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Scientific Advice Mechanism (SAM)

Cancer screening
in the European Union

Independent Expert Report

Group of Chief Scientific Advisors
Scientific Opinion No.12, March 2022

Research and Innovation

Cancer screening in the European Union

Group of Chief Scientific Advisors

European Commission
Directorate-General for Research and Innovation
Unit 03 — Science Policy, Advice & Ethics

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EUROPEAN COMMISSION

Chief Scientific Advisors
INDEPENDENT SCIENTIFIC ADVICE FOR POLICY MAKING

Cancer screening
in the European Union

Scientific advice on improving cancer screening across the EU

Group of Chief Scientific Advisors
Scientific Opinion No.12, March 2022
(Informed by SAPEA Evidence Review Report No. 10)

Brussels, 2 March 2022

2022 Directorate-General for Research and Innovation

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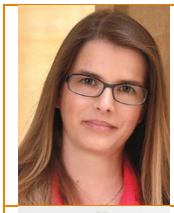
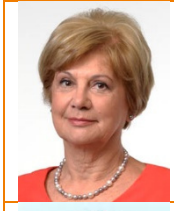
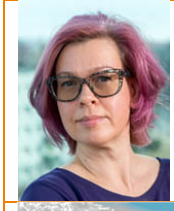
	**Nicole Grobert** **Chair** Professor of Nanomaterials at the Department of Materials, University of Oxford
	**Éva Kondorosi** Research Director Institute of Plant Biology, Hungarian Academy of Sciences Centre of Excellence, Szeged
	**Maarja Kruusmaa** (from 16 November 2020) Professor of Biorobotics, Vice-rector for Research, University of Technology (TalTech), Tallinn
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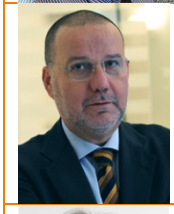	**Alberto Melloni** (from 16 November 2020) Professor of History of Christianity, University of Modena/Reggio Emilia, Chair of Religious Pluralism and Peace, University of Bologna
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The scientific advisors in charge of preparing this opinion were Éva Kondorosi (lead), Alberto Melloni, Eva Zažímalová and Nicole Grobert, as well as former advisor Janusz Bujnicki acting as an expert.

The scientific advisors would like to thank the many contributors for their invaluable support and input in preparing this scientific opinion:

The Science Advice for Policy by European Academies (SAPEA) consortium, which provided an Evidence Review Report (ERR) under the leadership of the SAPEA Working Group Chairs Professor Rebecca Fitzgerald and Professor Harry de Koning, aided by SAPEA staff, Hannah Whittle and Louise Edwards and with the support of Alison Weightman (Cardiff University) and Professor George Griffin and Professor Stefan Constantinescu (FEAM).

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All of the experts listed in Annex 3 who were consulted or informed the opinion.

EXECUTIVE SUMMARY

Cancer is a leading cause of death in Europe, and its prevalence is set to increase with an ageing population. Cancer is an individual diagnosis that has a major impact on patients, but it also severely affects the lives of their families and friends. The overall economic impact of cancer in Europe is estimated to exceed EUR 100 billion annually.

Europe needs a whole-of-government approach that is patient-centric and maximises the potential of scientific discoveries and new technologies, strengthens cooperation and opportunities for EU added value, eradicates inequalities and delivers improved health outcomes for patients.

Reducing cancer and its consequences is a key priority for the European Commission, in particular for the European Health Union, as announced in the State of the Union 2020 address by President Ursula von der Leyen. One of the pillars of the European Health Union is Europe's Beating Cancer Plan, presented in February 2021. With new technologies, research and innovation as its starting point, the plan sets out a new EU approach to cancer prevention, treatment and care.

Early diagnosis gives the best chances of survival. Therefore, population-based screening offers major opportunities to reduce the impact of cancer. One of the flagship initiatives of Europe's Beating Cancer Plan is to prevent cancer mortality and morbidity through population-based screening. A new EU cancer screening scheme should ensure that 90 % of the target population is offered breast, cervical and colorectal cancer screening by 2025.

Research and innovation dramatically advance our understanding of cancer initiation, progression, and relapse, and improved diagnosis, treatment and care interventions for people living with and after cancer. Emerging technologies with higher sensitivity for diagnosis can be applied to cancer screening, including molecular biomarkers, genomic data, liquid biopsy and artificial intelligence.

This scientific opinion of the Group of Chief Scientific Advisors (GCSA), informed by an evidence review report by experts of the Science Advice for Policy by European Academies (SAPEA) consortium, and extensive reviews of scientific literature and clinical trials through rapid reviews, examines how to improve cancer screening in Europe. It provides recommendations addressing three main questions:

- How can cancer screening programmes targeting breast, cervical and colorectal cancers, be improved throughout the EU?

- What is the scientific basis for extending such screening programmes to other cancers, e.g. lung, prostate and gastric cancers, and ensuring their feasibility throughout the EU?

- What are the main scientific elements to consider, and best practices to promote, for optimising risk-based cancer screening and early diagnosis throughout the EU?

Recommendation 1

Ensure that existing screening programmes for cervical, colorectal, and breast cancer integrate state-of-the-art scientific knowledge, are coordinated within the whole pathway of cancer management and are centred on the citizens.

1.1 Improve the participation of citizens in existing cancer screening programmes by making access to screening easy (e.g. through self-sampling, home-based testing), by providing information through decision-making aids and through shared decision-making between citizens and clinicians.
1.2 Ensure that best practices and standards are developed and applied in screening, along with staff training and continuous monitoring and evaluation for quality assurance.
1.3 Extend breast cancer screening for women below the age of 50 with mammography or digital breast tomosynthesis and for women with dense breasts with magnetic resonance imaging (MRI).
1.4 For cervical cancer, prioritise screening by testing for human papilloma virus (HPV) and support its eradication through the uptake of vaccination against HPV below 15 years of age.
1.5 For colorectal cancer, use faecal immunochemical testing (FIT) as the preferred triage test for referring individuals for follow-up colonoscopy.

Recommendation 2

Extend population-screening programmes to cancers for which scientific evidence demonstrates a good harm-benefit ratio, cost-efficiency, advantages of early detection, and feasibility throughout the EU, while regularly reviewing scientific evidence for screening of other cancers.

2.1 Extend screening programmes to lung cancer using low-dose computed tomography for current and ex-smokers, particularly in the light of the high numbers of deaths caused by this disease and the strength of the evidence.
2.2 Extend screening programmes to prostate specific antigen (PSA)-based prostate cancer screening, in combination with additional MRI scanning as a follow-up test, as there is good evidence that screening with PSA testing can reduce deaths from prostate cancer.
2.3 For gastric cancer, population-based screen and treat programmes for *Helicobacter pylori* are only recommended in regions with intermediate to high gastric cancer incidence.
2.4 At present, neither the experts nor the literature review finds scientific grounds for recommending population-based endoscopic screening for oesophageal cancer and ultrasound and CA125 screening for ovarian cancer.

Recommendation 3

Take advantage of the rapidly developing technological possibilities and scientific knowledge to optimise early diagnosis and risk-based cancer screening and throughout the EU.

3.1 Develop a system of "living guidelines" that can be rapidly modified and updated in response to scientific findings.
3.2 Further develop and implement risk-stratified screening in order to improve the harm-benefit ratio of screening programmes.
3.3 Ensure preparedness for the introduction of new screening methods, in particular for less invasive and blood-based cancer screening where large-scale clinical trials are expected to yield results for multiple cancer screenings in the coming years.
3.4 Support the establishment of biobanks appropriate for biomarker-based cancer screening research.
3.5 Support the harmonisation of protocols and quality assurance within and between countries

1. INTRODUCTION

1.1 Background

The human body is made up of trillions of cells. Cell multiplication and differentiation is normally strictly controlled. After an initial cell multiplication phase by division, cells differentiate into specific cell types and then die when they become old or damaged. Cancer arises when this cycle is disrupted; it refers to a group of non-communicable diseases characterized by the uncontrollable division of cells, which can then spread within the human body and harm its normal functions. In 2020, 2.7 million people in the EU were diagnosed with cancer. Extrapolating from the figures of the year 2020; it is estimated that one in two Europeans will develop cancer during their lifetime, and only half of all cancer patients survive (Ringborg et al. 2021).

Cancer can affect anyone, regardless of gender, social status, or age. The impact of cancer on patients, their families and society as a whole is devastating in multiple ways, reducing individual well-being and often affecting mental health, but also carrying heavy financial burdens. In addition to the loss of lives, the overall economic impact of cancer in Europe exceeds EUR 100 billion annually. Given the compounding factor of Europe's ageing population and—on the positive side—the potentially larger rates of survival afforded by new and improved treatments, the cancer incidence and related cost will increase (Ringborg et al. 2021).

Cancer is characterised based on the organ or body part where it first develops. Breast cancer is the most common cancer type in women. Over 355,000 people in the EU-27 were diagnosed with breast cancer in 2020. The next most prominent cancer types among the population as a whole are colorectal, prostate, lung, bladder and corpus uteri cancers.

