BACKGROUND NOTE ON
SCREENING AND EARLY DIAGNOSIS OF CANCER

According to the estimates of the EU’s Joint Research Centre, in 2020 about 2.7 million people were expected to be diagnosed with cancer in the EU-27, and nearly 1.3 million to die from it\(^1\). As over 40% of cancer cases are preventable, primary prevention remains the most cost-effective intervention in cancer control. Detecting as early as possible those cancers which could not be prevented, and providing appropriate treatment, is crucial for increasing significantly the chances for successful treatment, improving considerably patient outcomes, reducing further cancer mortality, as well as reducing notably the cost and complexity of cancer treatment.

Thanks to population-based screening programmes, a large population, who are asymptomatic and seemingly healthy but in an age group when they are susceptible to certain cancers, can be examined and their doubtful or positive test results can be followed up. Similarly, early diagnosis of cancer in already symptomatic patients at a stage when their cancer is not so advanced, can ensure the timely start of treatment before the cancer spreads and the patient’s condition worsen. E.g. the five-year survival rate for women diagnosed with cervical cancer at an advanced stage is 15%, compared to 93% if diagnosed when the cancer has not spread\(^2\); 57% of people with lung cancer survive their disease for 5 years or more when diagnosed at stage I compared with only 3% of those diagnosed at stage IV\(^3\).

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\(^1\) The estimates of cancer incidence and mortality are based on trends from previous years and do not reflect yet the effect of the COVID-19 pandemic on cancer burden.

\(^2\) American Society of Clinical Oncology: [https://ascopost.com/News/59711](https://ascopost.com/News/59711)

I. The rationale of screening and early diagnosis of cancer

Screening consists of a set of tests run across a targeted, seemingly healthy population group in order to identify those individuals who have cancer but their symptoms have not appeared yet, or who are unaware that their symptoms are cancer-related.

Successful cancer screening programmes have some essential components.

- Suitable disease: a cancer that is detectable at preclinical phase, for which early treatment is available, and which has a relative burden within the population.

- Suitable screening test: a valid testing method with high sensitivity (as few as possible with cancer get through undetected) and high specificity (as few as possible without cancer are subject to further diagnostic tests), which is accepted and at a reasonable cost.

- Suitable screening programme:
  - there is a clear definition of the target population;
  - the individuals to be screened are identifiable;
  - measures are available to ensure high coverage and attendance;
  - there are adequate field facilities for collecting the screening material and adequate laboratory facilities to examine it;
  - there is an organised quality control programme to assess the screening material and its interpretation;
  - adequate facilities exist for diagnosis and appropriate treatment of confirmed neoplastic lesions and for the follow-up of treated individuals;
  - there is a carefully designed referral system for management of any abnormality found; and
  - evaluation and monitoring of the total programme is organised.

Weighing harms against benefits is pivotal when deciding about carrying out screening programmes. Screening programmes should be undertaken only when their effectiveness have been demonstrated; when resources (personnel, equipment, etc.) are available to cover sufficiently the target group; when the health care system has facilities for confirming diagnoses and for treatment and follow-up; and when prevalence of the disease is high enough to justify the effort and costs of screening. Even with the best intention and proper

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5 WHO Europe: Cancer screening and early detection

6 IARC: World Cancer Report - Cancer research for cancer prevention, 2020, p. 542
implementation, screening programmes may cause harm: false positive results lead to additional testing, invasive diagnostic procedures and anxiety and psychological harm; false negative results come with false reassurance and defer diagnosis at a later stage, once symptoms have appeared; and over diagnosis or over treatment of preclinical cancers, which could have not caused symptoms nor posed a serious health threat, involve unnecessary treatment.

**Early diagnosis programmes** include increasing awareness about the first signs of cancer among the general public, but also among doctors (in particular primary health care providers), nurses and other health care providers; and improving accessibility and affordability of diagnostic and treatment services, and improving referral from primary care providers to specialised doctors and centres. Early diagnosis aims at reducing the proportion of patients who are diagnosed at a late stage. It is particularly relevant in cases of cancers of the breast, cervix, mouth, larynx, colon and rectum, and skin.

