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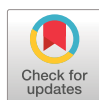


Important steps towards a big change for lung health: a joint approach by the European Respiratory Society, the European Society of Radiology and their partners to facilitate implementation of the European Union's new recommendations on lung cancer screening

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Enormous progress has been made on the epic journey towards implementation of lung cancer screening in Europe. A breakthrough for lung health has been achieved with the EU proposal for a Council recommendation on cancer screening. <https://bit.ly/3J400Jb>

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7 years on from the European Society of Radiology (ESR)/European Respiratory Society (ERS) white paper on lung cancer screening, which recommended low-dose computed tomography (LDCT) screening for lung cancer [1], we have movement in Europe. On 20 September 2022, the European Commission proposed a recommendation that lung cancer screening should be implemented in a “stepwise” approach in the 27 countries of the European Union (EU) (figure 1) [2].

Following an ERS Research Seminar on 23–24 June 2022 in Lisbon, Portugal reflecting on the latest scientific advances in LDCT lung cancer screening, the ERS held an event together with the Czech Pneumological and Phthisiological Society (CPFS) and Czech Presidency of the Council of the European Union [3] to consult on the Commission proposal and to present lung health more broadly to EU stakeholders. Participants agreed that the new EU approach to cancer screening has finally opened the door

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to the new possibilities to diagnose lung disease, giving us a greater understanding of how we can develop a prevention and early detection strategy for lung diseases. It was emphasised that big steps are needed and that certain clauses in the EU recommendations should not be used to impede the successful implementation of appropriate national lung cancer screening programmes. The ERS and others worked hard to make sure the Commission proposal became a reality at the EU Council on 9 December 2022. Encouragingly, alongside the recommendation, funding at both national and European levels will be released to support the implementation of screening [4]. The proposal was debated among the countries and after a significant reduction in ambition compared to the Commission's proposal, it was adopted at the EU Council of Ministers for Health (EPSCO) on 9 December 2022 [5].

In the context of the strong scientific evidence and the advice of the Commission's own scientific experts [6, 7], this gradual approach may seem too little too late. However, it is a remarkable achievement given the headwinds that LDCT for lung cancer has faced from authorities and politicians across Europe [8]. The ERS has worked tirelessly toward this recommendation for 7 years and will continue to argue for its full implementation in the coming months. The paradigm shift arrived with the publication of Europe's Beating Cancer Plan in 2021, in which the Commission committed to explore expanding the current Council recommendation on screening to other neoplasms, including lung cancer [9]. Initially, the ERS, together with 55 organisations that supported our position [10], faced considerable resistance to the roll-out of lung cancer screening from the European Parliament. That notwithstanding, the Parliament finally advocated "for the evidence that proves the positive effect of targeted lung cancer screening on mortality to be recognised" encouraging "the Council, based on the outcome of the above-mentioned [scientific] assessment, to consider including lung cancer screening in the update of the Council recommendation in 2022" [11]. Similarly, the Commission faced resistance to lung cancer screening and its final proposal is less ambitious than a previously obtained draft version [12, 13]. Unfortunately, further resistance from countries materialised during the EU Council negotiations and this is reflected in the final text of the recommendation [5, 14, 15].

Despite the setbacks, the recommendation on lung cancer screening is still paramount because it will encourage countries to provide access to lung cancer screening and support healthcare professionals in their effort to fight this deadly disease. The pioneer LDCT programme, the International Early Lung Cancer Action Program (I-ELCAP), which began in 1992 and includes >80 institutions globally, has paved the way in this field. It has continuously provided updates for protocol efficiency and quality assurance measures to maximise benefits and minimise harms associated with the screening process. Through careful monitoring of their participants, they have obtained long-term follow-up information regarding the results of treatment of screen-detected cancers, which should provide confidence to both high-risk participants and physicians regarding the importance of enrolling those at risk in a screening programme. Based on I-ELCAP, as well as the randomised-controlled LDCT trials from the USA (NLST [14] and LSS [15]) and

