

Working Group 1 *Cancer early diagnosis and screening implementation, optimization, data collection, and monitoring*

D1.1 Checklist of minimum requirements for implementing effective services for breast, cervical and colorectal cancers' early diagnosis and screening

Task 1.1 Objective

The objective of **Task 1.1** is to develop a **structured list of minimum requirements** necessary for the **planning, implementation, and monitoring** of early diagnosis and screening programs for **breast, cervical, and colorectal cancers**.

This list should include the essential components and basic conditions that need to be in place at the national, regional or local level to ensure that breast, cervical, and colorectal cancer control programs are effective, equitable, and sustainable. It is intended to serve as a strategic reference tool for policymakers, public health authorities, and program implementers, enabling them to:

- Assess system readiness to introduce or scale up cancer early diagnosis and screening initiatives;
- Identify critical gaps in infrastructure, workforce, governance, data systems, and service delivery;
- Prioritize actions and investments based on context-specific needs and capacities;
- Support evidence-based planning and ensure alignment with international standards and national cancer control objectives.

Ultimately, this list contributes to building robust, inclusive, and high quality-assured cancer screening and early diagnosis programs, helping to reduce disparities and improve outcomes across populations.

Concept and development of a "List of Minimum Requirements"

A minimum requirements list is a clearly defined set of critical criteria or conditions that must be met for a program or intervention to be considered technically feasible, operationally sustainable, and impactful. In the context of cancer screening and early diagnosis, these requirements serve as a basic standard for quality and effectiveness.

The development of these requirements followed a structured methodology based on the following steps:

1. Defining the scope and objectives: this involved clearly defining what the minimum requirements sought to achieve, such as identifying the essential components necessary to ensure effective, high-quality, and equitable cancer screening programmes. It also involved establishing specific targets for each cancer type

(breast, cervical, colorectal) in line with international standards, such as those from the World Health Organization (WHO) and the European Union (EU). This ensures that the minimum requirements are relevant, evidence-based, and aligned with global goals, such as the WHO targets for cancer control and early diagnosis.

2. Literature review: a **review of the existing literature** was conducted to gather the best available evidence on how cancer screening programs should be structured and implemented. The review focused on internationally recognized **guidelines, research publications, and national program documentation**, particularly from countries with well-established screening systems (see reference list).

3. Expert working group discussions: a multidisciplinary team of Italian and international experts actively contributed to a series of focused discussions aimed at identifying essential needs and requirements for the effective planning and implementation of cancer screening programmes. The group consists of epidemiologists, public health specialists, program coordinators, clinicians, and screening providers. Drawing on diverse professional and field experiences, participants addressed key components such as population eligibility, test selection, service delivery models, data management, monitoring and quality assurance, and strategies to improve equity and participation. The collaborative approach ensured that the resulting recommendations were scientifically sound and practically applicable in different healthcare systems, always taking into account regional variability and resource constraints.

4. Development of minimum requirements: using the insights gathered, the team compiled a comprehensive set of requirements, organized into thematic areas needed throughout the entire screening pathway, in order to ensure effective program implementation.

- Political and governance: include the policies, leadership, and decision-making processes that must be in place to effectively launch and sustain a national or regional screening/early diagnosis program. For example: political commitment, policy and legal frameworks, health system governance, regulatory and quality assurance systems, stakeholder political and governance engagement;
- Financial: funding, budgeting, and economic planning necessary to effectively establish, operate, and maintain a screening program over time. For example: initial investment costs, operational costs, program support costs, patient-related costs, long-term sustainability;
- Organizational: the systems, processes, and human resources that must be in place to effectively, efficiently and equitably coordinate and deliver early diagnosis/screening services. For example: program coordination and leadership, human resources and workforce planning, infrastructure and service delivery network, information systems and data management, quality assurance and standard operating procedures (SOPs), community engagement and communication;
- Structural: physical, institutional, and systemic foundations necessary for the efficient and equitable provision of early diagnosis/screening services. For example: health infrastructure, diagnostic and

treatment pathways, health workforce distribution, information and communication systems, supply chain and logistics, institutional structures;

- **Professional:** the skills, training, qualifications, roles, responsibilities, and standards that healthcare professionals must meet to ensure the program is implemented safely, effectively, and ethically. For example: trained and qualified workforce, continuing education and skills development, adherence to clinical guidelines and standards, ethical and communication competencies, multidisciplinary collaboration, workforce planning and distribution;
- **Technical:** tools, technologies, procedures, and technical expertise necessary to conduct screening effectively, accurately, and safely. For example: screening technology and equipment, diagnostic tools and capacity, standardized protocols and procedures, quality assurance systems, data and information systems, technical training and expertise;
- **Ethical:** principles, standards, and practices that ensure a screening program respects the rights, dignity, and autonomy of individuals, while promoting equity and public health. For example: informed consent, confidentiality and privacy, equity and accessibility, respect for autonomy, accountability and transparency, cultural sensitivity.

