where they currently live).
- Address unknown. *Temporary exclusion*

## **Participant:**

Person from the eligible population who has handed in the kit at their health centre and the result is valid (positive/negative). The date must be stated.

Types of participant:

- a) The incorporation of new population (who are over 50 years old, or who have immigrated to that area with ages between 50 -74 years old.
- b) The participating with a FIT - and non-participating population from the previous round.
- c) Losses from the last round, analysing whether a colonoscopy has been performed, if this has a definitive result. If this has not occurred, they will be invited to the Programme again.
- d) Persons who presented a Low-Risk Adenoma in the screening colonoscopy 4 years prior to the present invitation.
- e) Individuals who had a negative screening colonoscopy (normal - includes no findings, haemorrhoids, diverticula, diverticula, lipomas, melanosis or hyperplastic polyps) 9 years prior to the current invitation.
- f) Individuals in whom the diagnostic test, due to difficulty of an optical colonoscopy, was a virtual colonoscopy/CT with a non-pathological result, will be invited to the Programme in 5 years.

## **Non-participant (NP):**

- Person from the eligible population who has not handed in the kit at their Health Centre. Before the end of the campaign in the PCU, a letter is sent to all non-participants to remind them of the importance of participating (45 days after of sending the letter of invitation with the FIT KIT)
- People who return the kit letter or reminder letter to their PCU or who inform the PCC of their intention not to participate. Self-exclusion at the beginning of the Programme.
- Participant with an ERROR test result who does not have a subsequent positive or negative test result after receiving a new kit.
- They will be invited in the next round

## **Losses:**

Those persons who, during the invitation process, have participated in the Programme (have handed in the kit) but have not completed the diagnostic process. If the exclusion is temporary, a new invitation letter will be sent in the next round.

- Colonoscopy refused. - Temporary exclusion (new invitation in the next round).
- Address unknown/not located after active search by the Health Centre, in Eustat and other Databases after a positive FIT. Temporary exclusion (new invitation in the next round).
- Change of address outside the ACBC. - Total exclusion for the next round.
- Death during the programme. Total Exclusion.
- Illness diagnosed during the programme that prevents colonoscopy. Temporary exclusion
- Colonoscopy performed in private system with no report available after active search and sending a positive FIT letter certified and with acknowledgement of receipt to the user. Temporary exclusion (They will be invited in the next round)
- Colonoscopy without a definitive result: due to poor preparation, difficulties in carrying it out, non-appearance of the participant to complete it. Temporary exclusion (They will be invited in the next round)
- In the event the participant reports a COLONOSCOPY DELAY and more than 12 months have passed without having it performed, it will be recorded as a LOSS with the reason for exclusion: "Illness at the present time". Temporary exclusion (They are invited to the next round if it has not been performed prior to the invitation).
- Impossibility of contacting the positive FIT person and after sending a registered letter with acknowledgement of receipt to the user. Temporary exclusion (They will be invited in the next round).

## **FOLLOW-UP OF FIT-POSITIVE PERSONS**

### **Individuals with a definitive colonoscopy result:**

Persons with a positive FIT result should be referred for a full, optical, sedated colonoscopy for diagnostic confirmation.

A colonoscopy is considered definitive when a lesion has been ruled out/diagnosed (the most serious lesion is attributed).

This does not always occur in the first colonoscopy and sometimes it is necessary to repeat the colonoscopy (due to poor preparation, poor tolerance, difficulty in excising lesions in the first colonoscopy). On other occasions it is necessary to perform another less sensitive test for diagnostic confirmation (e.g. virtual colonoscopy). In our case, if it is not possible to perform an optical colonoscopy due to circumstances inherent to concomitant pathology of the participant, this alternative test is assumed as the definitive result, although one test will be clearly differentiated from the other in the database.

## ANNEX II INVITATION PROCEDURE

To be agreed upon according to annual planning with the Organisations at the beginning of the invitations.

The PCC will inform the PCUs and the Services Organisation (laboratory, endoscopy, pathological anatomy...). Of the start at least 15 days in advance. The PCU Head of each PCU will be informed of the availability of lists by quota of eligible and ineligible population.

Dissemination material, as well as a container for collecting kits and folders for collecting exclusions will be sent to each PCU and HC at the start of the campaign. The PCUs involved will be informed of the start and end of the dispatch of kits and SMS/letters to remind them of their basic area one week in advance.

The Programme Coordinating Centre (PCC) will collect the reasons for the calls and manage the demands received.

### 1. Sending SMS, invitation letters, and material

The delivery schedule will be in accordance with the response capacity of each IHO to possible positive cases for confirmation colonoscopy.

The HC will have a circuit for collecting samples from participants.

An SMS will be sent to the invited person to inform them that they will soon receive a kit to participate in the Colorectal Cancer Prevention Programme.

It will be sent by post:

1. Personalised letter according to gender which will include a barcode sticker with the Corporate Individual Code (CIC) for identification of the kit. (Annex XI).
2. Programme leaflet, free telephone and email, as well as access to the Programme's website.
3. Leaflet with instructions.
4. Sample collection kit in a plastic bag.

## PROGRAMME LEAFLET

El cáncer de colon y recto es el cáncer más frecuente en hombres y mujeres. Se origina a partir de un pólipo en el intestino grueso que puede degenerar en un cáncer con el paso del tiempo.

Generalmente tarda más de 10 años en desarrollarse.

### OBJETIVO DEL PROGRAMA

Detectar y tratar de forma precoz pólipos y cáncer (cáncer de colon y recto).

**¿A QUIÉN ESTÁ DIRIGIDO?** Mujeres y hombres entre 50 y 74 años.

**¿QUE PRUEBA SE REALIZA?** Test de sangre oculta en las heces cada 2 años. Si el resultado es positivo, se le realizará una colonoscopia con sedación para confirmar la procedencia de la sangre.

**¿POR QUÉ ES IMPORTANTE PARTICIPAR?** Se ha demostrado científicamente que la detección precoz mejora la calidad de vida y la supervivencia de las personas que participan.

**¿CÓMO PUEDO PARTICIPAR?** Recibirá en su domicilio una carta de invitación con las instrucciones y el tubo para recoger las heces.



Puede entregarla en su Centro de Salud durante todo el horario de apertura. No tiene que pedir cita. Hay una urna a la entrada del Centro para que deposite el tubo con la muestra.

**¿CUÁNDO RECIBIRÉ EL RESULTADO?** En una semana le comunicaremos el resultado. También lo podrá ver en su Carpeta de Salud.

### PARA SABER MÁS:

→ Infórmate en [www.osakidetza.euskadi.eus](http://www.osakidetza.euskadi.eus)

→ Teléfono gratuito: 900 840 070

→ [prevencionccr@osakidetza.eus](mailto:prevencionccr@osakidetza.eus)



Eusko Jauriaritza  
Osasun Saila

## Koloneko minbizia goiz detektatzeko programa.



Esta campaña ha sido financiada por la Unión Europea - NextGenerationEU

## LEAFLET WITH INSTRUCTIONS




### LAGINA JASOTZEKO PROZEDURA, ODOLA GOROZKIETAN ZEHAZTEKO

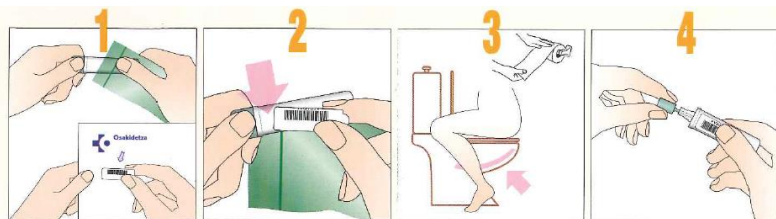
### PROCEDIMIENTO DE RECOGIDA DE LA MUESTRA PARA LA DETERMINACIÓN DE SANGRE EN HECEs

- Gorde hodia haurrek ez hartzeko moduko tokian.
- Ez egin proba, baldin eta odola darion hemorroideak edo hilekoa izanez gero harik eta 3 egun pasatu arte odol-galtzerik gabe.
- Saihestu gorozkiak pizarekin kutsatzea.

- Mantener el tubo fuera del alcance de los niños.
- No realizar la prueba si presenta hemorroides sangrantes o menstruación hasta que no hayan pasado 3 días seguidos sin pérdidas de sangre.
- Evitar la contaminación de las heces con orina.



## OC-SENSOR



**1**  
Atera hodia poltsa berdetik. Bereizi zure gutunaren goialdearen ezkerrean dagoen barra-kodea.

Extraer el tubo de la bolsa verde. Despegar el código de barras que se encuentra en la parte superior izquierda de su carta.

**2**  
Itsatsi etiketa hodlaren alde zapalean. Ez itsatsi hodiaren inguruan, edo diagonalan edo tapoi berdearen gainean.