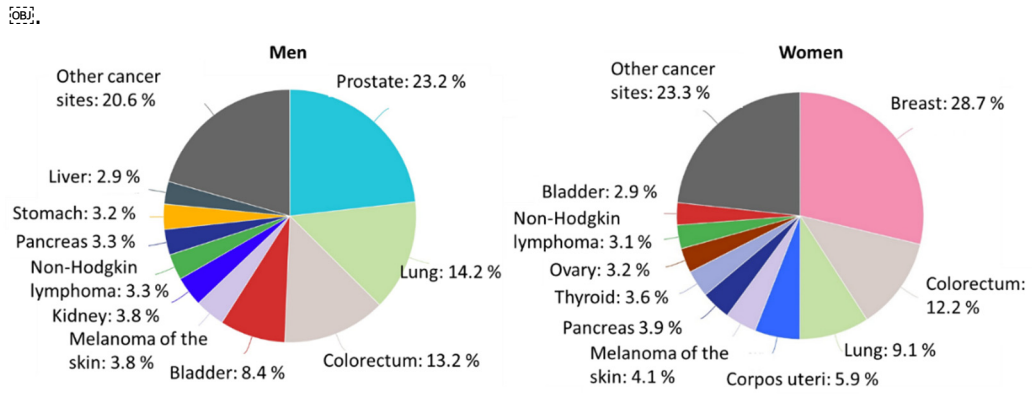


Figure 1: *Estimated percentage distribution of different cancers in the EU27 countries during 2020 in men (left) and women (right). (Source: ECIS: European Cancer Information System)*

Cancer is usually diagnosed in patients who already display symptoms or when it is discovered during medical tests performed for another condition. However, population-based cancer screening offers the possibility of diagnosing cancers at an early stage in otherwise healthy people, which in turn offers the highest probability of a positive outcome through treatment, and which directly save lives. Research on new and innovative screening techniques is constantly developing, expanding the types of cancer that can be successfully detected in their early stages and improving the detection possibilities for those that are already covered. To make the best out of these advancements, however, it is imperative that health care guidelines as well as the relevant national and international policies are also kept up-to-date. One of the lessons learned during the COVID-19 pandemic is that the EU should do more to support health, making the present day a good moment to act.

In November 2020, the first steps were taken towards building the European Health Union, announced in the *State of the Union 2020* address by President Ursula von der Leyen. The European Health Union was conceived to ensure stronger preparedness and response during current and future health crises, cancer included. It aims to equip the EU with the means to shore up prevention, treatment and aftercare for cancer, among other objectives. One of the pillars of the European Health Union is Europe's Beating Cancer Plan, published in February 2021. With new technologies, research and innovation as its starting point, the plan sets out a new EU approach to cancer prevention, treatment and care. One of the flagship initiatives of Europe's Beating Cancer Plan is to improve cancer prevention through population screening in the context of a new EU Cancer Screening Scheme to ensure that by 2025, 90 % of the target population is offered breast, cervical and colorectal cancer screening[1].

As of 2020, 25 EU Member States had introduced in their national cancer control plans population-based screening programmes for breast cancer, while 22 member states had done so for cervical cancer and 20 member states had done so for colorectal cancer. Full implementation has not yet been achieved, and inequalities persist within and between Member States. For example, throughout the EU, coverage of the target population ranges from 6% to 90% for breast cancer screening, and from about 25% to 80% for cervical cancer screening[2]. Thus, evidence-informed improvements to current programmes, best practices, and cancer screening are needed.

[1] European Commission. Europe's Beating Cancer Plan. (2021), eu_cancer-plan_en_0.pdf (europa.eu)

[2] OECD/EU Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris. (2018), https://doi.org/10.1787/health_glance_eur-2018-en

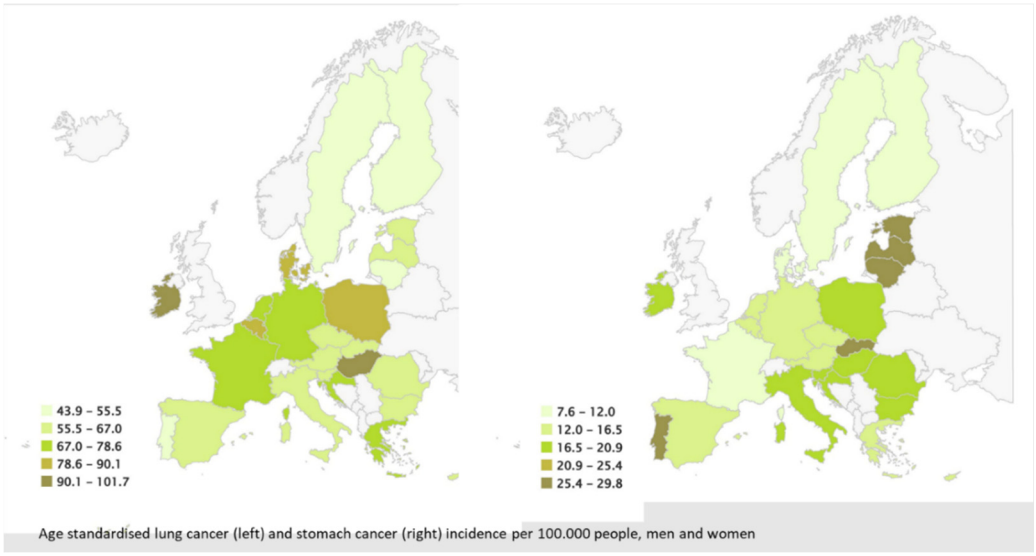


Figure 2: *Age standardised incidence of lung cancer (left) and stomach cancer (right) per 100 000 people*

1.2 Scope and objectives of the opinion

The Group of Chief Scientific Advisors (GCSA) was given the mandate to provide scientific advice on cancer screening in Europe.

A scoping paper (see Annex 2) describes the background of the questions to be addressed by the GCSA and directed the current scientific Opinion.

The scoping paper poses three questions:

- "How can cancer screening programmes targeting breast, cervical and colorectal cancers, be improved throughout the EU?"
- "What is the scientific basis for extending such screening programmes to other cancers, e.g. lung, prostate and gastric cancers, and ensuring their feasibility throughout the EU?"
- "What are the main scientific elements to consider, and best practices to promote, for optimising risk-based cancer screening and early diagnosis throughout the EU?"

The recommendations related to these scoping questions will inform different policy initiatives, including the revision of the 2003 Council of the European Union

recommendations on cancer screening (see Section 2.1), and the EU Mission on Cancer[3].

The revision of the Council of the European Union guidelines should ensure that the latest available scientific evidence is reflected in screening practices. One of the aims of this revision will be to consider the extension of cancer screening beyond breast, colorectal and cervical cancer to include prostate, lung and gastric cancer, as well as other cancers if supported by scientific evidence.

The updated guidelines will have to reflect the fact that the research and innovation underpinning cancer screening and treatment are rapidly evolving. Research and innovation increase our understanding of cancer initiation, progression, and relapse, as well as diagnosis, treatment and care interventions for people living with and after cancer. Personalised medicine - tailored to individual situations and needs - is changing patients' prognoses and will improve prevention, screening and early detection.

The Mission on Cancer is a major component of the EU's investment in cancer research and innovation. Missions will deliver impacts by putting research and innovation into a new role, combined with new forms of governance and collaboration, as well as by engaging citizens. The Mission on Cancer will deepen our understanding of the complexity of cancer. It will inform many of the key actions of Europe's Beating Cancer Plan's key actions and will deliver solutions for patients, including those with comorbidities. The Mission on Cancer could be informed by research gaps identified in the process of developing this scientific opinion.

This scientific opinion should contribute to a whole-of-government approach in Europe that is citizen-centric; maximises the potential of new technologies; strengthens cooperation between member states and governance levels, and increases opportunities for EU added value; reduces inequalities in access to cancer knowledge, prevention, screening, diagnosis and care; and delivers improved health outcomes for patients.

1.3 Policy context

1.3.1 EU's competence to act on cancer screening

The legal basis for action in the field of health largely falls on EU Member States, which, according to Article 168 of the Treaty on the Functioning of the European Union,[4] are responsible "[…] for the definition of their health policy and for the organisation and delivery of health services and medical care", including "[…] the management of health services and medical care and the allocation of the resources assigned to them". The same article, on the other hand, defines the EU's responsibility for "[…] improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health" noting that its actions should

[3] cancer_implementation_plan_for_publication_final_v2.pdf (europa.eu)
[4] http://data.europa.eu/eli/treaty/tfeu_2008/art_168/oj

complement the national policies of its Member States and encouraging cooperation between them. In particular, the EU is granted the power to act "[…] against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education […]".

Cancer is one of the most likely causes of deaths in the EU. To tackle this major health issue the European Commission has been working on policies for reducing the number of cancer deaths in Europe for the last four decades. This work has been conducted in close collaboration with its Member States and with international bodies such as the World Health Organisation and its International Agency for Research on Cancer. Fostering such collaborations as a mean to reduce cancer incidence and mortality as well as inequalities in detection and treatment resulted in several EU-wide initiatives, such as the European Code Against Cancer,[5] the first edition of which dates back to 1987. The Code provides recommendations that most people could easily put into practice by themselves in order to reduce their risk of cancer. In 2013, when the fourth and latest edition of the European Code Against Cancer was published, it was estimated that, if everyone was able to follow these recommendations, almost half of all deaths due to cancer in Europe could be avoided.

