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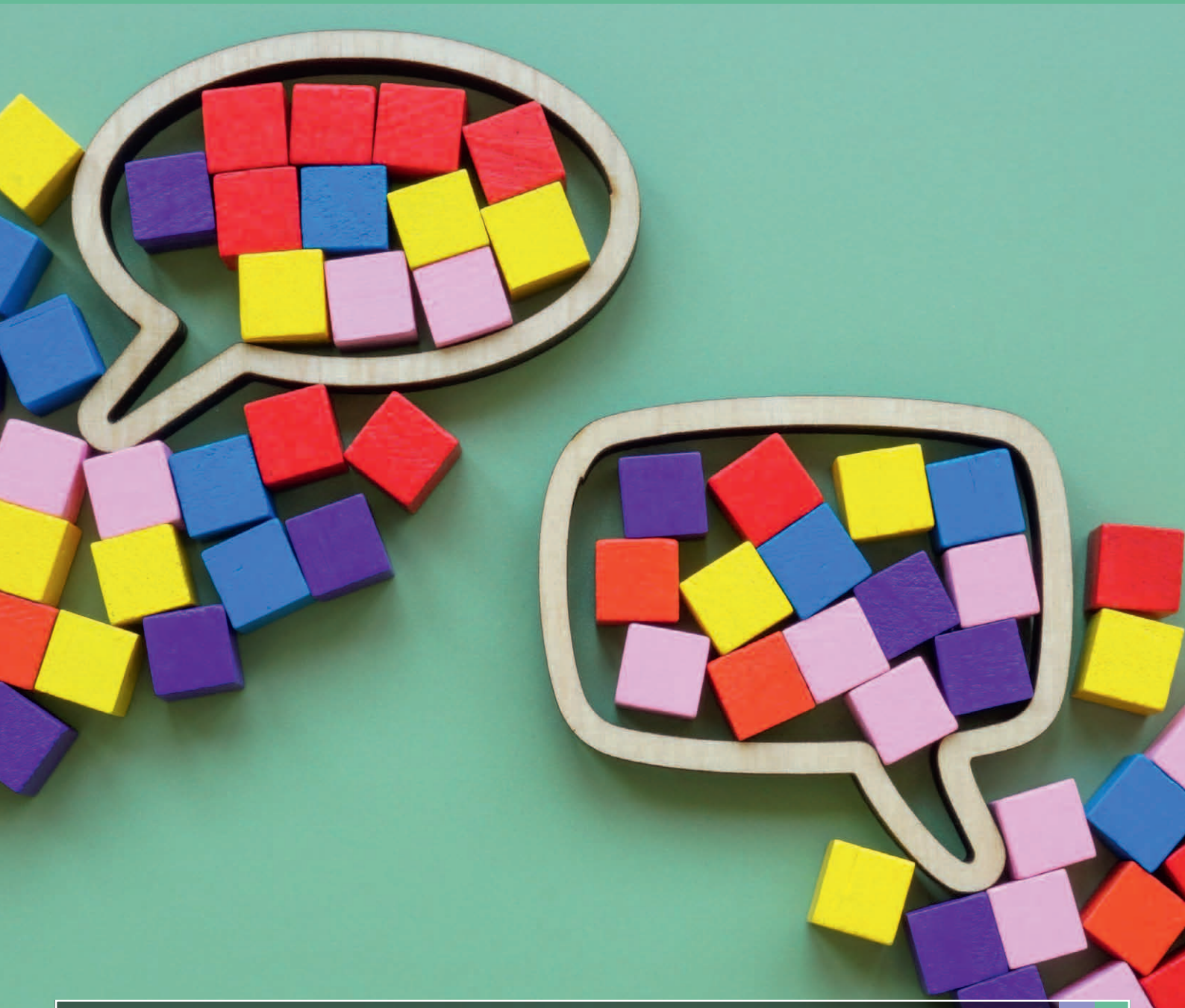
National Cancer Mission Hubs: towards beating cancer in Europe



› Advancing the EU Cancer Mission through policy dialogues

- Addressing the increasing cancer burden
- National Cancer Mission Hubs: from vision to impact
- Europe's Beating Cancer Plan
- Health system approaches to cancer control
- Cancer dialogues within the OBS-D&C4Cancer project
- Cervical cancer screening and early detection
- Implementing lung cancer screening programmes
- Increasing equity in clinical trials
- Community User Boards
- Precision oncology

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EU Mission on Cancer

Perspectives from key stakeholders

Key actions for advancing the Cancer Mission and the OBS-D&C4Cancer project

EDITORIAL

This special issue of *Eurohealth* emphasises the EU Mission on Cancer's vital role in addressing Europe's growing cancer burden.

Through the OBS-D&C4Cancer project, the European Observatory on Health Systems and Policies, in collaboration with the Establishing of Cancer Mission Hubs: Networks and Synergies (ECHoS) project, is facilitating cancer policy dialogues and supporting the establishment of National Cancer Mission Hubs (NCMHs).

These tailored dialogues are instrumental in fostering national and pan-European alliances, driving progress in cancer prevention, care, and research, and translating the EU Mission and Europe's Beating Cancer Plan into action at national level. The policy dialogues convene a broad and heterogenous group of cancer stakeholders with the aim of bridging gaps in cancer policy implementation, fostering consensus, and strengthening the NCMH network.

In this special issue, four key stakeholders in the European cancer space provide their perspectives on the principal challenges and priorities for cancer policy in Europe in the coming years. The European Commission (EC) Directorate-General for Research and Innovation (DG RTD) starts by introducing the **EU Cancer Mission**, launched under Horizon Europe, which aims to improve cancer prevention, treatment, and quality of life for 3 million people by 2030. Next, authors from the Portuguese Agency for Clinical Research and Biomedical Innovation discuss the establishment of NCMHs as the secretariat for the ECHoS project, a consortium tasked by DG RTD to accelerate NCMH set-up across European Union Member States. The EC Directorate-General for Health and Food Safety (DG SANTE) then discuss **Europe's Beating Cancer Plan**, launched in 2021 with a €4 billion budget, which takes a comprehensive approach to cancer prevention, treatment, and research. Finally, authors from the World Health Organization Regional Office for Europe highlight the importance of taking a **health systems approach** to cancer control in Europe, emphasising the need to invest in prevention, early diagnosis and ensure equitable access to care.

The subsequent six articles cover a range of critical topics on cancer. Tille and co-authors from the European Observatory on Health Systems and Policies and their project collaborators introduce the concept of **cancer policy dialogues**, which support the development of NCMHs in European Union Member States. The next 5 articles showcase topics which were subject to a policy dialogue within the OBS-D&C4Cancer project. Bhatia **et al** discuss promising approaches to reduce inequalities in **cervical cancer screening**, including fostering collaboration between organised screening programmes and community organisations, as well as the use of mathematical modelling to inform context specific screening strategies. This is followed by an article by Martin-Moreno and colleagues who examine targeted **national lung cancer screening programmes** and how effective implementation in Europe can be realised.

A discussion on cancer **clinical trials** by Castelo-Branco **et al** next highlights the importance of expanding and decentralising cancer trials in the European Union to improve patient access, enhance real-world applicability, and overcome geographic and regulatory barriers. Kirkegaard and co-authors explore how **Collaborative User Boards** address contextual challenges and ensure diverse representation in participatory cancer research, with country-specific examples. The final article by Litvinova and colleagues examines **precision oncology** and its potential to address current challenges in cancer care.

While this Special Issue reflects upon the great achievements of the OBS-D&C4Cancer project with its collaborators, it highlights that much work remains to be done in the joint fight against cancer. Building on the OBS-D&C4Cancer project is crucial for sustaining progress in cancer policy and ensuring equitable, effective responses to the growing cancer burden. Continued collaboration enables countries to share best practices, strengthen national strategies, and implement coordinated actions that align with the EU Mission on Cancer and Europe's Beating Cancer Plan. We hope you enjoy this special issue.

The Editorial teams of the *Eurohealth* special issue

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EU Cancer Mission – what it is and why it is so important

By: Kay Duggan-Walls, Annika Nowak and Gianpaolo Suriano

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As a new initiative under the Horizon Europe research and innovation programme (2021–27), the **European Union (EU) Cancer Mission** aims to improve the lives of more than 3 million people by 2030 through better prevention, cure, and quality of life for individuals and families affected by cancer.[1] Together with Europe's Beating Cancer Plan, the EU Cancer Mission represents the European Commission's response to addressing the increasing cancer burden, which poses a growing societal challenge.

The EU Cancer Mission brings together research, innovation and public health policies, along with a broad range of stakeholders and instruments, to deliver solutions that cannot be achieved through individual research activities and policy actions at EU, national, regional and local levels. To ensure that scientific knowledge gained through research, systematically informs policy choices, the Mission has established, for the first-time, joint policy dialogues at the EU level, among health and research ministries, as well as among stakeholders from different disciplines and sectors.

All actions launched under the EU Cancer Mission aim to achieve parallel progress in its four specific objectives: improving cancer understanding, prevention and early detection, diagnosis and treatment, and quality of life. Besides a considerable EU investment into new research and innovation (R&I) projects, the Mission supports flagship initiatives underpinning R&I launched under these objectives, namely the UNCAN.eu data platform, the European Cancer Prevention Centre, a network of Comprehensive Cancer Infrastructures, and the European Cancer Patient Digital Centre.

Between 2021 and 2024, the Mission has committed approximately €500 million to support a series of new projects, with a strong emphasis on building synergies with other parts of Horizon Europe (Health Cluster and its Partnerships, EIT-Health, European Innovation Council), other EU programmes (EU4Health, Digital Europe, Euratom Research and Training Programme) and policy initiatives (Europe's Beating Cancer Plan, European Health Data Space, A comprehensive approach to mental health etc). Thanks to this approach, the cumulative investment in cancer R&I under Horizon Europe reached €2 billion in 2024, for the period 2021–24.

Since its launch in 2021, the EU Cancer Mission has inspired many Member States to change governance approaches on cancer control. The Mission has made enormous effort to help establish "National Cancer Mission Hubs" (NCMHs) in each Member State and Associated Countries. These future hubs are expected to translate the Mission approach into the national and regional context, particularly by engaging a broad range of stakeholders from all sectors in collaborative initiatives and cross-policy dialogues on cancer. The close collaboration between the 'Establishing of Cancer Mission Hubs: Networks and Synergies (ECHoS)' project and the OBS-D&C4Cancer project led by the European Observatory on Health Systems and Policies (through facilitation of policy dialogues) have proven instrumental in this effort of establishing NCMHs.

For example, this integrated Mission approach has been instrumental at the EU level in shaping the **Council Recommendation on cancer screening**, which was revised 20 years after its first adoption to reflect the latest scientific developments. The future NCMHs will play an important role in rolling out the new recommendation in Member States by fostering the dialogue among relevant stakeholders, supporting the uptake of new or improved screening programmes, and facilitating necessary investments for their successful implementation at the national and regional levels.

To boost societal uptake of new solutions and approaches gained through R&I, **citizen engagement** is at the heart of the Mission approach. In 2023, the EU Cancer Mission launched a long-term **dialogue with young cancer survivors** to better understand their needs during and after cancer treatment and co-create effective solutions. Concrete outcomes of this dialogue shaped two new topics included in the Horizon Europe and the EU4Health programmes. The future NCMHs are expected to embed citizen engagement into national R&I and health policies. A pilot **bus roadshow** organised in three Member States (Poland, Lithuania and Romania) in 2024 is another Mission initiative aimed at demonstrating how to bring cancer prevention and screening closer to communities and promote behavioural changes.[2,3,4]

The EU Cancer Mission aims, through its new approach, to combine efforts across Europe with citizens, stakeholders, and Member States to bring concrete solutions to the fight against cancer and giving all involved a stake in its success.

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National Cancer Mission Hubs: from vision to impact

By: Hugo R Soares, José Salvado, Ana Domingos, Yasmin Fonseca and Anabela Isidro

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The Horizon Europe Missions (2021–2027), inspired by Marianna Mazzuccato's report on Mission-oriented research and innovation in the European Union (EU), introduced a bold new approach to EU-funded research and innovation. The mission-driven framework seeks to address pressing societal challenges through co-creation and multi-stakeholder engagement. The EU Mission on Cancer, a key initiative under this framework, has set out 13 inspirational recommendations and ambitious objectives to advance cancer prevention, care, and research across all Member States and Associated Countries.

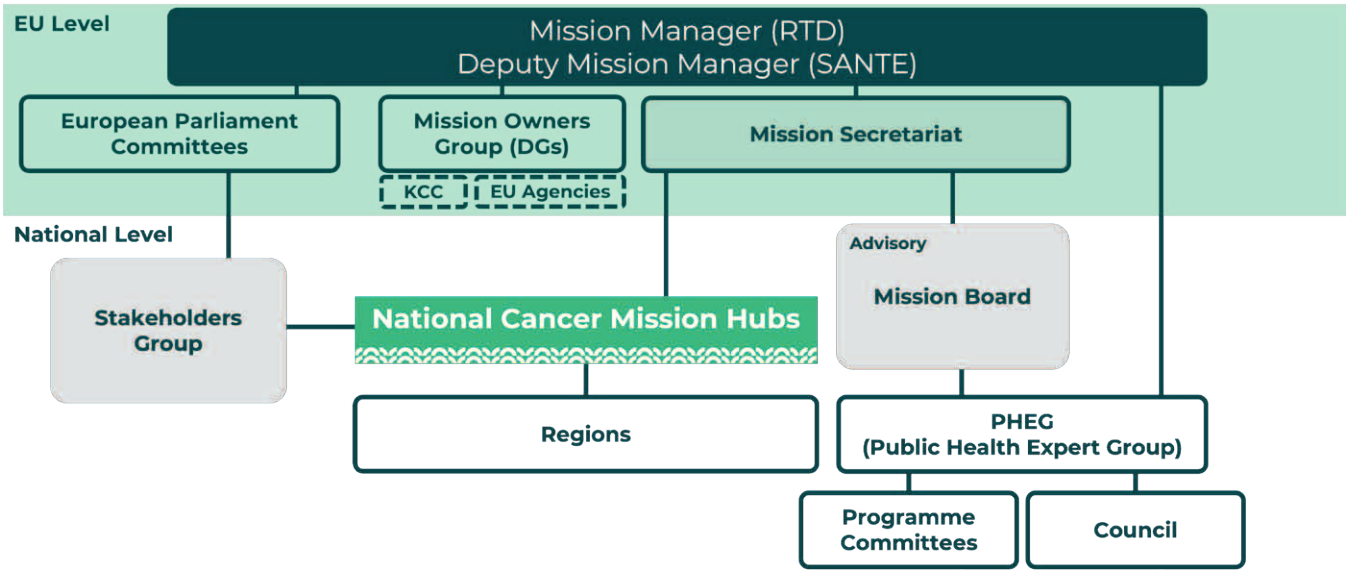
However, disparities in cancer care and research readiness among countries pose challenges to systematically implementing the EU Mission on Cancer. To address this, the European Commission has called for the establishment of **National Cancer Mission Hubs** **(NCMHs)**. These hubs serve as critical interfaces between the governance and implementation of the Mission on Cancer, bridging European, national, regional, and local levels (**see Figure 1**). They aim to promote synergies among multiple stakeholders and initiatives, align priorities and use of resources, and amplify the impact of actions beyond regional and sectoral boundaries.

A central convener role

NCMHs are envisioned as catalysts for change, working towards a future in which cancer is no longer a leading cause of death, and all individuals can enjoy long and healthy lives through the accelerated integration of innovative solutions into healthcare – ranging from prevention to quality of life – alongside enabling policies. To achieve this, NCMHs should act as facilitators of actions, diplomats, and consensus builders, fostering synergies among multiple stakeholders – policymakers, healthcare professionals, researchers, businesses, patients, and citizens. Their role is to ensure that efforts transcend regional and sectoral silos.

Activities developed by NCMHs should fall within five core categories: i) Establish and maintain cancer research and care as a national priority by aligning key national policies with the EU Mission on Cancer and Europe's Beating Cancer Plan (EBCP); ii) Enhance public awareness, advocacy, and engagement to drive the effective implementation of the EU Mission on Cancer at national level; iii) Cultivate a cross-sectoral, collaborative, and innovative ecosystem to optimise resource usage and maximise impact; iv) Foster participatory ecosystems that centre on the needs of patients, healthcare systems, and research communities through strategic and effective communication; v) Ensure the consistency, scalability, and local relevance of EU Mission on Cancer initiatives through continuous innovation and improvement.

Figure 1: NCMHs positioning in the national ecosystem and in the European context



Source: Adapted from [2]

Flexible Operational Models

The structure of individual NCMHs must be suited to national contexts. For instance, NCMHs can focus on different core competences, such as funding of projects or engaging in policy and regulatory activities. Nonetheless, it is important to ensure the inclusion of stakeholders from all sectors of the 'Penta Helix' (**see Box 1**) in governance, implementation bodies, and activities.

The EU-funded project **Establishing of Cancer Mission Hubs: Networks and Synergies (ECHoS)** spearheads the implementation of these hubs by 1) establishing a consensus definition of the role of NCMHs, and 2) creating a comprehensive body of knowledge around key areas of activity.