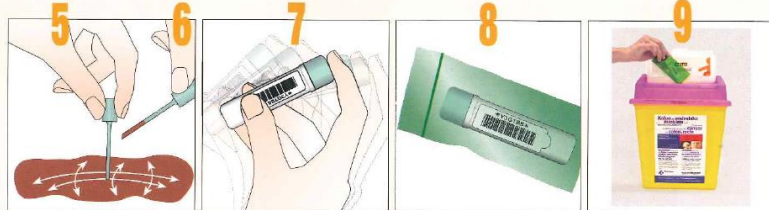
Pegar la etiqueta en la parte plana del tubo. No la pegue ni alrededor del tubo, ni en diagonal, ni sobre el tapón verde.

**3**  
Jarri komuneko papera komun-ontzi barruan eta eserri, ahal izanez gero, hari begira.

Colocar una capa de papel higiénico en el sanitario y sentarse si es posible de cara al mismo.

**4**  
Kendu tapoi berdea eta atera hagatxoa.

Desentrosar el tapón verde y extraer la varilla.



**5**  
Jarri hagatxoaren punta gorozki gainean eta ibilli alde batera eta bestera horizontalean eta bertikalean. Nahikoa da gorozki-kantitate txiki bat.

Poner en contacto la puntilla de la varilla con las heces y deslizarla dibujando líneas horizontales y verticales.

Es suficiente con poca cantidad de heces.

**6**  
Sartu hagatxo berdea hodian, ongi itxi eta eragin.

Introducir la varilla verde dentro del tubo. Cerrar bien y agitar.

**7**  
Gorde etiketatutako hodia poltsa berdean, eta eraman zure Osasun-Zentroa, ahalik eta azkarren. Berehala entregatu ezin baduzu, 3 egunez gorde dezakezu, gahiezez, zure hozkailuan.

Guarde el tubo etiquetado en la bolsa verde y llévelo a su Centro de Salud lo antes posible. Puede dejarlo en su frigorífico un máximo de 3 días, si no puede entregarlo al momento.

**8**  
Lagina jaso eta identifikatu ondoren, utzi zure osasun-zentroko sarrean aurkituko duzun edukiontzian.

Una vez identificada y recogida la muestra, depositela en el contenedor que encontrará a la entrada de su Centro de Salud.

## ANNEX III SAMPLES: DELIVERY AND PROCESSING

### **FIT sample delivery and processing**

- The invited person may deliver the kit at the Health Centre during the hours when the Health Centre is open and/or has the sample collection circuit enabled.
- The Health Centres will set up the collection system and send it to the referral laboratory for processing and assessment. A quality control system will be established in the PCU.
- The participant does not have to make an appointment, just hand in the sample, which will have been previously labelled, in the specific container of the Programme, located in the Customer Care Service (CCS). This must be placed in the CCS area in view of the staff for supervision, away from any source of heat or sunlight.

### **Management of FIT samples**

This is a series of activities that take place both in the SC and in the reference laboratory.

### **Sample collection and delivery to the laboratory**

1. The HC shall set up a sample collection circuit, which allows for the correct identification and dispatch of samples to the laboratory.
2. All the HCs will have the target population's database for rapid location of the participating person.
3. The containers shall be well identified. At the end of each shift (morning and/or afternoon) the samples collected shall be stored in the refrigerators of the CSs themselves for processing the day after receipt. It is important to maintain the cold chain.
4. The reading of the kit's barcode, within the CRC module of GestlabExt, will generate an internal flyer.
5. The request is automatically assigned to each Primary Care Physician (PCP) and the result is registered in Osabide.
6. Any kits with handling errors (incorrect labelling, opening and closing) will be collected and the PCC will be informed daily to send the participant an error letter with a new kit and a letter with a barcode label.
7. Samples should remain in the refrigerator until sent to the laboratory.

When the virtual request is generated, the person participating in the programme will be considered.

# Processing of samples in the laboratory

## 1. Intra-laboratory pre-analytical phase

Samples will arrive at the Pre-analytical Unit of the Biochemistry laboratories of the referral hospital from Primary Care by the usual delivery system.

The department staff will review the samples in the programme and place them on the racks of the biochemistry equipment for analysis.

## 2. Analytical phase

Samples shall be processed on the dedicated equipment in the Automation area of the Biochemistry laboratory.

The technical staff of the Automation area will be in charge of reagent supply and equipment loading, as well as internal quality control. Two levels of control (high and low) will be processed each day to guarantee the quality of the results. The assessment of these controls will be the responsibility of the Automation area.

The results of the samples will be sent on-line from the analyser to the Gest-lab laboratory's computer system, both quantitative and qualitative DBP.

The results will be validated by the medical staff of the Biochemistry Laboratory who will assess whether they need to be repeated, diluted or rejected. When this process is carried out, this date shall be considered as the date of the FIT result.

## 3. Post-analytical phase

Validated results will be sent online from GestLab to OGP automatically.

All causes of erroneous and typed samples will be validated. All incidents shall be sent to the Coordinating Centre (PCC).

A quantitative result (ng/ml) and a qualitative result (POSITIVE, NEGATIVE, ERROR) will be obtained, visible both from the PCC and in your medical record.

Samples analysed but not requested are retrieved by the laboratory physician, the request is created and the result is validated.

The coordinating centre receives the incidents on a daily basis and notifies the different PCUs for their knowledge and the implementation of improvement measures if necessary.

## ANNEX IV FIT RESULTS MANAGEMENT

### Communicating FIT results

**Negative results** ( $< 20\mu\text{g/g}$  or  $< 100 \text{ ng/ml}$ ) will be communicated by SMS from the PCC to the participant stating that the result of the faecal occult blood test was NEGATIVE. A negative result will only be communicated by letter (Annex XIII) in case the participant does not have a contact mobile phone number in the database.

**Positive results** ( $\geq 20\mu\text{g/g}$  or  $\geq 100 \text{ ng/ml}$ ) will be notified to the participants by letter and SMS (examples and format in Annex XIII) from PCC and will be visible in a differentiated way by the Primary Care physician (PCP) in order to avoid the loss of cases (specific alarm in pending tasks of Osabide PC). The letter will tell the person to request an appointment with their PCP. In the event of not attending the PC, both their primary care doctor and their nurse will contact the participant by telephone and subsequently inform the PCC of the outcome of the procedure: exclusion, colonoscopy in private system, refusal of colonoscopy. If the patient cannot be located, a registered letter with acknowledgement of receipt will be sent from PCC.

In the event of a **sample error**, the PCC will send an SMS and a new letter with a kit for its repetition.

## ANNEX V POSITIVE RESULTS MANAGEMENT

### 1. Health Centre

The Customer Service Area (CSA) of each HC will offer you an appointment with the PC doctor. In the case of an appointment via the web, the usual appointment will be requested with the reference PCP.

At the visit the PC doctor will:

- Provide information about the FIT result, reassuring the person.
- Propose colonoscopy with sedation and without admission to the referral Endoscopy Unit.
- Indicate the necessary preliminary tests according to risk and current protocol.
- Obtain the Informed Consent available at OG.

If colonoscopy is contraindicated, the Endoscopy Department will be informed in order to facilitate another diagnostic test. This circumstance will be communicated to the e-mail address: [prevencionccr@osakidetza.eus](mailto:prevencionccr@osakidetza.eus) in order to monitor losses.

The person's medical record in Osabide Global (OG) will include any surgical history, presence of chronic pathology, known allergies, treatment with antiplatelet agents, oral anticoagulants and/or oral iron and regular use of sedatives or hypnotics. All actions shall be recorded. This information should be copied onto the colonoscopy referral form to facilitate its review by the professionals who will perform the test.

The **visit by the PC nurse:**

To be performed 7-10 days prior to the colonoscopy. During this visit the individual will be offered personalised information, doubts will be answered and the preparation to be followed will be explained depending on the person's intestinal rhythm, as well as their dietary preferences and the time of the colonoscopy appointment<sup>26</sup>. This visit will be used to inform and review the discharge advice to be observed after the test, which will also be given to you in the Endoscopy area and after the test.

The reasons for non-acceptance will be noted in the participant's MR. In the event of acceptance, a referral form will be generated for colonoscopy screening with the service 90057.

---

26 Fernández Landa MJ, Portillo Villares MI, Bilbao Iturribarria MI, Idígoras Rubio MI, Regulez Campo V, Martínez Indart L. Impacto de una intervención en las consultas de Enfermería de Atención Primaria para la mejora de la calidad de la colonoscopia de cribado. *Metas Enferm* Mar 2020; 23(2):16-22. Doi: <https://doi.org/10.35667/MetasEnf.2019.23.1003081547>

In the event of detecting exclusions, refusal to participate in the programme, illness at the current time, the PCP will notify the PCC by e-mail. (*prevencionccr@osakidetza.eus*) so as to monitor and follow up all losses.

Pre-colonoscopy tests will be adapted to the risk of the participants, taking into account the ASA criteria.

Three types of low-volume pre-test preparations (Citrafleet® and Moviprep® / Pleinvue®) are currently used in screening and can be used interchangeably in addition to a peristaltic bowel (DULCOLAXO®). Citrafleet® is contraindicated in patients with renal insufficiency, hyperparathyroidism, phosphorus/calcium metabolism disorders, advanced liver disease (ascites, oedema, hepatorenal syndrome).