A preliminary list of requirements was circulated and reviewed within the entire WG1 of the Medi-CaSE Action to ensure comprehensive input and consensus. Following this collective review, the multidisciplinary team of experts conducted a structured prioritization process to assess the relative importance, feasibility, and impact of each requirement. Each requirement was categorized into one of the following three levels—reflecting its essentiality, recommended status, or optional nature—based on evidence, implementation considerations, and contextual adaptability.



Mandatory: essential, indisputable conditions that must be met for the effective launch and operation of early diagnosis and screening programs. Without meeting these requirements, it would be unrealistic or unsafe to implement such programs, as their absence would compromise effectiveness, safety, quality, or access. Examples may include: the existence of operational protocols, a trained workforce to perform screening and diagnostic procedures, basic infrastructure for diagnostic monitoring, systems for informing the target population, a referral pathway for individuals with abnormal results.



Advancements: important elements that significantly **improve service implementation**, contributing to better quality, efficiency, reach, or user experience of the services, but are **not strictly mandatory in the initial phase of program implementation.** They support progressive improvement of screening services and should be integrated as resources and capacity grow. Examples may include: use of digital



health records for screening data; targeted outreach strategies for underserved populations; advanced training modules or multidisciplinary teams.



Gold Standard: optimal end-goals that represent the highest level of quality implementation of early diagnosis and screening services. They represent the **ideal status** or **best-practice benchmarks** for early diagnosis and screening programs, aligned with the **highest international standards**. While not immediately achievable in all settings, these requirements define what a **fully mature, high-quality program** should achieve in the medium to long term. Examples may include: full population-based screening coverage with personalized invitation systems, integration with national cancer registries and electronic health systems, comprehensive quality assurance and accreditation programs, equity audits to monitor and address disparities in access and outcomes.

This prioritization was then presented to and discussed with the entire WG1, leading to a common agreement on the final classification.

The document was finalized, incorporating the contributions of WG1 member and the feedback received. Once completed, the document will be uploaded on the Medi-CaSE website as first output of WG1.

The next step for the Medi-CaSE Action will be the wide distribution of this document among representatives of national and regional screening programs, health authorities and policy makers, researchers and training institutions, as well as the wider scientific community and the COST network. Distribution could take place through various channels, including scientific publications, conferences, thematic workshops, and the official COST Action website. The aim of this process is to promote a wide exchange of results, support the practical implementation of the recommendations, and encourage the harmonization of screening standards in the Mediterranean countries.

The minimum requirements list for breast, cervical and colorectal cancer screening are attached to the document as Annex 1.

Key reference documents

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GLOSSARY OF CANCER SCREENING TERMS

This glossary has been developed to support participants of Working Group 1 in reviewing and refining the three sets of minimum requirements for planning and implementing cancer screening programmes for breast, cervical, and colorectal cancers. By offering clear, and consistent definitions of key technical terms related to these screening pathways, the glossary aims to foster a shared understanding of these essential concepts. Definitions are presented in alphabetical order.

Accreditation/certification system

An accreditation system for cancer screening is a formal process through which screening programs and facilities are evaluated and recognized for meeting established quality standards. The goal of accreditation is to ensure that cancer screening is conducted in a way that is accurate, safe, effective, and consistent with best practices. Accreditation systems provide assurance that screening centers follow rigorous protocols (concerning imaging, quality control, patient care, staff qualifications, etc.), maintaining high-quality standards, and contributing to improved outcomes in breast cancer detection.

Breast cancer

Cancer that forms in tissues of the breast. The most common type of breast cancer is ductal carcinoma, which begins in the lining of the milk ducts. Another type of breast cancer is lobular carcinoma, which begins in the lobules (milk glands) of the breast. Invasive breast cancer is breast cancer that has spread from where it began in the breast ducts or lobules to surrounding normal tissue. Breast cancer occurs in both men and women, although male breast cancer is rare.

