GOVERNMENT GAZETTE

A CALL TO ACTION FOR HEALTHCARE

LUNG CANCER

PROSTATE CANCER

BREAST CANCER

HIV

GOVERNMENT GAZETTE

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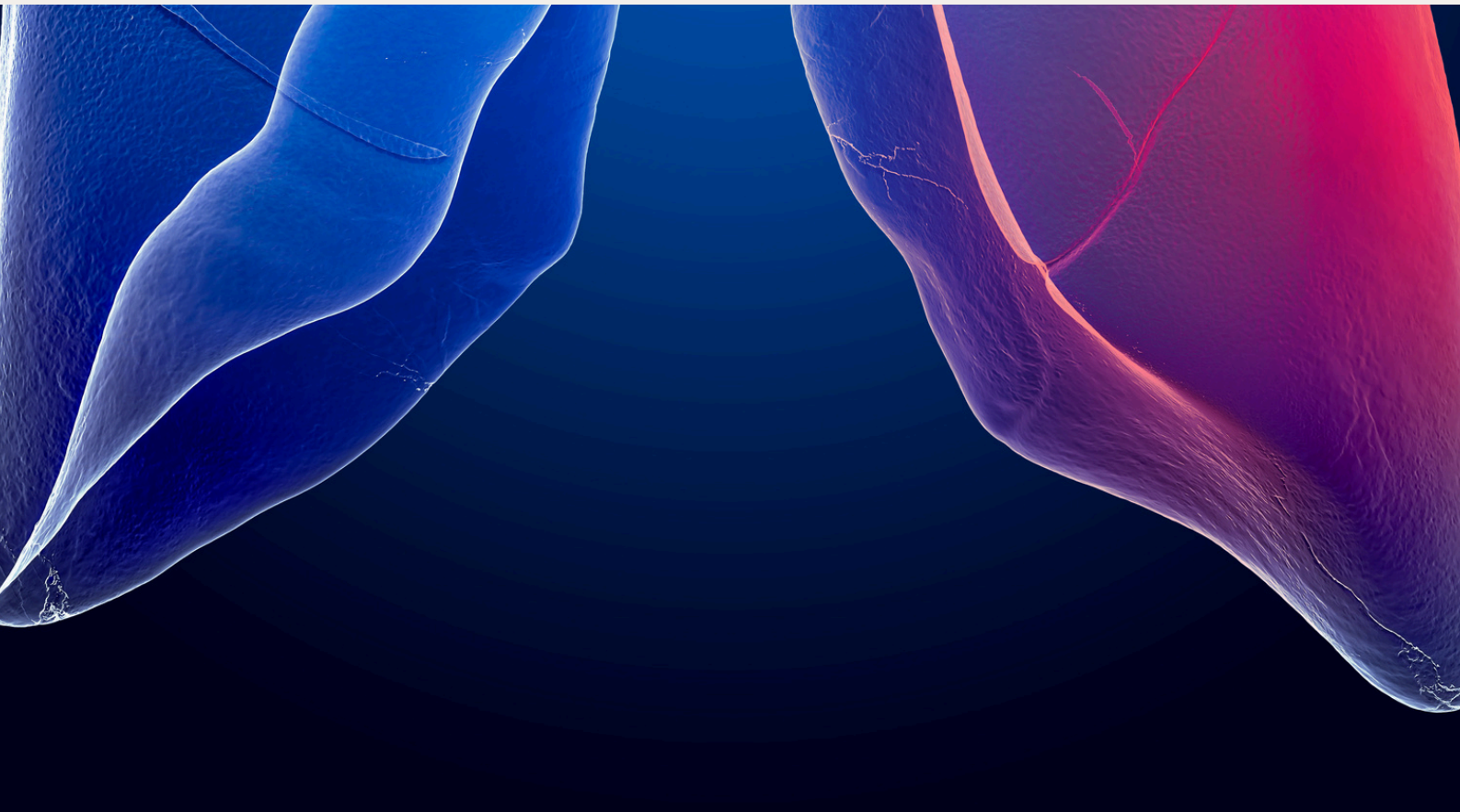


Lung Cancer Report

By Shivani Gupta Churiwala, International Centre for Parliamentary Studies

The State We Are In

Lung cancer is the most commonly diagnosed cancer and the leading cause of cancer-related mortality globally. According to the World Health Organization (WHO), there were approximately 2.2 million new lung cancer cases and 1.8 million deaths in 2020. This accounts for about 18% of all cancer deaths, making lung cancer more deadly than breast, colorectal, and prostate cancers combined. In Europe, lung cancer is the leading cause of cancer-related deaths in the region. It accounted for approximately 19.8% of all cancer deaths in the European Union in 2020, making it a critical public health concern. It is therefore pertinent to tackle the persisting gaps and missed opportunities in the EU battle against lung cancer. The basis for such an action lies in an objective and factual assessment of the situation. Smoking remains the most significant risk factor for lung cancer, although non-smokers can also develop the disease due to factors such as exposure to second hand smoke, air pollution, and occupational hazards. Ethnic and socioeconomic disparities also play a role, with higher incidence and mortality rates observed in more deprived areas. While less common, genetic predispositions can also contribute to lung cancer development.

Despite significant advancements in treatment pathways, there are clear inequalities in access to rapid diagnosis and treatments across Europe. While there are several good lung cancer services across the continent, wide variations in healthcare systems have resulted in inequalities in multidisciplinary care. This report aims to examine Europe's preparedness, assess current policy guidelines and schemes, explore new ways to improve prevention, diagnosis and treatment and discover practical solutions to build comprehensive prevention plans and ensure that effective measures, policies, and interventions would be in place.

Lung Cancer in Europe: At a Glance

- Lung cancer accounted for 19.8% of all cancer-related deaths in the European Union (EU) in 2020, making it the leading cause of cancer death in the region.
- In 2020, approximately 230,700 people died from lung cancer in the EU, representing 4.5% of all deaths.
- The age-standardised death rate for lung cancer in the EU was 48.4 per 100,000 inhabitants, with a higher rate for males (72.9 per 100,000) compared to females (29.6 per 100,000).
- Many EU countries have integrated lung cancer initiatives within broader cancer control plans, although specific national plans for lung cancer are less commonly reported.
- Despite efforts to control smoking, lung cancer incidence remains high, particularly among men, although the gender gap is narrowing as smoking rates among women have increased in some countries. This indicates a need for more targeted prevention strategies.
- The EU's Cancer Screening Scheme aims to enhance early detection through updated screening recommendations, but progress is varied.

Lung Cancer Report

By Shivani Gupta Churiwala, International Centre for Parliamentary Studies

Reformulating the European approach to managing lung cancer

Lung cancer is one of the most frequently diagnosed cancers in Europe. In 2020, it accounted for approximately 11.9% of all new cancer diagnoses and nearly a quarter of a million people died from lung cancer in the EU. Lung cancer therefore remains a significant health challenge within the European Union.

The treatment landscape for lung cancer has evolved with advancements in molecular diagnostics and targeted therapies. Non-small cell lung cancer (NSCLC), the most common type, can be treated with surgery, chemotherapy, radiation, targeted therapy, and immunotherapy. These treatments aim not only to extend life but also to improve the quality of life by reducing side effects. However, access to these advanced therapies remains uneven across Europe, highlighting the need for equitable healthcare policies.

It is well recognised that lung cancer is often diagnosed late, which means that fewer treatment options are available for people impacted by the advanced disease. Early detection through screening is therefore crucial for improving lung cancer outcomes.

Screening programmes, particularly those using low-dose computed tomography (CT), have the potential to detect lung cancer at an earlier stage when it is more treatable. However, the implementation of such programmes varies across Europe.