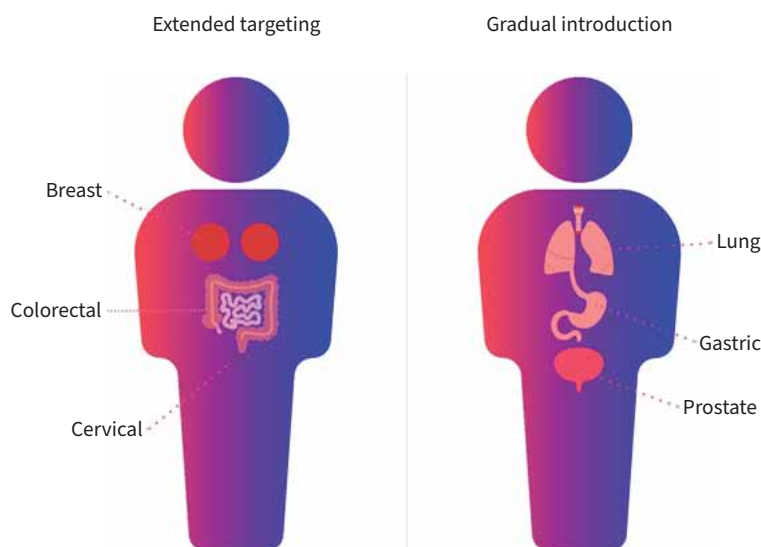


FIGURE 1 Updated proposal to the European Union (EU) Council recommendation as part of the EU cancer screening scheme. Image courtesy of the European Commission.

Europe (Netherlands/Belgium: NELSON [16]; Denmark: DLCST [17]; France: DEPISCAN [18]; Germany: LUSI [19]; Italy: MILD [20]/BIOMILD [21], DANTE [22] and ITALUNG [23]; UK: UKLS [24]), some countries within the EU are already demonstrating that screening is both feasible and an effective preventive and early detection strategy. In October 2020, Croatia started the first nationwide programme in Europe. Building upon general practitioners as gatekeepers and incorporating a cross-sector, user-oriented information technology platform, to date, >10 000 computed tomography (CT) scans have been performed and 94 lung cancers detected, mostly in early stages [25]. The Czech Republic [26] and Poland [27] have begun implementation of national lung cancer screening programmes in 2021–2022. Most recently, a national LDCT lung cancer screening programme has been officially recommended for introduction in the UK following the positive baseline results and safety profiles of five regional pilot studies [28]. Likewise, several other implementation pilot studies were performed or are ongoing within the EU (*i.e.* in Estonia [29], France (CASCADE), Germany (HANSE) [30], Hungary (HUNCHEST 1 and 2) [31], Ireland, Italy, the Netherlands with other countries (4-In-The-Lung-Run), Spain (CASSANDRA) and Sweden). Recent population-based observational study data from the USA already confirmed the positive impact since introduction of the national LDCT lung cancer screening programme with an increasing shift towards earlier stages correlating with improving mortality rates over time [32–35].

The wider implications of screening for lung health were also discussed at the EU Presidency event. The participants unanimously agreed with the statement that lung cancer is a serious threat in Europe and proffered their support for the implementation of screening programmes at the national level. Unfortunately, the majority of countries represented have not begun to implement lung cancer screening. The concept of wider lung health checks was debated and the possibilities for the future earlier diagnosis of other major lung diseases were discussed. The potential of CT scans to detect COPD, emphysema and pulmonary fibrosis at an early stage could be a real breakthrough in respiratory care. There was consensus that one of the trickiest elements of screening and lung health checks will be recruiting the hard-to-reach and disadvantaged, those most susceptible to lung cancer and poor lung health.

