

COCIR Contribution
to the EC [Call for evidence](#)
regarding the update and possible extension
of the 2003 Council Recommendation on cancer screening

Background

High-quality smart screening with precision diagnostic equipment for early cancer detection is essential in reducing cancer mortality in Europe. Early cancer detection and diagnosis are linked with curable stages of cancer, less invasive treatment options and better rehabilitation.

To date, significant disparities are observed across the EU Member States in both the adoption of and access to cancer screening programmes. This phenomenon has curtailed the widespread uptake - and subsequent health benefits - of the Council Recommendation and the European Guidelines for breast, colorectal and cervical cancer.

Against this backdrop, [COCIR](#) welcomes the European Commission's initiative to propose a roadmap for the update of the 2003 Council Recommendation on the screening of breast, cervical and colorectal cancers based on the latest scientific evidence and methodologies. We believe that the Council guidance can - and should - set minimum standards and promote harmonised screening programmes across the EU Member States. It should also accentuate the significance of the interoperable high-quality imaging databases and health data registries in cancer prognosis, diagnosis, treatment, and after-care.

We would particularly support a Commission proposal on the extension of the Council Recommendation on cancer screening to lung and prostate cancers, based on the emerging scientific evidence provided by international and EU-based clinical trials, on new screening tests and recent data about the optimal screening protocols, such as the magnetic resonance imaging and HPV testing.

In the same vein, we would also encourage the Council to mandate the European Commission to develop European guidelines and methodologies, in the form of European quality assurance schemes, for all the types of cancer addressed by the Council Recommendation.

Existing Screening Programmes

1. Breast Cancer

- The large inequities of access to breast cancer screening and care result in unequal outcomes across and within the EU Member States.
- Innovative technologies support early diagnosis and precision treatment in cancer care, while improved data collection methodologies ensure accurate prognosis.

According to the latest evidence:

- an improved stratification of risk groups can contribute to better addressing individual needs through personalized screening strategies¹. Relevant examples are tomosynthesis or MRI for younger women

¹ *Personalized breast cancer screening strategies: A systematic review and quality assessment. Marta Roman, et al, PLoS One 2019, <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0226352>*

with a family history of breast cancer, and tomosynthesis or contrast-enhanced mammography (CEM) plus ultrasound for women with elevated breast tissue density.^{2,3,4}

- The effective segmentation of target populations may improve breast screening outcomes, and significantly lower costs.

Indeed, paired with lower radiation dose, reduced needs for contrast agents (except for defined, higher-risk populations) and well communicated quality control procedures for personalised screening strategies, these screening programmes could significantly improve cost-effectiveness and patient acceptance.

Recommendations

COCIR encourages the European Commission to:

- I. promote targeted screening for high-risk groups, such as hereditary breast cancer, placing patients at the center of an integrated multi-disciplinary breast care, where patients actively participate in decision-making.
- II. support the Member States in running educational campaigns to promote breast cancer screening and informed choices. Adequate information about breast cancer screening would level out adoption discrepancies across the EU Member States and curb population resistance due to fear of diagnosis and consequences.
- III. support the Member States in the development and adoption of appropriate and transparent methodologies for assessing the value of new health technologies. Large scale clinical trials and investment programs drive the adoption of new and promising screening technologies - such as advanced software, machine learning and artificial intelligence in diagnostic devices - to improve confidence in clinical decisions, reduce error rates and minimise the time to diagnosis.
- IV. bolster design and implementation of European quality control procedures for personalised breast cancer screening programs.

2. Cervical cancer

According to the World Health Organisation [WHO], 'Cervical cancer is the fourth most common cancer in women. In 2018, an estimated 570,000 women were diagnosed with cervical cancer worldwide and about 311 000 women died from the disease⁵.'

Existing solutions can help reducing these numbers, both in terms of prevention and treatment. Screening techniques are becoming increasingly better-targeted and can significantly contribute to fighting cervical cancer. The current European guidelines on cervical cancer screening need to also consider the latest scientific advances, as per here below.

According to the latest evidence:

- there is a clear link between HPV and cancer. Screening tests targeting E6/E7 mRNA can identify high-risk HPV infections with high accuracy and specificity, optimising prevention and reducing false positives and patient recall rates. No screening programme is 100% failure proof. Therefore, recourse to treatment will still be necessary in some cases. Cervical cancer patients are entitled to the most advanced and effective treatment.