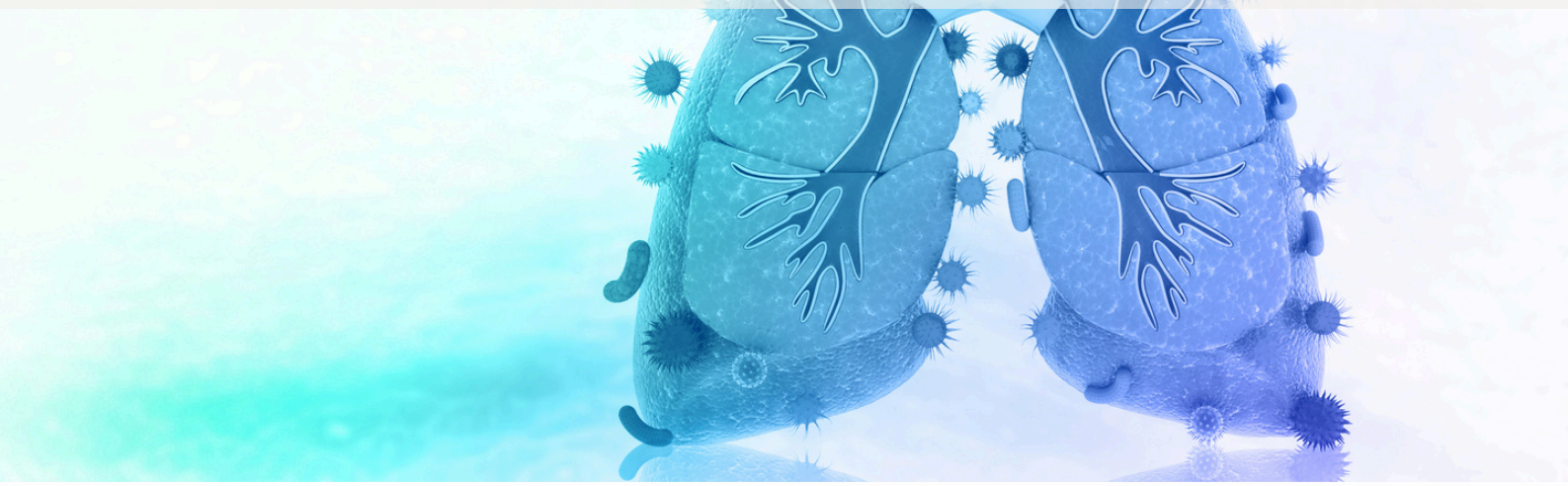
Advocacy plays a vital role in addressing lung cancer, particularly in overcoming the stigma associated with the disease due to its strong link with smoking. Advocacy efforts can be instrumental in setting research priorities and improving access to information and resources across different languages and regions in Europe.

Thus lung cancer remains a formidable challenge in Europe, with high incidence and mortality rates. While significant progress has been made in treatment and advocacy, further efforts are needed to ensure equitable access to care and to implement effective screening programs across the region. Addressing these challenges requires a concerted effort from policymakers, healthcare providers, and advocacy groups to improve outcomes for all individuals affected by lung cancer. In order to achieve this the International Centre for Parliamentary Studies brought together eminent parliamentarians, healthcare professionals, academic experts and industry stakeholders in a high-level policy roundtable on November 28th 2023 in Brussels, Belgium.

"Lung cancer is the most commonly diagnosed cancer and the leading cause of cancer-related mortality globally, accounting for about 18% of all cancer deaths, making it more deadly than breast, colorectal, and prostate cancers combined."

Impact of artificial intelligence on lung cancer screening

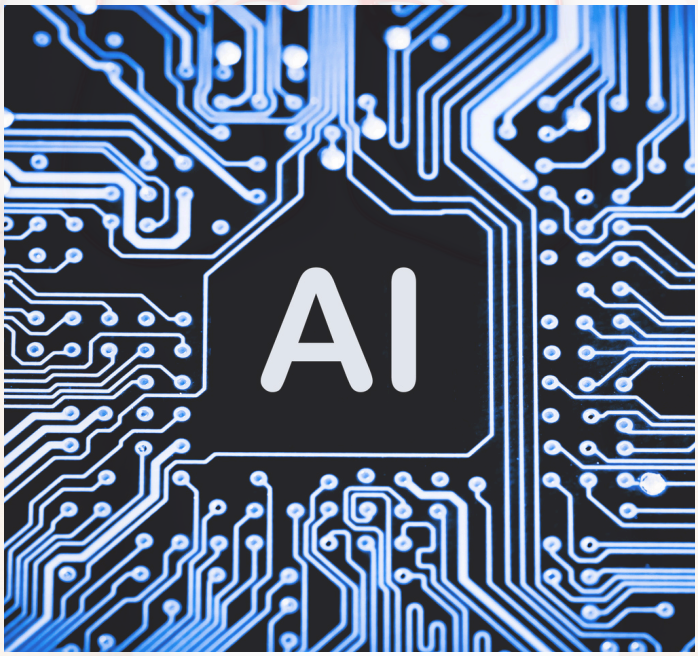
By Prof. Dr. Matthijs Oudkerk, University of Groningen for The Lung Cancer Group Cologne (LCGC)



Lung cancer screening using low-dose computed tomography (LDCT) has commenced in several European countries, and implementation trials are underway in others. Whilst screening promises to reduce lung cancer mortality, it is also guaranteed to produce an increased workload for radiologists who are needed to analyse all participant LDCT images. The current shortfall in trained radiologists, together with the impending increase in workload, will hinder large-scale implementation and reduce accessibility to all those who could benefit. Artificial intelligence (AI) has therefore been proposed as the solution and is considered pivotal to successful implementation.

AI is not a new concept in the field of medical imaging, the number of algorithms being developed has increased exponentially. For lung nodule detection on CT images, there are already a large number commercially available AI software. The majority of AI software has been developed to help improve the accuracy of radiologists, identifying small lung nodules in the periphery of the lung which were often missed by the human eye. Software of this kind is often used by the radiologist as an assistant in clinical practice but has limited impact on workload reduction in a large-scale lung cancer screening setting. A subsequent development of AI software was to incorporated nodule classification and malignancy risk calculators, such as the BROCK model, to rule-in lung nodules with a high risk of being a lung cancer for further work-up. This rule-in approach, separating malignant from benign lung nodules, has raised concerns regarding the number of false-positive results produced which could ultimately lead to overdiagnosis or overtreatment, and counter wise will increase workload of the radiologists. Likewise, as the number of nodules with a high-risk of malignancy requiring immediate referral are relatively limited in a lung cancer screening program, impact on workload reduction would again be restricted.

A major breakthrough for workload reduction would be the use of AI as a first reader to rule-out any individual negative cases where there are no nodules or only small nodules detected. The percentage of these cases varies per lung cancer screening population; however, it is generally in the region of 65-80%. Lung cancer risk in solid component nodules smaller than 100mm3 is negligible, meaning individuals with such nodules can safely be proceed to the next screening round. Therefore, if an AI software can safely rule-out negative cases, radiologists would only need to review approximately 20-35% of indeterminate or positive cases with larger nodules, to determine the appropriate nodule management strategy. This rule-out approach relies predominantly on achieving a very low false-negative rate, as the radiologist would not review any scans which the AI deemed negative.