Evacuants must be requested from the Service Organisation's Pharmacy Service.

## **PRE-COLONOSCOPY ACTIVITIES**

The protocols agreed with the Endoscopy Units of the referral hospitals will be followed in terms of:

- Patient referral
- Supplementary tests
- Specific documentation
- Anticoagulation
- Anti-aggregation guidelines

## ANNEX VI COLONOSCOPY APPOINTMENT MANAGEMENT

The CSA of the Health Centres will manage the **appointment for the colonoscopy** at Osabide, as a screening test, specific agenda "colonoscopy screening diagnostic screening 90057". The time elapsed until the test is performed will be less than 28 days from the visit to the PCP to minimise diagnostic uncertainty.

### Coordinating Centre

In all cases where **no colonoscopy appointment** has been made within 30 days of contact with your PCP, you will be monitored by the PCC for information and contact with the participant.

### Endoscopy Unit

#### Implementation

1. The hospital will have **specific agendas** for the appointment of individuals to be screened. As far as possible, they shall not be mixed with symptomatic patients.
2. A colonoscopy circuit shall be set up for colonoscopies, including subsequent recovery.
3. The endoscopy nurse will check that the person comes with Informed Consent and has carried out the preparation correctly.
4. Each endoscopist, prior to the colonoscopy, will confirm the information that the person has about the test, the preparation performed and the risk factors.
5. A complete colonoscopy (reaching the cecum) will be performed.
6. Once the colonoscopy is done, the person will stay in the recovery area for as long as necessary.
7. Endoscopists who perform this activity will have proven experience and will be endorsed by the Head of Digestive Service of the hospital.
8. The quality criteria for colonoscopies established by the scientific societies will be followed<sup>27</sup>.
9. Hospital facilities will be used in the morning or afternoon shift in specific screening schedules.
10. The colonoscopy **will be performed with sedation and the circuits of each centre will be adapted.**

---

<sup>27</sup> Tinmouth J, Kennedy EB, Baron D, Burke M, Feinberg S, Gould M, et al. Colonoscopy quality assurance in Ontario: Systematic review and clinical practice guideline. *Can J Gastroenterol Hepatol.* 2014 May; 28; 5:251–74.

11. The date of the first colonoscopy shall be used to calculate delays. An active search will be carried out in the Osabide databases to assess emergency admissions/episodes between 0-30 days post-colonoscopy.
12. All cases with poor preparation according to the Boston scale (<6), incomplete colonoscopy... will be registered and will be rescheduled.
13. All colonoscopy complications will be recorded based on the complete review of the clinical history 10 days after the colonoscopy and every 3 months the data will be reviewed together with the PCC.
14. The PCC will be informed weekly of the colonoscopies performed by the unit in order to monitor those that are from the Programme or have been erroneously cited with another service code.
15. If a new appointment is required (due to inadequate preparation or incomplete colonoscopy), it will be managed by the Endoscopy Unit.

## ANNEX VII COLONOSCOPY RESULTS MANAGEMENT

### INFORMATION ON THE RESULTS

Each endoscopist will inform the person of the results and the procedure to follow once the colonoscopy has been completed. Diagnostic confirmation and colonoscopy result will be available in OG.

**Normal or benign colonoscopy** results will be communicated to the participant at the end of the test and also by letter from the PCC 20 days after the test.

Any polyps/adenomas will be removed and sent for analysis to Anatomical Pathology. Specific follow-up will be indicated according to the results and then sent to the PCP, which will be reflected in the endoscopy report for its availability in Osabide.

In the case of malignant neoplastic pathology, patients will be referred preferentially to specific consultations and the colorectal cancer care circuit established in each OSI will be followed.

Post-colonoscopy follow-up will be based on the recommendations of the Diagnosis and Prevention CPG of colorectal cancer (2018)<sup>28</sup>

All colonoscopies will be coded at the PCC coordinating centre.

In all cases referred for colonoscopy, the time elapsed between the visit with the primary care physician, the request for colonoscopy and its performance by the PCC will be monitored to evaluate the commitments of the Contract-Programme.

---

<sup>28</sup> Cubiella J, Marzo M, Mascort-Roca J, Amador-Romero F, Bellas B, Clofent J, et al. Guía de Práctica Clínica. Diagnóstico y prevención del cáncer colorrectal. Updated 2018. International Marketing & Communication S.A., editor. Asociación Española de Gastroenterología y Sociedad Española de Medicina de Familia y Comunitaria; 2018

## Data for coding a colonoscopy (CCSP)

	CIC		
Name and surname(s):	FN:	Sex	
Extent of the examination:	<ol style="list-style-type: none"> <li>1. Complete colonoscopy</li> <li>2. Incomplete colonoscopy</li> <li>3. Not applicable</li> </ol>		
Duration of examination:	4. Numerical field, in minutes		
Quality of the preparation:	<ol style="list-style-type: none"> <li>1. Adequate (Boston = 6)</li> <li>2. Fair and Poor (Boston &lt;6)</li> <li>3. Not applicable</li> </ol>		
Sedation/analgesia:	<ol style="list-style-type: none"> <li>1. No sedation</li> <li>2. Superficial sedation</li> <li>3. Deep sedation</li> <li>4. General anaesthesia</li> <li>5. Not applicable</li> </ol>		
Immediate complications:	<ol style="list-style-type: none"> <li>1. NO</li> <li>2. DEATH</li> <li>3. NOT APPLICABLE</li> <li>4. SD. POST POLYPECTOMY</li> <li>5. HAEMORRHAGE : admission/ transfusion</li> <li>6. PERFORATION: surgical intervention/ conservative care</li> <li>7. SEDATION:</li> </ol>		
-		MINOR :	Heart rhythm disturbance Respiratory depression Intolerance Vomiting Others
		SERIOUS:	Asystole Anaphylaxis Bronchoaspiration Others
	8. OTHERS		
<b>Endoscopic findings:</b>	<ol style="list-style-type: none"> <li>0. Normal/no relevant findings</li> <li>1. Non-neoplastic polyps</li> </ol>		

- 2. Low risk adenomas
- 3M. Medium-risk adenomas (Advanced lesions)
- 3A. High risk adenomas

**3A<sub>1</sub>. High risk adenomas (Advanced lesions):** sessile or flat lesion  $\geq 20$  mm sessile with fragmented resection

**3A<sub>2</sub>. Adenomas High-risk adenomas (Advanced lesions)** More than 5 adenomas, or any one measuring  $\geq 20$  mm

- 5. Carcinoma
- 6. Relevant non-neoplastic pathology
- 7. Inconclusive
- 8. Not applicable

- Follow-up:
- 0. No follow-up FIT 10 years if  $< 60$  years at time of screening
  - 0A. FIT in 5 years
  - 1. Colonoscopy in 10 years
  - 2. Colonoscopy in 5-10 years
  - 3. Colonoscopy in 5 years
  - 4. Colonoscopy in 3 years
  - 5. Colonoscopy in 1-2 years
  - 6. Colonoscopy  $< 1$  year
  - 7. Follow-up specialist consultation
  - 8. Not applicable

## FINDINGS

Each person must have a conclusive finding. In other words, in all cases where colonoscopy is not definitive, it should not be "closed" if there is no certainty that the diagnostic confirmation of FIT is complete (the entire colon has been adequately explored, with adequate preparation and removal of all lesions). In other words, the diagnostic confirmation process could involve more than 1 colonoscopy.

The most severe lesion will always be assigned. If there is a discrepancy in size between endoscopist and pathologist, the size of the Anatomical Pathology report will be used as a reference, except in the case of fragmented polyps, where the size described in the endoscopy report will be used.

In case of non-recovery of the polyp after polypectomy, the size described by the endoscopist will be used to calculate the risk.

**0. Normality:** Specify in the colonoscopy report that no pathological findings have been found, or that there are only haemorrhoids or diverticula. Cases of melanosis coli shall also be included.

**1. Hyperplastic polyps:** They are described in the Pathological Anatomy report. Any adenomatous and/or serrated component must be ruled out.

**2. Low risk adenomas (non-advanced lesions):** (1-2 < 10 mm, tubular adenoma with low grade dysplasia).

**3M. Medium-risk adenomas (Advanced lesions):** Whenever *any* of these circumstances are present: 3 to 4 adenomas, or one of the adenomas is  $\geq 10$  mm and  $< 20$  mm, or has a villous, or tubulo-villous component, or presence of high-grade dysplasia or non-hyperplastic serrated polyps.

**3A1. High risk adenomas (Advanced lesions):** sessile or flat lesion  $\geq 20$  mm sessile with fragmented resection

**3A2. Adenomas High-risk adenomas (Advanced lesions):** More than 5 adenomas, or any one measuring  $\geq 20$  mm

**5. Carcinoma.** Lesion invading the submucosa with varying degree of infiltration of other structures. These cases will always require close monitoring for definitive classification.