The excellent national respiratory plan in Portugal was presented [19, 20], as was the recent publication of the International Respiratory Coalition's *Lung Facts* [36]. According to *Lung Facts*, lung cancer is the leading cause of cancer death in the world. In Europe, 726 000 suffer with the disease and in 2019 alone, 10.3 million healthy years of life were lost to lung cancer. It was pointed out that the prevention of lung cancer is synonymous with the prevention of lung disease. Lung cancer and other major lung diseases strongly associated with smoking are also linked to air pollution, a silent killer with a massive impact on many different diseases (*i.e.* asthma, COPD, allergies and pneumonia); so any reduction in air pollution can benefit entire populations, especially those at high risk of occupational exposure. Those present also agreed that to reduce the burden of noncommunicable diseases, we need a holistic approach and to tackle health inequalities. We already know that health promotion and primary disease prevention can reduce mortality by up to 70%, and efforts to strengthen these areas (reducing poverty, reducing smoking and air pollution) should go hand in hand with screening. With its Healthier Together initiative and allocated funding, the European Commission is aiming to support all those innovative actions that can fight the leading causes of premature death in Europe, such as chronic respiratory diseases [37].

The ERS and the wider respiratory community must continually advocate to ensure that lung health is not left behind by European and national institutions. These screening recommendations, together with the associated funded training for healthcare providers, exchange of knowledge and data across countries, and an overall more consistent international cooperation, will advance lung health and provide the best possible detection and care for individuals in Europe. For instance, sharing best practices as well as pitfalls could be highly beneficial to improve active identification and enrolment of individuals at high risk for lung cancer in individual programmes, particularly to target hard-to-reach populations better. The Croatian national programme and the UK pilots already provide a variety of real-world-validated approaches. Beyond the obvious international evidence for lung cancer screening, the update of the "Statement paper on lung cancer screening" by the ESR and ERS in 2020 [38] has called for explicit definition of participants, shared decision making, and standards for infrastructure, pathways and quality assurance. In these fields, lung cancer screening is much more advanced than screening efforts for prostate and gastric cancer. As such new collaborative protocols, standards and guidelines are currently being elaborated on by the ERS and the ESR together with their European partner societies, the European Society of Thoracic Surgeons, the European Society for Therapeutic Radiology and Oncology, the European Lung Foundation, and Lung Cancer Europe, as other relevant European patient-led organisations in the field.

The European Health and Digital Executive Agency recently invited the Strengthening the Screening of Lung Cancer in Europe (SOLACE) consortium, which consists of the aforementioned partners, and a large

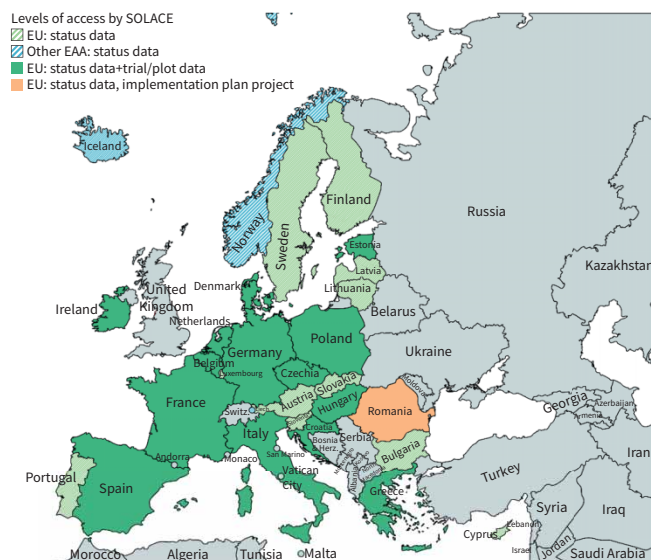


FIGURE 2 Pan-European level of access at the Union level by the EU4 Health Grant consortium Screening of Lung Cancer in Europe (SOLACE). EU: European Union; EEA: European Economic Area; Switz.: Switzerland; Liech.: Liechtenstein; Bosnia&Hrzg.: Bosnia and Herzegovina.

group of clinical-academic experts and institutions, to negotiate a grant agreement on the EU4 Health Call on the implementation of innovative approaches to lung cancer screening at the Union level [39, 40]. SOLACE represents a broad pan-European outreach to all national lung cancer screening programmes, most previous and ongoing European regional pilots, and relevant randomised controlled trials (figure 2).