² *The Life Savers: The value of medical and digital health technology in breast cancer care*, Science | Business [study](#) commissioned by COCIR, 2019

Duncan C Thomas, 2017, *Estimating the Effect of Targeted Screening Strategies: An Application to Colonoscopy and Colorectal Cancer*, [National Library of Medicine](#)

³ *Enhancing Value in Cancer Prevention and Care: Industry Perspectives and Recommendations*, [COCIR](#), 2020

⁴ *Screening Algorithms in Dense Breasts: AJR Expert Panel Narrative Review*, Wendie A. Berg, et al, *American Journal of Roentgenology* 2020, <https://www.ajronline.org/doi/pdf/10.2214/AJR.20.24436>

⁵ WHO on cervical cancer: https://www.who.int/health-topics/cervical-cancer#tab=tab_1

Recommendations

COCIR highlights the need for adequate investment in human resources and technical platforms, as well as in further training, reskilling, and upskilling of the medical workforce. We urge the European Council to mandate the European Commission to develop quality assurance schemes for cervical cancer.

3. Colorectal cancer⁶

Today, the cancer care pathway is impacted by cancer patients being diagnosed too late. Inadequate tumor diagnosis may then lead to inadequate treatment and poor patient outcomes.

In Europe, colorectal cancer is the second most common type of cancer with more than 500,000 European citizens diagnosed every year. The number of cases is increasing, driven by an ageing population (it is a disease that mainly affects the over 50s) as well as diet and lifestyle.

With a burden of 90 billion euros for colorectal cancer per year, it is important to remember that cancer detection at stage one is interpreted as 90% 5-year survival rate and cost of 4,000 euros, whereas at stage four, it means survival rates of 10% and cost of 40,000 euros⁷.

According to the latest evidence:

- the expansion of big and real-world data use could effectively improve diagnostics and treatment. These data could sustain the better analysis of tumors and the development of personalized therapies – therapies that are able to adapt to the individual patients' needs and whose success can be continuously monitored to inform future care.
- If done correctly, such efficient and effective cancer diagnostics and treatments could also lead to an overall reduction of costs for the national healthcare systems in Europe.
- Lastly, the increased use of real-world data could enable the timely assessment of innovative technologies and support their use in the clinical practice.

Recommendations

COCIR encourages the European Commission to:

- I. foster a strong 'hub and spoke' model between GPs and hospitals to improve cooperation in diagnosis and treatment and ensure continuous after-care follow up and monitoring.
- II. encourage innovation in (i) digital and big data, (ii) medical technology, (iii) pathways and (iv) treatment processes, to better support leapfrog progress in cancer prevention and treatment.

Proposed cancer screening programmes

4. Lung cancer

With 239.000 deaths per year, lung cancer is the most lethal cancer in Europe.⁸ Globally, lung cancer⁹ accounts for¹⁰ 2.21 million new cases per year or 11.4% of all new cancer cases. It is responsible for 1.8 million deaths per year or 18% of all annual cancer deaths. In 2019 this was interpreted as 45.9 million disability-adjusted life years and 45.3 million years of life lost¹¹.

⁶ Duncan C Thomas, 2017, *Estimating the Effect of Targeted Screening Strategies: An Application to Colonoscopy and Colorectal Cancer*, [National Library of Medicine](#)

⁷ Digestive Cancers Europe: <https://digestivecancers.eu/colorectal-what/>

⁸ European Commission cancer statistics: [website](#)

⁹ Lung cancer screening: the cost of inaction: July 2021, *The European Lung Ambition Alliance*

¹⁰ Ferlay J, Ervik M, Lam F, et al. 2020. *GLOBOCAN 2020 cancer fact sheet: all cancers*. Lyon: Global Cancer Observatory

¹¹ Institute for Health Metrics and Evaluation, University of Washington. [GBD Compare](#), 2019.

According to the latest evidence:

- early detection through targeted screening may transform lung cancer from a fatal condition to a curable one, bearing significant benefits to patients' quality of life. Experience from pilot programmes across the EU already showcases how lung cancer screening can be implemented. Risk-stratified screening programmes that leverage technological innovations, such as low-dose CT and AI-based image reading solutions, increase accuracy and precision in early detection. Large-scale clinical trials prove that targeted low-dose computed tomography [LDCT] screening is linked with reduced lung cancer mortality in high risk individuals by nearly 25%^{12,13}.
- Other clinical¹⁴ and economic¹⁵ evidence highlight lung cancer screening as a cost-effective tool to reduce lung cancer mortality in accordance with the adapted WHO-requirements for effective screening.¹⁶ These findings led the European Respiratory Society (ERS), the European Society for Radiology (ESR) and the Europe's lung cancer patient organisation (LuCE) to call on the EU to support the implementation of quality assured lung cancer screening programmes across Europe expressing the broad consensus of the clinical experts on the need of lung screening programs.^{17, 18}
- The combination of preventive and early detection approaches leads to further improved outcomes:¹⁹ Prevention measures, such as tobacco control, focus on decreasing the prevalence of the disease in the long run, while screening focuses on saving lives immediately, as it targets those at higher risk of illness from lung cancer or already affected by it.