In addition to prevention, diagnosis and treatment, screening for cancer is a major tool for reducing cancer mortality. In 2003, the Council of the European Union issued Recommendations on European guidelines for the development of effective cancer screening programmes in the EU, following the 1994's Council of Europe recommendations on screening as a tool for the prevention of chronic non-communicable diseases. The Council of the European Union recommendations outlined the fundamental principles of the best practices in cancer screening, urging the Member States to take common actions to implement such programmes through a population-based approach and in accordance with the European quality assurance guidelines. The first report on the implementation of such recommendations was published in 2007, which highlighted the progress made but also pointed out that people's participation in cancer screening programmes throughout the EU was still far from the desired level.

In 2008, both the European Parliament[6] and the Council of the European Union[7] reinforced the request to support Member States in their efforts to tackle cancer. In 2009 the Commission launched the European Partnership for Action Against Cancer,[8] which provided "[…] a framework for identifying and sharing information, capacity and expertise in cancer prevention and control, and by engaging relevant stakeholders across the European Union in a collective effort". Through this partnership, the Commission provided guidance for Member States on establishing national cancer

[5] https://cancer-code-europe.iarc.fr/index.php/en/
[6] https://www.europarl.europa.eu/doceo/document/TA-6-2008-0121_EN.html
[7] https://data.consilium.europa.eu/doc/document/ST%209636%202008%20INIT/EN/pdf
[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52009DC0291

plans and on cancer care. It tasked the Joint Research Centre with the development of the European Cancer Information System (associated with the European Network of Cancer Registries and acting as a repository of cancer burden indicators across the EU), and also produced or updated guidelines and supplements for quality assurance in screening and diagnosis for breast, cervical and colorectal cancer. In 2014, the European Commission established an EU Group of experts on cancer control and launched a joint action to produce a European guide on quality improvement in comprehensive cancer Control.[9]

1.3.2 The von der Leyen Commission

Tackling cancer is one of President von der Leyen's main priorities in the context of human health. Her Political Guidelines for the Next Commission[10] contain the promise to "[…] put forward a European plan to tackle cancer, to support Member States in improving cancer control and care", and explicitly mention the success of "early detection and screening programmes".

Consequently, in February 2021, the Commission published Europe's Beating Cancer Plan,[11] an ambitious political commitment to mobilising the collective power of the EU and driving positive changes in tackling cancer. This plan is structured around four key action areas, which tackle the entire disease pathway: prevention, early detection, diagnosis and treatment. It also highlights/supports the quality of life of cancer patients and survivors. It is built around 10 flagship initiatives and will be implemented using the whole range of Commission funding instruments.

It contains several supporting actions aiming to mitigate the impact of the COVID-19 pandemic on cancer care and to support structural improvements, and it anticipates the establishment of a cancer inequalities registry to "[…] identify challenges, guide investments and interventions" at EU and national levels. The European Cancer Inequalities Registry[12] was launched in February 2022.

Research and innovation are central to the cancer plan, with a focus on new technologies and on how the most advanced understanding of cancer initiation, progression, prevention and diagnosis can improve health outcomes for individual patients. A European Cancer imaging initiative will be set up to support the development of new computer-aided tools to improve personalised medicine and innovative solutions. The Knowledge Centre on Cancer[13]—led by the Joint Research Centre of the European Commission—was launched to help coordinate scientific and technical cancer-related initiatives at EU level. The Knowledge Centre on Cancer

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0584&from=GA
[10] https://ec.europa.eu/info/sites/default/files/political-guidelines-next-commission_en_0.pdf
[11] https://eur-lex.europa.eu/legal-content/en/TXT/?uri=COM%3A2021%3A44%3AFIN
[12] https://cancer-inequalities.jrc.ec.europa.eu/
[13] https://knowledge4policy.ec.europa.eu/cancer_en

provides scientific/evidence-based information, along with the necessary systems, portals and platforms. It will underpin the Cancer Plan by systematically identifying and exploiting research results related to cancer and accelerating their translation into public health and clinical practice. The knowledge centre can steer national efforts and streamline social and financial investments by setting a common strategic research and innovation agenda on cancer. In addition, it can foster cross-sectoral collaboration between relevant actors in health, research, innovation, finance, social sciences and humanities for a continuous interaction and exchange of experiences and best practices.

1.3.3 EU's cancer screening initiatives

As early as 1994, the Council of Europe issued recommendations on screening as a tool for the prevention of chronic non-communicable diseases.[14] The principles set out for screening programmes were to "[…] identify a certain disease or risk factor for a disease before the affected person spontaneously seeks treatment, in order to cure the disease or prevent or delay its progression or onset by (early) intervention", ensuring that "[…] the advantages prevail over the disadvantages", as such programmes are "[…] potentially capable of improving the health of the population but [can] also [have] adverse effects". The recommendations also set out criteria for selecting diseases suitable for screening; in particular, "[screening] followed by diagnosis and intervention in an early stage of the disease should provide a better prognosis than intervention after spontaneously sought treatment". The diseases should also "[…] be an obvious burden for the individual and/or the community in terms of death, suffering, economic or social costs", "[…] go through an initial latent stage or be determined by risk factors, which can be detected by appropriate tests", and allow for indispensable adequate treatment or other interventions as "[…] determined both by proven medical effect and ethical and legal acceptability".

The 2003 Council recommendations on cancer screening advise that national, population-based screening programmes be used for breast, colorectal and cervical cancer, along with other principles of best practice in their early detection. To support EU countries, the Commission has produced guidelines to assure hugh-quality screening of all three types of cancers and complementary recommendations on diagnosis.

[14] Council of Europe, Committee of Ministers, Recommendation No. R (94) 11 on Screening as a Tool of Preventive Medicine (Oct. 10, 1994).

1.4 Scientific context

1.4.1 The evidence review report (ERR) by the Science Advice for Policy by European Academies consortium

The central contribution that informed the present opinion was the evidence review report (ERR) of the Science Advice for Policy by European Academies (SAPEA) consortium entitled 'Cancer screening in the EU' (SAPEA, 2022), which contains a comprehensive analysis of the scientific evidence related to the three scoping questions. This ERR was developed on the basis of three experts' workshops, each one informed by an extensive literature review. Rapid literature reviews were conducted for controlled trials published since 2007, supplemented with studies from published systematic reviews.

The ERR first looks at the purpose and principles of cancer screening. The World Health Organisation describes screening as a rough sorting process that separates the people who probably do have the condition from those who probably do not. A screening test is never 100% accurate; but provides only a probability that a person is at risk (or risk-free) from the condition of interest. At the centre of the screening process is the individual human being, and the screening process should be based on respect for the dignity and autonomy of that person and on the principle of 'first do no harm'.

Screening programmes have to balance the harms and benefits. The gold standard of scientific evidence is the randomised controlled trial (RCT). Large-scale trials of screening either aim to demonstrate either a reduction in cancer-specific mortality or an increase in the cancer detection rate or a shift towards earlier cancer stage and reduction in metastases for one type of screening compared with another. Implementation trials can provide additional evidence, as the effectiveness of screening programmes may be different in the 'real world'.

The cost-effectiveness of screening programmes is often estimated in terms of cost per quality-adjusted life year (QALY) for a particular intervention. Estimating the costs and QALYs gained by screening is a significant challenge, but it can be supported by models that incorporate adjustments for lower adherence to screening in the real world than in a trial, as well as poorer health, higher disease risks and worse life-expectancy in the general population than a trial participant.

The ERR further discusses the design (e.g. who to screen, risk stratification and the frequency of screening), organisation and delivery of screening programmes, and the challenges of and barriers to delivering organised screening programmes in the EU. There is a particular focus on addressing inequalities and under-screened groups.

The ERR also summarises the evidence how to improve existing cancer screening programmes, that is for breast, colorectal and cervical cancer. On the basis of an evaluation of clinical trials and case studies the ERR discusses how to improve the harm-benefit ratio by increasing the sensitivity while maintaining its specificity. This

entails a reduction of unnecessary recalls after screening (false positives) and improving communication and prompt evaluation among women recalled, together with the development of more effective screening tools and technologies.

The SAPEA team investigated scientific evidence for screening programmes for lung, prostate, gastric, ovarian and oesophageal cancers. These cancers are among the most common fatal diseases in Europe. For lung cancer, clinical trials showed reduced lung cancer mortality and minimal harm due to false-positive results. Benefits and harms can be managed and balanced by adherence to evidence-based guidelines. Screening via low threshold prostate-specific antigen (PSA) test results in a reduction in deaths from prostate cancer, but the mortality benefit tends to be balanced against overdiagnosis and overtreatment of low-risk disease. Overdiagnosis can be reduced by imposing an upper age limit on screening and/or a high-quality magnetic resonance imaging (MRI) scan or other accurate additional testing for PSA-positive men. PSA testing with the addition of bi-parametric MRI for PSA-positive men is likely to be cost-effective for many EU Member States. Opportunistic testing for PSA results in more overtreatment.