Considering the critical role of stakeholders' participation in the implementation of the EU Mission on Cancer, and in the uptake of objectives and developed solutions, ECHoS explores the effective integration of multiple stakeholders within four different NCMH model structures. These model structures include Coordinated National Action, Consortium, Legal Organisation, and Joint Venture, providing a flexible framework for designing and structuring individual NCMHs. At national level, NCMHs should prioritise the development of robust communication and dissemination strategies to generate enthusiasm for the EU Mission on Cancer and the EBCP. NCMHs can either take an active role – by organising or funding these activities – or contribute indirectly by providing advisory or supportive functions.

The establishment of NCMHs will evolve over time, with their activities gradually having a greater impact. To support this, ECHoS is creating frameworks, models, and concepts that help NCMHs assess their practices and identify areas for improvement. These tools focus on designing participatory activities with multiple stakeholders and developing policy dialogues with the European Observatory on Health Systems and Policies. With a "Health in All Policies" [4] approach, NCMHs aim to foster a multi-stakeholder movement against cancer, addressing the needs of patients, families, healthcare systems, and society by promoting citizen-centred policies.

While the journey ahead is long and filled with challenges, this moment marks an exciting turning point in cancer care and research. The question remains: will there be enough support and empowerment of NCMHs at national level? If so, we may witness a paradigm shift – from traditional top-down policymaking to participatory, bottom-up approaches – breaking down entrenched silos in health, research, and beyond.

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Box 1: The Penta Helix model for multi-stakeholder collaboration

The Penta Helix model for multi-stakeholder collaboration is an effective strategy to achieve meaningful innovative solutions. This approach extends the classical collaboration between public and business sectors and academic institutions to also include the non-profit sector and citizens. By understanding their interactions and dependencies, and by engaging in co-creation processes, organisations are more prone to develop meaningful solutions to the problem at hand. The ECHoS project has adapted the Penta Helix framework model to reflect the needs of the health and care sector, including research, and applied it to the field of cancer. The five key group of stakeholders include:

i) **Public Administration**, representing policymakers, authorities, regulators, government, etc.;

ii) **Health and Care**, representing public and private hospitals, oncology centres, pharmacies, diagnostic centres, laboratories, etc.;

iii) **Knowledge and Academia**, representing both academic and non-academic research centres, knowledge hubs, innovation clusters, higher education institutions, etc.;

iv) **Business sector**, representing pharmaceutical and medical device industries, employers, media, banks, the commercial sector, etc.; and

v) **Citizens and Civil Society**, representing patients (and patient associations), citizens, charities, non-profit organisations, entities from the social and education sectors, etc.

Europe's Beating Cancer Plan: A comprehensive action plan working hand in hand with the Cancer Mission

By: Domenico Fiorenza Glanzmann, Vittoria Carraro, Philippe Roux

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Europe's Beating Cancer Plan [1] is one of the European Union's (EU) responses to the growing burden of cancer in the EU. It addresses the whole disease pathway, from prevention, early detection, diagnosis and treatment to quality of life of cancer patients and survivors. Adopted in 2021 with a budget of €4 billion, including €1.25 billion coming from the EU4Health Programme, it reflects the political commitment to leave no stone unturned to take action against cancer. In addition, the Cancer Plan aims to foster the use of new technologies and to drive forward research and innovation, to reduce cancer inequalities, and to put childhood cancer under the spotlight. To achieve this, the Plan has ten flagship initiatives and 32 further actions, with numerous sub-actions.

The EU Cancer Mission is complementary to the Cancer Plan. The two initiatives were co-developed from the start and their objectives aligned to maximise impact. They share a joint governance structure, bringing national health and research ministries together within the cancer sub-group under the European Commission's Expert Group on Public Health*. Patients, healthcare professionals and other key actors† support the Plan and the Mission through the Beating Cancer Stakeholder Contact Group on the EU Health Policy Platform.

As of December 2024, the EU has invested €393.6 million in 74 Cancer Plan initiatives with funding from the EU4Health Programme, which was adopted in response to the COVID-19 pandemic to build stronger, more resilient and accessible health systems. An additional €137.2 million is earmarked for actions currently under preparation. The EU4Health Programme focus on cancer is complemented by the Horizon Europe Programme funding coordinated by the Mission on Cancer.

Four years on, the Cancer Plan has already made a clear difference.[2] For example, Council Recommendations on cancer screening, on vaccine-preventable cancers, and on smoke- and aerosol-free environments provide recommendations to Member States and are extending access to important tools such as cancer screening, Human Papillomavirus and Hepatitis B vaccination, and strengthening protection from cancer risk factors such as tobacco. Overall, more than 90% of the Cancer Plan's actions have been completed or are well underway. Key initiatives such as the Knowledge Centre on Cancer, the Cancer Imaging Initiative, the Cancer Inequalities Registry and the EU Youth Network of Cancer Survivors have already shown an impact. EU funding supports the implementation of these actions. The work to set up the first EU Network of Comprehensive Cancer Centres by the end of 2025 is underway, with the objective of providing high-quality cancer care to EU citizens regardless of where they live.

The recently concluded Cancer Plan Review [2] has confirmed that the Cancer Plan is delivering on its high level of ambition. It points to strengths such as a comprehensive approach tackling the whole patient pathway, and its responsiveness to recent societal, political and technological developments, while identifying several challenges to the full implementation of the Cancer Plan actions at national, regional and local levels. Stakeholders have expressed widespread support for the Cancer Plan and consider that its objectives remain highly relevant.

Europe's Beating Cancer Plan has proven a successful way of addressing a major public health concern. The Commission will draw on this experience to step up its work on preventative health challenges and address other non-communicable diseases, such as cardiovascular diseases.[3]

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* The Expert Group on Public Health advises and guides the Commission on public health and health systems, about non-communicable and communicable diseases. It has set up a sub-group on cancer to follow and guide the implementation of the Cancer Plan.

† The main stakeholders include national cancer societies, non-profit organisations supporting cancer patients and their caregivers, societies and umbrella organisations focused on various types of cancer, as well as those involved in treatment, research, education, and training. Additionally, the stakeholders comprise different patient groups, disease-specific organisations, universities, representatives from national public health institutes, and consultancies representing health-related interests.

Health system approaches to cancer control in the European Region

By: Marilys Corbex, Margarida Paixão, Maria Lasierra, Gauden Galea

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In the WHO European region, the risk of developing cancer before age 75 is 27% and the risk of dying from cancer is 11.5%. This makes cancer the second most important cause of death and morbidity in the region.[1] [2] Important inequalities exist across countries, notably in term of the mortality-to-incidence ratio, reflecting differing health system capacities.[3] Social, commercial and political determinants also play a crucial role.[4] [5] Therefore, implementing cancer control policies requires a horizontal health system approach. However, taking such a health system lens has historically been challenging across Europe as cancer policies are often shaped by: 1) very clinical therefore vertical views, and 2) vested interests as cancer represents a big commercial opportunity.

Adopting a health system perspective is important for developing cost-effective cancer policies. There is a need to address structural health system challenges affecting not only cancer but other areas of health as well. For example, screening is the oft-proposed solution to late diagnosis; and innovative medicine for poor survival. However, workforce and medicine shortages also contribute to these challenges. Screening programs or innovative medicines will have limited impact unless the broader systemic issues are also addressed.

Taking the example of screening further, its popularity among policymakers is due to its high visibility and its appeal to corporate actors, who benefit from the increased demand for numerous machines and consumables. Yet, cancer screening programmes are effective only if rapid and efficient diagnosis pathways are already in place, i.e., the pathways that should ensure from the beginning that symptomatic individuals are promptly and effectively diagnosed and treated.[6] Therefore, from a systems perspective, the appropriate policy response to common late diagnosis might rather be incremental improvement of services to strengthen these pathways, in other words a well-funded "early diagnosis program".[6] This is the case even for "screenable cancers" like breast cancer, as was recently concluded in Ukraine.[6] In reality, early diagnosis remains a blind spot in most countries despite being the most adequate initial response when late diagnosis is common.

From a systems perspective, vertical approaches such as screening can even be counter-productive. This is because large-scale, population-based screening can easily overburden a health system, worsening delays, and resources shortages, especially when service gaps remain. For example, Belgium recently estimated that lung cancer screening was currently too resource-intensive for its health system and could be implemented for high-risk populations in the future only if the government was willing to pay €20,000–30,000 per quality adjusted life year (QALY) gained.[7] However, many countries with much weaker health systems than Belgium are initiating lung cancer screening. At the same time they are missing more cost-effective prevention measures; for example, almost 80% of countries in the region do not offer comprehensive tobacco cessation services as per WHO recommendations.[8] [9] Other best buys such as tobacco taxation are still not fully implemented in the region despite being very cost-effective. Notably, estimates suggest that tax increases that raise the price of cigarettes by 10% could have a cost-effectiveness of between US$ 83 to 2771 per QALY gained in high-income countries.[10]

WHO places screening within a broader, multifaceted strategy to combat cancer across Europe. This framing acknowledges that even in countries where cancer screening programmes have been successfully implemented, most cancers are not diagnosed through screening. For example participation in mammography programmes in Denmark is over 80% in women aged 50–70, yet less than 35% of all breast cancers there are diagnosed through screening which is expected due to the nature of the disease.[11] Overall, only 7.5% of all cancers in Denmark are diagnosed through screening; in England, this figure is around 6%.[12] Thus, a multi-pronged approach assessing where best to invest – screening, early diagnosis, improved access to care, etc. – is needed to make progress.

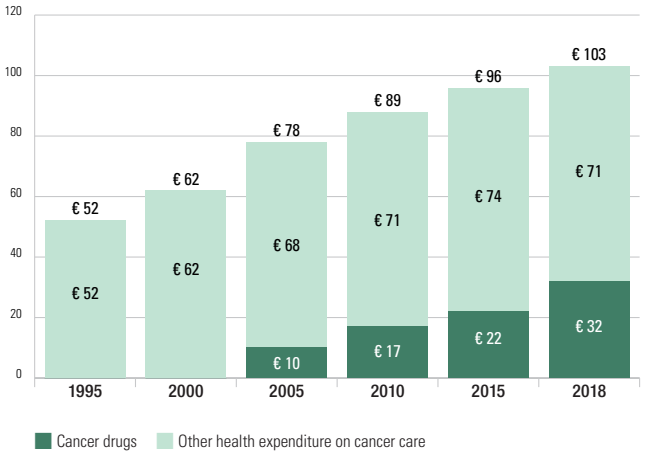
Besides, vested interests play a disproportionate role in shaping cancer policies, making it challenging for decision-makers to maintain a systems perspective. Not only are commercial determinants* such as alcohol, tobacco, processed food and beverages responsible for close to 7500 deaths per day in the region,[13] but their influence is felt also in screening, diagnosis and treatment.[5]

For example, industry influence is one of the significant drivers, among a complex interplay of factors, of the rising costs of cancer treatment in the EU (**see Figure 1**). From 2005 to 2018, cancer incidence rose by 25% in the EU, but cancer drug costs soared by 220%. By comparison, there was only a 4% increase in other healthcare costs, likely due to limited funding.[14] This trend reflects the prioritisation of costly innovative treatments promoted by the private sector, which often overshadows more cost-effective alternatives. This is unsustainable and comes with an opportunity cost.

In conclusion, adopting a health systems perspective to strategic cancer investments is essential for ensuring sustainability of

* Meaning marketing, pricing, and lobbying practices of the alcohol, food, tobacco, and other industries.

Figure 1: Direct cost of cancer screening, diagnosis and treatment in the EU 1995–2018 (in billion €)



Source: [13]

cancer control activities. For example, screening may be the right option in certain circumstances, but it needs to be carefully evaluated within the context of health system capacity and needs. Putting in place measures and regulations to uphold evidence-based recommendations while minimising the influence of vested interests is equally crucial for improving health outcomes and reducing inequalities.

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CANCER POLICY DIALOGUES: BOOSTING THE DEVELOPMENT OF NATIONAL CANCER MISSION HUBS

By: Florian Tille, Yulia Litvinova, Jose M. Martin-Moreno, Dheepa Rajan and Suszy Lessof

Summary: This article discusses how the European Observatory on Health Systems and Policies (OBS) has tailored its very particular approach to policy dialogues, to fit the cancer context. It highlights three types of dialogues – inception, issue-specific and cross-cutting – that have been developed under the "Dialogues and Comparisons for a Joined-up Approach to Cancer" (OBS-D&C4Cancer) project to support the establishment of National Cancer Mission Hubs (NCMHs). These cancer policy dialogues build around a concrete question and bring key stakeholders, the relevant evidence and expertise and careful facilitation together to create a safe space for discussion and informed decision-making.

Keywords: *Policy Dialogue, Evidence-informed Policymaking, National Cancer Mission Hubs, Cancer*

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Introduction

Policy dialogue is widely used to describe formal discussions of health policy issues. The European Observatory on Health Systems and Policies (OBS) understands the term slightly differently; it reserves it for a very specific approach to bringing policymakers and evidence together in a structured way to address a well-defined policy issue. Its policy dialogues can be designed for a country (or sub-national entity) or a group of countries but they are all carefully curated. Policy dialogues start from an understanding of the policy question; where it sits in the policy cycle; and who the key stakeholders are. They then draw in the specific evidence needed to inform that particular decision and tailor it to support the policymakers involved. This requires iterative rounds of development. Adapting and organising the technical evidence so that it is useful to a policy audience, rather than a (purely) academic one, is also central to the model. The idea is that evidence informs and supports discussion among stakeholders rather than crowding out their experience and perspectives. A dialogue's ultimate goal is to allow policymakers a safe space to consider the issues and to move towards an informed decision that works best for them in their context.

The European Commission's Directorate-General for Research and Innovation (DG RTD) is supporting the development of National Cancer Mission Hubs (NCMHs) and the Establishing of Cancer Mission Hubs: Networks and Synergies (ECHoS)" project consortium [1] (see Soares et al. in

this issue), specifically to foster synergies between diverse cancer stakeholders with a view to strengthening the integration of European Union (EU) cancer research and policy at national, regional and local levels. Dialogue is a key to developing synergies and fostering integration, but the cancer context is unusually complex. A dialogue on cancer can take as its starting point social determinants or genetic determinants; the site of origin or the histological classification; the health system perspective; prevention, screening, diagnosis or care (**see Figure 1**). What is more, very different population (sub-) groups and a very broad range of health professionals are affected by cancer and involved in cancer care with often significant disparities in knowledge, experience and power.

DG RTD recognised the lack of tools to support dialogue in the complicated cancer setting and so commissioned OBS to support ECHoS through the "Dialogues and Comparisons for a Joined-up Approach to Cancer" – (i.e. "OBS-D&C4Cancer") project (**see Box 1**). The project has adapted the OBS policy dialogue approach to the specificities of cancer prevention and care and to support the National Cancer Mission Hub goals of exchange and collaboration to beat cancer in Europe. Steps to tailor the approach to support ECHoS include a taxonomy to help define how any policy issue 'to be discussed' sits in the wider cancer context; guidance on embedding community and civil society collaboration in Hub thinking and dialogue work; and new models on facilitation and consensus building to accommodate dialogue between international experts.

Fig. 1: A Taxonomy of Cancer Issues

Source: [2]

Three types of dialogues to meet different NCMH needs

The specific demands of cancer and of the project mean that three types of cancer policy dialogues have been developed from the initial model – inception, issue-specific and cross-cutting dialogues. They all incorporate years of OBS experience with policy dialogues and have a shared set of fundamental elements (**see Box 2**).

Inception dialogues

Inception dialogues are the least like a conventional OBS dialogue. They are designed to support the process of setting up an NCMH and as with all policy dialogues they start with the concrete. If there is no existing base, it helps the ECHoS partner to build a group that can form the core of a new Hub and evolve it towards a fully-fledged Hub. If there is already a Hub-like structure, such as a 'Mirror Group'[3,4] which brings together a national coalition of cancer stakeholders, mirroring the Europe's Beating Cancer Plan (EBCP) focus areas and the country's priorities, it builds on that.

The inception dialogue handbook guides stakeholders through a systematic process of reviewing context, identifying key players and structuring a meeting to create the right connections and foster the right discussion to support a setup or (further) development of an NCMH. This may mean focusing on reaching a collective definition of a Hub and agreeing its objectives or a more practical discussion of the legal status of the Hub and its members. An inception dialogue may be a single, face-to-face "kick-off" meeting or as in Malta (**see Box 3**) there may be a need for multiple sessions to establish an effective Hub. But as with all policy dialogues, agreeing who is involved and what the agenda is, is an iterative process with key stakeholders.

Where Hub-like structures already exist, inception dialogues have been used effectively to expand their scope, diversify their membership, build consensus on political buy-in and funding, and formalise the transition to fully functioning Hub status. In Portugal, the inception dialogue convened a Hub that was already working well and created an opportunity to review progress, revisit objectives, and ensure alignment with current needs. It also provided an opportunity for collective reflection on funding and helped confirm and solidify the Hub's 'Penta Helix' structure involving government, clinicians, academics, civil society and private sector actors (see Soares et al. in this issue). The structure is specific to Portugal, but dialogue helped reinforce a very generalisable notion – the value of Hubs involving different 'strands' of society and of a clear framework for engagement.