Recommendation

- I. Lung cancer screening should be included into the updated Council Recommendation, as it contributes to reducing cancer mortality across the continent – which is the overarching goal of these Recommendations.
- II. A harmonized approach to lung cancer screening is timely and justified because numerous EU Member States are now implementing or are about to implement them²⁰. They realise that 'programme screening' for lung cancer ensures early detection and reduces 'opportunistic', 'non-programme', 'wild', 'grey testing'.

¹² de Koning H, van der Aalst C, de Jong P, et al. 2020. Reduced lung-cancer mortality with volume CT screening in a randomized trial. *N Engl J Med* 382(6): 503-13

¹³ Aberle DR, Adams AM, Berg CD, et al. 2011. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med* 365(5): 395-409

¹⁴ Two major randomized controlled trials – National Lung Screening Trial in the U.S. and NELSON in the Netherland and Belgium – provide evidence that screening a targeted high-risk population by means of low dose computed tomography can lead to a mortality reduction of about 20%. In addition, there are numerous comprehending smaller scale studies from various EU countries investigating additional aspects of how to design such a screening programme.

¹⁵ The available evidence on cost-effectiveness suggests that the costs of implementing LCS vary significantly due to the different cost-structures of healthcare systems. Regardless, all studies conclude that the costs for LCS are below the threshold of the local "willingness to pay" and would therefore be acceptable in the respective healthcare systems.

Especially if compared to recently launched drugs for therapy of late-stage lung cancer, LCS provides a cost-effective tool in the fight against cancer. – Hofer, F., et al. (2018). "Cost-utility analysis of a potential lung cancer screening program for a high-risk population in Germany: A modelling approach." *Lung Cancer* 124: 189-198. Gendarme, S., et al. (2017). "[Economic impact of lung cancer screening in France: A modeling study]." *Rev Mal Respir* 34(7): 717-728. Hinde, S., et al. (2018). "The cost-effectiveness of the Manchester 'lung health checks', a community-based lung cancer low-dose CT screening pilot." *Lung Cancer* 126: 119-124. Tomonaga, Y., et al. (2018). "Cost-effectiveness of low-dose CT screening for lung cancer in a European country with high prevalence of smoking-A modelling study." *Lung Cancer* 121: 61-69.

¹⁶ Jan P. van Meerbeeck, Caro Franck: "Lung cancer screening in Europe: where are we in 2021?", in: *Translational Lung Cancer Research*, Vol 10, No 5 (May 2021), [full publication](#)

¹⁷ "Lung Cancer Screening: Cutting Costs, Saving Lives": Joint ESR and ERS [publication](#)

¹⁸ "IV LuCE Report on Lung Cancer 2019", slide 49, [full report](#)

¹⁹ The probability of successful smoking cessation is even higher if smoking cessation is integrated in the LCS programme: Balata, H., et al. (2020): "Attending community-based lung cancer screening influences smoking behaviour in deprived populations." *Lung Cancer* 139: 41-46.

²⁰ Next to the prominent pilots in England, there are regional pilots in Poland, France, Italy, Belgium and Croatia and potentially other countries as well.

5. Prostate cancer²¹.

In Europe, one in seven men is expected to develop prostate cancer; it is the most common male cancer in the EU. In Germany it ranks second among other types of cancer in male mortality. Increasing age, ethnic origin and family history are established risk factors for prostate cancer, and there is a link between obesity and aggressive prostate cancer¹. Prostate cancer is not preventable and is asymptomatic in its curable stages. In some countries mortality from prostate cancer exceeds mortality from breast cancer.

Before PSA [Prostate-specific antigen test] screening, prostate cancer resulted in mortality for almost half of the patients. PSA testing in the 1980's led to overdiagnosis and overtreatment, but also curbed cancer mortality levels. Still, excessive screening discouraged countries from pursuing PSA testing; this steeped prostate cancer mortality by 16% between 2010 and 2018. In parallel, evidence²² suggests that opportunistic screening has little, if any effect, on prostate cancer mortality, and results in even more overdiagnosis.