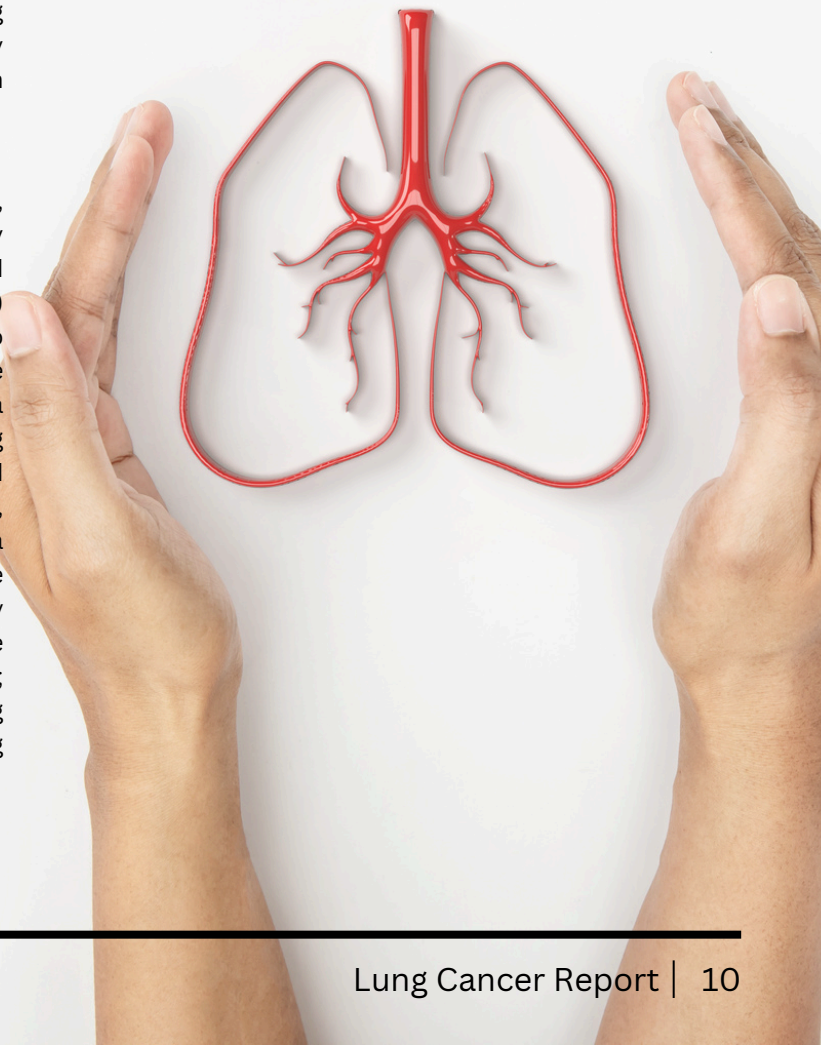


Impact of artificial intelligence on lung cancer screening

By Prof. Dr. Matthijs Oudkerk, University of Groningen for The Lung Cancer Group Cologne (LCGC)

Implementation of AI as first-reader using a rule-out approach is the optimal way to reduce workload, however there is still a long way to go before it can be implemented into standard lung cancer screening practice. To date, no medical imaging software, for any imaging modality or disease, has been approved for use as a rule-out device. In order to gain approval, the first step is extensive, rigorous validation. Most training and validation of AI algorithms for use in lung cancer screening have used imaging datasets from open-source online imaging archives such as the Lung Image Database Consortium (LIDC). Although the use of such open-source datasets has led to rapid progression of AI software, performance results should be interpreted with caution due to the significantly increased risk of bias due to overtraining. Additionally, images available are highly heterogeneous in terms of image acquisition parameters, image quality, lung nodule annotations, and clinical reason for imaging request, which could influence reproducibility of performance in a lung cancer screening setting. External validation of any AI software should be performed in a standardised, independent manner, using high-quality, sequestered, lung cancer screening datasets which have not been used previously for training or internal validation of the software. An international effort is required to provided large opensource, standardised, and representative lung cancer screening imaging datasets for AI training, with sequestered trustworthy datasets being reserved for external validation by an independent group.

"Artificial intelligence (AI) is considered pivotal to the successful implementation of large-scale lung cancer screening, promising to reduce the workload for radiologists and improve accessibility for all those who could benefit."



An AI software for lung nodule, detection, segmentation, and classification is currently being prospectively validated, on a large-scale, in the ongoing EU-funded European multicentre 4-In-The-Lung-Run (4ITLR) implementation trial. This unique study is the first to prospectively evaluate the performance of an AI software when used as a concurrent reader, independent from a radiologist, to analyse LDCT images during a screening trial. Further, once completed, the LDCT imaging and participant outcome data will provide a high-quality, standardised, trustworthy dataset for AI validation as a first-reader. Alongside, AI uses for lung nodules, the same software shows potential for detecting coronary artery calcium and emphysema scoring. This would enable the simultaneous screening of the Big-3 thoracic diseases; lung cancer, COPD and coronary artery disease, reducing morbidity and mortality associated with these smoking related diseases.

Lung cancer screening - the point view of a pneumo-oncologist

By Dr. Lonela Bold, Pneumologist & thoracic oncologist for UMC Sint-Pieter - CHU Saint-Pierre

In EU, breast cancer remains the most diagnosed cancer, with an estimated 380,000 cases (99% of these affecting women) which constitutes some 13.8% of all cancer diagnoses. This is followed by colorectal (356,000; 13% of all new cases), prostate (330,000; 12.1%) and lung cancer (319,000; 11.6%) (1).

The latest accounted for 328,327 cases in 2020 (2/3 in men and 1/3 in women), with a mortality of around 257,293 deaths per year (2).

Incidence is also rising in women, due to the social trend towards smoking among women. While smoking is the main risk factor (around 80%), there are other multiple risk factors such as: environmental exposures (e.g. radon), air pollution (diesel exhaust fumes, particulate matter), occupational exposures (asbestos) and low- vegetable diet.

Genetic predisposition increases the risk of bronchial cancer, even in non-smokers (e.g. EGFR gene mutation).
Several randomized trials have demonstrated that low-dose chest CT screening reduces lung cancer mortality. In 2011, the US NLST randomized trial achieved its primary objective, demonstrating a significant reduction in all-cause mortality of 6.7%, which is exceptional high for a screening trial.

Low-dose thoracic CT screening is now recommended by scientific societies, and many countries are beginning to organize lung cancer screening (3).

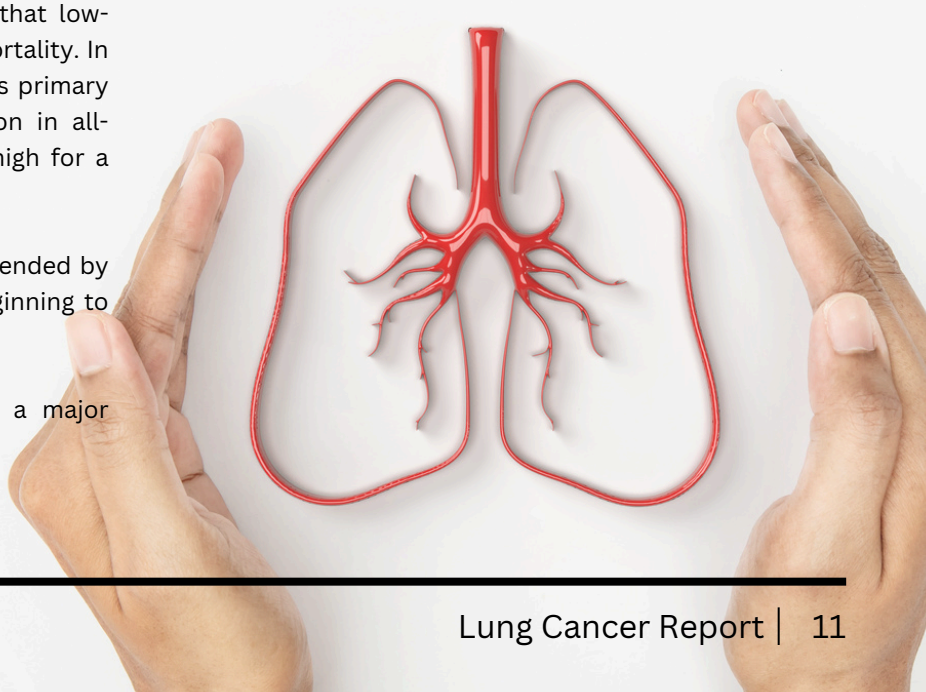
The European NELSON study has also made a major contribution to this field (4).

Combating tabaco also plays an important role, and the weaning methods to be proposed during screening still need to be defined by randomized controlled studies (5).

The literature provides a wealth of data on population eligibility criteria, CT scan modalities and explore also the role of biomarkers (6).

Better targeting of the screened population is likely to increase the cost-effectiveness of screening.

The PLCO m2021 model is the best-known of these risk models. It considers 11 predictive criteria (age, ethnic origin, level of education, BMI, history of chronic obstructive bronchitis, personal history of cancer, family history of lung cancer, smoking status, intensity and duration of smoking and duration of cessation in the case of former smokers).His impact on the number of incident cancers and life expectancy has been compared with standard American criteria (USPSTF 2013) in a prospective trial, the International Lung Screening Trials (ILST) (7).