**6. Other pathologies:** These are endoscopic findings usually related to Inflammatory Bowel Disease

(ulcerative colitis, Crohn's disease). They require follow-up by a digestive specialist. This includes cases with polyposis and those entities that will require a genetic/hereditary study.

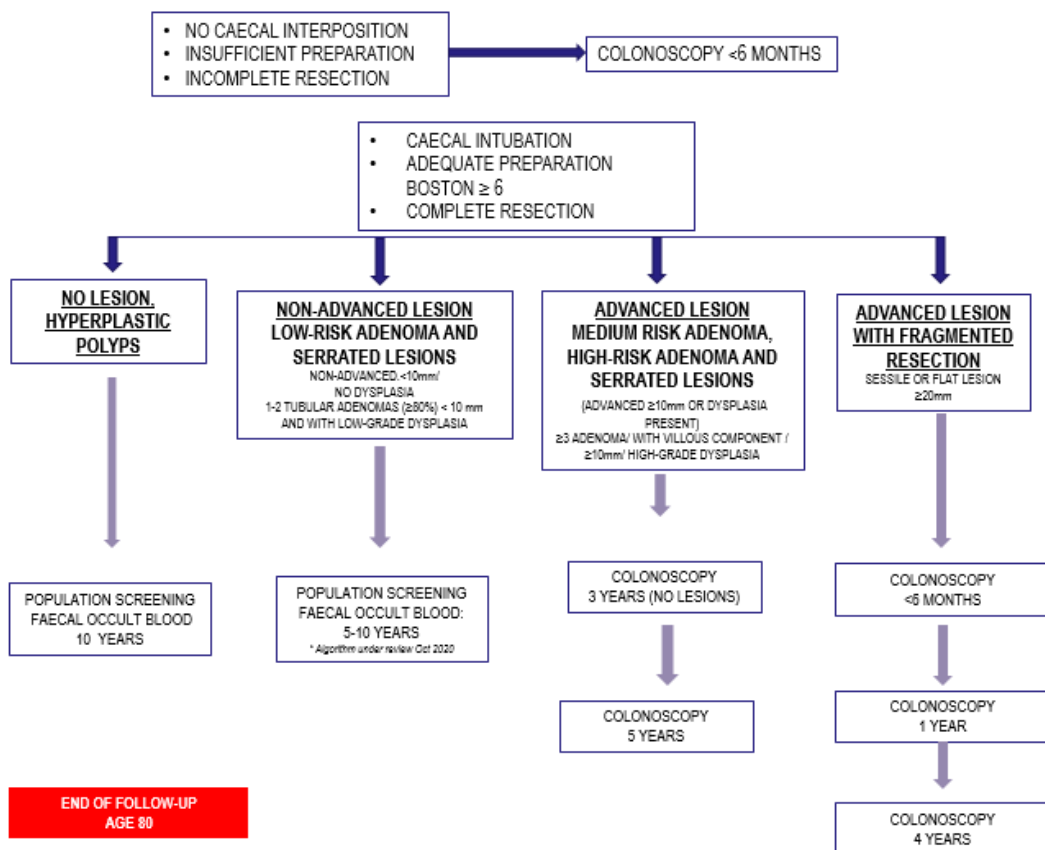
**7. Inconclusive:** A person with positive FIT who does not have a definitive diagnosis, either from a colonoscopy or if another test has been performed and this also does not have a conclusive diagnosis.

**OTHER TESTS**

When optical colonoscopy cannot be performed for various reasons (baseline pathology of the patient, characteristics of the colon, etc.), a CT scan and more frequently Virtual Colonoscopy can be performed. Neither of these tests is considered "gold standard" at the moment, so that, even if it is not pathological, at a given moment a definitive optical test will be required.

**FOLLOW-UP AFTER SCREENING COLONOSCOPY (Approved SNS Screening Network and Osakidetza network)**

**POLYPECTOMY SURVEILLANCE NOVEMBER 2020**



According to result:

**0. Normality:** exclusion from screening up to 10 years. Routine FIT screening in 10 years.

**1. Hyperplastic nodules:** exclusion from screening for up to 10 years. Routine FIT screening in 10 years.

**2. Low-risk adenomas (non-advanced adenomas):** 1-2 tubular adenomatous lesions with LGD and < 10mm. Repeat FIT 5-10 years (under review for implementation in 2021). You will receive an invitation letter from the PCC.

**3. Medium-risk adenomas (Advanced lesions):** 3-4 adenomas or one of the adenomas is  $\geq 10$  mm hairy component, presence of HGD). Repeat colonoscopy in 3 years.

**4. High-risk adenomas 1 (Advanced lesions):** Sessile or flat lesion  $\geq 20$ mm with **fragmented resection:** follow-up in specialised care and colonoscopy after 6 months.

**5. High-risk adenomas 2 (Advanced lesions):**  $\geq 5$  adenomas, or any one measuring  $\geq 20$  mm Repeat colonoscopy in 3 years.

**6. Other pathologies requiring Digestive assessment:**

- - (Inflammatory Bowel Disease): specialised consultation.
- - Any number of hyperplastic polyps proximal to the sigmoid colon in a patient with an affected first-degree relative with hyperplastic polyposis.
- -  $>30$  hyperplastic polyps of any size distributed throughout the colon. Individualised follow-up.

**7. Colorectal Cancer**

## ANNEX VIII OSAKIDETZA COLONOSCOPIES PRIORITISATION PROPOSAL

To facilitate better management of colonoscopies and perform screening colonoscopies, with proven evidence of a decrease in CRC incidence and mortality, it is necessary to adopt some criteria proposed by the AEG and the SEED (UEG Webinar 4 June 2020, Rodrigo Jover) and adapted to Osakidetza.

We have been working with a working group of endoscopists across the entire Osakidetza network throughout this semester to improve the bidirectionality of communication between Digestive-Primary Care-Digestive Care through non-face-to-face consultations. At this moment in Osabide there is a possibility this communication can be implemented.

On the other hand, we are working on the documents available on the screening and which require adaptation to the circuits of each IHO (e.g. many pre-operative tests are not routinely required).

However, we understand that there is excess bureaucracy in Primary Care and some unresolved issues:

- a) Colonoscopy preparation: There is a check-list available to improve this topic in Osabide for Nursing consultation.
- b) A proposal we received from Primary Care is to activate SMS reminders the day before from the time the appointment is made.
- c) Follow-up: uncertainty, especially in those who are not screened, post-screening colonoscopy and family history have already been carried out. Currently in Osabide this can be improved and reminders added.

**The proposal to prioritise colonoscopies is a general one**, for all colonoscopies, regardless of whether they are requested from Primary Care or Specialised Care.

It is possible to set priorities in Osabide, but above all we have to **reach a consensus on the criteria**, improve informed decision-making, i.e. take into account the benefit-risk balance for the patients. Colonoscopies are invasive tests with risks that increase with age and comorbidity.

Currently the priorities are Urgent, Preferential and Ordinary. We propose these new criteria that allow better organization of referrals and avoid intensive follow-ups and/or inadequacy (these had to be avoided and would leave agendas free for 1-2-3).

### PRIORITY 1 - < 4 WEEKS

- Suspicion of CRC or IBD on imaging or physical examination
- Rectal bleeding associated with dark blood and/or mixed with faeces and/or weight loss and/or change in bowel rhythm and/or absence of perianal symptoms.
- Iron deficiency anaemia > 50 years (in men, Hb < 11 g/dl; in women, Hb < 10 g/dl).
- **FIT positive - screening ( $\geq 20 \mu\text{g Hb/g stool}$ )**
- FIT positive - symptomatic with other manifestations ( $\geq 10 \mu\text{g Hb/g faeces}$ )

## PRIORITY 2 - < 4 WEEKS

- Iron deficiency without anaemia with negative FIT <10 10 µg Hb/g faeces with symptoms persisting > 4 weeks
- Iron deficiency and anaemia in < 50 with negative FIT <10 10 µg Hb/g faeces with symptoms persisting > 4 weeks
- Intestinal rhythm change < 50 years with negative FIT <10 10 µg Hb/g stool with symptoms persist > 4 weeks
- Evaluation after complicated acute diverticulitis
- Assessment of chronic diarrhoea, abdominal pain and other non-alarming digestive symptoms with negative FIT <10 10 µg Hb/g stool with symptoms persisting > 4 weeks

## PRIORITY 3 - POSSIBILITY TO ADJUST PROGRAMMING (window period of 6 MONTHS)

- Surveillance of polypectomy scars
- Surveillance of patients with hereditary CRC
- Surveillance of patients with CRC
- Surveillance of patients with IBD
- Post-polypectomy in poor preparation, incomplete resection and/or fragmented resection
- Screening in CRC relatives according to algorithm, hereditary syndromes, polyposis syndromes (we follow the 2018 Guidelines).
- **Post-polypectomy surveillance according to algorithm (New from 1/10/2020).**