II. **Cancer registries**

Cancer registries are **systems for data collection, storage, validation and analysis**, which allow for **extracting and disseminating information on cancer incidence, mortality, survival, and prevalence rates, time trends, and projections** in the populations covered. On a more advanced plan, cancer registries can give information on the stage at diagnosis, diagnostic and treatment delay, type of treatment, medical equipment use, and compliance with clinical care guidelines.

Cancer registries have a key role in:

- epidemiologic research, for monitoring the trends of cancer incidence, survival, and prevalence rates in geographical areas, social groups, or time periods;
- investigation of aetiological factors for cancer, by supporting the analysis of the impact of different social or environmental factors on cancer risk;
- public health policy measures:
  - planning of cancer control measures, helping to prioritise different actions according to the current and projected cancer burden;
  - assessment and monitoring of the effectiveness of cancer control measures such as primary prevention, screening programmes, treatment patterns, and health care quality;
  - assessment of the impact of differences in access to diagnosis and treatment between geographical areas or social groups, in order to create programmes for reducing health inequalities;
- clinical and translational cancer research.

The **completeness and validity of data, and data quality** is key for cancer registries assuming their roles. Data from screening programmes is one of the important inputs for cancer registries.

At international level, countries have been cooperating under the aegis of the **International Association of Cancer Registries**. At EU-level, it is the **European Network of Cancer Registries** (ENCR), operational since 1990, that promote collaboration between cancer

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7 A-M Forsea: Cancer registries in Europe - going forward is the only option; eCancer, 2016
https://ecancer.org/en/journal/article/641-cancerregistries-in-europe-going-forward-is-the-only-option
registries, defines data collection standards, provides training for cancer registry personnel and regularly disseminates information on cancer incidence and mortality in Europe.

The ENCR aims at improving the quality, comparability and availability of cancer incidence data; creating a basis for monitoring cancer incidence and mortality in the EU; providing regular information on the burden of cancer in Europe; and promoting the use of cancer registries in cancer control, health-care planning and research. Its full membership is open (upon the fulfillment of other, well-defined criteria) for population-based cancer registries, i.e. registries that collect data on all new cases of cancer occurring in a specified population in a defined geographical area. ENCR is affiliated to the International Association of Cancer Registries; it is supported by the Commission, and its secretariat is hosted at the Joint Research Centre.

III. Modern technologies: Artificial intelligence and big data in cancer screening and diagnosis

Artificial intelligence (AI) refers to systems with intelligent behaviour, which analyse their environment and take actions with some degree of autonomy in order to achieve specific goals. AI-based systems can be purely software-based and act in the virtual world, e.g. voice assistants, image analysis software, search engines, speech and face recognition systems; or can be embedded in hardware devices, as it is the case with advanced robots, autonomous cars or drones.

Machine learning refers to algorithms that autonomously improve their performance, without humans directly encoding their expertise. Usually, machine learning algorithms improve by training themselves on data. Deep learning is a sub-field of machine learning; it is concerned with algorithms called ‘artificial neural networks’ that are modelled on the structure and function of the brain. A deep learning algorithm is trained to classify objects by exposing it to a large number of labelled examples that are correctly categorised. Once trained, algorithms can correctly classify objects that they have never seen, in some cases with accuracies that exceed those of humans. Obviously, the development of AI requires massive datasets; the larger the amount of data is, the better even subtle relations in the data can be discovered.

There is increasing interest in the use of AI and machine- and deep learning in healthcare, for conducting complex calculation and assessing diagnostic images with minimal human intervention. In the field of oncology and cancer management, AI is used in screening and early detection, and in tailored or targeted therapy by obtaining genetic information of the patient and predictions of future outcomes.

In most oncology-related diagnosis, the applications of AI are crucial in radiology for various modalities such as X-rays, ultrasounds, computed tomography (CT/CAT), magnetic resonance imaging (MRI), positron-emission tomography (PET) and digital pathology.