Box 1: the OBS-D&C4Cancer project

The D&C4Cancer project is funded by the European Commission's DG RTD and is being carried out by OBS. It aims to equip NCMHs across EU Member States (that are part of the ECHoS network) with the tools and skills to conduct policy dialogues to support effective stakeholder engagement. These cancer policy dialogues fall into three groups. Inception dialogues on the Hub model itself; issue-specific dialogues on a wide range of cancer policy topics within a single country; and cross-cutting dialogues which bring countries (or experts from different countries) together. The project has developed new models of policy dialogues and handbooks to guide ECHoS partners as they take forward the work of the NCMHs.

Box 2: Key features of a cancer policy dialogue

Every dialogue is customised exclusively to the context, the issues and the people taking part. They are unique and yet all of them:

- Take a concrete cancer issue as their 'entry point' and focus on the core issue, whether that is a research or policy dilemma or around setting up an NCMH
- Are developed iteratively with the key stakeholders to capture their concrete concerns
- Engage key figures whether in cancer prevention, diagnosis or care – so decision-makers, leading researchers, community representatives, practitioners
- Work best with a (relatively) small group so participants can really talk and listen to each other
- Make terminology and understandings clear to avoid discussion 'at cross-purposes'
- Draw on evidence and experience that is tailored to the dialogue's focus and presented to support it and not to 'lecture'
- Rely on careful preparation and sensitive facilitation
- Apply an understanding of confidentiality which makes the dialogue a safe space for discussion.

Lessons from the policy dialogue model were that even where a group is up and running, external support and facilitation can help it reach the next level and that (as with Malta) linking a Hub to national policy (in this case the recently adopted National Cancer Control Strategy) gives salience and coherence.

Issue-specific cancer policy dialogues

Issue-specific dialogues help countries address and advance clearly defined cancer priorities (**see Box 4**). They are more like conventional OBS policy dialogues but tailored to the cancer context. They are a tool that helps NCMHs to convene the most relevant stakeholders around an (agreed) issue – whether on cancer prevention, control or care issues – with a handbook to guide them as they plan the dialogue. In Romania, preparing for the policy dialogue helped the Ministry of Health, the National Institute of Public Health, and others (including WHO/EUROPE) define where their concerns lay around the existing cervical cancer screening programme. It was instrumental in bringing a broad range of stakeholders together and – through the use of an external facilitator – gave them all an opportunity to express their views and to feel heard by others. The group was also supported by evidence but the international experiences presented were chosen not as 'lessons' to be imparted but as examples of how other countries managed similar challenges. The policy dialogue then was able to foster a shared understanding of issues and options, and enabled the group to chart a collaborative path forward (see Bhatia et al. in this issue).

Cross-cutting cancer policy dialogues

Cross-cutting dialogues are like issue-specific ones in that they address a clearly delineated and pressing cancer policy issue, but they are distinct in looking across regions and Member States. They apply the insights of the national (issue-specific) dialogue model but with adaptations because, although many cancer challenges have pan-European dimensions, bringing stakeholders from different countries together is complex. The difficulties of identifying stakeholders, of agreeing terminology and of understanding the impacts of context are all heighted by the multi-country dimension.

The experience of the cross-cutting dialogue on lung cancer screening held as a side event at the European Society of Medical Oncology (ESMO) conference in 2024 tested the approach. It discussed the implications of establishing population-based lung cancer screening programmes and demonstrated clearly that while there is growing consensus on cost-effectiveness, there are still significant differences in how far country experts see this as an optimal investment. The dialogue was careful to take account of the fact that different national settings have (different) competing screening priorities and health system limitations. The neutral facilitation sought to bring out the differing views and managed to encourage a better understanding of opposing perspectives. A second cross-cutting dialogue at a side event to the European Cancer Organization Annual Summit in 2024 tackled cancer workforce shortages and again a thoughtful curation of diverse national experiences helped build a common cross-cutting understanding on key workforce issues facing all countries, their impact on cancer care, and potential solutions.

Both dialogues demonstrated the value of tapping into existing networks and leveraging policy and scientific conferences that bring relevant experts together. They also made clear the need to manage participation with transparency and sensitivity so that the right people can be included without offending those who are not. Other lessons were that external facilitation that is seen to be neutral is critical – and perhaps even more than in a

Box 3: Malta's NCMH inception phase

Malta, the smallest EU Member State, is among the first to establish an NCMH, reflecting the strong national commitment to improving cancer care and research. There was no existing Hub like structure in Malta although there were active stakeholders – not least Xjenza Malta[5] (a government agency responsible for promoting and coordinating scientific research, technological innovations, and science communication) and the Foundation for Cancer Research and Innovation, which is hosted by Xjenza Malta and which integrates expertise from medicine, government, academia, civil society, and the private sector. Two inception events were held in 2024 under the auspices of the ECHoS project, supported by OBS.

The first cancer policy dialogue focused on identifying and engaging those key players, dubbed "founding stakeholders", that it was felt would be key to a future Maltese NCMH. Structured dialogue explored the (future) Hub's aims and role in coordinating national efforts and in connecting Malta to European cancer research initiatives. The second dialogue built on the first and allowed the founding stakeholders to shape the Hub's direction and database; agree on coordination of research initiatives; and ensure strong engagement with patients and communities.

The Maltese NCMH is now being developed with an emphasis on bringing researchers and communities together. Key lessons include the importance of a champion – in this case Professor Christian Scerri, the Foundation's chairperson; of aligning with the EU's cancer mission (here the Mission Hub Coordinator for Cyprus and Malta supported the initial dialogue); and of tapping into the right networks and expertise to ensure work is informed by and contributes to Malta's national cancer strategy.

Box 4: OBS-D&C4Cancer policy dialogues

The project has delivered a mix of inception, issue-specific and cross-cutting policy dialogues with the ECHoS project and DG RTD, based on country priorities.

- Cervical Cancer Screening (Romania), July 2024
- Pre-inception of the Maltese National Cancer Mission Hub (Malta), July 2024
- Lung cancer screening as a cross-cutting issue (Spain), September 2024
- Inception of the Portuguese National Cancer Mission Hub (Portugal), October 2024
- Cancer workforce as a cross-cutting issue (Belgium) – November 2024
- Inception of the Maltese National Cancer Mission Hub (Malta), November 2024
- Lung cancer screening (Portugal), November 2024
- Clinical Trials (Italy), February 2025
- Comprehensive Cancer Centers (Hungary), scheduled for March 2025
- Precision medicine (Sweden), scheduled for April 2025.

national setting – and that credibility and scientific track record matters. Similarly, the ability of an expert to steer and support a meeting without trying to instruct is paramount.

ECHoS plans to encourage NCMHs to hold policy dialogues that involve countries facing similar challenges or with similar health system contexts or where there are useful innovations to be shared. It will also continue the strand of cross-cutting dialogues that build on existing networks, both at conferences and through the growing chain of NCMHs.

Conclusion

A policy dialogue which is tailored to the cancer context is an effective tool for NCMHs as they build national alliances across sectors to advance cancer prevention and control. A careful and structured approach to policy dialogues helps define the issue, the 'right' people and the evidence and brings them together in a way that best fits the policy cycle. The OBS-D&C4Cancer project has provided guidance, support and a set of templates and handbooks that enable this iterative and systematic approach. It adapted the OBS policy dialogue concept to the cancer domain, the needs of the ECHoS project and the NCMHs network – developing three different dialogue models to fit three distinct contexts.

Cancer policy dialogues bridge gaps (between stakeholders, in the evidence, and in terms of shared understanding); foster consensus; and create a safe space that enables collaboration. ECHoS and OBS hope to move forward and to continue to refine and implement the dialogue formats together to support the establishment of the NCMHs network and to build stronger, more coordinated efforts to achieve the goals of the EU Mission on Cancer.

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ADVANCING EQUITABLE **CERVICAL CANCER SCREENING** AND EARLY DETECTION IN EUROPE

By: Dominika Bhatia, Mairead O'Connor, Nicholas Clarke, Jolanda Sinha and Urška Ivanuš

Summary: Advances in cervical cancer (CC) prevention, detection, and management have transformed it from a leading cause of death in women to a preventable disease. In 2020, the World Health Assembly adopted an ambitious global resolution to eliminate CC, setting out vaccination, screening, and treatment coverage targets to be achieved by 2030. Although many European countries have been operating national CC screening programmes for several decades, inequalities in screening uptake persist, rendering women in the most disadvantaged communities most at risk of CC. In this article, we will highlight the key considerations for reducing CC screening inequalities in Europe.

Keywords: *Cervical Cancer, Early Detection, Health Equity, National Screening Programmes, Population-based Cancer Screening*

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Introduction

Since the introduction of cervical cytology tests in the 1940s, biomedical and public health advances in cancer prevention, detection, and management have transformed cervical cancer (CC) from a leading cause of death in reproductive-aged women* to a preventable disease.[1] Screening with cytology tests detects early cellular abnormalities, which, if left untreated, may progress to invasive cervical cancer over time. In the 1990s, the establishment of human papillomavirus (HPV) as a necessary† cause for most CCs ushered in additional prevention strategies in the subsequent decades. This included testing cervical cells for the presence of HPV – which eventually became the preferred first-line screening strategy over cytology tests – and vaccinating girls and young women against HPV infection (with the first vaccine approved for use in Australia and the United States in 2006).[1] In the recent years, countries have been moving towards gender-neutral vaccination programmes, as this confers greater protection against HPV at the population level by breaking the chains of transmission. Although vaccination significantly lowers a person's risk of invasive cancer, it does not protect against all strains of HPV; as such, screening remains an essential complementary strategy for reducing CC burden.

To optimise its population impact, CC screening is delivered through organised programmes. These are resource-intensive public health interventions that involve systematic identification and invitation of the target population over multiple

* In this paper, we use the word "woman" to refer to persons with a cervix whose sex assigned at birth was female, recognizing that individual gender identity may differ.

† In epidemiology, a necessary cause is one that must be present for a health condition to occur.

screening rounds; referral pathways for follow-up of abnormal findings; transition to medical care in the event of a diagnosis; and monitoring, evaluation, and reporting of programme performance.[2] In many European countries‡, organised CC screening programmes were instituted between the 1960s and the 1990s [1] and are estimated to have reduced CC mortality by up to 90% in women that underwent screening, relative to those who never did.[3]

Yet, CC remains the fourth most commonly diagnosed cancer among women in Europe, comprising 16% of new cancer cases in Eastern Europe and 7% in Western Europe.[4] CC screening uptake varies widely across European countries, with 2019 estimates§ ranging between 22% and 80%.[5] COVID-19 has further hampered progress, with nearly all European countries reporting disruptions in cancer screening and care services during the early pandemic period due to overwhelmed health systems.[5] Screening rates have also been declining among younger women in some countries, which may be owed to the roll-out of HPV vaccination and the resulting lack of clarity about CC screening guidelines.[6] The competing family and occupational responsibilities often experienced by reproductive-aged women may also have intensified during the pandemic, leading women to deprioritise their own health.

Overall, given the availability of multiple effective CC prevention options, CC can be understood as a "disease of inequality", because gaps in screening tend to be greater among those experiencing poorer healthcare access and other systemic barriers.[6] In this article, we highlight important considerations for reducing CC screening inequalities in Europe.

Political momentum towards cervical cancer elimination in Europe

In August 2020, the 73rd World Health Assembly adopted the World Health Organization's (WHO) Global Strategy for Cervical Cancer Elimination as a Public Health Problem. The strategy specified three prevention targets that, if achieved by 2030, will reduce CC incidence to that of a very rare disease by the end of the present century (also referred to as the 90-70-90 targets): (i) vaccinating 90% of girls against HPV before age 15; (ii) screening 70% of women aged 35 to 45 years using a high performance test at least twice; and (iii) treating ≥90% of screen-detected precancers and invasive cancers.

Since many European countries are high-resource settings with well-established cancer screening programmes, Europe may achieve the elimination goal within the next 25 years and provide the roadmap for other regions.[7] Commitment to CC elimination – with attention to reducing inequalities – is affirmed in high-level European Union (EU) initiatives, including the 2022 Europe's Beating Cancer Plan (EBCP) and the 2022 European Commission (EC) cancer screening recommendations. In response to the WHO call for CC elimination, the European Cancer Organisation (ECO) and the European Society of Gynaecological Oncology (ESGO) proposed priority actions endorsed by other cancer organisations in the region, including vaccinating at least 90% of adolescents, preferably of all genders, by 2030.[7] The following priority actions related to CC screening:

- Countries should *adopt, communicate, and implement evidence-based CC screening policies* that align with the latest evidence and employ HPV testing as the primary screening modality;
- Countries should *ensure that CC screening is provided within an organised framework,* with systematic methods for target population identification and progression through the screening pathway, and performance monitoring for quality assurance;
- Countries should *optimise screening coverage, intensifying efforts to reach women not responding to the screening invitation* by offering HPV self-sampling options;
- *Countries should empower women and work closely with civil society* through patient and advocacy group collaborations to tailor CC prevention efforts.

Programme performance monitoring is key for identifying cancer inequalities

Ensuring that programme performance is regularly evaluated and disseminated is an essential criterion of organised screening programmes.[2] The 2023 WHO Framework for Monitoring the Cervical Cancer Elimination Strategy outlines 40 indicators aligned with the 90-70-90 targets.[8] Nine indicators are specific to screening, spanning the system level (e.g., availability of a national programme and referral pathways), health service level (e.g., screening coverage and test positivity), and outcome level (e.g., cervical precancer incidence). The framework also includes cross-cutting quality indicators, as the WHO encourages countries to develop robust information systems, integrated across multiple levels of care, to enable routine data collection and reporting. Slovenia presents a noteworthy example of how a country prioritised the development of a well-functioning performance monitoring system since its screening programme's inception (**see Box 1**).

With the WHO elimination targets and indicators as the basis, countries should set CC elimination targets, milestones, and indicators that are appropriate for their resource levels, resource allocation priorities, and evolving screening programme infrastructures.[6,8] Although vaccination and screening programmes largely tend to be delivered separately, countries should consider integrating vaccination and screening registers to monitor and tailor screening strategies according to HPV vaccination status. Importantly, disaggregating data across social determinants (e.g., geographical region, urbanisation, income, and deprivation level) can shed light on CC screening inequalities and inform targeted interventions and policy planning.[8] Two European initiatives encourage countries

‡ Unless explicitly stated, in this paper, "European countries" refers to countries in the WHO European Region, rather than EU Member States alone.

§ These figures are based on the data reported by the Organisation for Economic Co-operation and Development (OECD), which considers either programme data (i.e., data collected by individual programmes for performance monitoring purposes) or survey data. Programme data may be affected by differences in the target age, screening frequency, and screening modalities used in different countries. Survey data may be affected by recall bias. Thus, it should be acknowledged that the cross-country OECD figures may not be directly comparable.

Box 1: Resourcing a high-quality cancer screening monitoring system in Slovenia

In the span of two decades, Slovenia went from being a country with one of the highest CC burdens in Europe to a country with one of the lowest.[9] This is, in large part, credited to the implementation of Slovenia's national CC screening programme, ZORA, in 2003. A fully digitised central registry, established in connection with the Central Population Register, the Register of Spatial Units, and the laboratories, was an integral programme component from the outset, with national standardisation of cytology (since 2003) and HPV (since 2011) data.[10]

Annual reports on key programme performance and activity indicators, stratified across participant age and territorial region of residence, are publicly available.[10] Data publication serves as an accountability mechanism, reaffirming stakeholder commitment to quality improvement. Personalised performance reports are also shared with screening providers for feedback and quality assurance. Although providers initially feared that such performance monitoring may be used to penalise them, they have come to view it as a safety measure. Ensuring standardisation and digitisation of participant and laboratory data also brought additional administrative workload for screening providers and the laboratories; however, having a centralised and interoperable system is expected to alleviate this burden.

The data collected by the Slovenian national CC screening programme is widely recognised for its high quality. The WHO highlighted Slovenia's experience as an example of country success[11] and modeling studies relied on Slovenian data to derive the optimal HPV screening protocol for Eastern European countries.[12]

to collect data on inequalities. The European Cancer Inequalities Registry (ECIR) is a flagship EBCP initiative focused on identifying disparities in cancer control within and between EU Member States by producing country-specific and cross-country reports using data from supranational and national institutions that monitor cancer control (e.g., Eurostat, International Agency for Research on Cancer). A harmonised research and data framework with indicators of socioeconomic inequality is under development through the EU-CanIneq project and will be eventually integrated into the ECIR. The European Cancer Pulse – a complementary ECO initiative – collects data from the scientific literature and cancer communities on 120 inequality measures across 34 European countries.[13]

HPV self-sampling: a promising approach to reach under-screened women

CC screening tests are usually performed by clinicians during a clinic visit. Common CC screening barriers include practical issues (e.g., lack of transport and inconvenient clinic hours or locations), physical or psychological discomfort related to the procedure, and mistrust of clinicians.[6] The transition to HPV testing as the first-line screening modality presents an opportunity to address these barriers through HPV self-sampling, whereby women can self-collect vaginal samples at home or in clinics.[14] Although HPV self-sampling cannot confirm the presence of cancer on its own, it identifies women that are at higher CC risk due to persistent HPV infection. Those found to be HPV-positive must then undergo follow-up cytology tests to confirm the presence of cervical abnormalities.