Technologies and science are evolving rapidly. The ERR investigates novel screening technologies for detecting cancer at an early stage. There is growing interest in the use of 'liquid biopsy' blood tests to detect multiple different types of cancer from the same sample based on the presence of cells, proteins or other molecules, or genetic alterations. Alternatively, the improved detection of biomarkers including DNA, RNA and proteins can be applied to tissue samples (e.g. scrapings from the cervix, nose or oesophagus) either to improve the accuracy of cytology-based screening or as a triage test. The use of artificial intelligence (AI) is a vast and rapidly growing field but still in its infancy; the focus of the ERR was on image analysis, which is the most mature application of AI relevant to screening.

The governance of cancer screening is important. It needs a clear and transparent framework and political, financial and stakeholder support, and requires harmonised access, protocols and quality assurance. As the field of cancer screening is still evolving and the authors of the ERR call for "living guidelines" that can accommodate a changing innovation landscape.

Finally, knowledge gaps are identified throughout the ERR, ranging from a fundamental understanding of processes leading to cancer to the identification of the optimal screening protocols for certain cancers. These can inform the planning of research and innovation at EU level.

1.4.2 Use of artificial intelligence and machine learning in cancer screening

AI can be defined as the ability of a computer or computer-controlled robot to perform tasks commonly associated with intelligent beings, while machine learning (ML) is an application or subset of AI that allows machines to learn from data without being explicitly programmed (SAPEA, 2022). Advances in the field of neural networks and

deep learning algorithms, together with the current computing capabilities and the arrival of Big Data in cancer research, provide an unprecedented opportunity to integrate information and complex research outputs.

AI/ML approaches used in image analysis can help to streamline screening logistics and could reduce pathology and radiology bottlenecks in the future, for example through automated initial triaging of pathology images (SAPEA, 2022). The interpretation of digital images requires the analysis by two highly trained expert specialists (e.g. radiologists and pathologists). There is already a shortage of trained radiologists and pathologists in EU member states, and the demand is expected to increase in the future. Extending cancer screening programmes to lung and prostate cancer will require these inequalities in availability of radiologists to be addressed.

Computational AI and deep-learning-based frameworks for automated detection and diagnosis show promising results and improvements in terms of diagnostic accuracy, compared with previous computer-based methods used in breast cancer screening (Tran et al. 2020). With the increasing use of digital breast tomosynthesis, specific artificial intelligence (AI)-computer-aided detection systems are emerging. Other computer-aided detection systems are focusing on breast diagnostic techniques such as ultrasound and magnetic resonance imaging (MRI). Chest computed tomography (CT) is another major field of application for AI, especially in terms of large-scale lung cancer screening (Chassagnon et al. 2020). However, there are major limitations in the computer-assisted diagnosis of lung cancer, namely the lack of standardization of acquisition parameters, inconsistent methods, and the lack of reproducibility; once these are addressed, the use of AI/ML will become more acceptable within the medical community (Thawani et al. 2018).

The use of ML in pathology has two broad advantages: it can assist physicians by providing an 'extra pair of eyes', and thus reducing misdiagnosis, and it may make it possible to provide diagnostic capabilities outside the doctor's office. For skin cancer, in particular, smartphones equipped with the appropriate deep-learning software could allow individuals to spot high-risk moles, possibly prompting them to seek the assistance of physicians much earlier than they otherwise would have(Troyanskaya et al. 2020).

It also becomes possible to evaluate complex samples for cancer diagnosis and to integrate multimodal data and diagnostic ML systems that combine images with other sources of data, including demography and genomics (Troyanskaya et al. 2020). Mazzone et al. (2021) have shown that applying AI analysis to whole transcriptome RNA sequencing of samples obtained from nasal brushings in current or ex-smokers can help to distinguish people with benign lung nodules from those with cancer, helping to reduce over-investigation of harmless growths. The integration of multimodal data and diagnostic ML systems.

Risk stratification entails more sophisticated stratification approaches involving grouping individuals according to their specific risk profile (e.g. breast density or

inherited genetic makeup) followed by tailored screening and risk management strategies. There are innovations being developed to reduce the complexity surrounding the delivery of risk-stratified screening and management for healthcare providers, such as smartphone risk assessment apps (SAPEA 2022). The use of risk stratification in screening for, for example, prostate cancer (Maarten de Rooij et al. 2021) and breast cancer (Clift et al. 2021) to define high-risk populations can maximise the efficiency and specificity of screening. AI/ML can contribute to automating some of the tasks involved in the risk stratification of patients before imaging, which can help for example in managing MRI resources.

AI/ML have generated high expectations in medical research and health care. AI/ML can contribute to cancer screening in many different ways, including for molecular and genetic data analysis, imaging, risk assessment and stratification and the identification of novel biomarkers (SAPEA 2022). There are however also inherent outstanding challenges, such as potential implicit biases in training datasets, data heterogeneity and the scarcity of external validation cohorts (Troyanskaya et al. 2020). Any algorithm is only as good as the data it is trained on and AI/ML tools need to be independently validated in the population in which they are ultimately being used (Vokinger et al., 2021). The general consensus in the field is that these technologies need to be further validated before they can have an impact in cancer screening (Venkatesan, 2021).

When big data and neural networks/deep learning methods are used, the reasoning behind the result/classification is not readily explainable/transparent. Making ML transparent and explainable is currently a very important topic of AI research, and this is an especially critical aspect in the case of cancer screening decisions and operators who need to understand how results are reached.

1.4.3 Improving the participation in cancer screening

The EU has the ambition to achieve a participation level of 90% of the people in eligible groups in cancer screening. At present, the participation in cancer screening programmes varies substantially throughout Europe. There are inequalities in screening policies and organisation as well as differences in the underlying health systems, and different rates of participation between and within countries. Achieving a participation rate of 90% will require an expansion in access to screening.

1.4.3.1 Making access to screening easy

Some of the previous GCSA opinions contain recommendations that are also relevant for the question on how to increase participation in screening programmes. In the opinion on how to achieve a sustainable food system it is argued that consumer behaviour is constrained and formed by many actors and aspects which are together referred to as the 'food environment'. The SAPEA ERR entitles 'A Sustainable Food System' (SAPEA, 2020) defines a 'food environment' as "the collective physical, economic, policy and sociocultural surroundings, opportunities and conditions that influence people's food and beverage choices and nutritional status". The actors that

influence this include non-governmental and industry actors, including producers, retail networks, storage and distribution actors, educators, influencers and information providers as well as individuals as food consumers and citizen-consumers. In general, evidence shows that the choices people make and what people do is related strongly to these systems, influenced by many actors; people are rational not in any external 'economic person' sense but in relation to their social environments. This means that the provision of information or voluntary means are not sufficient to change behaviour, and that behaviour change cannot solely be relied upon. This concept of the role that total social environment plays holds equally true for energy systems; supporting informed participation requires that the social environment to make participation the default choice through the way it is incentivised, made available and presented. It should be the easy choice.

This requires attention to the regulatory framework and governance, with clear long-term goals. The geographical distribution of screening centres, the integration between screening programmes and healthcare services (in particular primary care) and a clear end-to-end care pathway from screening through to treatment are all important for avoiding people falling through the gaps. More accessible methods for screening, such as home testing, may also increase participation.

1.4.3.2 Shared decision making

Shared decision-making is a key component of evidence-based and patient-centred care and is considered fundamental for "preference-sensitive" medical decisions (Martínez-González et al. 2018). It is especially relevant when there are uncertain risks and benefits of conducting the screening (Maes-Carballo et al. 2021). Shared decision-making involves bidirectional information flow between the clinician and the participant. It has proved beneficial in situations in which more than one screening decision is possible. Shared decision-making increases satisfaction of the patient and reduces medical malpractice claims. It is also considered a cornerstone for ensuring high-quality cancer care and it is a legal obligation in developed countries. A balanced and comprehensible view of potential health-care options and of the associated risks and benefits is necessary for the implementation of shared decision-making implementation.

However, organisational- and system-level characteristics are likely to influence the implementation of shared decision-making; these range from organisational leadership, culture, resources, and priorities, and workflows; to policies, clinical guidelines, incentives, culture, education, and licensing (Scholl et al. 2018). Their characteristics can support or inhibit the implemention of shared decision-making in routine care and can support or inhibit implementation.

Decision aids are interventions that support patients by making their decisions explicit, providing information about options and the associated harm-benefit ratio, and helping clarify congruence between decisions and personal values (Stacey et al. 2017). Decision aids can be paper, video or web-based or multimedia.

Cancer screening participants exposed to decision aids feel more knowledgeable, better informed, and clearer about their values, and they probably play a more active role in decision-making and more accurate risk perceptions (Stacey et al. 2017). There is growing evidence that decision aids improve values-congruent choices.

Decision aids can significantly improve knowledge and increase the proportion of women who make informed choices in breast cancer screening, by providing an analysis of the benefits and harms of the options, and clarifying the value of breast cancer screening to patients, even when they have no effect on screening attitude, intention, decision conflict or regret (Yu et al. 2021).

There is evidence indicating improved knowledge and accurate risk perceptions when decision aids are used, either within, or in preparation for the patient-clinician consultation (Stacey et al. 2018). Further improving their use with lower literacy populations is desirable.