Breast Magnetic Resonance

Magnetic Resonance Imaging (MRI) for breast screening is a highly sensitive imaging technique that uses powerful magnets and radio waves to create detailed images of the breast tissue. Unlike mammography and ultrasound, which primarily rely on X-rays and sound waves, MRI uses magnetic fields to generate images, providing a more comprehensive view of the breast. Breast MRI is typically used as a supplemental tool rather than a primary screening method.

Breast Ultrasound

Ultrasound for breast screening is a diagnostic imaging technique that uses high-frequency sound waves to create images of the internal structures of the breast. It is commonly used as a complementary tool to mammography, especially in certain situations where additional clarity or information is needed. Ultrasound is particularly helpful for differentiating between solid masses (which could be cancerous) and fluid-filled cysts (which are generally benign).



Breast Unit

A Breast Unit is a specialized medical department or center that provides comprehensive care for patients with breast conditions, ranging from benign disorders to breast cancer. These units bring together multidisciplinary teams to offer tailored care, emphasizing early detection, diagnosis, treatment, and ongoing management. A Breast Unit is essential for modern breast care, offering a centralized, efficient, and patient-focused approach to managing breast health and disease.

Call-recall system

A call-recall system for cancer screening invitation is a structured approach used to manage and ensure that eligible individuals within a certain age group, are invited to participate in regular screening. This system involves two main components: *the initial invitation*, sent to eligible individuals, typically through phone calls, letters, or digital communication, to inform about the availability of screening, encourage participation, and provide information about the process, location, and benefits of screening; and *the recall* referred to the follow-up process where individual who missed their initial screening appointment or have not been screened for a certain period are reminded to reschedule. It can be done through automated systems, follow-up calls, or mail reminders.

Cancer detection rate

The proportion of screening examinations in which at least one cancerous lesion is detected.

Cervical cancer

Cancer that forms in tissues of the cervix (the organ connecting the uterus and vagina). It is usually a slow-growing cancer that may not have symptoms but can be found with regular Pap tests, HPV tests, etc.

Colposcopy

Examination of the vagina and cervix using a lighted magnifying instrument called a colposcope.

Colonoscopy

Endoscopic examination of the proximal and distal parts of the colon (large bowel) with a charge-coupled device camera or a fibre-optic camera on a flexible tube passed through the anus.

Colorectal cancer

Colorectal cancer, also known as bowel cancer, is the development of cancer from the colon or rectum (parts of the large intestine). Signs and symptoms may include blood in the stool, a change in bowel movements, weight loss, abdominal pain and fatigue.

Cone biopsy

Surgery to remove a cone-shaped piece of tissue from the cervix and cervical canal. Cone biopsy may be used to diagnose or treat a cervical condition. Also called conization.



Cancer early diagnosis

Early diagnosis programmes aim at reducing the proportion of patients who are diagnosed at a late stage. They have 2 main components: increased awareness of first signs of cancer, among physicians, nurses and other health care providers as well as among the general public; and improved accessibility and affordability of diagnosis and treatment services, and improved referral from first to secondary and tertiary levels of care.

Diagnostic assessments

Diagnostic assessments are additional tests to be performed when the screening test shows abnormal results or if people have symptoms that suggest cancer, to confirm or rule out cancer. These follow-up tests aim to provide more detailed information for a definitive diagnosis.

Eligible/target population

The eligible population for screening refers to the group of individuals who meet certain criteria to be invited or recommended for a specific screening test. These criteria are usually based on factors like age, gender, risk factors, and sometimes family history, to ensure that the screening is both appropriate and effective.

Examination coverage

The number of people screened with the recommended test in a given year divided by the number of people eligible for screening (the eligible target population per screening interval) in the same reference year.

Fecal immunochemical test (FIT)

A fecal occult blood test based on an immunological (antigen–antibody) reaction, where the antibody binds exclusively to human hemoglobin. FIT only detects human blood from the lower intestines.

Fecal occult blood test (FOBT)

A laboratory test used to assess stool samples for hidden (occult) blood. Occult blood in the stool may indicate colon cancer or polyps in the colon or rectum.

Fine needle aspiration

Fine needle aspiration (FNA) is another biopsy technique used to obtain a sample from a suspicious area in the breast. However, FNA uses a thinner needle than the core needle biopsy, and the sample obtained is typically a small number of cells or fluid rather than a solid tissue sample.