Lung cancer screening - the point view of a pneumo-oncologist

By Dr. Lonela Bold, Pneumologist & thoracic oncologist for UMC Sint-Pieter - CHU Saint-Pierre

This study demonstrated that the PLCO m2012 model was able to detect more cancers (162 cancers instead of 135). The improvement of thoracic CT scanning is off course a major topic in terms of prospects. For example, innovations that make it possible to reduce the radiation dose delivered without compromising reading quality, as well as the contribution of artificial intelligence, particularly for reading and interpreting examinations. A recent study showed that artificial intelligence could do as well as, or even better (in the presence of previous scans) than, radiologists in predicting lung cancer risk (8).

Although promising, the role of artificial intelligence in this indication remains to be assessed, and further studies are required. Far from being a static process, screening is an extremely active area of research and innovation. It is also a missing link in the drive to significantly improve lung cancer mortality and will undoubtedly be a new focus for our discipline.

New trials assess the feasibility of a nationwide screening in Europe is necessary and addressed major questions such as the role of biomarkers (lack of means, no established care pathway, costs, management of false negative) optimization of eligible population selection and the contribution of artificial intelligence.

"Screening is an extremely active area of research and innovation; it is also a missing link in the drive to significantly improve lung cancer mortality and will undoubtedly be a new focus for our discipline.

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Successes in lung cancer screening can benefit all of Europe

By Helena Wilcox and Eleanor Wheeler for Lung Cancer Policy Network

LUNG CANCER POLICY NETWORK

Lung cancer screening implementation in Europe is gaining pace. Since the first national programme was initiated in 2020 in Croatia, a further ten countries have either implemented, or committed to implementing, lung cancer screening.1 In 2022, the EU Council recommendations on cancer screening were revised to include lung cancer – a move that was welcomed by the Lung Cancer Policy Network and the wider global lung cancer community.2 3 These recommendations, as well as the commitments in Europe's Beating Cancer Plan, continue to support earlier detection and improve care of lung cancer.4 Despite these commitments in the EU, however, the benefits of earlier detection have not yet been fully realised. To do so needs immediate and concerted attention at the policy level.

Lung cancer is the leading cause of cancer death in Europe, causing nearly 250,000 deaths in 2020.5 It is common knowledge that smoking is a key risk factor, but up to one in four cases occur in people who have never smoked.6 Other factors or characteristics that affect someone's risk of developing lung cancer include age, exposure to indoor and outdoor air pollution, ethnicity, socioeconomic position and other health conditions.7 8

Detecting lung cancer earlier

Detecting lung cancer at an early stage (stage I or II) means that treatment options are more extensive, and potentially curative.9 10 The five-year survival when lung cancer is diagnosed at an early stage can be as high as 92%, compared with just 10% at a later stage.11-13 Unfortunately, most lung cancer is detected at stage III or IV.13 At earlier stages, symptoms may be minimal or similar to other respiratory conditions, which contributes to challenges in timely diagnosis.14

The most effective way to screen for lung cancer is via low-dose computed tomography (LDCT).15 This is a safe and effective tool to screening high-risk individuals and can reduce mortality by up to 25%.15

LDCT screening is considered an economical investment for health systems, and its cost-effectiveness compares well with other population-based screening strategies.16-21 Screening programmes are most cost-effective when they target people with the highest risk of the lung cancer (often people from socioeconomically disadvantaged and underserved groups)22, with eligibility criteria adapted according to the local risk profile.21 Targeted screening must be designed to facilitate uptake from those at greatest risk to ensure that programmes are implemented equitably.23 24

Implementing screening programmes for lung cancer

It is vital that knowledge is shared to optimise future screening activity; there is a wealth of evidence and examples to support implementation in countries where screening is in its infancy. Projects such as 'Strengthening the screening of Lung Cancer in Europe' (SOLACE) are facilitating implementation by exploring the feasibility and effectiveness of programmes.25 A critical component of SOLACE, and also a focus of the Lung Cancer Policy Network, is making sure programmes are designed in an equitable way and consider everyone at highest risk of the disease.

It is also critical that the lung cancer community collaborates as part of broader agenda for lung and respiratory health. Many of the risk factors for – and populations affected by – lung cancer are common with chronic respiratory diseases.26 We must proactively and collectively address these shared challenges through ensuring sufficient prioritisation and investment in research and policy.

Successes in lung cancer screening can benefit all of Europe

By Helena Wilcox and Eleanor Wheeler for Lung Cancer Policy Network

We urge the European cancer community to collaborate to accelerate the implementation screening programmes for lung cancer, leaning on the expertise and evidence that has been generated through other initiatives in the region. Policy commitments, including the EU Council screening recommendations, must be coupled with funding commitments and action on implementation. Initiatives such as the anticipated International Agency for Research on Cancer's Handbook for Cancer Prevention: Lung Cancer Screening will also deliver a robust framework to advance screening implementation globally.27 The Lung Cancer Policy Network will continue to support this progress through evidence-informed and consensus-driven policy. We stand as part of the European and global cancer community to drive action to ensure everyone with lung cancer has the best chance of survival.

The Lung Cancer Policy Network, through its members, has designed a practical implementation toolkit to guide for the planning and delivery of screening programmes.
The Lung Cancer Policy Network is a global multi-stakeholder initiative set up by the Lung Ambition Alliance. The Network is funded by AstraZeneca, Bristol Myers Squibb Foundation, Guardant Health, Intuitive, Johnson & Johnson, MSD and Siemens Healthineers. Secretariat is provided by The Health Policy Partnership, an independent health research and policy consultancy. All Network outputs are non-promotional, evidence based and shaped by the members, who provide their time for free.

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Pfizer health report on lung cancer

By Pfizer Inc.

Cancer is one of the most challenging health crises of our lifetime. Despite significant advancements, millions of people globally receive a cancer diagnosis each year. Lung cancer is a major burden in Europe, with around 230 700 deaths in the EU in 2020, accounting for almost one fifth of all cancer deaths and 4.5 % of total deaths[1].

At Pfizer, we are committed to delivering breakthroughs that change patients' lives. Our vision is a world where people with cancer live better and longer lives. We are accelerating the development of breakthrough cancer medicines that bring new hope to patients everywhere.

A holistic approach to lung cancer is essential to improve disease outcomes for patients. This includes a strong focus prevention, early diagnosis, treatment, and quality of life improvements. Lung cancer patients face specific challenges around treatment adherence and burden. Proactive therapy management and immediate interventions are needed to preserve patient tolerability and clinical benefit, and ensure patients have the support to complete their treatments. Recognizing the value of incremental innovation and focusing on the effectiveness of treatments beyond just overall survival, including quality of life, is essential.

Continued political momentum and adequate funding to tackle lung cancer, at both EU and Member States levels, are also necessary. The introduction of Europe's Beating Cancer Plan is a strong political signal that has led to encouraging developments, for example the updated EU Council recommendations on Cancer Screening, which recommend expanding screening programs for lung cancer[1]. However, while the Beating Cancer Plan is a good roadmap, there needs to be concrete action and implementation in Member States. National cancer control plans in all Member States should incorporate the measures and recommendations introduced under Europe's Beating Cancer Plan and put in place transparent monitoring of progress.

To continue bringing breakthroughs to patients, we need a European legislative framework that fosters innovation and provides faster access to novel treatments. Pfizer is making significant investments to drive the next wave of potential breakthroughs, with approximately 40% of all our R&D investment directed towards Oncology. A predictable and robust framework for research and development (R&D), clinical trials, and innovation will help advance oncology care, including for lung cancer. This includes striking the right balance between evidence generation and assessment and fostering the use of oncology-relevant endpoints in Health Technology Assessment (HTA) decision-making.

Significant disparities in cancer care and access to treatment exist between and within European countries, including in access to screening, biomarker testing, availability of medicines, and supporting infrastructure, resulting in unequal standards of care and disparities in outcomes. Many patients in Europe face delays or barriers in accessing innovative oncology treatments. On average, people with cancer need to wait more than 1.5 years to access an oncology treatment after marketing authorization is granted in the EU, ranging from 93 days in Germany to 828 days in Romania.[1] Policymakers, industry and regulators need to work together to address these unacceptable inequalities and ensure patients, no matter where they live, can get the treatments they need.
Finally, empowering lung cancer patients is key, including through improving health literacy and working towards health equity. Much remains to be done at EU and Member States level, and we stand ready to partner with policymakers and contribute our expertise to improve outcomes for lung cancer patients.