> “most people find HPV self-sampling acceptable

Self-sampling has comparable sensitivity and specificity¶ for detecting cervical precancers to clinician sampling when polymerase chain reaction amplification is used.[15] The 2022 EC and WHO recommendations support providing self-sampling options to under-screened women that do not respond to screening invitations, though some countries offer self-sampling universally. Opt-out dissemination strategies – when the self-sampling kits are mailed directly to women with prepaid return envelopes (or distributed and collected by health workers in remote communities) – were shown to achieve significantly higher uptake rates than standard care and opt-in strategies (where women may request self-sampling kits online or via telephone).[14] When implementing opt-out strategies, however, care must be taken to discourage double-screening (i.e., undergoing screening through both self- and clinician sampling), as it is costly and offers no clinical benefit.[16] The Netherlands presents an early real-world case study of opt-in and opt-out strategy implementation (**see Box 2**).

Most people find HPV self-sampling acceptable; this is consistent across age groups, income levels, countries of residence, and among under-screened women, women living with human immunodeficiency virus (HIV), lesbian and bisexual women, and trans men.[20] In surveys of people's preferences, home-based self-sampling was largely preferred to clinician sampling and clinic-based self-sampling due to its convenience and ease of use, the comfort and privacy of a familiar environment, and lower physical and psychological discomfort. Although improperly collected samples are rare,[15] the most commonly cited barrier to self-sampling is anxiety about collecting an

¶ Sensitivity is the ability of a screening test to accurately identify all people that have a health condition. Specificity is the ability of a screening test to accurately rule out the presence of a health condition (i.e., identify all people that do not have a health condition).

Box 2: Opt-in and opt-out HPV self-sampling strategies in the Netherlands

In 2017, the Netherlands became the first EU country to implement nationwide CC screening using HPV as the first-line screening test.[1] In the Dutch CC screening programme, regional screening organisations, overseen by the National Institute of Public Health and Environment (RIVM), select the eligible women based on their age and screening history and provide mailed invitation letters.

Initially, an opt-in strategy was used for self-sampling, whereby women could request a free self-sampling kit either by responding to their initial invitation letter or to their reminder letter.[1] In the first two years of this strategy, 7% of the invited women chose self-sampling.[17] Notably, never-screened women, those in the youngest and oldest age-groups, those unemployed or supported by social welfare, and those living in a one-person household were overrepresented in the self-sampling group.[17] These findings suggested that self-sampling may be a promising approach for addressing some barriers to CC screening, though better promotion and outreach were required.

In 2020, due to the COVID-19 pandemic, 16% of women that underwent screening, did so through self-sampling.[18] This observation, along with accumulating evidence from ongoing trials that mailing self-sampling kits directly to women resulted in higher uptake rates than the opt-in approach, led to the adoption of an opt-out self-sampling strategy in 2021.[18] Presently, newly eligible 30-year-old women receive self-sampling kits with their first invitation letter, while others receive self-sampling kits in their reminder letter after 12 weeks. Written and video information regarding proper test administration, the screening pathway, and the environmental impact of self-sampling tests are provided to the participants in the self-sampling kit and online.

At the time when the opt-out strategy was implemented, screening uptake was 51%[19] – the impact of the opt-out strategy on the overall screening uptake and screening disparities thus remains to be seen. In January 2025, in collaboration with the RIVM, the Dutch Cancer Organisation (KWF) launched a nationwide health promotion campaign called "Do it today!" ("Doe het vandaag!") to encourage women to undergo screening. The campaign is being promoted on the radio, television, and by influencers on social media, featuring first-person accounts of screening experiences for both the self-sampling and clinician sampling approaches. An online information platform was also created, with written and video materials addressing common concerns and providing education about HPV, CC, and the test options available.

unreliable sample.[20] Implementation of self-sampling strategies should thus be accompanied by clear instructions, illustrations, and clinician-delivered education.

Despite its promises, HPV self-sampling is a relatively novel CC screening approach with many unknowns. To ensure its effectiveness, it is imperative that HPV test results are clearly communicated to women in timely manner, with referrals to follow-up examinations for those testing positive or those with uncertain results. Self-sampling should also be offered as an option in tandem with clinician sampling to accommodate individuals who may still prefer in-person visits. Monitoring self-sampling performance using defined metrics is key, as the long-term impacts on screening uptake rates, precancer detection, CC outcomes, and healthcare utilisation and costs remain to be fully established.

Community collaborations are essential for effective outreach and health promotion

The WHO Gender Responsive Assessment Scale suggests that health promotive programmes may inadvertently exploit or accommodate existing gender-based inequalities if they do not actively seek to address and transform them. Gendered family roles and occupational responsibilities may, in part, explain the declining CC screening uptake among reproductive-aged women in some countries and the general challenges of engaging this population in preventive programmes for chronic diseases. However, women are not a monolith, and different groups experience unique barriers to participation.[6] In the CC context, certain ethnic or religious groups may have modesty concerns that could discourage screening. Language or cultural barriers may prevent women from ethnic minority or migrant populations to seek healthcare services like screening. Without proper supports, accessing and undergoing screening may be more difficult and uncomfortable for people with intellectual and physical disabilities. The nature of screening procedures may bring up feelings of gender dysphoria in trans and non-binary individuals.

> "different groups experience unique barriers to participation

Resourcing collaborations between organised screening programmes and community organisations that support identified groups may be an effective avenue for reducing CC screening inequalities. Such collaborations can take the forms of (i) participant-engaged research to explore CC screening practices, attitudes, and barriers; and (ii) co-design of intervention approaches.[6] Several community-engaged approaches

Box 3. Collaborative initiatives with under-screened communities in Ireland

Reducing inequalities in cancer screening is one of the strategic priorities of the National Screening Service (NSS) – the national body overseeing Ireland's organised screening programmes, including the national CC screening programme (CervicalCheck). The 2023–2027 NSS Equity Strategic Framework identified collaborations with under-screened communities as a key priority area.[22] A selection of these efforts is described below. Additionally, an NSS evidence-based toolkit is available to support community organisations in improving screening awareness, access, and participation.

Improving screening access in Traveller and Roma communities

Since 1994, the Pavee Point Traveller and Roma Centre has been running the Primary Health Care Travellers Project, which relies on trained female peer health workers to deliver health promotion information to Traveller families in North Dublin. As part of an NSS collaboration, peer health workers conducted face-to-face surveys about CC screening practices and barriers in the Traveller communities and provided CC screening education. CC screening uptake was 68% in the age-eligible women, but 90% among those who actually received an invitation.[23] A key finding was that the postal service was an unreliable mechanism for inviting the Traveller community; however, upon registration with Pavee Point, invitations could be mailed to Pavee Point and hand-delivered by the peer health workers.[22] Relatedly, about half of under-screened Irish Traveller women viewed HPV self-sampling as an acceptable alternative.[23]

Understanding screening practices in sexual and gender minority communities

In partnership with LINC – a non-profit organisation serving the needs of lesbian, gay, bisexual, and transgender (LGBT+) people in Ireland – the NSS studied the CC screening attitudes and practices among lesbian and bisexual women, trans men, and non-binary and intersex people.[24] LINC was involved in all aspects of the study, from the initial discussions about its relevance to proposal drafting, participant recruitment, and data collection. A Steering Group with representation from the NSS, CervicalCheck, and LINC provided oversight. Other Irish LGBT+ community organisations, including Transgender Equality Network Ireland (TENI), were engaged to participate in stakeholder interviews and advertise the study on their platforms. CC screening uptake in LGBT+ individuals was found to be 13% below the national average. Recommendations for improving uptake included challenging heteronormative assumptions in clinical environments and tailoring HPV and CC risk communication. Continued collaboration with LGBT+ communities was viewed as essential to inform public health messaging, promote screening, and support clinicians in safely caring for LGBT+ individuals.

have shown promise in increasing CC screening uptake in disadvantaged groups,[6][21] including:

- promotion of screening via tailored public health education;
- the use of patient navigators (usually allied health professionals or trained peer health workers) to provide screening invitations and reminders, coordinate screening and follow-up appointments, and advocate on behalf of individuals; and
- delivery of screening tests outside of healthcare settings (e.g., through mobile and community clinics).

Examples of successful collaborative initiatives in Ireland are described in **Box 3**.

Conclusion

In this article, we discussed the relevance of and promising approaches for reducing CC screening inequalities in Europe. CC screening and HPV vaccination are effective complementary evidence-based interventions, and both should be implemented to achieve CC elimination. Countries should develop their own targets, indicators, and milestones to monitor and improve the performance of their organised screening programmes, eventually integrating vaccination and screening registers. Home-based HPV self-sampling options, delivered via an opt-out strategy, may effectively increase uptake among under-screened women, if accompanied by instructive public health education that addresses women's concerns and discourages overscreening; however, an open and inclusive path for those preferring in-person clinician sampling should be maintained. The specific strategies for self-sampling implementation may ultimately vary across country contexts. Mathematical modeling studies that consider various screening scenarios alongside other preventive interventions, such as HPV vaccination, can inform the choice of local targets for the general screening population and under-screened groups.[6] Fostering collaborations between organised screening programmes and community organisations is key to understanding the unique CC screening barriers faced by different groups to co-develop tailored solutions. Collecting disaggregated data across social determinants remains imperative to monitor and act upon cancer inequalities.

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IMPLEMENTING NATIONAL **LUNG CANCER SCREENING** PROGRAMMES IN EUROPE: CHALLENGES AND PROMISING APPROACHES

By: Jose M. Martin-Moreno, Dominika Bhatia, Andre Carvalho, Carlijn M. van der Aalst, Harry de Koning, Ebba Hallersjö Hult, Burcu Yücel and David R. Baldwin

Summary: Low dose computed tomography (LDCT) is an effective tool for reducing lung cancer (LC) mortality by enabling early detection. In 2022, the European Commission endorsed LDCT screening for smokers; however, to date, only a few countries have implemented LC screening programmes. Effectively reaching groups most likely to benefit from LC screening and integrating screening with primary prevention methods, such as smoking cessation, remain implementation challenges. Looking ahead, countries must establish mechanisms to monitor programme performance and ensure quality assurance. This article examines the current understanding of these key issues to guide the effective implementation of LC screening programmes in Europe.

Keywords: *Lung Cancer, Early Detection, Implementation, Population-based Cancer Screening, National Screening Programmes*

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Introduction

Lung cancer (LC) is the leading cause of cancer-related deaths in Europe*. It has one of the worst prognoses of all cancers, with only 15% of patients surviving beyond 5 years by the time symptoms appear.[1] Tobacco smoking remains the primary risk factor for LC, followed by exposure to second-hand smoke, air pollution, and occupational hazards. Between 6 and 29% of European adults and teenagers are daily cigarette smokers, indicating that LC and other tobacco-related conditions will continue to pose significant public health challenges in the years to come.[2]

Clinical trials of low-dose computed tomography (LDCT) screening in high-risk populations have demonstrated significant reductions in LC mortality. For example, the Dutch-Belgian *NELSON* trial – the largest such study in Europe – reported a 24% LC mortality reduction among current or former smokers screened with LDCT over a decade, compared to those who were not screened.[3] Despite the substantial body of evidence supporting

* Unless explicitly stated, in this paper, "European countries" refers to countries in the WHO European Region, rather than EU Member States alone.

Table 1: Summary of Pan-European Technical Standards for Lung Cancer Screening with Low-Dose Computed Tomography

AREA	CONDITIONS
Capacity and infrastructure	• Full assessment of essential components affecting capacity, infrastructure, safety, and effectiveness.

Governance and roles	• Formulation of a clearly defined and documented structure including:
	  ◦ Oversight committees to monitor the programme.
	  ◦ A defined team with roles and responsibilities.
	  ◦ Mechanisms to ensure equitable access.

Invitation methods	• Identification of the eligible population (e.g., by electronic records containing smoking data). • Alternatively, target high-risk groups using invitation methods such as outreach in high-risk regions, smoking cessation clinics, community centres, occupational health clinics, or through other screening programmes. • Distribution of materials (written or video) with accurate information about lung cancer screening to high-risk individuals via channels like mail and social media. • Information and invitations tailored to address inequities in access and uptake for minority or underserved populations. • Where possible, initiate contact with potential participants via their primary care providers. • Invitation methods including information designed to align with the demographic profile and reduce fear or anxiety. Also pre-invitation letters, text reminders, pre-scheduled appointments, and follow-up appointments for those who initially do not attend. • Easy geographical and physical access to screening, along with simplified processes for rescheduling appointments. • Collaboration with patient advocacy groups to enhance outreach and engagement.
Risk assessment for entry into screening programmes	• Multivariable, validated models are preferred over age and smoking history alone. • Multivariable models or single criteria (e.g. presence of pulmonary nodules) may be used to stratify participants into annual or biennial screening intervals. • Participants should be reassessed for eligibility by risk threshold and fitness at each screening round.
Smoking cessation	• Smoking cessation should be comprehensive, integrating pharmacotherapy, cognitive-behavioural therapy, supportive measures, and regular follow-up. • Smoking cessation should be offered to all screening programme participants by default, combined with clear information on its benefits.
Non-attendance and exiting the programme	• First appointments as soon as possible after screening and reminders provided nearer the time of the scan. • Navigators (nurse, patient, or both) should support participants in ongoing screening and eventually also for smoking cessation. • Participants exit the programme when they no longer meet the eligibility criteria.
Imaging acquisition and reporting	• Key requirements for technical imaging acquisition must be ensured to maintain accuracy and reliability, including the implementation of quality assurance mechanisms for CT image interpretation and reporting. Key requirements for technical imaging acquisition must be ensured to maintain accuracy and reliability. • Radiologists interpreting the images should have specialised training and experience in thoracic CT interpretation. It is recommended that they report at least 500 CT scans annually, with a significant portion dedicated to lung cancer evaluation. • A structured reporting proforma (using a standardised template) must be used to ensure consistency and assist audit.
Interval and surveillance	• Annual LDCT is recommended if feasible. Biennial intervals may be applied for lower risk groups using LDCT findings or multivariable risk prediction models to select participants.
Communication of results	• Communication of results should be designed for local populations, with local patient representative input. • Communication should be timely (<4 weeks) and positive findings should be appropriately communicated.
Data management	• An end-to-end, validated data management system, supported by an agreed minimum dataset should be implemented. • Data should be assessed and reported regularly.

Source: Adapted from reference [7]

LDCT screening, it is important to recognise that current findings from LC screening trials have external validity limitations that must be considered when making implementation decisions across different contexts. Key trials, such as *NELSON* and the US National Lung Screening Trial (NLST) [4] were conducted in high-income countries and may not be fully generalisable to low- and middle-income settings, where differences in smoking prevalence, healthcare systems, and access to follow-up care could affect outcomes. Socioeconomic disparities and cultural factors affecting screening participation and adherence must also be considered to effectively tailor LDCT screening strategies to diverse populations and health systems.

In December 2022, the European Commission concluded that sufficient evidence supports the potential benefits of national LC screening programmes for smokers using LDCT, provided they are properly implemented. While only a few European countries have introduced such initiatives so far,[5] more are expected to adopt them in the coming years.

Organised cancer screening programmes are resource-intensive public health interventions requiring multiple coordinated activities, ranging from population invitation to diagnosis and multidisciplinary disease management.[6] To support the implementation of high-quality LC screening programmes, evidence-based pan-European technical standards were published in 2023, as summarised in **Table 1**.[7] Nonetheless, LC screening programmes present several unique complexities that require solutions tailored to each country's specific context. In this article, we highlight some of

these challenges and explore promising approaches to address them to inform the effective implementation of LC screening programmes across Europe.

> several unique complexities that require solutions

Effectiveness of cancer screening programmes hinges on uptake

Accurately identifying the eligible population for LC screening – typically, current or former tobacco smokers – is challenging because it requires a reliable data source to determine smoking status. Individual health records are the preferred source. Standardised mail or text message invitations, online surveys, and social media outreach in geographic areas with high LC incidence, community centres, occupational clinics, and other screening programmes may serve as alternative or complementary sources when smoking status records are unavailable or less accurate.[8] For instance, in a recent Swedish LC screening programme pilot, electronic surveys inquiring about smoking status were successfully used to identify and invite eligible women from the breast cancer screening programme register (**see Box 1**).

Once ever-smokers are identified, their LC risk must be assessed against a national threshold for smoking intensity, typically quantified in pack-years or time since quitting, to determine their eligibility for screening. Screening eligibility could also be assessed using multivariable mathematical models that predict individual LC risk by incorporating risk factors beyond age and smoking history. For example, the PLCOm2012 model, validated for use in many European populations, predicts LC risk using 11 risk factors (age, race or ethnicity, education, body-mass index, chronic obstructive pulmonary disease history, cancer history, LC family history, and smoking status and intensity).[9] There is evidence that models incorporating multiple risk factors are more sensitive for detecting LC than smoking history thresholds.[9] Models can also be used to personalise screening intervals (e.g., annual or biennial) based on individual risk.[10] Some limitations of the current LC risk models should also be acknowledged. For instance, current models tend to consider older individuals with limited life expectancy, who may derive less benefit from screening due to potential screening-related harms, as eligible. Additionally, it remains unclear whether model-based eligibility assessment ensures equitable access to screening.

After inviting eligible individuals to undergo screening, it is essential to maximise both the initial uptake of the screening invitation and the subsequent adherence to the programme. Valuable lessons have been learned from other cancer screening programmes. Invitations that come from primary care providers are associated with higher uptake rates;[8] however, pre-invitation letters, reminders, and pre-scheduled appointments have the greatest impact. Moreover, the use of patient navigators is known to improve programme adherence. A key challenge to LC screening uptake and adherence

Box 1: Identifying the target population in the Stockholm lung cancer screening pilot

Sweden does not currently have a national LC screening programme; however, several studies are underway to build the evidence base to enable the National Board of Health and Welfare to decide whether to greenlight the implementation of a national programme in the coming years.