## PRIORITY 4 - NO NEED SITUATIONS (20-30% OF COLONOSCOPIES)

- Intensive post-endoscopic surveillance (shortening of follow-up times). Many of these come from inappropriate recommendations from Digestive, Surgery, Primary Care). Here we must invest in improving this bidirectional communication.
- **Colonoscopies in family history of CRC (not adjusted to the criteria).** If we follow the CPG 2018, the first thing to do is to rule out hereditary cancer and/or associated polyposis. In cases of  $\geq 2$  FDR, colonoscopy is recommended every 5 years (starting at age 40 or 10 years before the youngest index case in the other cases (1 FDR, 2SDR and TDR) population screening (starting at age 50). If in doubt: Digestive non-face-to-face consultation.
- Endoscopic surveillance in individuals with negative FIT. Each year we exclude before inviting for screening about 15,000 persons who have previously had a negative FIT but have had a colonoscopy before the next invitation. Because of its alarming frequency and **in the absence of alarming symptoms (priority 1-2): colonoscopy should not be indicated for people who have a negative FIT at the previous screening invitation.**
- Post-acute diverticulitis surveillance. As scientific evidence advises against routine colonoscopies and in view of the frequent difficulty for Primary Care to make an assessment, a non-face-to-face consultation with the Digestive Department should be requested to assess each case.
- Positive FIT: normal colonic result or non-advanced adenoma. **We will invite them to a screening. (Algorithm)**

- Surveillance of individuals with a life expectancy < 10 years (80 years) and/or high comorbidity. Although age is a controversial subject, it is important to consider the risk-benefit balance. **Nor request an FOB unless it meets criteria.**

## ANNEX IX STRATIFICATION CRITERIA

### CRITERIA FOR ACTION AND REFERRAL TO DIGESTIVE CONSULTATIONS IN CASES OF A FAMILY HISTORY OF COLORECTAL CANCER FROM PRIMARY CARE.

The Osakidetza Endoscopy group, which advises the Colorectal Cancer Programme, has drawn up and reached a consensus on the criteria for the care and referral of persons with a high risk of Colorectal Cancer due to a family history.

Following these criteria, a Non-Presential Consultation will be carried out with the Digestive Specialists of the Outpatient Departments, for assessment, advice and referral according to High-Risk Hospital Consultations criteria (HRC).

The HRC will assess each patient and their risk, ruling out the hereditary element following the recommendations based on the available evidence. The patient will be informed and advised about the follow-up (Digestive and/or Primary Care Consultations, Population Screening), which will be recorded and available at Osabide.

1. Referral to out-of-hospital Digestive Consultations (outpatient consultation).
  - A) Person with no personal history of CRC who has a FDR (father/mother, sibling, child) with:
    - CRR<50 years
    - Synchronous or metachronous CRC
    - CRC and EC \* synchronous or metachronous
    - CRC and >10 polyps
  - B) Person with no personal history of CRC who consults because in his/her family there are 2 individuals who are FDR between them (father/mother - son/daughter, brother/sister - brother/sister) with:
    - Both CRC
    - One CRC and the other Endometrial C (EC)\*
    - One CRC and other >10 polyps

In addition, the person consulting us must be the FDR (parent, sibling, child) of at least one of the above 2.

\*EC being the 2<sup>nd</sup> most frequent tumour in Lynch syndrome (= most frequent cause of hereditary CRC syndrome).

## 2. Referral from out-of-hospital Digestive Consultations to High-Risk Consultation (Presential)

Secondary prevention of CRC will be carried out as follows:

Colonoscopy every 5 years from age 40 years for:

- Individuals without CRC with 1 FDR with CRC < 50 years
- Individuals without CRC in whose family there are 2 persons with CRC who are FDR between them (father/mother - brother/sister) and said individual without CRC is FDR of at least one of the 2 (father/mother, brother/sister, son/daughter)

Participation in population-based CRC screening in:

- CRC-free individuals with 1 FDR with CRC > 50 years of age

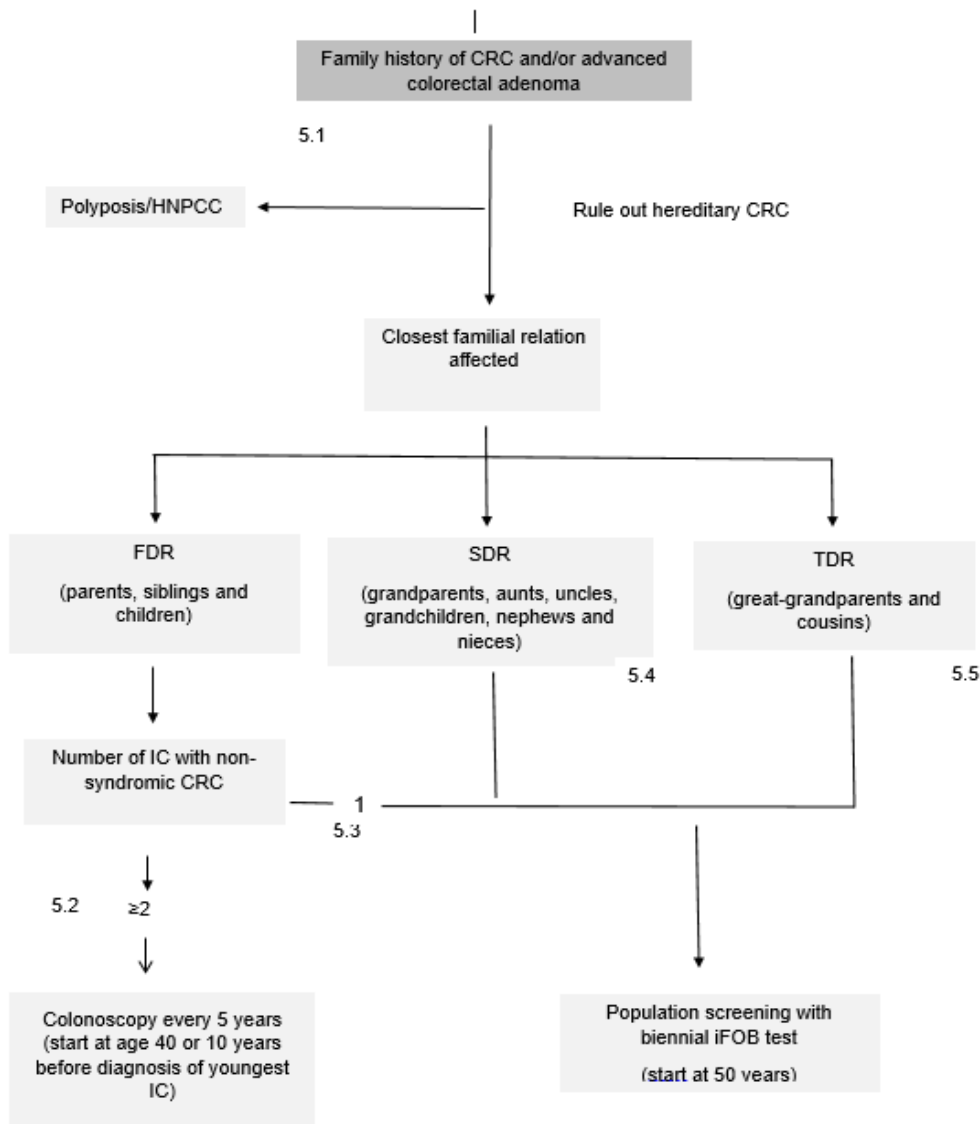
CRC-free individuals with SDR (grandparent, uncle/uncle, nephew/niece) and TDR (great-grandparents, great-uncles/uncles, cousins) with CRC will participate in population-based CRC screening.

Insist on primary CRC prevention measures, as families often share non-hereditary CRC risk factors, which are important in the occurrence of new CRC cases in the same family\*\*.

(avoidance of smoking, excess OH, overweight, sedentary lifestyle/ promotion of a Mediterranean diet and regular physical exercise) \*\*.

**ALGORITHM 5**

**SCREENING STRATEGY FOR FAMILIAL COLORECTAL CANCER**



HNPCC Hereditary non-polyposis colorectal cancer; CRC: colorectal cancer; IC: index cases; FDR: first degree relatives; SDR: second degree relatives; TDR: third degree relatives; iFOB: Immunological faecal occult blood. Authors' own preparation.



## CONSIDERATIONS

The clinical criteria for referral seek to identify subjects without CRC at risk of having a hereditary syndrome due to their family history. They have been selected by consensus between the Genetics, Anatomical-Pathology and Digestive System Departments of Basurto Hospital, based on previous bibliography. The clinical practice guidelines are limited to the European level, as agreed at the last meeting.

An attempt has been made to simplify the criteria, choosing the most significant ones, such that they can be applied by Primary Care professionals in daily clinical practice.

The limitations of clinical suspicion criteria for identifying hereditary CRC syndromes, especially the most common, Lynch syndrome, are well known.

Therefore, it is recommended that screening for Lynch syndrome in incident CRC and EC be implemented in all hospitals. Ideally, it should be applied to all CRC and EC (universal screening), but we acknowledge that the workload and resources involved, especially for pathology departments, may not prove feasible in all hospitals.