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Breast Cancer Report

Policy Recommendations

Future of breast cancer care in Europe

By Dr. Didier Verhoeven, AZ Klina; Prof. Dr. Kerstin Sandelin, Karolinska University Hospital and Dr. Agnes Jager, Erasmus MC

Breast cancer care is a costly global health issue where efficacy depends on the possibility of early detection and availability of treatment options. A breast cancer diagnosis may for the individual patient imply an insurmountable financial burden especially in low and middle-income countries. Inequities in breast cancer care are also observed in Europe and should be prevented.

Prevention and personalized screening: “The way to go”

Awareness-education and primary prevention, including lifestyle changes, are responsible and effective measures to prevent the development of breast cancer from a health economic point of view. For example , both high alcohol consumption and high body mass index (BMI) are associated with an increased risk of breast cancer.

While overviews confirm the effectiveness of mammography screening and thus remain cornerstones in national and international guidelines, questions are occasionally raised about efficacy and effectiveness. Quality control and quality management are of paramount importance to achieve and maintain a positive balance between positive and negative effects of screening programs. Furthermore, the most reliable early indicator of the efficacy of a screening program is the reduction of the incidence of advanced stage cancers in the population offered screening and thereby improving survival. With the increasing sensitivity of screening methods, more very small, often indolent tumors will be detected that do not contribute to survival but give rise to much overdiagnosis and unnecessary treatment. Therefore, the introduction of personalized screening is now being tested with the aim of further improving this balance by preventing overdiagnosis but also improve identifying early aggressive cases and selecting patients with higher risk than the general population.

Encourage independent education

To help improve quality of breast cancer care globally, the development and use of easy available, non-pharma sponsored, educational programs for medical oncologists and specialized nurses should be encouraged. In collaboration with eCANCER (ecancer.org) freely available, high profile educational webinars: “Grand Rounds in Breast cancer series” have been created. These webinars as example promote peer to peer discussions about high-quality breast cancer care.

Treatment: “doing more with less”

Societal health care expenditures, of which a considerable part is due to breast cancer care, are rising to levels that may not be sustainable in the future. The treatment of cancer causes high costs both within and outside the health care system, especially due to the rising cost of cancer drugs, along with the growing incidence. Economic evaluations of new and existing therapies can be used to inform budget allocations in a way that maximizes health outcomes and broader value to the patient. Personalized care, defined as better selection of those patients getting most advantage of treatment can offer more value for patients and at the same time provide value for money. Current clinical practice guidelines should adhere to this concept of personalized approach, acknowledging the patient’s voice, as well as the cost to society of therapy.

Future of breast cancer care in Europe

By Dr. Didier Verhoeven, AZ Klina; Prof. Dr. Kerstin Sandelin, Karolinska University Hospital and Dr. Agnes Jager, Erasmus MC

Value-based breast cancer care

Integrated practice units with timely conferences with a dedicated multidisciplinary breast cancer team and patient navigators (breast nurses) are required to achieve high value, personalized breast cancer management in the European Union. Evaluation of breast cancer outcomes must include the financial cost of delivered care. The resulting value perspective should guide resource allocation and program priorities.

Health executives, policymakers, clinicians, and patient advocates must collaborate to design and implement comprehensive breast care services, encompassing the full cycle of breast health from the asymptomatic individual presenting for screening through diagnosis, treatment, supportive care, survivorship phase and end-of-life for breast cancer patients. Such initiatives are necessary to address challenges and implement opportunities to improve the value of breast care across diverse geopolitical and socio-economic environments.

Focus on patient-centered research

The “minimal effective dose” should replace the old paradigm of “maximum tolerated dose” and become the golden standard.

Breast cancer survival and quality of life should be defined as most relevant endpoints. Surrogate endpoints as DFS (disease free survival) are many times not leading after approval of the medication to a better survival. In the adjuvant setting, invasive disease-free survival (iDFS) can temporarily serve as a surrogate endpoint provided survival gain is also demonstrated at some point. The time frame to provide this evidence will depend on the breast cancer subtype.

Patient reported outcome measures will be pivotal for following the plethora of adjuvant treatments now available for breast cancer patients.
The use of a complete pathologic response after neo-adjuvant treatment could also provide a way to shorten the use of expensive and toxic adjuvant medication.

A more intelligent selection of the use of new treatments must provide less toxicity at a lower cost as recently proven by the SONIA trial (use of CDK4/6 inhibitors in second instead of first line metastatic breast cancer).

"Breast cancer care is a costly global health issue where efficacy depends on early detection and equitable access to treatment options, yet inequities persist and must be addressed."

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Enhancing Breast Cancer Research and Care

By Dr. Christine Desmedt, Assistant Professor at the Katholieke Universiteit Leuven

1) Multi-disciplinary attention and recognition of ILC:

- 15% of breast cancers (NOT RARE); often grows without disturbing architecture of the organ.
- need for better and more homogenized path and imaging diagnosis.
- Role of imaging: need for better staging and monitoring disease via imaging.
- need to specific follow-up (dormancy) and treatment (different biology but unknow if current drug work equally well or not since ILC is not reported, also need to test different ILC specific therapies)
- -better information and communication needed.

2) Trying to advocate for all new trials to be developed:

- having additional data (BMI, histology, ...) to be always reported in trials.
- having always an endpoint on QoL
- request on ICF for data and samples to be used for retrospective research (re precision medicine)

3) More focus on impact of BMI (adiposity) on BC biology, treatment efficacy (and make sure that BMI is reported in clinical trials).

More focus as well on lifestyle intervention in patients with cancer not only after treatment but also during active treatment.

4) Revigorate concept of personalized medicine given large number of drugs that have come to the market and are being clinically investigated for pts with BC

- understand if we can predict which pts will experience side-effects
- research to understand if we can predict which patients will and will NOT benefit from a given treatment
- research to understand acquired treatment resistance mechanism (arising after treatment has been given).
- do this through collaborative research with pharma on retrospective analyses on trial data and samples and using real-world data.
- discuss and recognize challenges of companion diagnostics (re PD-L1 IHC);

5) involvement of patient advocates at all stages

- Co-creation process of research and trials needed, not only reviewing protocols and ICFs at the end.
- Education of patient advocates needed.
- Remuneration of patient advocates (as done for example in CRUK Grand Challenges projects).
- Find solution to language issue related to fragmentation of Europe.

Advancing Breast Cancer Screening: Embracing AI and Risk-Stratified Approaches

By Dr. Fredrik Strand, MSc MD PhD, Karolinska Institutet, Stockholm, Sweden

Breast cancer screening programs, which have traditionally relied on mammography, must evolve to address the significant limitations of a uniform approach, especially for women with dense breast tissue. Dense tissue increases both cancer risk and the likelihood that cancers will be missed in mammograms, leading to aggressive interval cancers that arise between scheduled screenings. The recent ScreenTrustMRI trial conducted at the Karolinska University Hospital, which utilized the AI tool AISmartDensity, demonstrated the power of AI in risk-stratified screening, offering a path to improved outcomes and reduced healthcare costs.

The Challenge of Dense Breast Tissue

Women with dense breasts are at a distinct disadvantage under current mammography-based screening programs. Mammograms have reduced sensitivity for dense breast tissue, leading to missed cancers and more interval cancers, which tend to be more aggressive. Approximately 30% of breast cancers in screened women fall into this category. While the U.S. has taken steps by requiring that women be informed if they have dense breasts, Europe has not widely adopted such practices. The lack of entrenched density legislation actually presents an opportunity for Europe to move directly toward AI-based risk models like AISmartDensity, which provide more actionable and individualized risk assessments.

ScreenTrustMRI Trial: AI-Driven Precision

The ScreenTrustMRI trial used AISmartDensity to identify women at high risk of undetected cancer after negative mammograms. With this tool, the trial achieved a cancer detection rate of 64.4 cancers per 1,000 MRI exams—almost four times higher than traditional density selection methods used in, for example, the DENSE trial from the Netherlands. Importantly, most cancers detected thanks to AISmartDensity were smaller but invasive, meaning they were caught at an earlier, more treatable stage. This shows that AI-driven risk stratification can focus limited resources for supplemental imaging, whether with MRI or contrast-enhanced mammography, on those most at risk.