In one review study, decision aids reduced the proportion of undecided participants in cancer screening and appeared to have a positive effect on patient-clinician communication. Moreover, those participants exposed to decision aids, were equally or more satisfied with their decision, the decision-making process, and/or the preparation for decision-making than those in usual care. Decision aids also reduced the number of people choosing major elective invasive surgery in favour of more conservative options (Stacey et al. 2018).

In terms of specific types of decision aids, the use of electronic media has proven to increase the uptake of colorectal cancer-screening. In one study of a shared decision-aid intervention in colorectal cancer screening, increased rates of screening preference (84 % versus 55 %) and readiness to receive screening (52 % versus 20 %) were found in the intervention group compared to the control group (Ramli et al., 2021).

In lung cancer, shared decision-making is an essential and effective component of screening the decision to screen is complex owing to the delicate balance between the risk and benefit (Tanner and Silvestri, 2019). Shared decision-making has been used in support of tobacco cessation and for improved communication between referral centres and clinicians. Studies have shown that smokers have known barriers to lung cancer screening including fatalistic beliefs, a distrust in the medical system, denial of the cancer risk, and a fear of screening. Shared decision-making is necessary for lung cancer screening to reach its full potential for decreasing mortality and morbidity in this high-risk group (Houston et al., 2020).

In the context of prostate cancer screening, where men face critical and highly preference-sensitive decisions involving a variety of potential risks and benefits, twice as many men recalled discussing the potential advantages of screening as those who recall discussing the disadvantages with their physician. However, compared with usual care, decision aids reduced the number of people choosing prostate-specific antigen (PSA) screening. For prostate cancer the harms and benefits need to be carefully

balanced and shared decision-making is recommended for all men in function also of the remaining life expectancy (Drazer et al. 2014; Martínez-González et al. 2018).

Despite the wide acceptance of shared decision-making in cancer screening, there still exists no normative definition of shared decision-making, there is significant variation in its implementation; and the evaluation of the results of shared-decision making in terms of patient outcomes is lacking (Martínez-González et al. 2018).

Box 1 – Implementation and governance of cancer screening

Screening involves an entire pathway, beginning with the initial identification of target populations and followed by invitation, risk assessment, the delivery of screening, the notification of results, and either follow-up and possible treatment or reminders for further screening rounds if appropriate. All of this requires appropriate governance, solid infrastructure, and independent systems for evaluation and quality control (SAPEA, 2022).

Appropriate governance can influence participation and reduce inequalities. Implementation and organisational theory could provide useful guidance in addressing facilitators of and barriers to change. The role of organisational- and system-level characteristics in further supporting the adoption of shared decision making in population screening programmes is key (Martínez-González et al. 2018; Figure 3). The availability of resources within an organisation and organisational workflows (e.g., patient information and dissemination strategies, scheduling routines and the use of the electronic health record) influences the implementation of shared decision-making. In addition, facets of the organizational culture and teamwork within an organization all play an important role. A culture of healthcare delivery influences the implementation of shared decision-making, but more so, incentives, policies and guidelines, healthcare professional education and licencing.

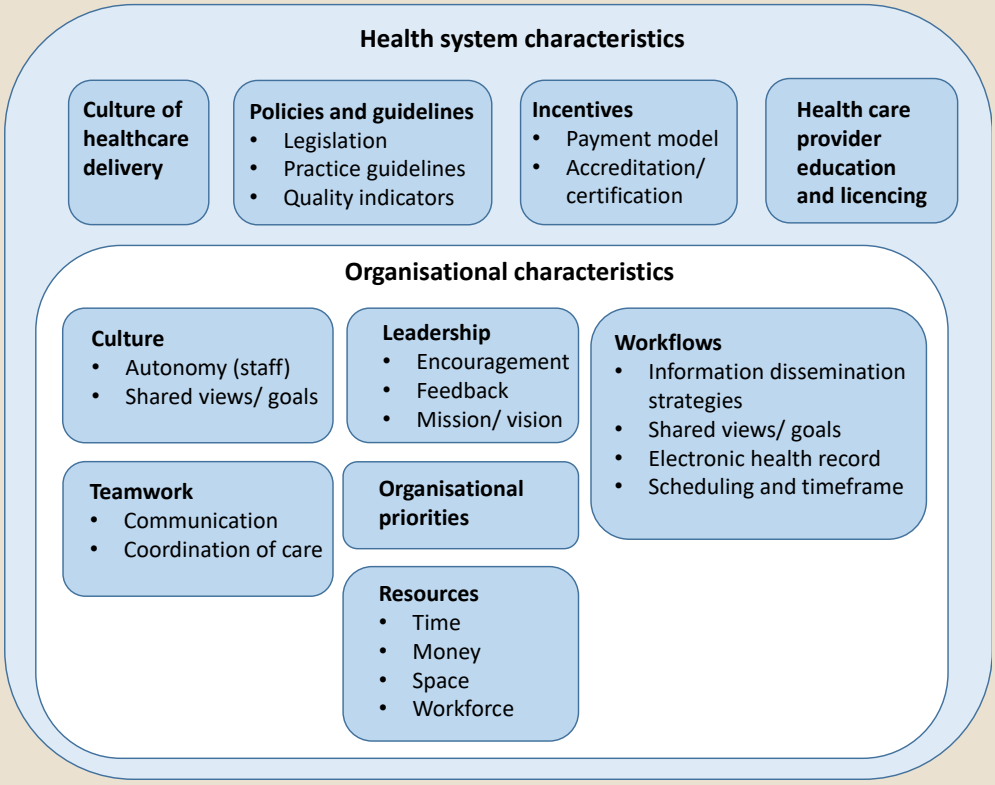


Figure 3: *Organization and system characteristics influencing the implementation of shared decision-making. (Source: Scholl et al., 2018)*

2. RECOMMENDATIONS

Recommendation 1:

Ensure that existing screening programmes for cervical, colorectal, and breast cancer integrate state-of-the-art scientific knowledge, are coordinated within the whole pathway of cancer management and are centred on the citizens.

1.1 Improve the participation of citizens in existing cancer screening programmes by making access to screening easy (e.g. through self-sampling, home-based testing), by providing information through decision-making aids and through shared decision-making between citizens and clinicians.

Most EU countries have screening programmes for breast, cervical and colorectal cancers. The target of the Europe's Beating Cancer Plan is to offer at least 90% of people in eligible groups the opportunity to participate in existing screening programmes. However, there is wide variation in governance and participation between and within member states. The participation in a screening programme depends on availability and convenience and also varies with socio-economic status, demographic and cultural factors and individual beliefs. Delivering equity involves an effort by identifying communities that or individuals who are currently underserved and develop strategies that give them an equal opportunity to participate.

The EU should support awareness campaigns, striving to make them more effective by using information material co-created with the public, and should aim to improve shared decision-making by including participants. Communication about risks and benefits can increase positive attitudes, can increase trust of social services and health policies oriented to the general public and can help people to make better-informed choices, although it does not necessarily increase the uptake of screening.

Decision aids and publicity by mass media should provide clear, understandable explanations and counter false information. Information strategies such as properly used publicity and mass media can have a considerable impact.

Screening strategies should be made as convenient as possible for people to participate (e.g. by prioritising at-home sampling for blood in stool or HPV, or by integrating of screening programmes with primary care and other healthcare services).

Further implementation research could lead to a better understanding on how individual and social barriers to taking part in cancer screening programmes can be overcome. There should be careful consideration of values that are transmitted implicitly; intuitions, beliefs, social/cultural identity largely define how people make decisions on screening (SAPEA, 2022).

1.2 Ensure that best practices and standards are developed and applied in screening, along with staff training and continuous monitoring and evaluation for quality assurance.

One common platform should be developed to exchange best practices and to encourage EU screening agencies to participate and contribute. At the national level, we recommend that screening programmes are coordinated with national comprehensive cancer centres to ensure optimal communication and integration of cancer screening in the whole pathway of cancer management. Cancer screening should be integrated in a comprehensive and integrated service that includes result interpretation, follow-up testing, confirmed cancer diagnosis and facilitation into oncology care

Standards for measurements, technologies, image quality, data formats, transfer and information channels should be developed and promoted to mitigate the variability between tests and machines.

Training programmes for staff operating on equipment should be supported to adhere to best practices and standards.

Imposing an upper age limit on screening at the population level is expected to improve the harm-benefit ratio for the group of participants as a whole, as the number of cancers found without benefits for the individual increases with age. Generally, age limits and screening intervals should be set so as to achieve the best outcome at the participant and population level. In time it may be possible develop ways to set a biological age, rather than a chronological age, to better adapt upper age limits.

1.3 Extend breast cancer screening for women below the age of 50 with mammography or digital breast tomosynthesis and for women with dense breasts with magnetic resonance imaging (MRI).

Breast cancer is the most common cancer in Europe (see Figure 1); about 1 in 11 women in the EU will develop breast cancer before the age of 74 (SAPEA, 2022). The stage at which breast cancer is detected has a major impact on the outcome, with almost all women for whom breast cancer is detected at stage 1 surviving for 5 years, with only 26% of women surviving for five years when diagnosed at stage 4.