Taking into account the significant proportion of unidentified cases if the screening age is too low, and at the same time achieving a balance with the care capacity available in each hospital, it would be desirable to at least extend the screening age for Lynch syndrome to 70 years.

At the hospital in Basurto we have agreed to extend it until the age of 80. In a recent American study with this cut-off point loss of 1.6 % of cases.

This protocol is subject to revision based on the available evidence and the consensus reached in the Osakidetza Network.

## ANNEX X PROGRAMME VARIABLES

NAME OF VARIABLE	DESCRIPTION	VALUES
<b>PERSONAL DATA</b>	Name	Text
	Surname 1	Text
	Surname 2	Text
	CIC	Chain:
	IHC	Chain
	DNI	Chain
	Date of birth	Date
	Sex	0 Man 1 Woman
<b>POSTAL DATA</b>	STREET	Text
	Portal	General
	Bis	
	Block	
	Staircase	
	Flat	
	Door	
	PC	
	Telephone no.	
	Province	
	Municipality	
	Town	
<b>HEALTH CLINIC LOCATION</b>	District	Osabide Codes
	PC Medical Code	Osabide Codes
	Name of PC physician	Osabide
	Health Centre	Osabide Codes
<b>POSTING LETTERS</b>	Excluded Letter	Upload date
	Information Letter + Brochure	Age range: 0. 50-54 years 1. 55-59 years 2. 60-64 years

		3. 65-69 years 4. >69  Instructions Letter+ Kit      Date  Kit Shipment Pending      Date  Kit delivery reminder      Date  Positive FIT result      Date  Negative FIT Result      Date  FIT error result      Date  Negative FIT Result      Date
<b>Participation</b>  <b>FIT Delivery/Process</b>          <b>Colonoscopy</b>          <b>Colonoscopy Result</b>	Kit Sent Sample Received FIT result FIT result FIT Value Definitive  Performance/Non-attendance/Cancellation Appointment record Appointment  Definitive diagnosis Hospital Endoscopy Extension of examination  Duration of examination	Date Date Date Positive/Negative/Error (Ng./ml) Yes/No  Date Date Date  YES/NO Osabide Code Date Complete/ Incomplete/ Not Applicable  (minutes)  Adequate/Regular/Poor/Not Applicable

	<p>Quality of preparation</p> <p>Sedation/Analgesia</p> <p>Complications (non-exclusionary)</p> <p>Findings</p> <p>Follow-up</p>	<p>No sedation/ Deep S./Superficial/Not Applicable</p> <p>1. No</p> <p>2. Death</p> <p>3. Not Applicable</p> <p>4. Post-polypectomy syndrome</p> <p>5. Haemorrhage: admission/ transfusion</p> <p>6. Perforation: surgical intervention/conservative care</p> <p>7. Sedation:</p> <ul style="list-style-type: none"> <li>- minor: Heart rhythm disturbance, Respiratory depression, Intolerance, Vomiting.</li> <li>Others</li> <li>- Serious: Asystole, Anaphylaxis, Desaturation, Broncho-aspiration, Others,</li> </ul> <p>0. Normal/Not Relevant Findings.</p> <p>1. Non-neoplastic polyps</p> <p>2. Low Risk Adenomas</p> <p>3M. Medium Risk Adenomas</p> <p>3A High Risk Adenomas</p> <p>5. Carcinoma</p> <p>6. Relevant non-neoplastic</p> <p>7. Inconclusive</p> <p>8. Not Applicable</p> <p>0. No follow-up/FIT within 10 years &lt; 60 years</p> <p>0A. Colonoscopy/FIT in 5 years</p> <p>1. Colonoscopy in 10 years</p> <p>2. Colonoscopy in 5-10 years</p> <p>3. Colonoscopy in 5 years</p> <p>4. Colonoscopy in 3 years</p> <p>5. Colonoscopy in 1-2 years</p> <p>6. Colonoscopy in &lt; 1 year</p> <p>7. Specialised Consultation</p> <p>8. Not Applicable</p> <p>Date</p>
--	--	--

		Number
		SNOMED Code
	Performance	
	Biopsy	Yes/No
	Value	Osabide Code
		Date
	Definitive diagnosis	Virtual Colonoscopy / Barium Enema / CT / Other
	Centre	
	Test	Normal / Pathological / Inconclusive
	Type	
	Result	
	Size	
		Alphanumeric
		Alphanumeric
	Topography	Alphanumeric
	Morphology	Alphanumeric
	T	Alphanumeric
	M	0/I/IIA/IIB/IIC/IIIA/IIIB/IIIC/IVA/IVB /Not determined or not indicated
	N	
	Stage.	Good / Moderate / Little or poor / Undifferentiated or Anaplastic / Not determined or not indicated
	Degree of differentiation	
<b>Anatomical Pathology</b>		
		Pathological yes/no
<b>Virtual Colonoscopy</b>		
	If colonoscopy is nonconclusive	Date
<b>Follow-up of lesions in case 5. Carcinoma</b>		
	First Treatment	Untreated / Surgery / Chemotherapy / Radiotherapy / Radical Endoscopic / Other Therapies / Symptomatic
	Type of Treatment	Osabide Code

Polyps	Hospital  Adjuvant treatment  Number Recovered Size Location Paris Classification Histology Degree of dysplasia En bloc or fragmented resection	YES/NO

## Assessment Indicators

### Structure evaluation indicators

Indicator	Algorithm	Information source
% informed professionals	No. of professionals who have participated in at least 1 session/No. of professionals Unit/HC/Service	Staff Attendance register
% resources dedicated to the programme Human, equipment, materials	No. of resources dedicated to the programme/resources planned	Hiring HR Dept.

### Process indicators

Indicator	Algorithm	Information source
% of valid invitations	Population / Eligible population	Postal returns Notifications
% valid tests processed	Population with definitive FIT (positive or negative) / Number of persons who have handed in the Kit	Gestlab Incidents
% Persons with positive FIT results	No. of persons with positive FIT results / No. of persons with definitive FIT results	Gestlab
Total number of colonoscopies performed	Total no. of colonoscopies performed in the programme	Osabide
% Colonoscopy rate	No. of colonoscopies performed total/ No. of colonoscopies performed on participants with FIT (+) as last result * 100	Osabide
% Colonoscopies according to results:	No. of persons with colonoscopy according to most serious outcome/ No. of persons with colonoscopy performed and FIT (+) * 100	Osabide /Integra SNOMED
% complete colonoscopies	No. colonoscopies performed reaching cecum/no. colonoscopies performed total in programme * 100	Osabide /Integra
% Complications	No. colonoscopies with any complication/No. colonoscopies performed in the sigma * 100	Osabide /Integra
% Colonoscopies by type of complication (bleeding/perforation/death/other)	No. colonoscopies with complications by type/no. colonoscopies performed total in the programme* 100	Osabide /Integra
% persons under follow-up according to finding	% persons in follow-up by finding/persons with colonoscopy performed * 100	Osabide /Integra

## Organisational indicators

INDICATOR	Algorithm	Information source
% Participants > 10 days in sending results	No. of participants with Date result sent - Date letter > 10 days/total number of participants	Osabide CCSP Programme
% Participants > 28 days undergoing colonoscopy	No. participants with Date 1st colonoscopy performed-Date PCP Contact >28 days/total participants with date 1st colonoscopy performed after a positive FIT	Osabide
% Participants with an endoscopic finding of Colorectal Cancer (CCSP code 5) with > 30 days of starting treatment	No. of cases with Date of 1st treatment-Date of colonoscopy (finding 5) > 30 days / Total no. of participants with CRC finding (CCSP code 5)	Osabide
Delays (P25, Median, and P75) between FIT (+) and 1st Treatment. CRC	No. of days of delay/participant in percentiles	CRC Programme

### Delays (p25, median and p75) between FIT+ and first CRC treatment

	P25	P50	P75
Days Delay Diagnosis			
Days Treatment Delay			
Total Days Delayed			

**ANNEX XI PROGRAMME QUALITY CRITERIA  
(EUROPEAN COMMISSION, 2010)**

<b>Indicator</b>	<b>Acceptable</b>	<b>Desirable</b>
Invitation	95%	>95%
Participation rate	>45%	>65%
Inadequate FIT rate	<3%	<1%
Time between performing the test and receiving the result	90% under 15 days	
Colonoscopy indication rate	90%	>95%
Time from FIT (+) diagnosis to colonoscopy	90% under 31 days	>95% under 31 days
Rate of complete colonoscopies	>90%	>95%
Time interval between definitive colonoscopy and treatment	>95% under 31 days	
Number of procedures to be performed by endoscopists in the CRC screening programme	300	>300
Percentage of biopsies and lesions identified in the programme that should be reported as per format	>90%	
Identification rate of HRA dysplasia recorded by pathology at colonoscopy in the screening programme	<5%	
Identification rate of HRA neoplasia recorded by pathology in the screening programme	<10%	

## ANNEX XII AWARENESS-RAISING AND TRAINING PROCEDURE

### Prior

1. Preparation of posters to distribute in Health Centres
2. Preparation of leaflets with the characteristics of the programme and the tests involved, which will be mailed to the participants and made available at the health centres.
3. Internet. The same information in the brochures and an application will be available on the Internet [Colorectal cancer - Osasun Eskola \(Basque Country.eus\)](http://Colorectal cancer - Osasun Eskola (Basque Country.eus))
4. Free information helpline for the public and professionals. **900 840 070 with answering machine.**
5. Email account for communication and queries [prevencionccr@osakidetza.eus](mailto:prevencionccr@osakidetza.eus)
6. Presentation for the professionals involved, explaining the characteristics of the programme, circuits and protocols. At least 1 with managers and 1 per HC and reference hospital in which all those involved (doctors, nurses, auxiliary nurses, administrative staff and any other persons considered appropriate) will be addressed.