Reducing Costs with Early Detection

Earlier cancer detection not only saves lives but also reduces treatment costs. Late-stage cancer treatments—such as extensive surgery, chemotherapy, and radiation—are far more expensive and taxing on healthcare systems compared to early-stage treatments. By catching cancers earlier, AI-based risk stratification may reduce the need for these costly interventions. Moreover, women whose cancers are detected earlier have better survival rates, further decreasing the long-term healthcare burden.

Ethical Considerations: Women Expect Action

A key ethical issue emerges in the context of risk stratification: now that we can identify women at high risk of having undetected cancer, it becomes unacceptable to do nothing. Women who participate in screening expect that if they are flagged as high risk, proactive steps will be taken to protect their health. The AISmartDensity tool provides the means to identify these individuals, and leaving this knowledge unacted upon would undermine the trust in screening programs. Policymakers must ensure that existing precision medicine tools are used to identify high-risk women whose cancer is likely to be detected by supplemental screening.

Advancing Breast Cancer Screening: Embracing AI and Risk-Stratified Approaches

By Dr. Fredrik Strand, MSc MD PhD, Karolinska Institutet, Stockholm, Sweden

Europe's Opportunity: Moving Beyond Density Reporting

Unlike the U.S., where the FDA mandates that women are informed about dense breast tissue, European countries have an opportunity to leapfrog traditional density-based models and adopt AI-driven risk assessments like AISmartDensity. These AI tools provide a more comprehensive evaluation of breast cancer risk, enabling more targeted screening. However, to ensure the reliability of these AI models, a standardized evaluation process is crucial. Establishing a common dataset for testing different AI models would allow for consistent risk stratification thresholds and ensure that the tools work effectively across diverse populations.

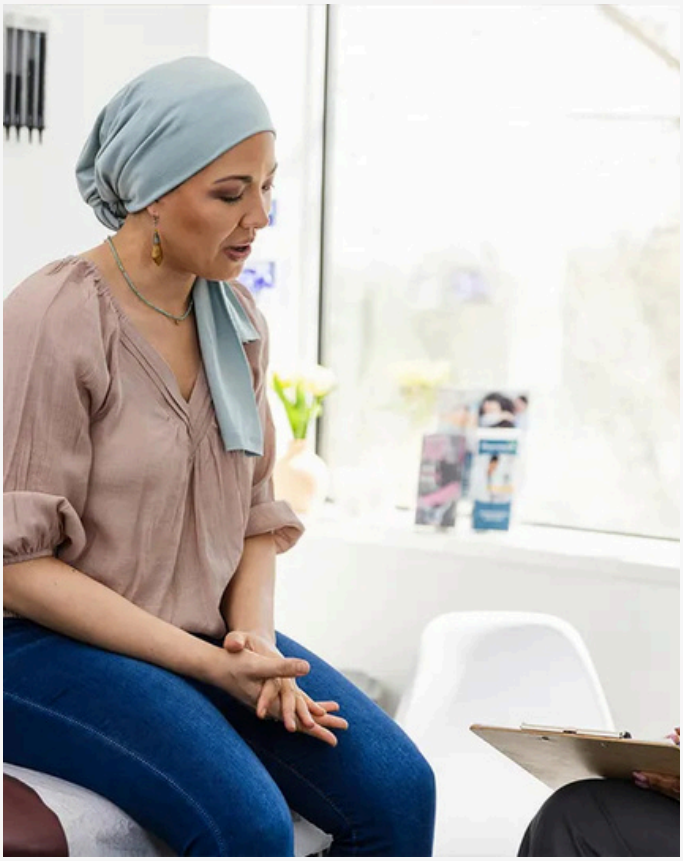
Policy Implications: The Case for Risk-Stratified Screening

The results from ScreenTrustMRI make a compelling case for adopting risk-stratified screening in Europe. By focusing MRI on women at the highest risk, healthcare systems can optimize resource allocation, improving cancer detection rates while reducing the costs associated with unnecessary imaging. The cost per Quality-Adjusted Life Year (QALY) for MRI screenings was estimated at €37,181 based on findings with traditional density approaches, but with AI-based risk stratification offering four times the cancer yield, this figure would be significantly reduced.

Conclusion: A Smarter, More Ethical Approach to Screening

The ScreenTrustMRI trial demonstrated the transformative potential of AI tools like AISmartDensity in breast cancer screening. By identifying high-risk women more accurately and detecting cancers earlier, AI-driven risk models can save lives while reducing healthcare costs. As European policymakers consider the future of breast cancer screening, they must recognize the ethical imperative to act on high-risk classifications and seize the opportunity to embrace AI. By moving directly to AI-based stratification, Europe can build a smarter, more efficient, and ethical screening system—one that better meets the needs of women and the demands of modern healthcare.

"By identifying high-risk women more accurately and detecting cancers earlier, AI-driven risk models can save lives while reducing healthcare costs, offering Europe the chance to build a smarter, more ethical screening system."



Breast Cancer Care in Europe: A Call for Equity and Action

By Europa Donna, The European Breast Cancer Coalition

Breast cancer is the most common cancer among women in Europe, with an estimated 1 in 11 women in the EU-27 expected to develop the disease before age 741. Although Europeans represent just one-tenth of the world's population, approximately 25% of global annual cancer cases are found in Europe.

While significant advancements have been made in breast cancer care over recent years, substantial inequalities remain, impacting women's access to optimal treatment options and critical information. EUROPA DONNA - The European Breast Cancer Coalition, has been at the forefront of advocating for equitable care for breast cancer patients across Europe for the past 30 years. Our mission is to eliminate these disparities and ensure that every patient, regardless of where they live, has equal access to the best possible care and support.

European policymakers play a crucial role in closing these gaps and improving outcomes for millions of patients. Alarmingly, the number of new cancer cases in the EU and European Free Trade Association (EFTA) countries is projected to rise by 21.4%, from 2.8 million in 2020 to 3.4 million by 20402. During the same period, cancer-related deaths are expected to increase by 32.2%, from 1.3 million to 1.7 million. This trend highlights the urgent need for comprehensive preventive measures and targeted actions to mitigate cancer risk factors, along with a stronger emphasis on research to combat the rising incidence of cancer in Europe. Without these efforts, the growing cancer burden will strain healthcare systems and workforce.

A recent report from the Organisation for Economic Co-operation and Development (OECD)3 reveals significant inequalities throughout the cancer care pathway, from risk factors to outcomes. Even within the EU, access to care and resources can vary drastically based on geographical location. Tobacco remains the leading risk factor for cancer deaths in EU+2 countries, contributing to over a quarter of all cancer fatalities, followed by alcohol consumption, poor diet, and lack of physical activity.

Risk factors are more prevalent among individuals with lower socio-economic status, often resulting in limited access to advanced treatment options for women in lower-income regions. Consequently, these disparities can lead to delayed diagnoses and suboptimal treatment, severely impacting outcomes. Socioeconomic factors continue to affect access to care, with lower-income women often unable to afford additional treatments or seek second opinions, resulting in outdated or less personalized care.

The economic burden of these inequalities is significant, as breast cancer is costly to treat, particularly in later stages. As new cases increase, healthcare systems will face mounting pressure, leading to rising costs for governments, hospitals, and patients.

Notwithstanding the screening programmes in place in almost all EU countries and the advancements made in research and treatment options, breast cancer remains the leading cause of cancer death for women in Europe. Prevention has long been a cornerstone of Europa Donna's advocacy, and our annual Breast Health Day on October 15th aims to raise awareness about breast cancer risk factors. Effective prevention strategies can significantly reduce the burden of breast cancer and its associated costs.