The risk of cancer increases with age. Most countries in the EU operate national screening programmes, usually targeting women in the age group between 50 and 69. The evidence presented in the ERR (SAPEA, 2022) supports the extension of mammographic screening to women from the age of 45, as also recommended in current European Commission Initiative on Breast Cancer (ECIBC) guidelines[15].

[15] European guidelines on breast cancer screening and diagnosis | ECIBC (europa.eu)

The SAPEA experts were asked to focus on population-wide screening and did therefore not assess screening of women with inherited predispositions to breast cancer, such as those with mutations in the BRCA1 and the BRCA2 genes. However, early detection of cancer in women with an inherited predisposition could benefit from the development of special harmonised EU-wide guidelines (Dullens et al. (2020). Recently an international group of experts, including geneticists, medical and surgical oncologists, pathologists, ethicists and patient representatives, commissioned by the French Society of Predictive and Personalised Medicine (SFMPP) also proposed guidelines for BRCA1 and BRCA2 genetic testing (Pujol et al., 2021). The EU could consider taking up the development of guidelines for people with inherited predispositions to breast cancer.

The breast differs between women in terms of the quantity of fatty, fibrous and glandular tissues. Breasts composed of more fibrous/glandular tissue are known as 'dense' breasts. This is both a risk factor for breast cancer and makes the screening by mammography more difficult. Recent evidence and modelling suggest a sufficiently good harm-benefit ratio for risk-based strategies using magnetic resonance imaging (MRI) screening. These are also likely to be reasonably cost-effective for high-risk groups. Therefore, MRI should be considered in women with dense breasts and screening should be initiated from pre-menopause.

The use of artificial intelligence, and machine learning algorithms in particular, could improve cost effectiveness and reduce workload.

1.4 For cervical cancer, prioritise screening by testing for human papilloma virus (HPV) and support its eradication through the uptake of vaccination against HPV below 15 years of age.

Almost all cervical cancers are caused by infection with the human papillomavirus (HPV), although not all women infected with HPV will develop cervical cancer. The vaccination of girls against HPV at young age gives full protection and could lead to the eradication of cervical cancer in future generations. Until then, testing for HPV is necessary. HPV-based screening is more effective than cytology testing (SAPEA, 2022) and having a negative HPV test is associated with a low risk of developing cervical cancer for 6 years. Therefore, we recommend supporting the further roll out of testing for HPV. Once HPV testing programmes are generalised, traditional cytology testing can be reserved for individuals with persistent HPV infection.

When developing HPV screening programmes, it should be taken into account that self-sampling increases the screening uptake. Screening intervals could be extended with negative HPV test results and as participants get older.

1.5 For colorectal cancer, use faecal immunochemical testing (FIT) as the preferred triage test for referring individuals for follow-up colonoscopy.

Colorectal cancer represents 12.7% of all cancer cases and 12.4% of all cancer deaths in the EU. Improving the effectiveness of screening for colorectal cancer saves lives, as the stage of the cancer at diagnosis has a major impact on the outcome.

Screening for colorectal cancer involves analysing traces of blood in stool using FIT, the guaiac faecal occult blood test (gFOBT) or by colonoscopy/sigmoidoscopy to look for the presence of adenomas and/or malignant tumours. In terms of accuracy, FIT is a better triage test than the older gFOBT as the latter is more susceptible to false positives and requires several stool samples. Colonoscopy-based screening has higher sensitivity than testing for blood in stool, but it is less acceptable to participants and requires costly equipment and highly trained staff. Based on available evidence we recommend the use of FIT as a triage test.

The EU must support the standardisation of FIT through the development of reference materials or measurement procedures and standardisation protocols for the further implementation of generalised cut offs.

At present, most screening programmes use single cut-off values for FIT. The selection of candidates for colonoscopy could be improved by using sex- and age-specific cut-off values and by taking into account results from previous FIT tests. However, this requires more research to establish exactly which FIT thresholds are appropriate based on factors including age, sex, test manufacturer, and time since previous test.

Recommendation 2:

Extend population-screening programmes to cancers for which scientific evidence demonstrates a good harm-benefit ratio, cost-efficiency, advantages of early detection, and feasibility throughout the EU, while regularly reviewing scientific evidence for screening of other cancers.

Currently, the 2003 guidelines of the Council of the European Union call for EU-wide screening for breast, cervical and colon cancer. As scientific knowledge evolves, screening for additional cancers becomes possible. The GCSA and SAPEA evaluated evidence on lung, prostate, oesophageal and gastric cancers, in terms of the possibility of making earlier diagnoses, reducing cancer mortality and improving patient outcomes, the harm-benefit ratio and the cost-effectiveness of screening strategies. These cancers were selected based on the disease burden, measured by mortality and/or disability-adjusted life-years, and if screening performance has been investigated in large-scale trials.

2.1 Extend screening programmes to lung cancer using low-dose computed tomography for current and ex-smokers, particularly in the light of the high numbers of deaths caused by this disease and the strength of the evidence.

Lung cancer accounts for about 20 % of cancer deaths in the EU. The poor prognosis for lung cancer (only 13 % survival rate at 5 years) is linked to the fact that it is usually diagnosed late. Screening for lung cancer at an early (asymptomatic) stage can result in earlier diagnosis, reduced mortality and reduced expenditure.

Screening for lung cancer can be done through low-dose computed tomography (LDCT) or chest X-rays. Randomised clinical trials show that LDCT screening can detect more cancers and early-stage disease, reduce the mortality of lung cancer, and allow for the design of cost-effective screening programmes. The experts contributing to the SAPEA ERR therefore find a strong scientific basis for extending screening programmes to lung cancer using LDCT screening based on effectiveness and the mortality burden.

The optimal strategy based on age, sex and risk factors (smoking) and screening intervals should be further developed and tested in well-designed implementation trials and pilot screening programmes at local levels.

An important aspect of lung cancer screening is the capacity in terms of CT-scanners and trained radiologists and surgeons to provide expertise for low dose CT, lung biopsies, radiation therapy and surgery (Meerbeeck and Franck, 2021). The capacity varies significantly between European countries, and initiatives and guidelines at the EU level should consider this in developing a stepwise approach to the implementation of national screening programmes. The implementation of lung cancer screening should be supported by training and the exchange of scientific and technical information, the development of quality controls and standardised protocols and by financial support for technical improvements.

Finally, screening for lung cancer can be combined with preventive measures encouraging people to stop smoking.

2.2 Extend screening programmes to prostate specific antigen (PSA)-based prostate cancer screening, in combination with additional MRI scanning as a follow-up test, as there is good evidence that screening with PSA testing can reduce deaths from prostate cancer.

Prostate cancer is the most commonly diagnosed cancer and the leading cause of cancer deaths in non-smoking European men. Screening by testing of blood levels of PSA results in a significant reduction of prostate cancer mortality.

Overdiagnosis and overtreatment have been major concerns in prostate cancer screening, as prostate cancer is a highly heterogeneous disease, with possibly only about one third of cancers growing aggressively. The risk of overdiagnosis and overtreatment have long dominated the debates on screening for prostate cancer. However, these risks can be reduced with multiple but limited rounds of PSA testing (SAPEA literature review), following up PSA-positive individuals with MRI (allowing malignant tumours to be better identified and making biopsies more targeted) and risk

stratification (taking into account medical history, family history, digital examination, and prostate volume; black African/Caribbean family background is an additional risk factor). Prostate cancer screening can be cost-effective and further research is needed on how the cost-effectiveness and harm-benefit ratio of prostate cancer screening can be improved using the aforementioned strategies.

2.3 For gastric cancer, population-based screen and treat programmes for *Helicobacter pylori* are only recommended in regions with intermediate to high gastric cancer incidence, there is only a strong rationale for H. pylori test-and-treat strategies in countries with high rates of gastric cancer.

Gastric cancers are strongly linked with infection with *Helicobacter pylori*. Estimates, suggest that around 35-40% of gastric cancer deaths could be prevented through the identification and treatment of *H. pylori* infection. The incidence of gastric cancers in EU members differs significantly (three to four-fold differences), and the countries with the highest gastric cancer incidence and death rates should consider screening for *H. pylori.* Furthermore, it should be ensured that guidelines for endoscopy referral in at risk groups are followed to maximise opportunities for earlier diagnosis.

2.4 At present, neither the experts nor the literature review finds scientific grounds for recommending population-based endoscopic screening for oesophageal cancer and ultrasound and CA125 screening for ovarian cancer.

Novel technologies involving less invasive sampling techniques or blood testing and risk-stratified screening strategies may have potential for the future. The guidelines should be updated if and when the relevant technologies and scientific evidence make it possible to screen for these cancers.

Recommendation 3:

Take advantage of the rapidly developing technological possibilities and scientific knowledge to optimise early diagnosis and risk-based cancer screening and throughout the EU.

The scope of the recommendations related to this area include the rapid scientific developments being made in screening technologies and risk stratification.

3.1 Develop a system of "living guidelines" that can be rapidly modified and updated in response to scientific findings.

Guidelines on cancer screening are developed by taking into account tests, biomarkers, risk stratification processes and possibilities for treatments. These are evolving rapidly, as the whole field of biotechnology and medical sciences changes at a rapid pace.