Studies on the attitudes of 50–74-year-old current and previous smokers towards LC screening showed that 90% had a generally positive view of LC screening and 70% would participate in screening when offered. In addition to traditional mass media, most people preferred to be informed about the availability of LC screening via healthcare contacts and mailed letters, similar to other established national cancer screening programmes.

The first LDCT screening pilot was initiated in 2019 in the Södersjukhuset catchment area of Greater Stockholm. To identify the eligible population, the Stockholm Gotland Regional Cancer Centre (RCC), which coordinates regional cancer care, mailed LC screening information to 35,000 women aged 55–74 years in the breast cancer screening register, with the aim of screening 1,000 women. Those interested in LC screening completed an online survey about their smoking habits via the provided web link or QR code. Eligibility was confirmed immediately upon survey completion and women were invited to the LDCT clinic at the Karolinska University Hospital in Solna.

About 30% of those that received the programme information completed the eligibility survey, with 10% considered eligible. Most notably, 94% of the eligible women attended LDCT screening. With 995 investigations completed, 10 women without symptoms received curative treatment for early-stage LC. Abnormalities that turned out to be harmless were found in 17 women. 47 women had abnormalities that needed to be followed up; some of these abnormalities had a high suspicion of cancer, but they were still too small to be biopsied. As a secondary finding, cancers of the oesophagus and kidneys were also detected in two women.

Building on this pilot, a second phase has begun in January 2025, with 1,000 women and men planned to undergo LDCT screening in Stockholm. Implementation studies by the North and West RCCs together with Umeå University Hospital and Sahlgrenska University Hospital are also underway. A cost-effectiveness analysis preceded the decision to carry out the Stockholm pilot and was followed-up during the pilot, with results expected at the project's completion.

is the fact that people experiencing greater socioeconomic marginalisation and poorer healthcare access are also those disproportionately affected by LC.[11] The European Union (EU)-funded "Strengthening the Screening of Lung Cancer in Europe" (*SOLACE*) project has developed core recruitment materials and best practices for targeting populations previously underrepresented in LC screening, including women, socially deprived populations, ethnic minorities, those living in remote regions, and those with heightened LC risk due to existing comorbidities.[12] Countries that have prioritised LC screening programme rollout in the most marginalised areas were able to achieve high uptake.[5 13 14] For instance, in England, more than a third of LC screening programme participants from the 20% most disadvantaged areas were diagnosed with LC at an early stage.[14]

Integrating lung cancer screening and smoking cessation to improve outcomes

Integrated smoking cessation and LC screening programmes have been shown to reduce both LC-specific and overall mortality more effectively than smoking cessation alone.[15 16] It could be argued that this integration is also an ethical requirement, given the socioeconomic gradient in both smoking prevalence and healthcare access. Achieving adequate uptake in programmes with both LC screening and smoking cessation components could help reduce smoking-related health inequities.

The target population for LC screening is complex, as they often have an extensive smoking history and smoking-related comorbidities, a high nicotine dependency, and multiple quit attempts. Therefore, multimodal smoking cessation interventions delivered in-person, with both behavioural and pharmacological support, are most effective in this group.[17 18] Frequent telephone or web-based follow-up is also essential to prevent smoking relapse. Programme participants should also be educated about the risks of using tobacco alternatives, such as e-cigarettes and vapes.

Individuals that undergo LC screening report higher smoking cessation rates than the general smoking population, indicating that LC screening presents a valuable opportunity for health promotion.[17] LDCT scans can offer personalised risk information not only for LC, but for other tobacco-related conditions, such as coronary heart disease and chronic obstructive pulmonary disease. This biofeedback, when effectively communicated, can serve as a motivational tool to encourage smoking cessation.

> Performance indicators typically encompass the entire cancer control continuum

For optimal uptake, smoking cessation should be offered to all LC screening programme participants by default, with clear information about its benefits to increase adherence. Smoking cessation services should be accessible both financially, by being offered free of charge, and physically, through co-location with LC screening sites. Smoking cessation provision is usually a responsibility of general practitioners; however, there is often limited time for routine preventive counselling during primary care appointments, particularly in patients with complex needs. Employing specially trained smoking cessation counsellors at LC screening sites could effectively alleviate this burden from general practitioners.

Performance monitoring and evaluation are critical for quality assurance

Ongoing performance monitoring for continuous quality improvement is a critical feature of cancer screening programmes.[6 7] Performance indicators typically encompass the entire cancer control continuum, from screening to diagnosis, management, and outcomes. It is theorised that under-performance at any point in the continuum will result in suboptimal cancer outcomes. Established breast, cervical, and colorectal cancer screening programmes already utilise evidence-informed monitoring and evaluation frameworks with indicators that can be adapted for LC screening programmes. These adaptations should account for the unique aspects of LC screening, such as target population definitions, smoking cessation success rates, and the management of incidental findings and nodules.

Two EU-funded projects have collaborated to achieve consensus on LC screening programme indicators. The *CanScreen-ECIS* project is developing and piloting a new cancer screening data management system to be integrated into the existing European Cancer Information System *(ECIS)* of the European Commission.[19] The *SOLACE* project is supporting LC screening programme implementation across Europe by highlighting strategies to improve access for all socioeconomic groups.[12] The methodology to develop LC screening-specific indicators involved systematic searches for existing indicators, literature reviews to identify best practices, and the development of key indicator themes, namely: (i) identifying and reaching the eligible population; (ii) smoking cessation; (iii) unnecessary biopsies or resections; (iv) radiation exposure; (v) incidental findings; (vi) early rescreening, and (vii) artificial intelligence (AI) utilisation.

Given the differences in funding, trained personnel, and infrastructure across countries, indicators must be adaptable to different country resource levels. The robustness of population health data and cancer registry infrastructures is also critical for accurate monitoring and evaluation. Countries should continue to improve their data systems to enable tracking of long-term outcomes (e.g., see recent efforts in Türkiye in **Box 2**), and consider data-sharing and collaboration with other countries. The screening

Box 2: Expanding the cancer data infrastructure in Türkiye

Türkiye has one of the highest rates of tobacco smoking in Europe and significant LC burden. In 2016, a national LC screening programme was deemed not feasible due to occupational and environmental exposures, such as asbestos and radon, as well as the risk of false-positive results and overdiagnosis due to endemic tuberculosis infection.[20] There are no imminent plans for programme implementation; however, independent investigations are ongoing. For instance, a 2024 modelling study found that population-based LC screening according to the *NELSON* trial protocol in 50–74-year-olds may be cost-effective, based on a willingness-to-pay threshold of $28,588.[21]

In 2021, *Registurk-lung* (NCT05254119) – an ongoing prospective observational clinical database – was established to collect nationally-representative real-world data on patients diagnosed with non-small-cell or small-cell LC from 42 hospitals and clinical centers. The database contains diagnostic, pathological, treatment, and course of disease information, including molecular tumor characteristics, types and number of cycles of multimodal cancer therapies, and cancer outcomes. Recent analyses of *Registurk-lung* data provided useful insights regarding early LC diagnosis, the effectiveness of chemotherapy regimens according to tumor subtypes, and LC survival.[22] [23]

programme implementation stage can also influence indicator prioritisation; for instance, during the initial rollout, indicators related to uptake and early detection may take precedence, while mature programmes might focus on long-term outcomes and quality of life. Finally, all data management processes should be fully compliant with the General Data Protection Regulation (GDPR).

> allied health professionals are a vital resource

Importantly, monitoring and evaluation can reveal LC screening and outcome disparities, providing evidence to drive policy change. Two ongoing European initiatives present an opportunity for collaborative data collection, analysis, and reporting on LC inequalities. The "European Cancer Inequalities Registry" *(ECIR)* is a European Commission-funded initiative that synthesises information from EU Member States on social determinants, including age, sex, education, income urbanisation, employment, and disability status, across the cancer control continuum. The *European Cancer Pulse* is a complementary initiative led by the European Cancer Organization, covering 34 European countries and reporting on 120 inequality measures.[24]

Conclusion

In this article, we explored the challenges and promising practices for the upcoming implementation of LC screening programmes across Europe. Countries should consider the current best evidence, leverage reliable databases, and validate and employ multivariable mathematical models to identify the eligible population. Screening should be integrated with free smoking cessation services to optimise LC outcomes. Qualified and trained allied health professionals are a vital resource for ensuring adequate uptake of and adherence to both LC screening and smoking cessation services. Despite the unique features of LC screening programmes, existing screening programmes for other cancers may offer useful insights regarding the participant invitation mechanisms, navigation approaches, monitoring and evaluation frameworks, and data infrastructure development.

Ensuring health equity – a cornerstone of Europe's Beating Cancer Plan – should be an explicit consideration in all LC screening programme components. This is particularly important in the LC context, as those most at risk of LC also tend to experience more socioeconomic marginalisation and have poorer access to healthcare. Lastly, although this article focused on the early steps of the screening process, countries must also plan for resourcing downstream steps related to cancer diagnosis and management. This includes ensuring availability of suitable radiological equipment, personnel capacity, and access to treatment, as well as exploring potential AI applications. Overall, countries should prioritise adapting the pan-European technical standards for LC screening programmes to their national contexts.

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Strengthening Europe's Nursing Workforce: Strategies for Retention

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Policy brief 66

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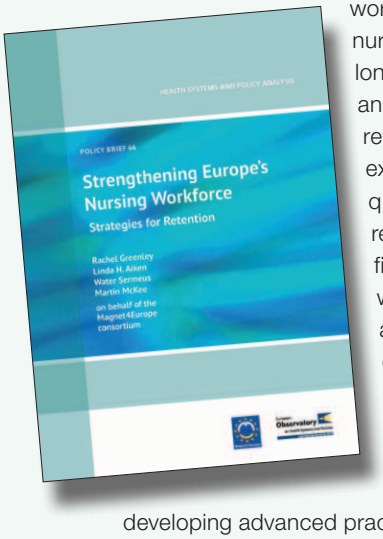
The COVID-19 pandemic highlighted severe shortcomings in the nursing workforce across Europe, exacerbating existing understaffing and exposing the constraints of historically poor work environments. This policy brief explores the scale and nature of these problems and the reasons for nurse attrition, and proposes strategies for retention. It was written as part of the European Union Horizon 2020 project, Magnet4Europe, which aims to improve clinician well-being and the quality of patient care in European hospitals.

The brief highlights that the nursing workforce can be increased by recruiting more staff, retaining more of the existing staff, and possibly by changing the composition of the workforce. Training more nurses is crucial but takes a long time to have an impact and requires significant resources that may not exist in sufficient quantities. International recruitment offers a quick fix but can deplete the workforce in what are already under resourced countries, while migrant nurses are at risk of exploitation and discrimination. Changing the skill mix by developing advanced practice roles for nurses can improve retention and job satisfaction. The brief argues that policymakers need to address shortages and skills imbalances in the nursing workforce by giving attention to staffing policies and investing in nursing education and training.



CHALLENGES AND OPPORTUNITIES WITH EQUITABLE ACCESS TO **CANCER CLINICAL TRIALS** IN THE EUROPEAN UNION

By: Luis Castelo-Branco, Florian Tille, Eva Jolly, Iwona Ługowska, Dario Trapani, Jose Luis Perez-Gracia and Dheepa Rajan

Summary: Clinical trials are the gold standard for demonstrating the benefits of medical innovation, including anti-cancer treatments. However, most are conducted in selected centres under strict protocols, which often fail to reflect the complexity and heterogeneity of real-world practice and populations. Thus, many patients in the European Union (EU) may not benefit from access to cancer clinical trials due to geographic, clinical and normative barriers. Expanding investments in training and infrastructure, increasing the number of participating centres, developing more pragmatic and sustainable clinical trials that better reflect real-life practice across regions, and promoting decentralised research are some of the key solutions.

Keywords: *Clinical Trials, Oncology, Patient-centredness, Equitable Healthcare, Pragmatic Clinical Trials*

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Background: Current inequities in access to cancer clinical trials in the EU

Global investment in cancer research has historically been significant, exceeding that of many other clinical fields. However, the majority of this funding has been directed towards developing oncological medicines and technologies within major cancer research centres and among highly selected populations. Comparatively little investment has been allocated to better understanding other practical, real-world cancer challenges, such as treatment for multimorbid older patients or those under 18, optimal supportive care, people-centred care processes, and even primary prevention and early detection.[1,2]

The conditions required for classic clinical trials often exclude many individuals who could benefit from their results, namely, those with rarer tumour types, greater disease heterogeneity, or comorbidities.[3,4] While such highly selective inclusion may be scientifically justified to ensure robust evidence generation, they limit the generalisability of findings and their applicability to routine clinical practice.

Several international initiatives have assessed the dimension of inequitable access to cancer clinical trials globally and for several subgroups of patients with cancer.[5,6,7] Others have proposed recommendations for mitigating these problems.[8,9] This remains a current and important challenge for the EU, and this article will reflect on current obstacles and actionable steps to improve access to clinical trials in the region.

Uneven access to clinical trials across Europe between and within countries

Access to clinical trials is marked by significant inequities, both regionally and within countries. Notably, around 75% of countries globally do not have any ongoing cancer clinical trials and research is mainly centred in North America, Europe and more recently in China.[2]

Moreover, despite a 38% global increase in clinical trials over the past decade, Europe's share of commercial trials has dropped from 25% in 2013 to 19% in 2023, with geographic reallocation of trials to Asia, particularly China.[10]

The slow and fragmented regulatory environment in Europe, coupled with administrative burdens has contributed to this trend. For instance, a current challenge, identified by different stakeholders such as the European Society for Medical Oncology (ESMO) is the In Vitro Diagnostic Regulation (IVDR), which imposes strict requirements on diagnostic tests used in clinical trials, creating operational barriers for multinational cancer studies.[11] With oncology moving towards a biomarker-driven approach for treatments, requiring also innovative diagnostics, the increased complexity and administrative burden of IVDR compliance have led to delays in trial initiation and reduced participation of European centres in global research efforts. While regulatory mechanisms are essential, it is crucial to ensure they do not hinder the efficiency and competitiveness of cancer research in Europe.

Within the European region, Western European countries disproportionately benefit from the cancer research ecosystem, while Eastern and parts of Southern Europe remain underrepresented,[9,10] with some ongoing initiatives to mitigate these gaps (**see Box 1** and **Box 2**). Disparities have also been exacerbated by the historical lack of a harmonised procedure for trial registration and conduction across borders, with national regulations governing clinical trials on top of European, broader and general regulations.[6] In acknowledging these issues, the EU has been working to improve the regulatory environment at various levels (see "European incentives and regulation" section below).

Limited resources and technology capacity make some countries, or centres within the countries, less attractive to clinical trial sponsors due to a lack of the required certifications and quality accreditations, personnel, expertise, with protected research time, testing capacities equipment, and clinical trial facilities – including to attain normative regulations and quality. This is also a missed opportunity as clinical trials bring relevant financial incentives, early drug access, and advanced training and experience with new treatments.

Furthermore, the centralisation of cancer clinical trials is often seen in countries in which such centres – for example, in the structure of Comprehensive Cancer Centres (CCCs) – are well-positioned to conduct more trials because they have dedicated infrastructure, trained staff, resources, experience and high recruitment rate. These features attract trial sponsors, who look for the optimal conditions to ensure success of their research projects and their investment.

However, this can limit patients from other regions or even other centres in the same

Box 1: Poland: Reducing gaps in access to clinical trials through investment in solid infrastructure

Poland has been expanding access to clinical trials across various medical fields, driven by national policies and close collaboration with the different stakeholders (including researchers, healthcare institutions, patients advocates and industry).

A crucial development has been the streamlining of regulatory processes to accelerate trial approvals and reduce administrative burdens by working closely with European regulators. As a result, the country has seen an increase in trial applications, with over 780 new clinical trials registered in 2023. Many newly launched oncology trials focus on immunotherapy and targeted therapies, not only advancing treatment options for patients but also supporting the national healthcare budget, providing more access to these innovative yet expensive treatments.

A key player in Poland's clinical trial ecosystem is the Medical Research Agency (MRA), established in 2019 to fund and support clinical trials, particularly academic research. Another major initiative is the Polish Clinical Trials Network (PCTN), launched by the MRA to connect multiple research centres, reduce regional disparities, and provide equal opportunities for trial participation in both urban and rural areas. Additionally, the MRA is enhancing Poland's digital infrastructure for clinical trials through the establishment of Regional Centres for Digital Medicine with Biobanking (RCDM), supported by AI-driven analytics to improve trial efficiency and precision medicine approaches.

With increasing recognition of clinical trials as a key component of the healthcare system, Poland has significant potential for further growth in this sector. However, challenges remain, particularly regarding the reimbursement of genetic profiling for patients, which is a critical requirement for sponsors to initiate innovative, personalised clinical trials in the country. Addressing this gap will be essential in ensuring Poland remains a competitive and attractive location for cutting-edge medical research.