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8 Z. Dlamini, F. Z. Francies, R. Hull, R. Marima: Artificial intelligence (AI) and big data in cancer and precision oncology; *Computational and Structural Biotechnology Journal*, 2020

9 European Parliament Research Service: How artificial intelligence works, 2019

Differentiating between normal and abnormal medical images is a key aspect to accurate diagnosis. It is done by analysing images with highly specialised algorithms with increased speed and accuracy. The generated datasets include information about variants with classifications such as benign, likely benign, variant of unknown significance, likely pathogenic and pathogenic variants. Categorising all variants into classes and recognising its clinical significance is imperative. Additional to diagnosis, data obtained can be useful for cancer management.

AI brings a surge in big data and costs: big data management and interpretation is resource-intense, it requires large servers and skilled bio-informaticians; AI systems have specialised computational requirements for fast processing of data; and intended users need proper training before implementing AI-based systems for routine clinical practice. Using patient data for training AI and enabling machine learning, and the protection of patients’ safety and privacy remain crucial.

![Overview of the applications of AI in some major sectors](image)

Source: *Artificial intelligence (AI) and big data in cancer and precision oncology; Computational and Structural Biotechnology Journal, 2020*

In 2018 the Commission set out the **EU’s AI strategy** (COM(2018)237) with the aim to place Europe ahead of technological developments and encourage the uptake of AI by the public and private sectors; prepare for socio-economic changes brought about by AI; and ensure an appropriate ethical and legal framework. Together with the strategy, the Commission also proposed a set of initiatives to grow the European data space, including a communication on enabling the digital transformation of health and care in the Digital Single Market, including sharing of genomic and other health data sets (COM(2018)233)\(^{11}\).

Europe’s Beating Cancer Plan (COM(2021)44)\(^{12}\) announced the launch of a **new European Cancer Imaging Initiative**, promoting new methods to improve the quality and speed of screening programmes using AI. The work of the **Cancer Mission** of the Horizon Europe

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research programme will also contribute to the initiative by developing novel approaches for screening and early detection.

IV. Population-based screening programmes in the EU - screening for specific cancers

IV.1. Overview of the current European framework on cancer screening

Pursuant to the 2003 Council recommendation, Member States should implement systematic population-based national or regional screening programmes to reduce the burden of common cancers. Female breast, cervical and colorectal cancer, the three cancers in the scope of the recommendation, caused a collective burden of over 261,000 deaths in the EU-27 in 2020 (estimates from the European Cancer Information System).

To achieve this, the following tests have been recommended:

- pap smear screening for cervical cancer precursors, starting not before the age of 20 and not later than the age of 30;
- mammography screening for breast cancer in women aged 50 to 69; and
- faecal occult blood screening for colorectal cancer in men and women aged 50 to 74.

The recommendation underlines the importance of quality assurance at all appropriate levels of screening programmes, on the basis of European evidence-based guidelines on best practice. For the appropriate organisation and monitoring of the screening programmes, Member States should ensure adequate human and financial resources.

Since the adoption of the Council recommendations, several initiatives have been developed (and kept updated) for the rolling out, management and monitoring of cancer screening programmes:

- European guidelines for quality assurance in breast, cervical and colorectal cancer screening, published by European Commission Directorate General for Health and Food Safety (DG SANTE). The guidelines aim at optimising all aspects of screening from information and invitation messages, to administration of tests and interpretation of results, and patient referral. The guidelines are kept updated based on

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13 N. Couespel, R. Price: Strengthening Europe in the fight against cancer - Going faster, further, pp 48-64; 2020
15 Council Recommendation on cancer screening (2003/878/EC)
16 European guidelines for quality assurance in breast cancer screening and diagnosis: 4th edition, supplements
17 European guidelines for quality assurance in cervical cancer screening: 2nd edition, supplements
18 European guidelines for quality assurance in colorectal cancer screening and diagnosis
https://op.europa.eu/en/publication-detail/-/publication/e1ef52d8-8786-4ac4-9f91-4da2261ee535/language-en/format-PDF/source-194464733
new evidence and best practices, e.g. for breast cancer the preparatory work for the 5th edition has already started.