Therefore, the typical lifespan of guidelines in the past (i.e. 7-20 years) may no longer appropriate anymore.

A system of living guidelines should be set up that can initiate revisions of guidelines when significant new developments are mature enough to be introduced into screening programmes mandated at EU level.

3.2 Further develop and implement risk-stratified screening in order to improve the harm-benefit ratio of screening programmes.

Risk-stratified screening aims to optimise the criteria for the selection of the groups to be screened and the frequency of screening. This requires the development of a set of principles for targeted screening, and the support of implementation trials of risk-stratified cancer screening at the local level.

There will be a need for clear communications about these new approaches and to understand the reasons for different screening types and frequencies (e.g., by underlying differences in risk).

Machine learning, and artificial intelligence in general, can improve state-of-the-art risk models for breast cancer detection. Computational approaches and opportunities for risk-stratified cancer screening must be further explored in prostate and lung cancer prediction.

For example, in prostate cancer, patient demographic factors and biochemical markers, in addition to PSA may improve risk stratification when used as classifiers in machine learning models. When calculating breast cancer risk for stratifying priorities for screening, personal health data relevant to breast cancer risk can be used as model inputs or incorporate mammographic breast density can be incorporated as a classifier. While these risk prediction tools show promise, they still need to be made generalisable (not only appropriate to a specific subgroup of the general population), standardised, and simpler to use in order to guide clinical decisions. However, the time when more precise risk management for cancer screening and improved decision making regarding personalized screening strategies will be possible may just be around the corner.

3.3 Ensure preparedness for the introduction of new screening methods, in particular for less invasive and blood-based cancer screening where large-scale clinical trials are expected to yield results for multiple cancer screenings in the coming years.

Using genomic technologies samples that are obtained for screening can be analysed for a range of cancers. These samples may take the form of brushings or swabs directly from the organ site (e.g. the oesophagus or nasopharynx) or liquid biopsies such as urine, breath or blood.

Current blood-based technologies are the most advanced in measuring circulating tumour DNA, its methylation, or tumour cells or other biomarkers including protein and RNA. This offers the potential for the detection of a larger range of cancers, including those for which population-wide screening is not possible at the moment (e.g. pancreatic cancer). However, the currently reported sensitivity of the emerging technologies must be improved for early-stage disease detection of most cancer types. Trials are ongoing, and as trial data emerge in the near future, the conclusions may change. In addition, these new technologies must be validated and standardised, as a number of different assays are becoming available. Emerging tests and novel multi-cancer screening technologies are promising but are not yet ready for implementation at the moment.

If innovative screening approaches such as "liquid biopsies" can be used to detect cancers earlier, it will be necessary to focus in parallel on the development and testing of suitable treatments that improve outcomes in terms of survival and quality of life.

3.4 Support the establishment of biobanks appropriate for biomarker-based cancer screening research.

Samples derived from large cohorts with known clinical background could support cancer-screening research, particularly for investigating blood borne biomarkers and testing the effectiveness of new technologies. Informed consent must be obtained from participants in cancer screening trials for novel technologies so that biological samples are available for future research to enable more effective comparison between technologies through national and EU research infrastructures.

3.5 Support the harmonisation of protocols and quality assurance within and between countries.

ANNEX 1 – METHODOLOGY

The Group of Chief Scientific Advisors (GCSA) provides independent scientific advice to the European Commission to inform policy making. The advisors work closely with the Scientific Advice for Policy by European Academies (SAPEA) consortium, which gathers expertise in engineering, humanities, medicine and natural and social sciences from over 100 academies and societies across Europe. Together with a secretariat in the Commission's research and innovation department, the Advisors and SAPEA constitute collectively the Scientific Advice Mechanism (SAM).

In this context, the Group of Chief Scientific Advisors (GCSA) to the European Commission (EC) has been asked to provide a scientific opinion cancer screening. The background to this request and the specific question to be answered by the advisors is laid down in the 'Scoping Paper' (Annex 2). The recommendations presented here by the GCSA build upon the Evidence Review Report (ERR, SAPEA 2022) developed by SAPEA, additional literature, and expert and stakeholder consultation (see Annex 3).

The scoping of the question included a proposal by the Federation of European Academies of Medicine (FEAM), a (grey) literature search and was aided by consultations with policy experts, scientific experts and expert practitioners. On this basis a Scoping Paper (Annex 2) was prepared, in consultation with Directorates-General responsible for cancer screening policy, setting out the request for advice. The Scientific Advisors agreed to take up the work as detailed in the Scoping Paper (April 2021). Éva Kondorosi (lead), Alberto Melloni, Eva Zažímalová and Nicole Grobert, as well as former advisor Janusz Bujnicki acting as an expert led the development of the Scientific Opinion on behalf of the Group of Chief Scientific Advisors.

The Scientific Advisors were aided by SAPEA which supplied the supporting evidence underpinning the Scientific Opinion. For this, it SAPEA organised three workshops in which scientific evidence was gathered and synthesised. Each workshop was underpinned by a rapid literature review by Cardiff University's Specialist Unit for Review Evidence, overseen by Academia Europaea. Evidence from the SAPEA Evidence Review Report and further academic and 'grey' literature was supplemented with expert elicitation, covering academic experts, policy experts and expert practitioners (see Annex 3).

The SAM Secretariat helped the Scientific Advisors in organising a discussion with policy experts of the European Commission on the scientific evidence and policy relevance and an expert 'sounding board meeting' on the draft Scientific Opinion.

Finally, the SAM Secretariat aided the Scientific Advisors in organising a stakeholder meeting, where the preliminary outputs of the SAPEA Evidence Review Report and the areas under consideration for the Scientific Opinion were presented by the SAPEA Working Group chairs and the Scientific Advisors, respectively.

This Scientific Opinion was thus informed by various sources of evidence, notably:

1. Scoping paper 'Cancer Screening' (SAM, 2021)
2. SAPEA Expert workshops – September, October and November 2021;
3. An Evidence Review Report by SAPEA – (SAPEA, 2022), referred to as the ERR.
5. Sounding Board Meeting – January 2022
6. Stakeholder Meeting – January 2022

Meeting reports or summarising notes are published online.

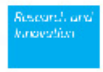
ANNEX 2 – SCOPING PAPER

Scientific Advice Mechanism

European Commission's Group of Chief Scientific Advisors

Scoping paper:
Cancer screening

22 April 2021



1. ISSUE AT STAKE

In 2020, 2.7 million people in the European Union were diagnosed with cancer, and another 1.3 million people lost their lives to it[1]. Cancer is an individual diagnosis that has important impacts on patients, but it also severely affects the lives of their families and friends. Today, Europe accounts for a tenth of the world's population, but a quarter of the world's cancer cases, and lives lost to cancer in the EU are set to increase by more than 24% by 2035[2], making it the leading cause of death in the EU. The overall economic impact of cancer in Europe is estimated to exceed €100 billion annually. Moreover, the COVID-19 pandemic has severely impacted cancer care, disrupting prevention, screening programmes and treatments, delaying diagnosis and vaccination, and affecting access to medicines. Since the pandemic began, the number of cancer diagnoses has decreased, foreshadowing a future increase in cases.

The EU has been working to tackle cancer for decades and its actions, for example on tobacco control and protection from hazardous substances, have saved and prolonged lives. However, the last European action plan against cancer was developed in the early 1990s and the world has seen major progress in cancer treatment in the years since. Personalised medicine – tailored to individual situations and needs – has radically changed patients' prognoses and will improve prevention, screening and early detection. Meanwhile, research and innovation, have dramatically advanced our understanding of cancer initiation, progression, and relapse, and diagnosis, treatment and care interventions for people living with and after cancer .

Europe needs a whole-of-government approach that is patient-centric and maximises the potential of new technologies; strengthens cooperation and opportunities for EU added value; eradicates inequalities in access to cancer knowledge, prevention, screening, diagnosis and care; and delivers improved health outcomes to patients. Europe's Beating Cancer Plan and the Horizon Europe Cancer Mission are the EU's response to these needs, while fully respecting Member States' responsibilities in health policy[3]. The aim is to tackle the entire disease pathway.

Europe's Beating Cancer Plan is structured around four key action areas where the EU can add the most value: (1) prevention; (2) screening and early detection; (3) diagnosis and treatment; and (4) quality of life of cancer patients and survivors. Over the coming years, it will focus on research and innovation, tap into the potential that digitalisation and new technologies offer, and mobilise financial instruments to support Member States.

[1] Most recent estimates from the European Cancer Information System (ECIS) for the EU-27 countries. New diagnoses cover all types of cancer, apart from non-melanoma skin cancer.
[2] https://gco.iarc.fr/tomorrow/en/
[3] See Article 168 of the Treaty on the Functioning of the European Union.