Free of charge

Free of charge for a screening test means that the individual being screened does not have to pay any out-of-pocket costs for the test. This includes not only the cost of the test itself (e.g., mammogram, HPV test, etc...) but also any related services such as consultations, follow-up exams, or diagnostic procedures directly associated with the screening. In the context of healthcare programs or public health initiatives, offering a screening test "free of charge" often means that the costs are covered by the government, insurance, or a specific health organization.

Hard-to-reach populations

The definition refers to groups of people who face greater challenges in accessing or engaging with services, programs, or initiatives due to various barriers. These barriers may be social, economic, cultural, geographic, or systemic, making it harder for these populations to participate in essential activities such as healthcare, education, or public health campaigns. Addressing the unique needs of these groups is crucial to ensuring equitable access to preventive healthcare, including services like breast cancer screening.

HPV testing

Detects presence of HPV genetic material (DNA) high-risk for cervical cancer.

HPV vaccine

A vaccine being studied in the prevention of human papillomavirus infection and cervical cancer. Infection with certain types of HPV increases the risk of developing cervical cancer. HPV vaccination is recommended in early adolescence, aged 9–14 years.

Invitation coverage

Annual invitations as a percentage of the annual target population.

ITC information and communication technology

It is the set of hardware and software technologies that enable the acquisition, storage, transmission, and manipulation of information.

Liquid-based cytology

A method for screening for cancerous or precancerous changes of the cervix performed by scraping cells from the cervix and rinsing the sampling device into a vial containing a liquid preservative.

Mammography

Mammography is a traditional method of breast cancer screening that uses X-rays to create images of the breast tissue on a special film. It was the standard technology for mammography until the development of digital mammography, which is now more commonly used. Digital mammography, also known as full-field digital mammography (FFDM), is an advanced breast imaging technology that uses X-rays to create detailed digital images of the breast. It has largely replaced traditional analog mammography due to its superior image quality, flexibility in image manipulation, and better integration with modern healthcare systems, improving detection rates, particularly in women with dense breasts.

Mastectomy

A mastectomy is a surgical procedure in which all or part of the breast tissue is removed. Depending on the type and extent of the cancer, mastectomy may involve removing surrounding tissues such as lymph nodes or chest muscles. It is a key treatment option for breast cancer, particularly for larger tumors, multiple cancer sites, or when breast-conserving surgery (lumpectomy) is not viable.

National Cancer Control Plan

A National Cancer Control Plan (NCCP) is a strategic framework developed by a government or health organization to guide the prevention, detection, treatment, and care of cancer within a country. It outlines specific goals, policies, and actions aimed at reducing the cancer burden, improving patient outcomes, and ensuring equitable access to cancer care services across the population.

Needle biopsy

A needle biopsy (more specifically core needle biopsy) is a procedure in which a larger needle is used to remove a small sample of tissue from a suspicious area in the breast. The tissue sample is then examined under a microscope to check for cancer cells or other abnormalities.

Negative result

A negative result for cancer screening refers to the outcome where no signs of cancer are detected in the screening test, the tissue appears normal, and there are no abnormal growths or suspicious areas that would indicate the presence of cancer.

Non-Government Organizations

Non-Government Organizations (NGOs) are non-profit organizations that operate independently of government influence and aim to address social, humanitarian, environmental, or development issues. They can be local, national, or international in scope and typically work on behalf of marginalized groups or causes. NGOs focus on direct services and humanitarian aid (such as poverty reduction, human rights, education, healthcare, environmental protection, and disaster relief).

Opportunistic/Spontaneous cancer screening

Opportunistic/Spontaneous screening refers to a type of cancer screening where individuals independently decide to undergo screening tests, often without a formal recommendation or invitation from a healthcare provider or organized screening program. This type of screening is typically driven by personal choice, awareness, or concern about one's health, rather than being part of a structured or population-based screening initiative.

Organized cancer screening program

An organized cancer screening program is a structured, systematic approach to screening for a specific cancer within a target asymptomatic population. This type of program actively invites eligible people to participate through coordinated, regular efforts. Key features of an organized screening program include: a *targeted age group*; *standardized methods*; *systematic invitations*; *quality assurance* and *follow-up* and support.

Pap smear

A method for screening for cancerous or precancerous changes of the cervix performed by scraping cells from the cervix and fixing them on a glass slide. Also known as conventional cytology.



Participation rate

The number of people who have a screening test as a proportion of all people who are invited to attend screening.