Box 2: Spain: Heterogeneities in the access to clinical trials within the same country

Spain is one of the leading countries in Europe for participation in clinical trials. Yet, patient access to trials largely depends on their location of residence. For example, the 2024 report by Farmaindustria[12] indicated that more than half (51.1%) of clinical trial participation is concentrated in Catalonia and Madrid. Even accounting for patients who may travel from other regions, these figures demonstrate considerable room for improvement in terms of guaranteeing equity in access to clinical trials.

Access to clinical trials is perceived as a problem by all Spanish stakeholders, including patients, patient associations, physicians, health authorities and pharmaceutical companies. Specific actions proposed to expand access beyond Catalonia and Madrid include the provision of adequate resources by health authorities, including staff, infrastructures and technical equipment, to enable the expansion from main clinical trial centres to other centres and regions. Pharmaceutical companies also have a role to play by investing in and using smaller trial sites. Collaborative work among these stakeholders may facilitate an aligned strategy and more efficient investments considering the interests of all (sponsors, researchers, health institutions and patients).

city to access the same opportunities for trial participation (**see Box 2**). For instance, a patient with metastatic breast cancer living in a rural area may not have access to a clinical trial testing a new drug that could potentially increase her survival, while a patient with a similar clinical condition living near a metropolitan CCC may have a higher chance to gain access to innovative experimental treatments, resulting in potentially better health outcomes – generating an indirect but tangible dividend of disparities, within the same country. It thus renders the equity objective difficult to achieve, calling for more strategic investments in training and capacities (e.g., by governments) to smaller and more decentralised structures to help reduce these gaps.

This disparity, driven solely by a patient's place of residence, restricts access to innovative cancer research and its benefits to large urban centres and wealthier regions.

Funding of clinical trials – misaligned incentives

Clinical trial funding poses an important barrier to equitable trial access. With trials being extremely costly and public funding limited, private sector investments often prioritise financial returns and focus their collaborative research in experienced centres to maximise the output; in principle, without a primary interest for capacity-building. As such, investments are oriented towards areas where profit may be maximised, as the likelihood of success – with clinical trials involving smaller sample size of the population that could demonstrate the clinical benefit for a regulatory approval, and further expanded clinical use. These trials frequently rely on early surrogate endpoints, such as progression-free survival instead of overall survival, to allow for faster follow-ups and expedited outcomes. Expanding to more patients, centres, countries and larger follow-ups increases costs, time, and bureaucratic complexity for sponsors.

Conversely, public-funded and academic research is subject to harsh economic pressures, and more limited chances of success.

These factors collectively divert trials away from less affluent, multi-morbid, rural, or sicker populations, making it difficult to generalise results for a broader, more heterogeneous real-world population. It thus renders the equity objective difficult to achieve, and may also aggravate the problem: centres excluded from trials will have less experienced staff and financial incentives to improve their infrastructure, thus lower conditions to be "competitive" in attracting trials and sponsors. Strategic investments in training and capacities (e.g., by governments) may help reduce these gaps.

Demand-side barriers to inclusive recruitment to clinical trials

The same factors that make it difficult for certain populations to access the health system also hinder their participation in cancer clinical trials. In other words, the social and economic determinants of health are closely correlated with access to and participation in clinical trials. These factors include cultural and language barriers, lack of trust in the health system, lack of clear understanding of all clinical trial conditions, lack of awareness of the existence or benefits of trials, or living far from the cancer centre.[13]

Patients with lower health literacy, disadvantaged social backgrounds, or certain ethnic backgrounds are often excluded, based also on subjective perceptions of their ability to fully understand and adhere to strict research protocols.[7] Patients living in remote areas are less likely to participate in clinical trials due to the frequent hospital visits required. The indirect costs associated with clinical trial participation – such as transportation, accommodation, and time away from work – pose also significant barriers, particularly for those travelling long distances.[14]

These issues are often interrelated and compound each other, creating further challenges for those with the poorest health outcomes, preventing them from accessing innovative clinical trials and benefiting from novel therapies.

Moving towards innovative solutions to improve equitable access to clinical trials

European incentives and regulation

Europe's Beating Cancer Plan and the EU Mission on Cancer explicitly prioritise improving access to cancer medicines and research, including clinical trials, for the broadest possible group of citizens. Several opportunities are being explored at the European level to this end, including the harmonisation of

regulatory frameworks under the Clinical Trials Regulation, expert guidance from the European Medicines Agency (EMA) through its PRIME scheme (**see Box 3**) and funding mechanisms like Horizon Europe and the Innovative Health Initiative (IHI).

The Clinical Trials Information System, from January 2025 and in accordance with EU regulations,[15] can be used to request authorisation to conduct a clinical trial in up to 30 European Economic Area (EEA) countries via a single online application, simplifying some bureaucratic tasks including the dialogue with national regulators for trial monitoring. This system is expected to create new opportunities to expand clinical trials to EU countries that have often been excluded.

Reducing bureaucracy and the administrative burden of clinical research has been widely recognised by stakeholders as a major challenge to enabling smoother and broader clinical trial implementation across the EU. For instance, ESMO has developed the Clinical Research Observatory (ECRO), which provides specific experts-based recommendations to advance towards this goal.[16]

Some of these recommendations are being regularly incorporated into the Good Clinical Practice (GCP) Guidelines by the European Medicines Agency (EMA), which establishes international standards for the design, conduct, recording, and reporting of clinical trials. In the last version (under revision) places particular emphasis on decentralised and pragmatic clinical trials.

Collaborative research networks

A possible strategy to mitigate inequities is to establish broader and stronger connections between major academic cancer centres and smaller health institutions (e.g., those in rural areas or smaller cities). By co-sharing patient care under well-developed research protocols, these collaborations can enhance access to cutting edge treatments. Such a paradigm could follow a hub-and-spoke model, decentralising clinical trials while assuring centralised quality assurance, governance and research capacity. This approach can lead to the inclusion of more patients from smaller centres in clinical trials, helping to reduce the disparities caused by social and geographic determinants of health and improving access to innovation. It can also increase the speed of enrolment when smaller centres are engaged for specific and defined responsibilities (e.g., conducting regular clinical and laboratory follow-ups), as patients would not need to travel to large urban cancer centres as frequently.

The COVID-19 pandemic provided a window of opportunity to demonstrate the feasibility of many of these strategies.[8] That experience showed what can work when coupled to specific protocol rules (e.g., follow-up and laboratory visits conducted in centres closer to patient's residency rather than the main research centre, or even telemedicine for some well-defined and simpler follow-ups), shared reimbursement incentives, and adequate training for all participating staff.

Sweden (**see Box 4**) provides an example of how well-established networks between centres, founded in a well-organised health system, can provide similar opportunities for patients to access cancer clinical trials even in more remote areas.

The Personalised Cancer Medicine for the European Union (PCM4EU) initiative, supported by the EU, was designed to enhance access to personalised anti-cancer treatments across Europe. Grounded on a solid network connecting diverse stakeholders (including research institutions, hospitals, and biotech companies), it aims to integrate molecular diagnostics, innovative clinical trial designs, and data-driven treatment strategies into routine cancer care. This initiative ensures that patients across Europe, including those in underserved regions, benefit from the latest advancements in precision oncology. Additionally, it has the potential to enhance European competitiveness in precision oncology while reducing disparities in cancer care by expanding access to cutting-edge therapies beyond major research centres.

The recently created EU-funded National Cancer Mission Hubs (NCMHs) also open diverse avenues to strengthen collaborative clinical trial research through funding, design and implementation, and by doing so, can broaden access and opportunities for patients.

Innovative Trial Designs Enhancing Inclusivity and Representation

To address the drawbacks of more classical clinical trials – such as limited generalisability, adaptability, patient burden, and inefficiencies in time and cost – several stakeholder groups, including health professionals, researchers, public health entities, and increasingly payers and policymakers, advocate for approaches such as hybrid, emulated or pragmatic clinical trials (PCTs).[18] [19]

Box 3: PRIority MEdicines (PRIME) scheme as an opportunity to improve access to innovation

PRIME[17] is an EMA initiative to support the development of medicines to address unmet medical needs, including in oncology, an important priority in clinical care and research.

It is focused on conditions for which no treatment option exists (e.g., rare cancers), or where the treatment under study can offer a major therapeutic benefit (e.g., targeted therapies that could improve survival for patients with advanced tumours).

Through early dialogue and enhanced interaction, it helps to optimise development plans and accelerate evaluation, aiming to ensure faster patient access to promising treatments. The various rounds of interactions engaging different stakeholders (e.g., sponsors, regulators, clinical experts or patient advocates) is also a mechanism that can improve patient diversity and equitable access to research across the EU.

Box 4: (Inter-) National Networks for Patient Inclusion and Equal Opportunities in Sweden

Sweden is working towards a more cohesive and accessible clinical trial system through the SweTrial initiative, which aims to create a streamlined, efficient, and unified entry point for clinical studies. The establishment of national therapy networks and trial units enhances the capacity of healthcare systems to provide patients with equal opportunities to participate in clinical trials, regardless of their location. Efforts to strengthen research-supporting competencies, streamline application and biomaterial release processes, and provide consolidated national statistics on clinical trials are key priorities. Removing legal barriers that hinder clinical studies is also a crucial aspect of the initiative.

Key stakeholders, including the CCCs and Clinical Studies Sweden, play a vital role in developing national therapy networks and supporting regional participation in clinical trials. The Swedish CCCs have established a network for collaboration and have also initiated a Nordic-Baltic CCC network with a focus on clinical trials. The 2024 Swedish Life Science Strategy emphasises the importance of a national digital infrastructure to facilitate the sharing of health data for research and innovation. Furthermore, Biobank Sweden ensures the secure and efficient handling of biological samples for research and healthcare purposes.

To maintain Sweden's competitiveness in clinical trials, national coordination and simplified approval processes are essential. Proposed national therapy groups aim to handle trial inquiries, planning, and execution more effectively. International collaborations, such as projects under Europe's Beating Cancer Plan and the EU Mission on Cancer, provide valuable opportunities for knowledge exchange and cross-border cooperation. Sweden's ability to contribute high-quality population-based data positions it well for innovative research and validation of findings. Moving forward, continued development of national networks and strategic partnerships is crucial to ensuring equal opportunities for patients to participate in clinical trials.

PCTs are designed to evaluate interventions in real-world clinical settings, focusing on outcomes that are directly relevant to patients, healthcare providers, and policymakers.[20] They typically have broader inclusion criteria, allowing for a more diverse patient population that better represents the complexity of real-world clinical practice, moving away from highly selective trial conditions, generally conducted only at large research centres. Practical, real-world patient care issues are embedded into these PCTs, such as patient adherence, comorbidities, and variations in care delivery and conditions (e.g., timely access to radiology modalities or novel predictive or prognostic biology analysis).

These trials hold significant potential to enhance clinical relevance, promote equity in access or even feasibility for some trials (e.g., in rarer populations or disease settings).[21] By focusing on more real-world clinical practice conditions, more research centres including those in less urbanised peripheric areas could potentially participate.

Clinical trials with pragmatic features provide evidence from broad real-world clinical setting, to better inform clinical and policy decisions and are also an important opportunity for more inclusive access to oncology clinical trials in the EU.[18] [20]

However, enrolling more patients and involving multiple centres significantly increases costs and administrative complexity, posing a major challenge for its implementation. Therefore, close collaboration among stakeholders is crucial for establishing the right conditions for the wider implementation of PCTs across the EU.

Conclusions

Addressing inequities in access to cancer clinical trials across the EU is a critical step towards improving cancer outcomes and fostering inclusive healthcare innovation. The current disparities – rooted in geographic, economic, and social barriers – limit the reach and applicability of cancer research, disproportionately affecting underrepresented regions, populations, and research centres. This undermines both equity and the potential to fully integrate clinical trial findings into routine practice.

Promising initiatives, such as Europe's Beating Cancer Plan and the harmonisation of regulatory frameworks, provide a foundation for change. Innovations in trial design, such as PCTs, and collaborative approaches like shared research networks, offer viable solutions to overcome existing barriers. These strategies can expand trial participation to smaller centres and underrepresented populations, ensuring that more patients benefit from advances in cancer treatment and care.

Overall, there are several reasons, with a magnitude not fully studied, that are reducing access to clinical trials to many patients globally. It is important to better study the impact of these factors on access to cancer clinical trials in Europe, which may guide more evidence-based decisions aiming to mitigate these differences.

To achieve these goals, a concerted effort is needed from policymakers, physicians, researchers, health providers, and sponsors (**see Box 5**). By investing in equitable trial access and fostering innovation in trial methodologies, the European cancer research ecosystem can move closer to delivering more inclusive and impactful cancer care for all.

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Box 5: Ways forward to improve equitable access to clinical trials across Europe

- More in-depth assessments on the current state of inequitable access to cancer clinical trials in Europe:
  - Between countries and regions (e.g., south compared to north and east compared to west)
  - Within the same country, across regions
  - Different population groups (e.g., populations and/or patients with comorbidities commonly excluded)
- Government investments and incentives to improve clinical trials infrastructure
- Collaboration among diverse stakeholders to identify synergies and common goals to increase access to trials for patients across the EU
- Broader implementation of innovative solutions, such as pragmatic clinical trials
- Promotion of decentralised clinical trials with reimbursed incentives for collaborative centres
- Reduction of bureaucracy and patient travel for instance with telemedicine for some monitoring visits
- Innovative sponsorship aiming for more publicly-funded clinical trials
- Development and use of innovative digital and artificial intelligence tools to identify and provide more efficient access to available clinical trials for patients with cancer
- Development of an active role for National Cancer Mission Hubs to:
  - Identify local/regional heterogeneities
  - Promote collaboration between institutions for cancer research
  - Provide conditions to facilitate patients access to clinical trials.

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EMPOWERING VOICES: COLLABORATIVE USER BOARDS AS A MODEL FOR INCLUSIVE CANCER PREVENTION

By: Pia Kirkegaard, Anneli Uusküla, Anna Tisler, Arman Rahman, William M. Gallagher, Marc Bardou, Keitly Mensah, Rachel Greenley and Martin McKee

Summary: Engaging patients, the public, and stakeholders meaningfully is vital for equitable and effective cancer policies. Initiatives like CBIG-SCREEN and ECHoS demonstrate participatory approaches that build trust, legitimacy, and sustainable solutions, particularly for marginalised groups. Barriers to engagement remain including geographic, economic, and institutional constraints, as well as mistrust and power imbalances. Therefore, tailored strategies are essential for addressing these challenges. This article examines how Collaborative User Boards work to overcome contextual challenges and ensure diverse representation within participatory cancer research. It also highlights why overcoming hierarchies is necessary for co-design to work and flourish.

Keywords: *Stakeholder Engagement, Participatory Approaches, Marginalised Communities, Health Equity, Cancer Policies*

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Introduction

Cancer remains a formidable global health challenge, necessitating strategies that effectively prevent and manage its impact on diverse populations. The story of cervical cancer is one of success, initially due to the implementation of population-based screening programmes and, subsequently, through immunisation against the Human Papilloma Viruses that cause it (see Bhatia et al. in this issue).[1] Yet, despite the existence of well-designed screening programmes in many countries,[2] certain vulnerable groups face persistent barriers,[3] including stigma, mistrust, and socio-economic disadvantage, impeding access to services. Few countries have developed dedicated policies designed to broaden coverage among groups at particularly at high risk.[4] Addressing these barriers requires a shift in policy and practice, placing community and patient engagement at the forefront.

Community engagement is vital if we are to overcome the persisting systemic inequities in cancer prevention and treatment.[5] [6] Without it, marginalised populations risk exclusion from policies meant to serve them, perpetuating health disparities.[7] In this paper, we describe the experience of one form of engagement

implemented within a European Union-funded project, CBIG-SCREEN, prioritising public and patient engagement to find sustainable, inclusive solutions for challenges in cancer policy.

CBIG-SCREEN seeks to increase cervical cancer screening among women in vulnerable situations across Europe.[8] A core element is the creation of Collaborative User Boards (CUBs), dynamic, participatory spaces that bring together stakeholders from multiple levels to co-design solutions. CUBs operate as advisory boards, learning environments, and focus groups, facilitating dialogue among local governments, healthcare providers, and communities. Experience with the CUBs illustrates how participatory frameworks can address the many challenges involved in including disadvantaged groups, providing a replicable model for inclusive cancer prevention strategies that align with the objectives of ECHoS and the European Union's Cancer Mission, in particular the need to reduce systemic inequities in access to care.[9] They help bridge the gap between grassroots realities and high level policies.

The Policy Imperative for Community Engagement in Cancer Prevention

The EU Cancer Mission, part of Europe's Beating Cancer Plan,[10] underscores the importance of reducing inequities in prevention, diagnosis, and care. In cervical cancer screening, participation gaps are often linked to structural and societal barriers, including language, cultural differences, and economic constraints. These obstacles disproportionately affect ethnic minority women, rural populations, and economically disadvantaged groups, leading to lower screening uptake.[3]

Community and patient engagement provide an opportunity to challenge these disparities by fostering trust, dismantling stigma, and ensuring culturally appropriate care. Policies informed by meaningful community input can encourage uptake of preventive measures, improve health literacy,[11] and enhance the legitimacy of interventions.[12]

Box 1: Efforts to counteract unequal representation: Collaborative User Boards

Collaborative User Boards (CUBs) are currently being implemented as part of HORIZON EUROPE and EU4HEALTH projects across several EU countries, including Portugal, Estonia, Lithuania, Romania, Bulgaria, Poland, France, Denmark, Italy, and Ireland. These boards aim to engage patients, the public, practitioners, and policymakers to share their experiences and perspectives. By doing so, they help identify context-specific solutions to barriers in cancer screening, thereby reducing risks often associated with healthcare interventions' preparation and implementation.