- **European Commission Initiatives on Breast Cancer** (ECIBC) is a multidisciplinary platform, bringing together health care professionals, researchers and patient advocates. The initiative aims at reviewing, developing and facilitating the implementation of European guidelines addressing the entire care pathway for these cancer types, including screening programmes.19

**European Commission Initiative on Colorectal Cancer** (ECICC): The Joint Research Centre has launched the call for experts and patients to form a working group for the development of evidence-based guidelines and a quality assurance scheme for the new European Commission Initiative on Colorectal Cancer.20

- **Implementation reports** on the 2003 Council recommendation on cancer screening, prepared by the International Agency for Research on Cancer (IARC) for the European Commission. The first edition was published in 2007, the second one in 2017. The report keeps track of the progress with the implementation of recommended cancer screening programmes across the EU. It also assesses the performance of the programmes in terms of population coverage and detection rates, and provides justification for further initiatives at the European and the national level in relation to cancer screening.21

- **The European Code Against Cancer** and its recommendation on cancer screening encourages European citizens to take part in organised cancer screening programmes for breast, colorectal and cervical cancer.22

### IV.2. State of play with the implementation and performance of recommended cancer screening programmes

Member States have made substantial progress over the last years with the **implementation of cancer screening programmes**. As of 2016, when closing the 2nd implementation report,

- 25 Member States were planning, piloting or rolling out (ongoing or completed) population-based breast cancer screening programmes (compared to 18 Member States in 2007);
- 22 Member States were planning, piloting or rolling out (ongoing or completed) population-based cervical cancer screening programme (17 in 2007); gradual implementation reports on the 2003 Council recommendation on cancer screening, prepared by the International Agency for Research on Cancer (IARC) for the European Commission. The first edition was published in 2007, the second one in 2017. The report keeps track of the progress with the implementation of recommended cancer screening programmes across the EU. It also assesses the performance of the programmes in terms of population coverage and detection rates, and provides justification for further initiatives at the European and the national level in relation to cancer screening.21

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23 All the EU Member States (and the UK), except Bulgaria, Greece and Slovakia had population-based screening programmes at the time of closing the 2nd implementation report. • Bulgaria, Greece and Slovakia had only non-population-based screening programmes. • Bulgaria had implemented a pilot programme that was concluded in 2014. • Romania had only a small-scale pilot or demonstration project, so the majority of the potential target population was subject to non-population-based screening.
The introduction of the HPV test as primary screening modality is offered in the context of organised screening in (some programmes or areas of) six Member States; and 20 Member States were planning, piloting or rolling out (ongoing or completed) population-based colorectal cancer screening programmes, and 3 non population-based programmes (12 in 2007).

Despite the progress, considerable differences still exist across the EU, as it is also shown in footnotes 24-26; some programmes are still at a planning phase owing to recent legislation, at a pilot phase only in a limited geographical area, or having their rollout ongoing or complete.

| Implementation of recommended breast, cervical and colorectal cancer screening programmes in EU Member States and the UK in 2016 |
|--------------------------------------------------|-----------------|-----------------|-----------------|
| Population-based screening program               | Breast cancer screening | Cervical cancer screening | Colorectal cancer screening |
| Population-based screening program               | 25 (95%)          | 22 (72%)         | 23 (72%)        |
| Rollout complete                                 | 21 (88%)          | 9 (28%)          | 9 (27%)         |
| Rollout ongoing                                  | 3 (3%)            | 10 (27%)         | 8 (26%)         |
| Piloting                                         | 1 (4%)            | 1 (<1%)          | 4 (3%)          |
| Planning                                        | 0                 | 2 (17%)          | 2 (18%)         |
| Non-population-based screening program           | 3 (5%)            | 4 (25%)          | 2 (4%)          |
| No screening program                             | 0                 | 2 (2%)           | 3 (24%)         |

Source: Strengthening Europe in the fight against cancer - Going faster, further.

Note: Numbers correspond to the number of EU Member States (and the UK) reporting their situation regarding the respective cancer screening program; percentages in brackets correspond to the proportion of EU populations targeted by the respective screening program living in the corresponding countries.

The 2nd implementation report evaluates the performance of the screening programmes based on their examination coverage rate. The examination coverage rate is the proportion of individuals from the recommended target population group who (i) in the framework of the screening program, received a personal invitation to screening within the scheduled screening interval (invitation coverage rate), and (ii) participated in the test within the scheduled screening interval (participation rate).