Performance indicators

Performance indicators for cancer screening are quantitative measures used to evaluate the effectiveness, quality, and efficiency of screening programs (i.e. invitation coverage, examination coverage, participation rate, recall rate, detection rate, positive predictive value). These indicators help monitor how well the screening process is functioning, assess patient outcomes, and identify areas for improvement. Performance indicators are critical for ensuring that cancer screening programs achieve their primary goals: detecting breast cancer early, minimizing false positives and false negatives, and improving overall patient outcomes.

Polyp

A polyp is an abnormal tissue growth that involves the most superficial (mucosal) layer of the colon wall. Endoscopically, polyps are described according to their macroscopic appearance and can be broadly divided into two types. Polyps attached to the mucosa by a stalk are designated as pedunculated, and polyps without a stalk are designated as sessile.

Population-based cancer registry

A population-based cancer registry is a comprehensive database that systematically collects, stores, and analyzes information about cancer cases within a specific geographic population. These registries track the occurrence, types, and outcomes of cancer diagnoses, as well as demographic and clinical data such as age, gender, stage of cancer, and treatment. The primary goal of a population-based cancer registry is to monitor cancer trends, inform public health policies, support research, and improve cancer prevention and control strategies. By providing a detailed picture of the cancer burden, these registries help identify patterns, risk factors, and areas where healthcare interventions are needed.

Positive predictive value

PPVs determine, out of all of the positive findings, how many are true positives.

Quality assurance

Quality assurance in cancer screening refers to a systematic process designed to ensure that cancer screening programs are effective, safe, accurate, and meet established standards. QA is critical for maintaining high-quality care, minimizing errors, and ensuring that individuals receive timely, appropriate, and reliable screening for breast cancer. Through regular audits, standardized procedures, training, and follow-up, QA helps ensure that cancer screening remains a reliable and effective tool for early diagnosis and prevention.

Recall rate

The number of people recalled for diagnostic assessments as a proportion of all people who were screened.



Screening

Testing asymptomatic individuals in order to detect disease at an earlier, more treatable stage and minimize adverse outcomes.

Screening interval

The fixed interval between routine screenings decided upon in each programme, depending on screening policy.

Screening policy

A policy for a specific screening programme that defines the targeted age and sex group, the geographical area, and other eligibility criteria; the screening test and interval; and requirements for payment or co-payment, if applicable. As a minimum, the screening protocol and repeat interval and determinants of eligibility for screening are stated.

Screening positive result

A screen positive result in cancer screening refers to a situation where the screening test detects an abnormality that suggests the possibility of a cancer. This result does not necessarily mean that cancer is present, but it indicates that further investigation is needed to confirm the diagnosis.

Screening protocol

A screening protocol is a set of standardized guidelines or procedures used to determine who should be screened for a specific health condition, how the screening should be performed, and what actions should be taken based on the results. The protocol ensures that screening is conducted consistently, safely, and effectively, with clear recommendations for follow-up care or treatment if necessary. Key components of a screening protocol include: target population, screening method; screening interval, criteria for positive results, follow-up session, quality assurance, informed consent, and education. Screening protocols are designed to be evidence-based, meaning they are created using the latest scientific research and clinical guidelines to ensure the most effective and efficient screening practice.

Screening test

A test applied to all people participating in a screening programme.

Sigmoidoscopy

Endoscopic examination of the rectum and sigmoid colon, potentially also examining the descending colon, splenic flexure, and distal transverse colon. There are two types of sigmoidoscopy: flexible sigmoidoscopy, which uses a flexible endoscope, and rigid sigmoidoscopy, which uses a rigid device. Flexible sigmoidoscopy is the preferred and most commonly used method nowadays.

Third sector organizations

A third sector organization is a nonprofit entity operating outside the public (government) and private (business) sectors, including charities, social enterprises, NGOs, and advocacy groups. These organizations focus on





addressing social, environmental, cultural, and humanitarian issues, driven by a mission to create positive social impact rather than generating profit. Often referred to as the voluntary, charitable, or civil society sector, third sector organizations typically rely on donations, grants, volunteers, and fundraising to support their activities, though some may also generate income through social enterprises or service provision.

VIA

Visual inspection of the cervix with acetic acid (VIA) is an effective, inexpensive screening test that can be combined with simple treatment procedures for early cervical lesions, provided by trained health workers.

Online references

<https://www.iarc.who.int/>

<https://publications.iarc.fr/604>

<https://publications.iarc.fr/573>

<https://publications.iarc.fr/Book-And-Report-Series/iarc-Handbooks-Of-Cancer-Prevention/Breast-Cancer-Screening-2016>

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