### Training

#### OBJECTIVES.

##### Strategic Objective

For professionals from the different Primary Care Units and hospital referral centres to be aware of the Early Detection of Colorectal Cancer Programme and the results obtained, with the aim of planning the necessary actions for developing it further and involving them in its implementation and monitoring.

##### Specific Objectives

###### To learn about:

- The epidemiological bases of colorectal cancer.
- Circuits created for the CCSP, valid.
  - FIT sample reception and processing circuits.
  - Results management in FIT+ cases:
    - Informed Consent,
    - Medical Record Data: Usual medication (anticoagulants, antiaggregant), personal and family history,
    - Pre-operative if applicable.
  - Preparation for colonoscopy
  - Colonoscopy results management: Classification of findings and follow-up of lesions.

**Develop:** Skills for the implementation and follow-up of the programme to ensure the participation of the population and the appropriate management of positive cases.

**Involve** professionals in the monitoring and evaluation of the programme to ensure quality.

**Involve** professionals in areas of improvement, evaluation and research to promote good practice and knowledge in colorectal cancer prevention.<0}

### **Training Development:**

1. - Epidemiology, rationale of the Programme. Process and results obtained.
2. - Sample management, management of positive cases and referral for colonoscopy. Preparation for colonoscopy.
3. - Presentation of results by PCU and Service Organisation. Comparison by age and sex.
4. - Planning invitations at the PCU.

### **Training Methodology:**

- Theoretical presentations
- Use of Power-Point, videos and Programme documentation.
- Zoom/face-to-face meetings

ANNEX XIII LETTERS / SMS

<b>STANDARD LETTERS</b>	
<a href="#"><u>n11_0</u></a> <a href="#"><u>4</u></a>	NEGATIVE RESULT LETTER
<a href="#"><u>n11_0</u></a> <a href="#"><u>6</u></a>	ERROR LETTER
<a href="#"><u>n11_0</u></a> <a href="#"><u>8</u></a>	NEGATIVE COLONOSCOPY LETTER LAST PARTICIPATION
<a href="#"><u>n11_0</u></a> <a href="#"><u>9</u></a>	NEGATIVE COLONOSCOPY LETTER
<a href="#"><u>n11_1</u></a> <a href="#"><u>3</u></a>	EXCLUDED LETTER
<a href="#"><u>n11_1</u></a> <a href="#"><u>4</u></a>	INCORRECT ADDRESS LETTER
<a href="#"><u>n11_1</u></a> <a href="#"><u>5</u></a>	LRA INVITATION LETTER
<a href="#"><u>n11_1</u></a> <a href="#"><u>6</u></a>	NEGATIVE COLONOSCOPY INVITATION LETTER
<a href="#"><u>n11_1</u></a> <a href="#"><u>7</u></a>	REMINDER LETTER
<a href="#"><u>n11_2</u></a> <a href="#"><u>5</u></a>	MEN'S KIT LETTER
<a href="#"><u>n11_2</u></a> <a href="#"><u>6</u></a>	WOMEN'S KIT LETTER
<a href="#"><u>n11_3</u></a> <a href="#"><u>5</u></a>	POSITIVE RESULTS LETTER. MEN
<a href="#"><u>n11_3</u></a> <a href="#"><u>6</u></a>	POSITIVE RESULTS LETTER. WOMEN
<a href="#"><u>n11_0</u></a> <a href="#"><u>3</u></a>	LETTER OF INVITATION FOR NON-PARTICIPANTS IN 2 INVITATIONS

## N11\_35 POSITIVE RESULT LETTER



Financiado por la Unión Europea  
Europako Batasunak Finantzatu  
NextGenerationEU



MINISTERIO  
DE SANIDAD  
Berreskuratzeko,  
Eraldaketa eta  
Erresiliencia  
Plana



Osakidetza



EUSKO JAURLARITZA  
GOBIERNO VASCO  
OSASUN SAIA  
DEPARTAMENTO DE SALUD

Jaun hori:

Eskerrak eman nahi dizkizugu Kolon eta Ondesteko Minbiziaren Prebenitzeko Programan parte hartu izanagatik. Osakidetza eta Osasun Saila gauzatzen ari dira programa.

Gorozkietan odol ezkutua detektatzeko probaren emaitza **POSITIBOA** izan da. Hau da, odola aurkitu dugu gorozkien laginean.

Odoluste horren arrazoiak egiaztatzeko, **kolonoskopia** bat egin behar da.

**Joan Lehen Mailako Arretako medikuarengana.** Emaitza eta jarraitu beharreko urratsak jakinaraziko dizkizu.

**Programako datuen arabera, 10 gizonetik 5i detektatuko zaio gaiztotu aurreko lesioa edo lesioa gaiztoa, eta goiz diagnostikatu eta tratatuko zaio.**

Programari buruzko informazio guztia webgune honetan dago eskuragarri:



Zalantzarik baduzu, jarri harremanetan Programarekin **900 840 070** telefonoan edo **prevencionccr@osakidetza.eus** helbidearen bidez.

Agur bero bat.

Estimado Sr:

Le agradecemos su participación en el Programa de Prevención de cáncer de Colon y Recto que lleva a cabo Osakidetza y el Departamento de Salud.

El resultado de la prueba para detectar sangre oculta en heces ha sido **POSITIVO**. Es decir, se ha encontrado sangre en su muestra de heces.

Para comprobar los motivos de este sangrado, es necesario realizar una **colonoscopia**.

Le indicamos **que acuda a su Médico de Atención Primaria** quien le informará de su resultado y de los pasos a seguir.

**Según los datos del Programa, en 5 de cada 10 con resultado positivo, se detectará una lesión pre-maligna o maligna que será diagnosticada y tratada de forma precoz.**

La información completa del Programa está disponible en la página web:



Si tiene alguna duda, póngase en contacto con el Programa: **900 840 070** o por correo electrónico **prevencionccr@osakidetza.eus**

Reciba un cordial saludo,

Iz/Fdo.: Isabel Portillo Villares  
Kolon eta Ondesteko Minbiziaren Prebenitzeko Programaren Koordinatzailea  
Coordinadora del Programa de Prevención de Cáncer Colorrectal

\*Kanpaina hau Europar Batasunaren Berreskuratzeko Tresnak (NextGenerationEU) finantzatu du.

Datuak babesteari buruzko oinarriko informazioa: Interesdunari jakinarazten zaio bere datu pertsonalak Osakidetza - Euskal osasun-zerbitzuak tratatuko dituela. HISTORIA KLINIKOA tratamenduaren xedea da pazientearen historia klinikoren datuak izatea, horren jarraipena egiteko eta laguntza-jarduera kudeatzeko, zeregin bat betetzeko interes publikoaren izenean edo tratamenduaren arduradunari esleitutako ahal publikoak gauzatzeko. Posible da datuak honako hauei jakinaraztea: Eusko Jaurlaritzaren Osasun Saila, GSIN, agintari judizialak eta aseguru-etxeak. Datuak interesdunak berak, Eusko Jaurlaritzaren Osasun Sailak eta Osakidetza langile sanitarioek eman dituzte. Interesdunak eskubidea du datuetara sartzeko eta horiek zuzendu edo ezabatatzeko, eta tratamendua mugatzeko edo horri uko egiteko. Datuen babesari buruzko informazio gehiago duzu webgune honetan: <http://www.osakidetza.euskadi.eus/babesdatuak>

\*Esta campaña ha sido financiada por la Unión Europea - NextGenerationEU.