CUBs are an innovative methodology combining elements from advisory boards (for consultancy), learning spaces (to foster mutual learning, intra-group inspiration, and local support), and focus groups (using prompting techniques, interaction, and recorded data for analysis). This approach was developed in 2019 as part of the EU-funded CBIG-SCREEN project, which seeks to improve access to cervical cancer screening for women in vulnerable situations across European countries.

Collaborative User Boards have the following key features:

- Eliciting Voices and Perspectives: The process ensures representation from all stakeholder levels – macro (policy), meso (practitioner), and micro (community) – to identify barriers and propose solutions to healthcare interventions.
- Promoting Learning and Commitment: This approach fosters mutual understanding, collaboration, and stakeholder engagement by facilitating discussions within diverse groups.
- Enabling Cross-Country Comparison: The methodology collects comparable data across different countries to inform European-level policy recommendations while allowing for local adaptation. An analytical framework supports this cross-national comparison.
- Stakeholders gather in facilitated sessions to discuss their perspectives, ensuring that all voices are heard and documented. The CUB process is a "consultancy process involving macro, meso, and micro-level stakeholders to identify barriers and solutions to proposed interventions through structured discussions."

Due to varying hierarchical structures in participating countries, the implementation of CUBs has differed significantly. In Denmark, where the methodology originated, including stakeholders from all levels in the same discussions was feasible. In other countries, however, practical and contextual constraints meant stakeholder levels were often engaged separately. In most cases, interactions occurred between the meso- and macro-levels or between the meso- and micro-levels. Despite these differences, the approach maintained its core goal of fostering inclusivity and collaboration across contexts.

This flexibility highlights the importance of tailoring engagement processes to fit local realities while maintaining overarching objectives. CUBs represent a promising model for integrating diverse perspectives into healthcare interventions, advancing inclusivity and effectiveness locally and in Europe.

The CUB model recognises that participation must be more than just tokenism. It creates a platform where diverse stakeholders engage as equals, addressing power imbalances often hindering meaningful dialogue (**see Box 1**). By involving diverse voices in decision-making, CBIG-SCREEN has fostered a sense of shared ownership and transparency, creating momentum for emerging initiatives.[13] For instance, CUB-facilitated discussions in Estonia enabled local government representatives

and women from the Russian-speaking minority to address misunderstandings about cervical screening letters, leading to tangible improvements in communication strategies (**see Box 2**). Meanwhile, in France (**see Box 3**), they helped overcome resistance to engage with underserved communities. The participatory action research model employed in Ireland (**see Box 4**) further underscores the value of collaborative design, as initiatives like the Invisible Spectrum Program effectively engaged ethnic minority women using bilingual materials and trusted community ambassadors.

Structure and Operation of CUBs

CUBs have at least three functions. They act as advisory boards, identifying barriers to screening and recommending actionable solutions. They provide learning spaces, encouraging mutual understanding between policymakers, healthcare providers, and communities. And finally, they serve as focus groups, collecting qualitative data to inform tailored interventions. A CUB meeting takes place in-person with attendance by two to four stakeholders from macro (policy), meso (practitioner) and micro (community) levels. The number of stakeholders on each level is flexible and must consider power imbalances. In this way, it can be better to have two from the macro level and four from the community level than vice versa. The meeting is held in-person and lasts 1.5–2 hours. Like a focus group session, it follows a topic guide (**see Box 5**)

The CUB meetings can take place several times depending on the topic, thereby functioning, in effect, as advisory boards.

They are designed to align with local structures and contexts, recruiting participants through outreach to community organisations, healthcare institutions, and advocacy groups. Recruitment prioritises the inclusion of marginalised voices, ensuring representation from all levels.

Facilitators play a critical role in setting up CUBs, often engaging trusted community leaders to build credibility and encourage participation. Proactive strategies, including in-person visits and culturally sensitive communication, address recruitment challenges, such as mistrust or logistical barriers.

Each CUB session is carefully structured to foster mutual learning and collaboration. Facilitators, often with social science or public health backgrounds, employ techniques to ensure all voices are heard. This includes breaking large groups into smaller discussions, using culturally appropriate language, and valuing lived experiences alongside professional expertise. These procedures are discussed further in the Estonia and French examples (**see Box 2** and **Box 3**).

Challenges of implementing CUBs

Implementing Collaborative User Boards (CUBs) has revealed several challenges, highlighting the complexities of fostering inclusive participation. One of the most significant obstacles is the presence of power imbalances within the CUBs. Hierarchies often emerged, with healthcare providers or other authority figures inadvertently dominating discussions, which can marginalise the voices of

Box 2: Collaboration with the CUB in Estonia

Collaboration with CUBs in Estonia played a crucial role in the development of the CBIG-SCREEN intervention, ensuring a community-driven and culturally sensitive approach.

Regular meetings and transparent communication through skilled facilitators were key to designing an effective study and recruiting participants. This approach ensured that stakeholders stayed engaged and informed, enabling meaningful collaboration.

CUBs were pivotal in accessing participants. Their trusted community relationships greatly improved recruitment and engagement. Beyond advocacy, they provided insights into cultural sensitivities and potential biases, helping shape a respectful, inclusive approach tailored to community needs.

CUB members also contributed to study documents, ensuring consent forms, information sheets, and questionnaires were accessible, clear, and jargon-free. They participated in pilot testing, identifying issues with comprehension, wording, and sensitivity, which improved the materials' effectiveness.

Throughout the process, CUBs were active and responsive to challenges and opportunities. Macro and meso-level members openly shared perspectives, while micro-level challenges included encouraging participation, addressing hesitancy in smaller towns, and raising awareness about cervical cancer in areas with low screening rates.

The intervention which was then created, in part through this process, aims to improve participation in cervical cancer screening by sending an opt-out self-sampling kit along with the screening invitation letter. The package also includes a questionnaire, a leaflet explaining HPV test result interpretation, and information on the cervical cancer screening pathway. The study population consisted of women living with HIV in a low-participation county. To ensure the materials were appropriate and accessible, representatives from this population were involved in developing and refining the study materials and wording.

Co-creation was essential to the study's success. Incorporating diverse perspectives fostered trust and made the intervention relevant to the target population. Reflecting community input increased acceptance and enhanced the likelihood of developing an effective, culturally appropriate intervention aligned with community needs.

Box 3: CUBs in France

France is a highly centralised country where public health policy, including the organisation of screening programmes, is decided at national level by the General Directorate of Health. The regional structures, which are responsible for operational management, have no power to decide on the adaptation of organised screening programmes. In addition, the organisation, management and monitoring of screening programmes involve several national actors in different roles: the French National Health Authority, the French National Cancer Institute and Santé Publique France.

Time constraints limited recruitment to the Paris area and reduced the intended participant diversity. Although potential stakeholders were identified through the WP2 survey, engagement varied significantly. Macro-level stakeholders were particularly reluctant, often declining participation and citing concerns about impartiality.

Recruiting micro-level stakeholders, through NGOs working with underserved populations, was time-intensive. Many were unresponsive to emails and calls, necessitating repeated phone calls and in-person visits to secure responses. In contrast, meso-level participants were more receptive due to established relationships, which helped balance the recruitment process.

The facilitators, with social science and public health backgrounds, worked effectively together to create a safe space for women to share openly. They clarified roles and anticipated challenges in advance, using humour to ease discussions and limiting their involvement to timekeeping. However, hybrid participation during the second session was challenging, reducing the involvement of some online NGO representatives.

Micro-level stakeholders responded positively, expressing a sense of duty to help improve access to cervical cancer screening for vulnerable women. Macro-level responses were less favourable. While the CUB did not alter the project since France is not an intervention country, it inspired meso- and micro-level discussions on collaboration and influenced meso-level stakeholders to reconsider projects on cervical cancer and care access.

Box 4: Ireland experience of participatory action research to improve access

The Invisible Spectrum programme is an annual engagement initiative designed to improve healthcare accessibility and research participation among ethnic minority communities in Ireland, particularly those of Bangladeshi origin. This programme was developed in response to the traditionally low levels of engagement with healthcare services observed within these communities, aiming to empower them in their healthcare decision-making. Aims of the programme include raising awareness of cancer symptoms, encouraging uptake of cancer screening, improving communication between attendees and the medical/scientific communities and promoting research participation among the attendees.

The programme employs a participatory action research design, which involves community members, activists, and scholars in co-creating knowledge and social change. This approach ensures that the programme is tailored to the specific needs and cultural contexts of the community. A significant aspect of the programme is its reliance on oral communication networks, recognising the importance of "word of mouth" in minority communities. Over four years, the Invisible Spectrum programme has evolved based on feedback from attendees, with each iteration focusing on different thematic areas. The programme includes bilingual materials and live translation to overcome language barriers, and it involves community leaders as ambassadors to build trust and facilitate participation. The programme's success is attributed to its collaborative structure and co-design process, which have strengthened ties with the community and increased engagement. The Invisible Spectrum serves as a model for similar initiatives aiming to enhance minority inclusion in cancer healthcare and research.

Source: [14]

community participants. In France, for example, CUBs faced initial resistance from macro-level stakeholders, such as policymakers, who feared impartiality issues. However, persistent engagement led to productive dialogues with meso-level stakeholders, such as NGOs, resulting in targeted outreach to underserved women (**see Box 3**). Facilitators addressed this by actively encouraging quieter members to share their views and emphasising the unique value of lived experiences to the overall discussion. In Estonia, CUB members provided critical input on consent forms and information sheets, ensuring materials were clear and respectful of cultural sensitivities.

Another challenge lies in the recruitment of vulnerable populations. Engaging these groups required extensive effort, as many were initially distrustful of institutions or unaware of the programme. Persistent outreach, including personalised communication and collaborations with trusted local leaders, proved crucial in overcoming these barriers. Additionally, resource limitations posed difficulties, particularly in hybrid sessions where technological disparities made it challenging for some participants to engage effectively. Bridging these gaps remains a priority for the programme.

Successes of CUBs

Despite these challenges, CUB implementation has achieved significant success. Campaigns co-designed with input from CUB members successfully reduced the stigma around Pap smears, particularly in rural communities, where misconceptions about the procedure had previously hindered participation.

Establishing trust between community members and stakeholders also emerged as a key achievement. Transparent communication and visible action on CUB recommendations fostered a sense of shared ownership, encouraging sustained engagement. Furthermore, insights generated through the CUBs influenced local and national policies, demonstrating the transformative potential of participatory approaches in shaping effective cancer prevention strategies.

Multilevel Engagement: Macro, Meso, and Micro Perspectives

The CUB framework illustrates how engagement can operate effectively across macro, meso, and micro levels. At the macro level, policymakers used insights from CUB discussions to develop broader health policies and allocate resources more effectively. At the meso level, healthcare providers adapted their practices based on direct community feedback, leading to improved service delivery. At the micro level, community members actively designed and implemented interventions, ensuring that these measures were culturally relevant and accessible.

CUBs have facilitated a deeper understanding of the barriers to cervical cancer screening, yielding several critical insights. Open discussions about cervical cancer within these boards helped to destigmatise the topic, empowering women to prioritise their health. The co-creation of culturally tailored materials and outreach strategies ensured that the initiatives resonated with diverse communities, significantly improving their effectiveness. Participants often became advocates within their own networks, amplifying the programme's impact and extending its reach. In this way, CUBs extend beyond traditional meeting spaces, creating dynamic and impactful learning environments

Another powerful example of multilevel engagement comes from Ireland, whose "Invisible Spectrum" programme leveraged a multilevel engagement framework to engage Bangladeshi women, addressing cultural barriers through bilingual materials and live translation services. This multilevel approach enhanced the program's relevance and ensured broader acceptance and participation among the target population (**see Box 4**).

Box 5: Excerpt from a CUB topic guide

- What specific aspects of the (topic) are you particularly **interested in or concerned about?** Why?
- What are your **expectations** for the outcomes of the (topic)?
- What potential **challenges** do you foresee in the implementation of the (topic)? Why?
- How would you prefer to **give/receive information** about the (topic)?
- How can we ensure a **positive experience for patients** in relation to the (topic)?
- Are there considerations or strategies to enhance accessibility for **diverse populations** (vulnerable populations, ethnic minorities, transgender people)
- How can we best **collaborate** to ensure the success of the (topic)?
- What **coordination** mechanisms do you think would enhance the effectiveness of the implementation?
- What specific **resources** (financial, human, technological) do you believe are crucial for the (topic)?
- How can we ensure effective engagement with the **community** during the implementation of the (topic)?
- What strategies do you think would be most effective in **reaching and involving** community members?
- How would you prefer to provide feedback on the ongoing implementation?
- What do you think should be considered for the **long-term sustainability** of the (topic)?
- How can we plan for **continuous** improvement and adaptation based on evolving needs?

Conclusion

The success of CUBs underscores their potential as a cornerstone of cancer prevention strategies. By fostering inclusive, participatory spaces, CUBs address the systemic inequities that hinder cervical cancer screening. Their integration into National Cancer Mission Hubs can promote community engagement as a standard practice, amplifying the voices of people, communities, and civil society in cancer prevention and care. To achieve sustainable change, cancer policies must embrace the principles demonstrated by CUBs. Prioritising patient and community engagement ensures that interventions are not only effective but also equitable, paving the way for a future where no one is left behind in the fight against cancer.

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TRANSFORMING CANCER CARE WITH **PRECISION ONCOLOGY**

By: Yulia Litvinova, Kjetil Taskén, Torben Frøstrup Hansen, Karina Dahl Steffensen, Sander Pajusalu, Tarang Sharma, Anastasia Constantinidou and Dimitra Panteli

Summary: Precision oncology tailors cancer care by considering individual genetic, molecular, lifestyle, and environmental factors. It can enhance prevention, early detection, diagnosis, and treatment through tumour profiling and targeted therapies. Despite its potential, widespread implementation faces challenges like ethical concerns, infrastructure needs, costs, and uneven access. Multidisciplinary teams and robust evidence generation are crucial for effective use. Workforce skills development and innovative reimbursement strategies are essential. Balancing data protection with data use is vital for ethical implementation. Addressing these barriers can enable equitable integration of precision oncology into healthcare systems, improving patient outcomes and care quality.

Keywords: *Precision Medicine, Targeted Therapies, Risk Prediction, Oncology*

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Introduction

Precision oncology tailors medical interventions for individuals by considering their unique genetic, molecular, lifestyle and environmental factors, with the objective of enhancing the effectiveness and safety of their healthcare.[1,2] This model is increasingly being implemented in clinical practice and has the potential to transform the entire cancer care continuum, encompassing primary prevention and risk prediction,[3] early detection,[4] diagnosis and treatment selection based on tumour profiling [5] as well as the use of targeted cancer therapies.[5,6]

The term precision oncology commonly refers to the practice of leveraging the inherent variability of cancer tumours (tumour profiling) to guide more accurate diagnosis and personalised treatment selection. However, using an individual's genetic and molecular profile for primary prevention, risk prediction and early detection of cancer can further optimise clinical outcomes and care. Precision approaches in general entail the molecular, cellular and functional analyses of tumours or the human genome, and rely on legal, regulatory and operational frameworks that enable data and evidence generation essential for these analyses, as well as the reimbursement for related services.

> Equitable access is a key ethical concern

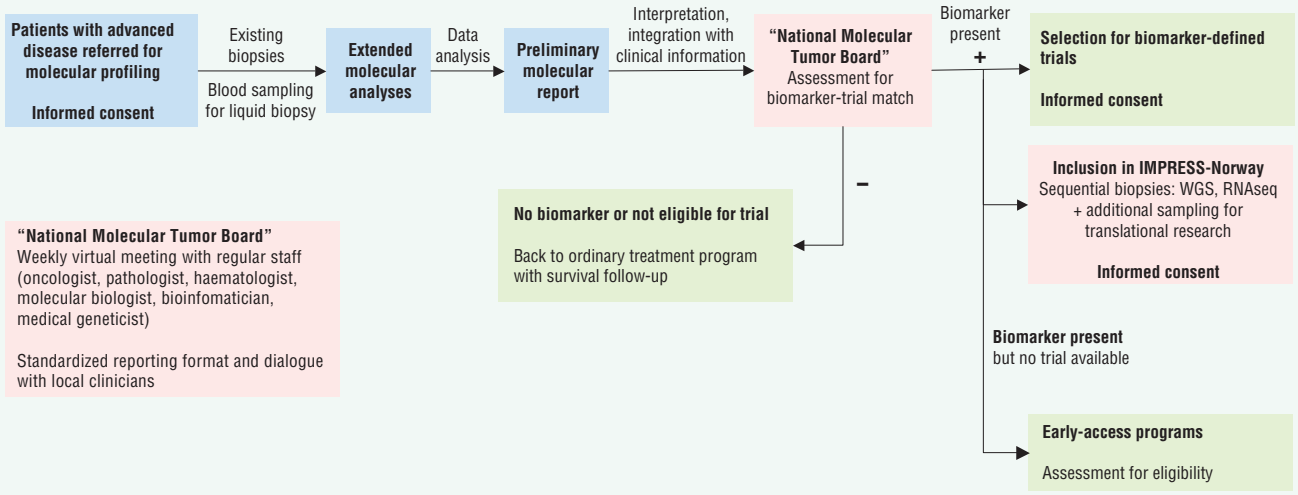
Box 1: Norway aims to achieve equitable access to precision diagnostics by implementing a nationwide infrastructure

Norway has made significant progress in implementing precision oncology in its publicly funded healthcare system, creating a comprehensive framework to ensure equitable access and integration into standard cancer care.