The European Commission lung cancer screening recommendation and the SOLACE project provide a great deal of hope as well as a positive outlook for the future of lung health. SOLACE will focus on important aspects for patients, including language and terminology, offering support for smoking cessation, appointments outside usual clinic times, delivering screening and lung health checks to the community rather than restricting them to a hospital setting, and providing the opportunity for discussions on other aspects of lung health. Early detection, in many cases, is synonymous with curative intent, which can drastically change the lives of many patients and their families.

We have made enormous progress towards the implementation of lung cancer screening in the EU. This recent breakthrough will allow us to take further important steps leading to momentous change for lung health in Europe.

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Conflict of interest: B. Ward is a current employee of the European Respiratory Society. C. Robalo Cordeiro reports payment or honoraria for lectures, presentations, speakers' bureaus, manuscript writing or educational events from AstraZeneca, GSK, Menarini, Sanofi, Pfizer, Boehringer Ingelheim, Roche and MSD, outside the submitted work. J. Chorostowska-Wynimko reports grants or contracts from AstraZeneca, Pfizer, CSL Behring, Grifols and Mereo Biopharma, outside the submitted work; payment or honoraria for lectures, presentations, speakers' bureaus, manuscript writing or educational events from AstraZeneca, MSD, Roche, Pfizer, Takeda, Amgen, Grifols, CSL Behring, Novartis, Chiesi, Celon Pharma and Adamed, outside the submitted work; support for attending meetings and/or travel from MSD, Amgen and Pfizer, outside the submitted work; leadership or fiduciary roles in other boards, societies, committees or advocacy groups, paid or unpaid, for the European Respiratory Society, Polish Respiratory Society, International Respiratory Coalition, Polish Coalition for Respiratory Disorders, Polish Coalition for Treatment of Asthma, and Polish Foundation for Patients with Alpha-1 Antitrypsin Deficiency; and receipt of equipment, materials, drugs, medical writing, gifts or other services from Roche, Biocartis, Amoy, CSL Behring and Pfizer, outside the submitted work. H-U. Kauczor reports grants or contracts from Siemens, Philips and Boehringer Ingelheim, outside the submitted work; consulting fees from Media outside the submitted work; and payment or honoraria for lectures, presentations, speakers' bureaus, manuscript writing or educational events from Siemens, Philips, Boehringer Ingelheim, MSD and Sanofi, outside the submitted work. C. Henschke is a

named inventor on a number of patents and patent applications relating to the evaluation of pulmonary nodules on CT scans of the chest that are owned by the Cornell Research Foundation (CRF). Since 2009, C. Henschke has not accepted any financial benefit from these patents including royalties and any other proceeds related to the patents or patent applications owned by CRF. C. Henschke is the President and serves on the board of the Early Diagnosis and Treatment Research Foundation. They receive no compensation from the Foundation. The Foundation is established to provide grants for projects, conferences, and public databases for research on early diagnosis and treatment of diseases. Recipients include I-ELCAP, among others. The funding comes from a variety of sources including philanthropic donations, grants and contracts with agencies (federal and nonfederal), imaging and pharmaceutical companies relating to image processing assessments. The various sources of funding exclude any funding from tobacco companies or tobacco-related sources. Z.J. Andersen reports grants or contracts from the Health Effects Institute, USA, outside the submitted work; support for travel from the European Respiratory Society and Health Effects Institute to their respective conferences, outside the submitted work; and is Chair of the Environment and Health Committee of the European Respiratory Society, and Councillor (Member of the Executive Committee) of the International Society for Environmental Epidemiology, outside the submitted work. P. Powell is an employee of the European Lung Foundation, funded in part by the European Respiratory Society. L. M. Seijo reports grants or contracts from Serum, Median and IS Carlos III, outside the submitted work; consulting fees from AstraZeneca, Sabartech, Serum and Median; payment or honoraria for lectures, presentations, speakers' bureaus, manuscript writing or educational events from AstraZeneca, MSD and Roche, outside the submitted work; and participation on a data safety monitoring or advisory board for Serum and Median, outside the submitted work. The remaining authors have nothing to disclose.

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