Información básica sobre protección de datos: Se informa a la persona interesada de que sus datos personales serán tratados por Osakidetza - Servicio vasco de salud. La finalidad del tratamiento HISTORIAL CLINICO es la de disponer de los datos de la historia Clínica del paciente para el seguimiento del mismo y la gestión de la actividad asistencial, conforme al cumplimiento de una misión realizada en interés público de poderes públicos conferidos al responsable del tratamiento. Pueden realizarse comunicaciones de datos al Departamento de Salud del Gobierno Vasco, al INSS, a autoridades judiciales y entidades aseguradoras. Los datos proceden de la propia persona interesada, del Departamento de Salud del Gobierno Vasco y del personal sanitario de Osakidetza. La persona interesada tiene derecho de acceso, rectificación, supresión de sus datos, y la limitación u oposición a su tratamiento. Podrá ampliar información en materia de protección de datos en la siguiente dirección web: <http://www.osakidetza.euskadi.eus/protecciondatos>

## N11\_06 ERROR RESULT LETTER



Financiado por la Unión Europea  
Europako Batasunak Finantzatua  
NextGenerationEU



MINISTERIO  
DE SANIDAD



Berreskuratze,  
Eraldaketa eta  
Erresilientzia  
Plana



Osakidetza



EUSKO JAURLARITZA  
GOBIERNO VASCO  
OSASUN SAIA  
DEPARTAMENTO DE SALUD



Jaun/Andre hori:

— Zuregana jotzen dugu berriz ere Kolon eta Ondesteko Minbizia Prebenitzeko Programatik. Osakidetza eta Osasun Saia gauzatzen ari dira programa.

Jakinazten dizugu gorozkietan odol ezkutua detektatzeko proba **EZ DELA BALIOZKOA IZAN**, beraz, **proba errepikatzea** gomendatzen dizugu.

Berrito bidaliko dizugu **materiala jarraibideekin**.

Gogoratu:

- Ireki hodia honekin batera doazen jarraibideak kontuan izanik.
- Bildu gorozki kopuru txiki bat bakarrik.
- Itsatsi etiketa hodiaren alde lauan.
- Gehienez 3 egunez utz dezakezu hozkailuan, momentuan entregatu ezin baduzu.

Programari buruzko informazio guztia webgune honetan dago eskuragarri:



— Zalantzarik baduzu, jarri harremanetan Programarekin **900 840 070** telefonoan edo **prevencionccr@osakidetza.eus** helbidearen bidez.

Agur bero bat.

Estimado/a Sr/a

Nos dirigimos nuevamente a usted desde el Programa de Prevención de Cáncer de Colon y Recto que lleva a cabo Osakidetza y el Departamento de Salud.

Le informamos que **el resultado de la prueba de sangre oculta en heces NO HA SIDO VALIDO**, por lo que le recomendamos **repetir la prueba**.

Le volvemos a enviar el **material con las instrucciones**.

Recuerde:

- Abra el tubo siguiendo las instrucciones que le adjuntamos.
- Recoja únicamente una pequeña cantidad de heces.
- Pegue la etiqueta en la parte plana del tubo.
- Puede dejarlo en su frigorífico un máximo de 3 días, si no puede entregarlo al momento.

La información completa del Programa está disponible en la página web:



Si tiene alguna duda, póngase en contacto con el Programa: **900 840 070** o por correo electrónico **prevencionccr@osakidetza.eus**

Reciba un cordial saludo,

Iz/Fdo.: Isabel Portillo Villares  
Kolon eta Ondesteko Minbizia Prebenitzeko Programaren Koordinatzailea  
Coordinadora del Programa de Prevención de Cáncer Colorrectal

\*Kanpaina hau Europar Batasunaren Berreskuratze Tresnak (NextGenerationEU) finantzatu du.

Datuak babestean buruzko oinarritzko informazioa: Interesdunari jakinarazten zaio bere datu pertsonalak Osakidetza - Euskal osasun-zerbitzuak tratatuko dituela. HISTORIA KLINIKOA tratamenduaren xedea da pazientearen historia klinikoren datuak izatea, horren jarraipena egiteko eta laguntza-jarduera kudeatzeko, zeregin bat betetzeko interes publikoaren izenean edo tratamenduaren arduradunari esleitutako ahal publikoak gauzatzeko. Posible da datuak honako hauei jakinaraztea: Eusko Jaurlaritzaren Osasun Saia, GSI, agintari judizialak eta aseguru-etxeak. Datuak interesdunak berak, Eusko Jaurlaritzaren Osasun Sailak eta Osakidetza lanegile sanitarioek eman dituzte. Interesdunak eskubidea du datuetara sartzeko eta horiek zuzendu edo ezabatzeko, eta tratamendua mugatzeko edo horri uko egiteko. Datuen babesari buruzko informazio gehiago duzu webgune honetan: <http://www.osakidetza.euskadi.eus/babesdatuak>

\*Esta campaña ha sido financiada por la Unión Europea - NextGenerationEU.

Información básica sobre protección de datos: Se informa a la persona interesada de que sus datos personales serán tratados por Osakidetza - Servicio vasco de salud. La finalidad del tratamiento HISTORIAL CLÍNICO es la de disponer de los datos de la Historia Clínica del paciente para el seguimiento del mismo y la gestión de la actividad asistencial, conforme al cumplimiento de una misión realizada en interés público de poderes públicos conferidos al responsable del tratamiento. Pueden realizarse comunicaciones de datos al Departamento de Salud del Gobierno Vasco, al INSS, a autoridades judiciales y entidades aseguradoras. Los datos proceden de la propia persona interesada, del Departamento de Salud del Gobierno Vasco y del personal sanitario de Osakidetza. La persona interesada tiene derecho de acceso, rectificación, supresión de sus datos, y la limitación u oposición a su tratamiento. Podrá ampliar información en materia de protección de datos en la siguiente dirección web: <http://www.osakidetza.euskadi.eus/protecciondatos>

SMS Format

**SMS INVITATION WITH KIT**

Birth Date :xx/xx/xxxx sex:x

You will soon receive a kit to participate in the Colorectal Cancer Prevention Programme.

Further info at <https://www.osakidetza.Basque Country.eus/colorrectal/>

Jaioteguna:xxxx/xx/xx sexua: x

Laster, Koloneko eta Ondesteko Minbizia Prebenitzeko Programan parte hartzeko kit bat jasoko duzu.

Info gehiago: <https://www.osakidetza.Basque Country.eus/minbizia-gaixotasuna/-/kolon-eta-ondesteko-minbizia/>

**SMS ADDRESS UNKNOWN**

Birth Date :xx/xx/xxxx sex:x

Due to an unknown address your invitation to the Colorectal Cancer Prevention Programme has been returned. We are re-sending you the material to participate. Update your details at your health centre

Further info at <https://www.osakidetza.Basque Country.eus/colorrectal/>

Jaioteguna:xxxx/xx/xx sexua: x

Zure helbidea zuzena ez zenez, itzuli digute Koloneko eta Ondesteko Minbizia Prebenitzeko Programan parte hartzeko bidali genizun gonbidapena.

Info gehiago: <https://www.osakidetza.Basque Country.eus/minbizia-gaixotasuna/-/kolon-eta-ondesteko-minbizia/>

**SMS NEGATIVE/POSITIVE FIT RESULT**

Birth Date :xx/xx/xxxx sex:x

The result of the faecal occult blood test was NEGATIVE/POSITIVE.

Further info at <https://www.osakidetza.Basque Country.eus/colorrectal/>

Jaioteguna:xxxx/xx/xx sexua: x

Gorzkietan odol ezkutua detektatzeko probaren emaitza NEGATIBOA izan da.

Info gehiago: <https://www.osakidetza.Basque Country.eus/minbizia-gaixotasuna/-/kolon-eta-ondesteko-minbizia/>

## ANNEX IV INVITATION OF PERSONS WITHOUT AN IHC

### INDIVIDUALS W/O IHC

There are persons without an IHC who will receive an invitation to the programme as their details may not be up to date. These users will call the coordinating centre and will be registered as a NON-IHC patient, after verifying that 18 months have passed since their last participation, if any.

- In the event of NOT having an IHC and therefor not being included, their name and surname, date of birth, DNI and address will be registered for the registry of "NO IHC" persons in the PCC, which will contact them with their invitation.
- Persons who, being NON-IHC, find out about the programme and call to register for it. For which a form is mailed to them.
- The samples will be analysed at the Hospital de Cruces.
- The results are sent by letter. Positive cases must be managed in private health care.

## ANNEX XV PATHOLOGICAL ANATOMY

Following the last meeting held in November 2019 between the CRC Coordinating Centre and the anatomic pathology working group, it was decided to incorporate the **2017 WHITE PAPER ON ANATOMIC PATHOLOGY IN SPAIN** into this programme, "Recommendations of the Digestive Pathology Club of the SEAP:

### ***“White paper on pathological anatomy in Spain 2017”***

*Sociedad Española de Anatomía Patológica. International Academy of Pathology*

*5<sup>th</sup> edition (2017) URL: [www.seap.es/libros-blancos](http://www.seap.es/libros-blancos) ISBN 978-84-697-3704-0*

- I. Checklist of material and information on Polypectomy, to be provided by digestive endoscopy anatomical pathology.
- ii. Checklist of the contents of the pathological anatomy report
- iii. Checklist of the contents of the pathological anatomy report on malignant colon polyp removed by endoscopic polypectomy.

- **Adenocarcinoma infiltration level for sessile and pedunculated polyps:**
- **Tumour budding (isolated tumour cells or nests of <4 tumour cells at the infiltrative margin of the tumour)** (based on\*Pai RK Mod Pathol 2017)