Breast Cancer Care in Europe: A Call for Equity and Action

By Europa Donna, The European Breast Cancer Coalition

Europe's Beating Cancer Plan (EBCP) for 2021-2027 identifies prevention as a key pillar, noting that about 40% of all cancer cases in the EU are preventable4. However, tailored approaches are needed to address underlying risk factors that vary by region. For example, obesity rates are higher in Eastern and Southern Europe, while alcohol consumption is a greater risk in Northern Europe. This highlights the need for localized prevention strategies that consider cultural and societal contexts.

Patients advocate for shifting the emphasis away from costly treatments and towards more sustainable, long-term solutions that empower women to be in control of their health. This shift will not only reduce Europe's reliance on pharmaceutical companies but also lead to healthier lives, where fewer women must endure the physical, emotional, and financial hardships that come with a breast cancer diagnosis.

Early detection is crucial in breast cancer prevention, and technology plays a transformative role. Artificial intelligence (AI) is improving breast cancer screening and diagnostics, enhancing the accuracy and efficiency of the diagnostic process. AI can automate routine tasks, reducing the burden on the already worrying shortage of workforce and allowing healthcare professionals to focus on complex cases5. To fully harness the benefits of AI, Europe must invest in the necessary infrastructure and training for healthcare professionals while ensuring equitable access to these advancements.

Patient education is vital. Many patients are unaware of treatment advances or available options, especially in under-resourced countries. Robust patient education programs can empower women to make informed health decisions. However, initiatives are often fragmented and inconsistently implemented.

In conclusion, significant progress has been made in breast cancer care across Europe, but critical inequalities remain that affect access and outcomes. Addressing these disparities requires coordinated efforts at national and EU levels, with a focus on prevention, equitable access to advanced treatments, and the integration of emerging technologies like AI. By collaborating, policymakers, healthcare providers, and patient advocacy groups can create a future where every individual affected by breast cancer receives the best possible care, regardless of location or socioeconomic status.

"Significant progress has been made in breast cancer care across Europe, but critical inequalities remain that affect access and outcomes, requiring coordinated efforts to ensure every patient receives the best possible care, regardless of location or socioeconomic status."

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In need of more ambitious and targeted EU policies to beat Breast Cancer

By Elena Kountoura, Member of the European Parliament, Greece, President Europa Donna Hellas

Breast cancer is one of the most prevalent cancers, the most diagnosed cancer in the EU, with an estimated 380,000 cases, about 23% of all cancer cases among women. It is a major health threat.

As an MEP since 2019, member of the Group of MEPs against Cancer and President of EUROPA DONNA HELLAS, the Greek branch of EUROPA DONNA – The European Breast Cancer Coalition, I advocated for placing breast cancer issues high on the European agenda, for increasing awareness and enhancing EU policies.
Although breast cancer is one of the key priorities in Europe's Beating Cancer Plan, introduced by the European Commission in 2021, the level of care and access to advanced treatments varies dramatically across members states and regions, even within the same state.

To reduce both the incidence and mortality rates associated with breast cancer, the EU must reinforce key policies that address prevention, early detection, treatment, research, and patient support through adequate infrastructure, services, mechanisms, and highly specialized health professionals.

The greatest challenge is achieving convergence. We therefore continue to claim at the European level and at national level, across the EU, more comprehensive measures to eliminate inequalities in breast care services, that affect millions of women.

It is a priority to ensure that all women, regardless of their financial means and whether they live in urban centers, islands or remote and rural areas, will gain equal access to optimal services for prevention, early detection, innovative treatment, survivorship and quality of life.

As early detection is crucial in improving breast cancer outcomes, we continue to pursue more ambitious measures that will secure universal and immediate access to standardized and widespread mammography screening programmes and specialized breast units in all countries and in all regions of each country.
All member states must not only fully adopt the EU recommendations for screening programmes, but also age recommendations for screening must be expanded to include women under 50 and those over 70, particularly those with high-risk factors such as family history or genetic predisposition.

The EU can help reduce these inequities by innovative treatments across all member states, ensuring that the most advanced life-saving therapies, surgical techniques and drugs are available and affordable for all patients. Also, to intensify the funding of research and new technologies, into innovative treatments in breast cancer and metastatic forms, and new methods of rehabilitation.

Cross-border healthcare collaboration is mandatory for allowing patients to receive treatment in neighboring EU countries with more specialized breast cancer facilities.

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Moreover, European and national cancer registries must be established, in order to collect reliable and comparable data on breast cancer across the EU, which are crucial for implementing concrete policies in the future.

The elimination of stigma and discrimination is a critical social issue, concerning the protection of human rights. Women who are battling or have beaten cancer, should not feel or be left alone.

We claim new multifaceted interventions in the European framework for women's wellbeing. For the right of every woman to psychosocial support services as part of standard breast cancer care. For providing personalized care to breast cancer survivors, who often face long-term health issues related to treatment, including fatigue, their emotional and mental health, their sexual life, fertility challenges and their overall wellbeing. To ensure all member states will establish the Right to be Forgotten, so that all breast cancer survivors, after a certain period following their treatment, will be treated equally when requesting insurance services or bank loans.

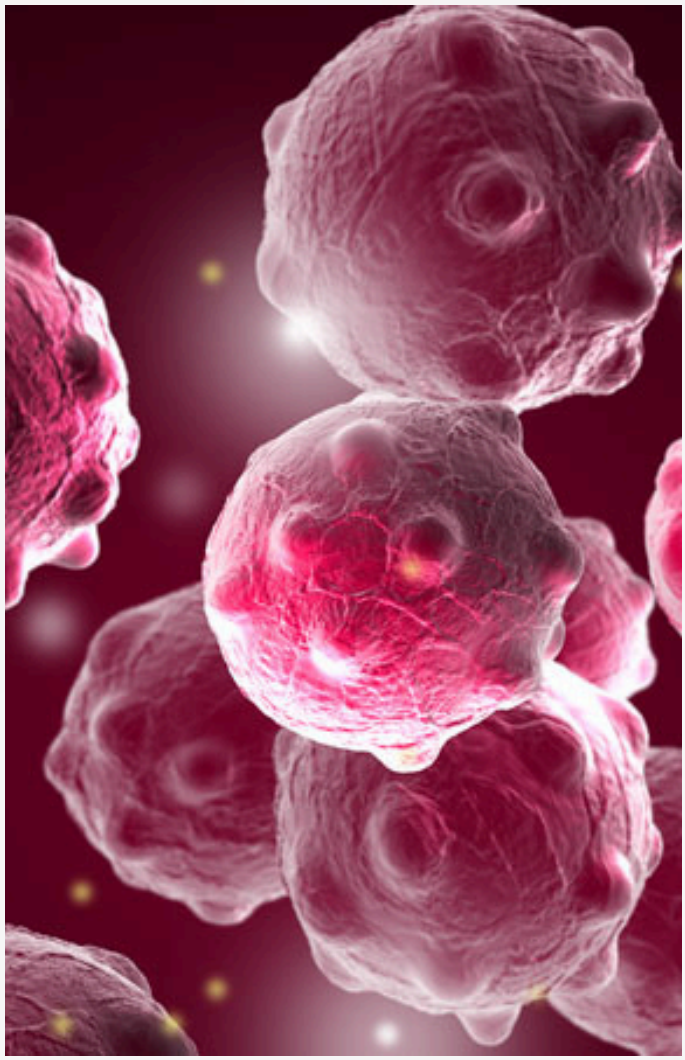
And to promote workplace protection, ensuring that women undergoing treatment have the right to flexible working conditions and job security.

Information has a catalytic role in prevention. It is a priority to invest in expanded public awareness and prevention campaigns to encourage all ages and especially the new generations to abandon habits associated with an increased risk of developing breast cancer, including alcohol consumption, smoking and poor diet.

Adopting a healthy lifestyle, with good nutrition, exercise and regular check-ups is a preventive shield against breast cancer. Breast health care is the best gift any woman can give herself.

Men and women, together we join forces, for our collective right to enjoy good health and good life. For building a future in Europe where breast cancer is no longer a leading cause of death for women.

"Breast health care is the best gift any woman can give herself. Together, we strive for a future in Europe where breast cancer is no longer a leading cause of death for women."