The Mission on Cancer[4], will be a major component of the EU's investment in cancer research and innovation. It will deepen our understanding of the complexity of cancer. Drawing on research and innovation, public health and policy development, it will inform many of the Cancer Plan's key actions and deliver solutions for patients, including those with comorbidities.
Furthermore, the new Knowledge Centre on cancer will help foster alignment and coordination of EC cancer-related activities at the scientific and technical level. It will utilize and build upon the European Cancer Information System, the European Guidelines and Quality Assurance Schemes for Prevention, Screening, Diagnosis and Care and the Health Promotion and Disease Prevention Knowledge Gateway.

2. BACKGROUND

Cancer screening and early detection offer the best chance of beating cancer and saving lives. As of 2020, 25 EU Member States had introduced in their National Cancer Control Plans population-based screening programmes for breast cancer, 22 for cervical cancer and 20 for colorectal cancer. However, many programmes have not been fully implemented, and unacceptable diversities and inequalities persist within and between Member States. For example, coverage of the target population ranges from 6% to 90% for breast cancer screening, and from about 25% to 80% for cervical cancer screening[5]. Before this summer, the Commission will deliver the European Guidelines and Quality Assurance Scheme for Breast Cancer Screening, Diagnosis and Care. These Guidelines are already being updated, as new evidence becomes available, and the Quality Assurance Scheme will facilitate implementation in all Member States. Furthermore, the Commission has started working on the Colorectal Cancer Guidelines and Quality Assurance Scheme.

To guide further EU action on cancer screening with the most recent evidence, the Commission will launch work in 2021 to prepare a 3rd report on the implementation of the Council Recommendation on cancer screening[6]. Alongside this, in the medium term, the upgraded European Cancer Information System will work with Member States and the International Agency for Research on Cancer to develop the routine collection of indicators to monitor and assess cancer screening programmes. As one of its flagship Europe's Beating Cancer Plan will put forward a new EU-supported Cancer Screening Scheme to help Member States ensure that 90% of the EU population who qualify for breast, cervical and colorectal[7] cancer screenings are offered screening by 2025. The scheme will focus on making improvements in three key areas: access, quality and diagnostics.

[4] The Cancer Mission Board, an independent expert group of the Commission, has prepared an outline with 13 recommendations for consideration which will serve as basis for the implementation of the Cancer Mission, https://ec.europa.eu/info/publications/conquering-cancer-mission-possible_en

[5] https://ec.europa.eu/health/sites/health/files/state/docs/2018_healthatglance_rep_en.pdf

[6] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003H0878

[7] The three types of cancer addressed by the Council Recommendation on cancer screening which, in 2003, were the only ones to have the prerequisite to be addressed by population based screening.

The Commission will make a proposal by 2022 to update the Council Recommendation on cancer screening to ensure it reflects the latest available scientific evidence. One of the objectives will be to consider the extension of cancer screening beyond breast, colorectal and cervical cancer to include prostate, lung and gastric cancer, and other cancers if supported by scientific evidence. This will be done according to the criteria under the point 6 of the Council Recommendation on cancer screening[8], addressing the 'Introduction of novel screening tests taking into account international research results'. This work is expected to be informed by the advice from the European Commission's Group of Chief Scientific Advisors[9], by the Joint Research Centre, and by the relevant outcomes of EU initiatives funded under the public health and research and innovation programmes, for instance, inter alia, the two projects 'Innovative Partnership for Actions Against Cancer' (iPAAC) and 'Towards Improved Cancer Screening' (EU-TOPIA) projects. In Addition, the new Partnership on Personalised Medicine, due to be set up in 2023 and funded under Horizon Europe, will identify priorities for research and education in personalised medicine, support research projects on cancer prevention, diagnosis and treatment, and make recommendations for the roll-out of personalised medicine approaches in daily medical practice. As a preparatory action to the Partnership, the Commission will establish a roadmap to personalised prevention, identifying gaps in research and innovation, and will support an approach to map all known biological anomalies leading to cancer susceptibility, including hereditary cancers.

3. REQUEST TO SCIENTIFIC ADVICE MECHANISM

The questions to be answered by the Scientific Advice Mechanism are:

(First question) **"How can cancer screening programmes targeting breast, cervical and colorectal cancers, be improved throughout the EU?"**

(Second question) **"What is the scientific basis extending such screening programmes to other cancers e.g. lung, prostate and gastric cancers, and ensuring their feasibility throughout the EU?"**

(Third question) **"Which are the main scientific elements to consider, and best practices to promote, for optimising risk-based cancer screening and early diagnosis throughout the EU?"**

As the proposal to update the Council Recommendation on cancer screening should be finalized no later than the first quarter 2022, the Commission would need an answer by no later than February 2022.

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0878&from=EN

[9] https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/group-chief-scientific-advisors_en

ANNEX 3 – LIST OF EXPERTS AND STAKEHOLDERS CONSULTED

Name	Current Institution	Category
Anttila Ahti	Mass Screening Registry/ Finnish Cancer Registry	Sounding board
Baird Anne-Marie	Lung Cancer Europe	Stakeholder
Baldwin David	Nottingham University Hospitals NHS Trust	Stakeholder
Berns Anton	European Academy of Cancer Sciences (EACS)	Sounding board
Blum Torsten	European Respiratory Society	Stakeholder
Borras Josep M.	Instituto Catalán de Oncología (ICO)	Sounding board
Breyel C	MedTech Europe	Stakeholder
Bujnicki Janusz	Int'l Institute of Molecular and Cell Biology in Warsaw	Stakeholder
Campbell Alistair	European Society of Radiology	Stakeholder
Carrato Alfredo	Pancreatic Cancer Europe	Stakeholder
Cattaneo Ivana	European Federation of Pharmaceutical Industries and Associations	Stakeholder

Charalampopoulou Ioanna	COCIR – the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries	Stakeholder
Couespel Norbert	European Cancer Organisation	Stakeholder
Dalmas Miriam	Ministry for Health, Malta	Sounding board
de Koning Harry	SAPEA and Erasmus University	SAPEA
De Andrea Silvia	Italian Society for Breast Cancer Screening	Stakeholder
Deschamps Andre	Europa Uomo	Stakeholder
Dudek-Godeau Dorota	Cardinal Stefan Wyszyński University	Sounding board
Fiorenza Domenico	Directorate-General for Health and Food Safety	Policy expert
Fitzgerald Rebecca	SAPEA and Medical Research Council Cancer Unit, University of Cambridge	SAPEA
Garel Pascal	European Hospital and Healthcare Federation (HOPE)	Stakeholder
Girvalaki, Charis	European Cancer Patient Coalition	Stakeholder
Grobert, Nicole	GCSA, President – University of Oxford	GCSA
Guex, Morgane	European Association for the Study of the Liver	Stakeholder

Horgan, Denis	European Alliance for Personalised Medicine	Stakeholder
Jepsen, Peter	European Association for the Study of the Liver	Stakeholder
Kalloniemi, Olli	Karolinska Institutet	Sounding board
Katajamaeki, Sasu	Directorate-General for Health and Food Safety	Policy expert
Kauczor, Hans-Ulrich	European Society of Radiology	Stakeholder
Klein, Barbara	Europa Donna – The European Breast Cancer Coalition	Stakeholder
Lenaerts, Liesbeth	KU Leuven – Department of Oncology	Stakeholder
Majek, Ondrej	Institute of Health Information and Statistics of the Czech Republic	Stakeholder
Malats, Nuria	Spanish National Cancer Research Centre	Stakeholder
Nedelcheva, Yoanna	European Association for the Study of the Liver	Stakeholder
Nurse, Paul	Francis Crick Institute	Sounding board
Olsen, Matias	European Confederation of Pharmaceutical Entrepreneurs	Stakeholder
Ponti, Antonio	CPO Piemonte and Città della Salute e della Scienza (university hospital), Turin	Sounding board

Revel, Marie-Pierre	European Society of Thoracic Imaging	Stakeholder
Ritchie, David	Association of European Cancer Leagues	Stakeholder
Roobol, Monique	Erasmus University Medical Center Cancer Institute	Stakeholder
Ryll, Bettina	European Society for Medical Oncology and Melanoma Patient Network Europe	Sounding board
Schuppe, Matthias	Directorate-General for Health and Food Safety	Policy expert
Senore, Carlo	Città della Salute e della Scienza (university hospital), Turin	Stakeholder
Ungurean, Carmen	National Institute of Public Health, Romania	Sounding board
Van De Loo, Jan-Willem	Directorate-General for Research and Innovation	Policy expert
Van Poppel, Hein	European Association of Urology	Stakeholder

ANNEX 4 - REFERENCES

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This scientific opinion by the Group of Chief Scientific Advisors examines how the European Commission can contribute to improving cancer screening across the EU and informs the 2022 Commission's proposal to update the 2003 Council Recommendation on cancer screening.

Cancer is a leading cause of death in Europe, and its prevalence is set to increase with an ageing population. Reducing cancer and its consequences is a major priority for European Commission. This scientific opinion focuses on improving the participation in existing screening programmes for cervical, colorectal and breast cancers and examines the extension of screening programmes to other cancers.

The GCSA recommends, among others, extending breast cancer screening to women below 50 as well as extending the screening programmes to lung and prostate cancer. For these and other cancers, the GCSA advises „living-guidelines" allowing rapid improvements of screening programs. Scientific developments should be continuously reviewed, and guidelines updated regularly, to adapt novel cancer screening technologies.

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