It established the **InPreD-Norway** national infrastructure for precision cancer diagnostics, connecting all six university hospitals nationwide. This system fully reimburses advanced molecular diagnostics, including comprehensive 500-gene panel testing and liquid biopsies for patients with advanced cancer. In addition, a national Molecular Tumour Board (MTB) has been established as an integral part of standard care, bringing together experts in oncology, pathology, haematology, molecular biology and bioinformatics to provide personalised treatment recommendations generated during weekly virtual meetings (**see Figure 1**). As of January 2025, the MTB had evaluated more than 2400 patients, expanding access to experimental therapies and enabling enrolment in precision oncology clinical trials.

Norway's ecosystem also includes **IMPRESS** Norway national intervention precision cancer medicine trial, which strengthens translational research through biobanking, national registries and data generation, while providing critical insights into drug efficacy of 25 drugs, indicated for use based on specific characteristics of the tumour profile. Finally, these publicly funded initiatives are part of the **CONNECT** public-private partnership for precision cancer medicine that comprises over 28 partners (pharmaceutical and biotech companies, public partners and non-governmental organisations) into a broader precision cancer medicine ecosystem. CONNECT is a strategic initiative that fosters collaboration between the public and private sectors by integrating the publicly funded InPreD and IMPRESS initiatives. It serves as a platform for policy discussions involving regulators and payors, addressing key topics such as health economics, reimbursement models, and the regulatory and legal framework.

Figure 1: InPreD allows the diagnosis and assessment of cancer patients where experimental treatment and clinical trial inclusion is an option



Source: adapted from [6]

However, despite numerous initiatives and policies, equitable access to these innovations – both across and within countries – remains uneven and often limited due to various challenges around both availability and affordability. The largescale implementation of precision oncology can be constrained by infrastructure and operational needs and costs, workforce development, evidence generation and regulatory alignment, and ethical and social considerations, all of which must be addressed to ensure its equitable adoption. Balanced investment strategies, where access to promising innovations is carefully weighed against other public health priorities can be challenging to achieve. This article describes developments in precision oncology through the lens of molecular tumour profiling and polygenic risk scores for prevention, and discusses key health system factors around broadening access to these services. The importance of a

patient-centred approach is highlighted. It showcases examples from selected countries, reflecting the activities of the OBS-D&C4Cancer (Dialogues and Comparisons for a Joined-up Approach to Cancer) project (see article by Tille et al. in this issue).

Investment in infrastructure and multidisciplinary teams is essential for the delivery of precision oncology

Tumour profiling involves two key steps: the generation of tumour profiling data and its interpretation to inform clinical decision-making and consequently, select suitable cancer treatment.[7]

To achieve the first step, a robust genetic sequencing and biomolecular diagnostics infrastructure is essential. Next-generation sequencing (NGS) can generate comprehensive tumour profiles to identify actionable mutations or biomarkers that can guide therapy selection or the development of targeted treatments.[7] However, this is resource-intensive and investing in the widespread adoption of such approaches requires robust evidence of their clinical and economic impact. The costs, coupled with competing health priorities, pose challenges for health systems. A holistic approach to ensuring efficient access to high-quality sequencing should not be limited to establishing new testing facilities, but also evaluating the clinical utility and cost-effectiveness of large NGS panels, promoting collaboration between key stakeholders, and ensuring laboratory accreditation and quality control. In addition, for NGS testing it is important to think about secondary data use (in line with existing regulations) to facilitate research and clinical trials thus maximising the benefit of costly diagnostic tests.

The need to interpret these profiles has led to a growing recognition of the importance of multidisciplinary collaboration. In practice, once the tumour profile is available, specialised multidisciplinary teams are needed to interpret the data and decide on treatment options. Such teams, generally called Molecular Tumour Boards (MTBs), have been established in several health systems and they are comprised of oncologists, pathologists, geneticists, bioinformaticians and molecular biologists.[1] The advice provided by MTBs is particularly valuable for patients with advanced or treatment-resistant malignancies who may benefit from molecularly targeted therapies beyond standard treatment options.[1,5,6] Some countries in the European Union are actively moving towards adopting of MTBs as the standard of care for advanced malignancies. For example, Norway established comprehensive genomic profiling with full reimbursement and a national MTB for patients with advanced cancer to enable all to benefit from precision oncology advancements (**see Box 1**).

However, establishing MTBs is only part of the puzzle. There is a clear need to further develop workforce skills for integrating precision medicine into healthcare systems. This would enable clinicians, data scientists, case managers and others to navigate the technical and ethical complexities of precision oncology, engage effectively with patients, and collaborate across disciplines to deliver high-quality, patient-centred treatment and care.[8] Comprehensive training programmes based on competency frameworks that cover specialised areas such as genomics, digital health, data management and ethics, as well as cross-cutting skills such as communication, leadership and collaboration, are essential. Relevant academic curricula would need to be updated to integrate these competencies to equip the future health and care workforce, and specialised programmes in precision medicine (such as the one offered in Cyprus, **see Box 2**) would need to be developed to enable the high-quality application of precision approaches in clinical practice and across the care continuum.

The ethical implications of applying precision approaches beyond diagnosis and treatment require attention

Precision oncology in prevention and early diagnosis has shown success particularly in families with high-risk monogenic genetic variants e.g. in BRCA1 or BRCA2 mutations. When a family history suggests a higher risk for certain cancers (e.g. breast, ovarian and prostate cancers), cascade screening of family members can provide a cost-effective, genetics-based prevention strategy.[3] However, expanding

Box 2: The postgraduate programme at the University of Cyprus Medical School emphasises skills application for care enhancement

The **Master's Programme in "Precision Medicine in Clinical Practice" at** the University of Cyprus was accredited in 2020 and accepted its first cohort in 2021. It provides healthcare professionals and biomedical scientists with specialised training in the cross-disciplinary application of precision medicine in clinical settings.

The programme emphasises core skills in clinical trials, genetics, molecular diagnostics, pharmacology, statistics, analytics and ethics, and focuses on their clinical applications in different medical fields. Its primary goal is to bridge the gap between cutting-edge scientific advances and practical implementation in healthcare and equips students to address key challenges in precision medicine, including ethical considerations, data management and equitable access. By promoting the critical evaluation and implementation of tailored therapeutic strategies, the programme also aims to accelerate the integration of precision medicine into clinical practice, and contribute to improving patient outcomes.

Cyprus, along with other countries such as Austria, Germany, Sweden, and the United Kingdom, is investing in skills and capacity development by promoting educational programs that foster a more holistic approach to applying precision medicine in healthcare service delivery.[9]

Box 3: Estonia's personalised prevention approach

Estonia's first personalised medicine services, to be launched in 2025, will initially focus on breast cancer prevention. It builds on several decades of biobank-based research calculating personal disease risk scores for breast cancer and other common complex diseases.[3,16] The aim is to pilot the integration of genetic risk screening into regular screening programs at the national level. The aim of the PRS-based breast cancer screening approach is to start regular mammography screening at age 40 for women whose personalised risk is assessed to be equal to or higher than an average 50-year-old woman in Estonia – the current starting age for mammography screening. Innovatively, Estonian biobank participants (approximately 20% of adults in Estonia) will receive their personalised risk calculations based on readily available biobank data, while others will undergo a new genotyping assay, which will be analysed in a medical genetics laboratory. Independent of the data source, PRS calculations will be conducted on a centralised infrastructure built into national health information system. Ensuring equal access to precision screening has been a key consideration, to make to service available for everyone in the target group.

population-wide screening for these high-risk monogenic pathogenic variants is challenging due to the high cost of sequencing which is needed for accurate detection. An alternative approach is the use of polygenic risk scores (PRS), which can be calculated from more affordable microarray-based genotyping assays. PRS offer a way to access cancer risk, such as for colorectal and breast cancers,[10,11] at a broader scale. While the risk increase for individuals identified through PRS is more modest compared to the monogenic high-risk variants, the combined contribution of polygenic factors to overall genetic risk in the population has been calculated to exceed the rare monogenic pathogenic variants.[12] This can make PRS a valuable tool for population-level cancer risk prediction and prevention strategies. PRS are being tested in clinical practice (**see Box 3**), aiming to enable the more effective stratification of screening strategies and support the implementation of preventive lifestyle interventions. However, their practical application is complex: successful integration requires combining individual biomarkers with broader health system and behavioural factors, as well as robust shared decision-making (SDM) processes, alongside a high level of literacy by both healthcare professionals and patients.[13,14]

Interpreting results of PRS, tumour profiling, and other advanced analyses in precision oncology requires clear communication and education to ensure these tools are used effectively and ethically within clinical settings, also considering their high psycho-social impact.[14,15] The practice of SDM in Denmark (**see Box 4**) serves as a good practical example of such mechanisms established in clinical practice. This concept has universal applicability in healthcare, particularly in oncology, where decisions are numerous and often revolve around potentially life-changing issues. The complexity of precision oncology makes SDM an essential approach, helping to align patient preferences with the possibilities discussed in MTBs.

Balancing innovation and sustainability in precision oncology calls for new ways of generating evidence and reimbursement

Measuring the effect of new diagnostic or therapeutic approaches in precision oncology requires a certain departure from traditional evidence-generation methods, with clinical trials becoming smaller and focusing on ever more specific patient subgroups. While adaptive trial designs are being piloted, ensuring their reliability and robustness is essential. Master protocols provide an overarching framework for conducting parallel analyses of multiple therapies or disease targets, with the potential to improve both efficiency and standardisation. Several subtypes, for example, platform and basket trials, allow for the incorporation of real-time adjustments that can help address the complexity and smaller sample sizes of precision oncology. Where platform trials are multi-arm, multi-stage designs that compare multiple interventions at the same time using a shared control group, basket trials allow for the evaluation of a single targeted treatment on different diseases that share the same genetic or molecular feature intervention all within a single study master protocol.[2]

Furthermore, the use of real-world data and real-world evidence (RWE) offers valuable insights that complement clinical trials.[2] For instance, by leveraging data from electronic health records and other sources, RWE can help fill gaps in understanding the long-term safety and efficacy of personalised oncology approaches, providing a more complete picture and support reimbursement decisions.

> "further develop workforce skills transformative for cancer care

How these particularities factor into health technology assessment and reimbursement decisions needs to be further explored and developed, including through governance frameworks and knowledge sharing (**see Box 5**). Flexible reimbursement frameworks, such as managed entry agreements or other risk-sharing models, can help balance financial sustainability with patient access to innovative therapies but are not without their challenges.[18] A combination of adaptive evidence generation and innovative reimbursement strategies would be

Box 4: Denmark's effort to implement SDM

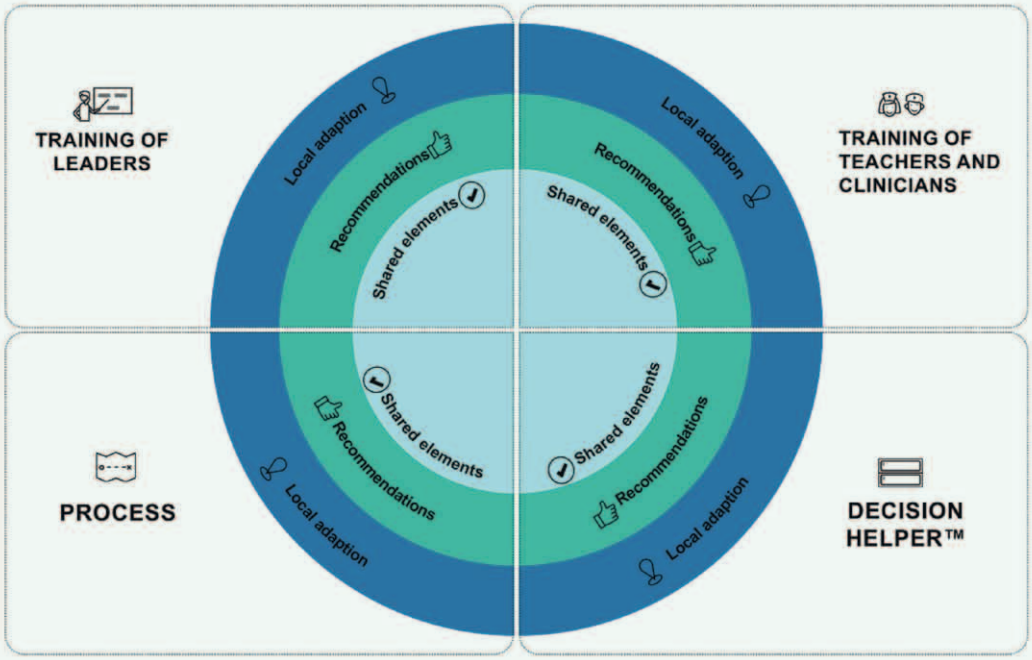
SDM is a collaborative process in which the patient and clinician make decisions about diagnosis, treatment, or care together, using evidence-based knowledge about available options, benefits, risks, and uncertainties to guide the decision-making process. This approach supports the patient in exploring their own values and preferences, ensuring that the best option is chosen according to their priorities.[17]

In 2014, Lillebælt Hospital established a Centre for Shared Decision Making, initially launched as a research-based initiative. The centre has gained extensive expertise in SDM and has developed, tested, and evaluated patient decision aids. Building on the positive outcomes of these test, the Region of Southern Denmark established a regional Center for Shared Decision-Making in 2019 to strengthen the implementation of SDM in all regional hospitals. Its mission is to consolidate knowledge, build competencies, and train healthcare professionals while supporting local hospital departments with a standardised and systematic approach based on research and improvement methodologies. In 2024, the centre became a national **Centre for Shared Decision-Making** to support SDM across Denmark, also in the light of the active developments in the area of innovation and precision medicine.

The centre has developed and uses the **SDM:HOSP model**[13] to facilitate the implementation of SDM in hospitals by focusing on leadership training, education of trainers and clinicians, development of patient decision aids and a structured and clear implementation process. It emphasises both professional skills and leadership understanding of SDM (**see Figure 2**).

In the Region of Southern Denmark, almost 5,000 people have been trained in SDM, including about 300 teachers, 400 leaders and 4,300 clinicians. In addition, more than 80 different patient decision aids have been developed.

Figure 2: In Denmark, SDM is at the heart of ensuring patient-centred care in the complexity of precision oncology



Source: adapted from [13]

needed to support the implementation of precision oncology while taking into account both economic and clinical considerations.[18]

Balancing data protection and data use is a fundamental act in the implementation of precision oncology

The collection of patient samples and associated data for precision oncology requires a clear understanding of their potential uses and benefits, especially since such data may remain valuable over time for technological advancements and the generation of new knowledge in further research. Strong informed consent processes can help ensure patients' rights to privacy and their protection from genetic discrimination, as well as contribute to responsible data management and literacy development for both healthcare professionals and patients.[19] Robust technical and governance frameworks are essential for protecting sensitive cancer-related molecular data.

The World Health Organization (WHO)[20] has outlined key principles for the ethical collection, access, use and sharing of human genomic data (**see Box 5**). These guidelines aim to ensure responsible

Box 5: WHO guidelines on genomic data call for more responsible collection and use, focusing on safeguarding patients' rights

In November 2024, WHO published a set of **Principles for the Ethical Collection, Access, Use and Sharing of Human Genomic Data**, establishing an important framework for ethical genomic research and application. These principles represent a global approach to managing the complex landscape of genetic information, balancing scientific progress with individual rights and societal interests. By prioritising informed consent, privacy and transparent data collection processes, WHO aims to establish a robust international standard that transcends regional differences.

genomic data management, while safeguarding patients' rights and promoting equitable access to the benefits of precision oncology.[20] The ethical use of sensitive data also extends to the risk of not using available data to their full potential. Therefore, policy approaches need to strike a balance between ensuring the highest possible protection while making the best use of available datasets to support access to innovation.

These guidelines recognise human genomic data as a public good, while emphasising the need to respect patient preferences and prior consent, particularly by addressing inequalities that have excluded certain populations from genetic studies. The principles promote inclusive research practices that represent diverse genetic backgrounds, thereby enhancing the scientific validity and societal benefit of genomic investigations. By providing clear guidance, WHO aims to build public trust, facilitate responsible data sharing and support capacity building in regions with limited genomic infrastructure.[20]

Conclusion

Precision oncology aims to harness advances in genomics, molecular diagnostics and data science to tailor cancer prevention, diagnosis and treatment strategies. While it has the potential to transform cancer care, large-scale implementation is often lagging and equitable access is not ensured. Key barriers include high costs, competing healthcare priorities, inadequate infrastructure for advanced diagnostics such as NGS, and workforce capacity limitations with a need for skills development. Technological, evidence and governance frameworks need to be further developed and implemented in practice. Equally important is addressing the ethical, legal and social concerns that affect public confidence and trust in these innovations. To enable equitable implementation, policymakers will need to tackle health inequalities, design innovative reimbursement strategies, and prioritise the sustainable integration of precision oncology into healthcare systems.

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