24 Germany adopted on 2013 the law to convert their current non-population-based screening programme into population-based screening programme; in 2016, the new programme was still in the planning phase. Slovakia initiated planning for population-based screening programme, but in 2016 only non-population-based service was available. • Non-population-based screening programmes were reported for Austria, Greece, Luxembourg and Spain. • Bulgaria completed a pilot in 2014, and no population-based programme was initiated. No programme was reported for Cyprus. • Ten Member States had their population-based cervical cancer screening programme still in the process of rolling out: Belgium, Croatia, Czechia, France, Hungary, Ireland, Italy, Lithuania, Portugal and Romania. • Denmark, Finland, Italy, Sweden, Romania and Portugal offers HPV tests as primary screening modality of cervical cancer.

25 Greece and Latvia only had non-population-based screening programmes. • Germany adopted law in 2013 to transform their current non-population-based screening programme into a population-based one. • No programme was initiated in Bulgaria, Romania and Slovakia. • In Austria, Sweden and Portugal the screening activity was not yet covering the entire country.
The WHO considers that for cancer screening programmes to be efficient, the examination coverage of the target population (by organised screening) should be over 70%.\(^{26}\) This as efficiency threshold was only achieved by five EU Member States and the UK in breast cancer screening, one in cervical cancer screening and by no EU Member State in colorectal cancer screening\(^{27}\). In addition, the IARC in the 2nd implementation report sets acceptable and desirable standards for participation rates, differentiated by cancer types, ranging between 45-70% and 65-85% respectively.

However, the coverage rates above do not take into account participation in opportunistic screening, when screening is not part of a nation-wide campaign but initiated by the patient or his/her healthcare provider. It leads to lower coverage and participation rates in organised screening programmes, while the actual screening rates in the target population is higher. It is especially true for cervical cancer screening, where opportunistic activity accounts for the majority of examinations in several Member States (up to more than 90%).

Another important consideration is that all screening rates differ considerably across the EU, but even within the territory of Member States across regions. The 2nd implementation report shows e.g. that in certain Member States examination coverage rates within their territory ranged between 17% and 84% for breast cancer screening, 4% and 71% for cervical cancer screening and 1% and 53% for colorectal cancer screening. These rates also demonstrate a low or very low coverage and participation of the target population in recommended cancer screening programmes in many European countries.

Organised cancer screening programmes also have to comply with a number of organisational requirements, including:

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\(^{26}\) WHO guide for effective programmes: Cancer control - Knowledge into action
[https://www.who.int/cancer/modules/Early\%20Detection\%20Module\%203.pdf](https://www.who.int/cancer/modules/Early%20Detection%20Module%203.pdf)

\(^{27}\) Examination coverage reaching or over 70% for **breast cancer** screening: Denmark, Finland, Ireland, The Netherlands, Sweden and the UK. • Examination coverage reaching or over 70% for **cervical cancer** screening: Sweden
an explicit screening policy, stipulated by law or an official notification, which defines the target population, screening tests and screening intervals;

public funding of the screening programme, and provision of screening tests free of charge;

well-defined plan for invitation to the eligible population, through letters or through primary healthcare providers;

a management team responsible for programme implementation and quality assurance;

existence of screening registries and linkage with cancer registries.

Data shows that the vast majority of Member States have publicly funded screening programmes, thus access to free screening and diagnostic tests is ensured. Almost all Member States with population-based screening programmes have teams responsible for implementation and quality assurance. The invitations to participate in the screening programmes are sent by specified organisations, by primary health care or by the general practitioners. A majority of Member States practice sending invitation letters with pre-fixed appointments or with faecal occult blood test kits for colorectal screening. However, many screening programmes still do not have screening registries linked to the cancer and cause-of-death registries that is a necessary condition to identify the cancer occurrence and deaths in the targeted population.