The lack of a harmonized approach across the EU Member States leads to either overdiagnosis and overtreatment or underdiagnosis. Prostate cancer screening should, therefore, be included into the updated Council Recommendation.

According to the latest evidence:

- if administered correctly, prostate cancer screening saves as many lives as screening for colon or breast cancer, if not more, while preserving the socio-economic and health benefits of early diagnosis.
- Game changing technological innovations, such as multiparametric MRI, allow for developing efficient and patient centric early detection programmes. A multiparametric MRI scan shows in an easy and cost-effective way, whether a biopsy is indeed required after a PSA²³ test result that leads to suspicion of prostate cancer^{24,25,26}
- The effective segmentation of target populations may improve prostate screening outcomes, while significantly lowering costs. Imaging and risk stratification should be considered in prevention and early detection.
- The interoperable use and reuse of quality big- and real data is key for accurate prognosis, diagnosis, and treatment of prostate cancer.
- The early detection of prostate cancer can decrease mortality significantly²⁷. Cancer detection at a curable stage can reduce overdiagnosis and overtreatment. Moreover, it is linked with smart screening and early detection programs. Targeted, precise, and personalized screening approaches can improve both the efficiency of such programmes and the experience of participating patients in the most cost-

²¹ *White Paper on Prostate Cancer - Recommendations for the EU Cancer Plan to Tackle Prostate Cancer, 2020, European Association of Urology [EAU], <https://uroweb.org/wp-content/uploads/EAU-Prostate-Cancer-Pca-WhitePaper-Recommendation-for-Recommendations-for-the-EU-Cancer-Plan-May-2020.pdf>*

²² *Rebecka Arnsrud Godtman et al, 2015, Opportunistic testing versus organized prostate-specific antigen screening: outcome after 18 years in the Göteborg randomized population-based prostate cancer screening trial, <https://pubmed.ncbi.nlm.nih.gov/25556937/>*

²⁴ *Gandaglia, G., et al., The Problem Is Not What to Do with Indolent and Harmless Prostate Cancer-The Problem Is How to Avoid Finding These Cancers. Eur Urol, 2016. 70(4): p. 547- 548.*

²⁵ *Futterer, J.J., et al., Can Clinically Significant Prostate Cancer Be Detected with Multiparametric Magnetic Resonance Imaging? A Systematic Review of the Literature. Eur Urol, 2015. 68(6): p. 1045-53.*

²⁶ *Ahmed, H.U., et al., Diagnostic accuracy of multi-parametric MRI and TRUS biopsy in prostate cancer (PROMIS): a paired validating confirmatory study. Lancet, 2017. 389(10071): 815-822.*

²⁷ *European Commission's Group of Chief Scientific Advisors 2021 Scoping Paper: [Cancer Screening](#)*

- *Van Poppel H. et al., 2020, Early Detection of Prostate Cancer in 2020 and Beyond: Facts and Recommendations for the European Union and the European Commission; [KU Leuven 2021](#)*
- *Van Poppel H. et al, 2021, Prostate-specific Antigen Testing as Part of a Risk-Adapted Early Detection Strategy for Prostate Cancer: European Association of Urology Position and Recommendations for 2021, Science Direct, [pdf](#)*
- *Collen S, Van Poppel H. Early Detection and Diagnosis of Prostate Cancer in Well Informed Men: The Way Forward For Europe; [BJMO](#), Issue 7 Novembre 2020*

effective way. Indeed, a PSA test costs €10, and the game changer mpMRI test costs €136. Accordingly, an early detected significant prostate treatment costs €10-15,000 compared to the costly treatment of castrate-resistant disease of €240,000. Therefore, early detection means cost-efficiency, less prostate cancer deaths and better quality of life for prostate cancer patients.²⁸

Recommendation

COCIR urges the European Commission to promote public health equity through targeted screening to high-risk groups. Smart screening is a cost-efficient and effective way to diagnose prostate cancer at a curable stage. Prostate cancer screening should, therefore, be included in the updated Council Recommendation.

Conclusion

COCIR, together with our members, never tire of showcasing the advantages of targeted screening for people, and society.

Our members are striving to provide new innovative solutions to meet evolving patient and clinical needs. So that all European citizens profit from personalised care and cure, and sustainable outcomes. So that the whole of society benefits from improved patient experience, increased health professional satisfaction, better clinical pathways, and overall cost efficiency.

To this end, COCIR will continue to provide our full support to this European Commission initiative. We are looking forward to the results of this consultation and the planned next steps on this topic.

²⁸ *Idem.* 21