IV.3. Adaptation to scientific and technological developments, and possible broadening of the scope of screening to new cancer types

Scientific and technological developments have advanced cancer screening since the entry into force of the 2003 Council recommendation. New screening tests are being progressively implemented within screening programmes, such as full field digital mammography, digital breast tomodraphy or supplemental magnetic resonance imaging (MRI) in women with extremely dense breast tissue, for breast cancer screening; HPV test for cervical cancer screening; and faecal immunological test or endoscopy for colorectal screening. In addition to the implementation of new screening tests, cancer screening programmes may also benefit from scientific progress in the field of cancer risk prediction allowing for the development of risk-adapted screening.

For the introduction of new screening programmes, establishing effectiveness, benefit-harm ratios and cost-effectiveness through evidence is the first step. Upon supporting evidence, implementation research in each country is needed to assess the feasibility of fulfilling the national requirements in practice. Screening programmes need good governance, monitoring with standard key indicators throughout the screening chain and evaluation of outcome. Establishing sustainable models for funding is still in focus in many Member States. The wide variation in resources for health care between Member States should be taken into account when planning for Europe-wide recommendations and research strategies.

The Europe’s Beating Cancer Plan considers extending cancer screening programmes to additional cancers (prostate, lung or gastric cancers). The European cancer community keeps discussing intensively the possibility of screening programmes for additional cancer types. In particular, Prostate-Specific Antigen (PSA) test for prostate cancer screening28, and

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low-dose computed tomography (CT) screening for lung cancer\textsuperscript{29,30} are being discussed. Other prospects for additional cancer screening tests include gastric cancer screening, through endoscopy/fluoroscopy, pepsinogen testing or \textit{Helicobacter pylori} testing, and CA125-based ovarian cancer screening. The \textbf{EU co-funded Cancer Control Joint Action} (CanCon), which concluded its work in 2017, acknowledged the untapped potential for cancer prevention through extending population-based screening to new cancer sites, but was of the view that further evidence was needed and advocated for financing mechanisms for trials through pan-European cooperation. In particular, CanCon noted that some prostate cancer screening policies might be cost-effective but questions remain on the optimal benefit-harm balance; forthcoming results of European trials would inform policy-making on lung cancer screening in Europe; and new trials would be needed to be financed to investigate optimal strategies for gastric cancer screening.

V. \textbf{Europe’s Beating Cancer Plan}

Europe’s Beating Cancer Plan (\textit{COM(2021)44}) thrives to make improvements in three key areas of early detection of cancer: access, quality and diagnostics.

- \textit{Access}: The Commission plans to put forward a proposal by 2022, \textbf{updating the Council Recommendation} on cancer screening. In the context of the revision, the broadening of the scope of targeted cancer screening by including additional cancers (prostate, lung and gastric cancer) will be considered. Furthermore, in 2021-2022 the \textbf{European Cancer Information System will be upgraded}, and will start to routinely collect indicators to monitor and assess cancer screening programmes.

- \textit{Quality}: In addition to the ongoing Commission Initiative on Breast Cancer, the Knowledge Centre on Cancer will provide \textbf{new guidelines and quality assurance schemes} on cancer screening, diagnosis, treatment rehabilitation, follow-up and palliative care for colorectal and cervical cancer. These will include voluntary accreditation and certification programmes for cancer centres and screening programmes.

- \textit{Diagnostics}: As ‘Flagship 4’ of the EBCP, a \textbf{new EU-supported Cancer Screening Scheme} will be established, with the purpose to help Member States to offer breast, cervical and colorectal cancer screening to 90\% of their eligible population by 2025. This will be accompanied by the \textbf{new European Cancer Imaging Initiative}, promoting new methods to improve the quality and speed of screening programmes using AI. The \textbf{Cancer Mission} of the Horizon Europe research programme will strengthen further the Cancer Screening Scheme, and will generate evidence on optimising existing population-based cancer screening programmes, develop novel approaches for screening and early detection, and provide options to extend screening to new cancers.


\textsuperscript{30} ESR/ERS white paper on lung cancer screening; \textit{European Respiratory Journal}, 2015
- **Funding:** The EU4Health programme will provide funding for the new scheme, together with support from the Technical Support Instrument, and loans from the European Investment Bank. The European Regional Development Fund can also support investments in early detection.