Navigating Life After Breast Cancer: Silent challenges female breast cancer survivors face

By Dr. Mimi Marcellow, MSc, PhD(c), Advanced Physiotherapist, VP Europa Donna Hellas

Breast cancer remains the most commonly diagnosed cancer in women worldwide, with over 2.3 million new cases reported in 2022 alone. While advancements in early diagnosis and treatment have significantly increased survival rates, the journey of survivorship presents unique challenges, particularly concerning sexual dysfunction and reproductive issues that can impact quality of life (QoL). Often overlooked, they can greatly affect a woman's post-treatment progress.

The Impact of Breast Cancer Treatments

Several physical and psychological challenges may result from breast cancer treatments.
Studies indicate that up to 75% of women undergoing such treatments report temporary or permanent concerns, including sexual dysfunction, which encompasses issues such as pain during intercourse (dyspareunia), reduced libido, and diminished sexual satisfaction. The repercussions of these issues can lead to profound feelings of inadequacy, affecting self-esteem and intimate relationships. The physical changes brought on by treatments - such as alterations in body image and hormonal fluctuations - can be stark. Women may experience premature menopause or symptoms associated with the Genitourinary Syndrome of Menopause (GSM), including vaginal dryness, decreased lubrication and dyspareunia. These symptoms can create a cycle of anxiety and avoidance, wherein fear of pain or discomfort inhibits intimacy, further straining relationships.

The Silence Around Sexual Health

Despite the prevalence of these issues, many healthcare providers are ill-equipped to address them. Most oncologists lack the training and/or the time to discuss or treat sexual dysfunction, which can leave women feeling isolated and unsupported. Cultural norms and societal stigma around discussing sexual health often exacerbate this issue, causing many women to suffer in silence. In fact, approximately 50% of breast cancer survivors (BCS) are hesitant to bring up sexual health concerns with their healthcare providers, opting instead for alternative treatments lacking scientific validation. This silence not only affects individual well-being but also prevents a broader understanding of the prevalence and impact of sexual dysfunction among BCS. Unmet needs and unaddressed concerns can perpetuate feelings of isolation and distress.

A Comprehensive Approach to Survivorship

Recognising the importance of sexual health in the context of survivorship is crucial. It is essential for healthcare professionals to initiate discussions about sexual health early in the treatment process and to provide ongoing support as women transition to life after treatment. Interdisciplinary care teams comprising oncologists, gynaecologists, psychologists, and pelvic floor specialists, can offer a holistic approach to care.
Among the recommended interventions are non-hormonal vaginal lubricants/moisturizers, vaginal dilators, and pelvic floor physical therapy. These options aim to alleviate symptoms and enhance sexual function, thereby improving overall QoL. Moreover, psychotherapy and couples therapy can play vital roles in addressing emotional and relational aspects affected by cancer.

Navigating Life After Breast Cancer: Silent challenges female breast cancer survivors face

By Dr. Mimi Marcellow, MSc, PhD(c), Advanced Physiotherapist, VP Europa Donna Hellas

The Role of Pelvic Floor Physical Therapy

Pelvic floor physical therapy (PFPT) is a promising intervention for addressing sexual dysfunction and GSM symptoms. PFPT can help women understand their pelvic floor muscles, improve blood flow to the vulvovaginal area, and relieve pain associated with sexual activity. Through individualised assessments and tailored exercises, women can gain confidence in their bodies and enhance their sexual experiences. The benefits of PFPT are augmented with the use of approved nonhormonal vaginal lubricants/moisturisers. A recent cross-sectional study headed by the author of this article, titled "Genitourinary Syndrome of Menopause in Greek Breast-Cancer Survivors", surveyed 108 women aged 30 and older, revealing that 85.2% experienced vaginal dryness, while 60.2% reported dyspareunia. Importantly, 83% of participants from this European-based population were unaware that PFPT exists as a treatment, nor that it can help alleviate their sexual dysfunction and other GSM symptoms.

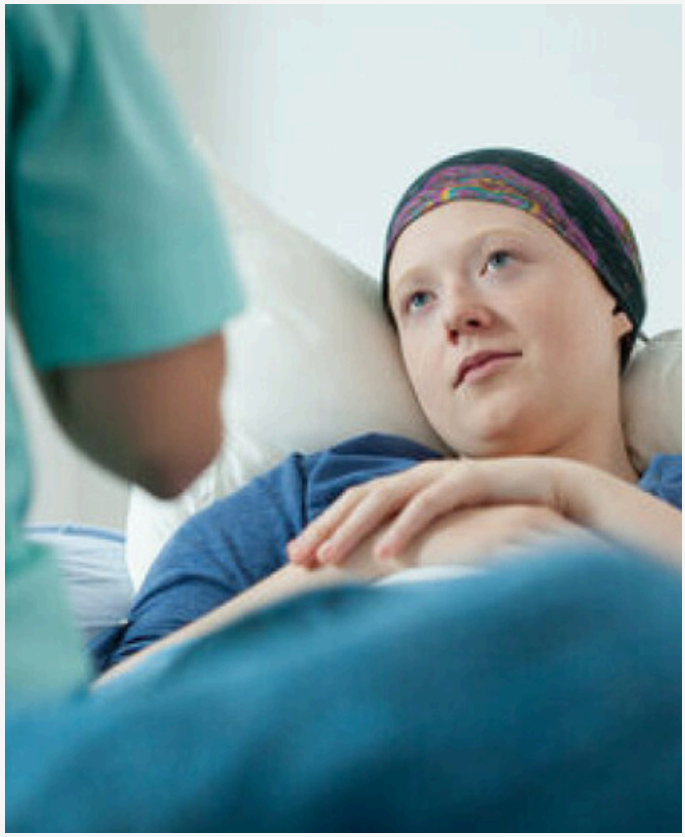
Breaking the Silence and Changing the Narrative

For BCS, addressing sexual health concerns it's not just about physical treatment; it's about fostering an environment where women feel comfortable discussing their bodies and experiences. It is a vital step towards healing. As for healthcare professionals, it's imperative to create open lines of communication and encourage patients to voice their concerns. Breaking cultural taboos surrounding sexual health is also essential for improving their QoL.

Conclusion

Breast Cancer survivorship is a multifaceted journey, fraught with challenges that extend far beyond the physical ramifications of the disease. As awareness grows, it becomes increasingly clear that addressing sexual dysfunction and reproductive issues is essential for improving the QoL of female BCS. By fostering up in communication, providing comprehensive care, and advocating for research in this area, we can help ensure that women not only survive breast cancer but thrive in the post-treatment lives. The establishment of national and European guidelines can raise awareness and improve access to effective treatments for these patients. Additionally, creating multidisciplinary treatment centres for BCS that address issues such as GSM and sexual dysfunction could greatly facilitate care and significantly benefit this patient group.

"Breast cancer survivorship is a multifaceted journey, where addressing sexual dysfunction and reproductive issues is essential for improving quality of life, enabling women not only to survive but thrive in their post-treatment lives."



Training and Education for Breast Specialists

By EUSOMA, European Society of Breast Cancer Specialists

Aims of EUSOMA

The primary aims of the European Society of Breast Cancer Specialists (EUSOMA) are to improve and harmonize breast cancer care. Its goals include identifying and implement the most effective diagnostic and treatment pathways and promoting their adoption, making high-quality, specialized breast services accessible to all women in Europe. EUSOMA also defines the standards for such services and contributes to the certification and audit processes of Breast Centres (www.eusoma.org).

Certification of Specialist Breast Centers, Data Collection, and Quality Indicators

In 2000 EUSOMA defined the Requirements for specialists Breast Centres (BC). The requirements have been regularly up-dated, latest publication in 2020 (The Breast 2020; 51: 65-85) with the endorsement from the European CanCer Care Organization (ECCO). These requirements are the base for the EUSOMA voluntary certification for Breast Centres (www.breastcentrescertification.com).

The Certification process also includes the evaluation of the Breast Centre performance towards the EUSOMA Quality Indicators (Rubio et al, EJC 2024; 198:113500). These QIs reflects the whole patient pathway, are aligned with international guidelines for breast cancer care and are regularly updated.

EUSOMA has developed a data-centre to validate BC database, calculating and reporting on Quality Indicators (QIs) that measure the effectiveness of treatments provided. Up to know EUSOMA database includes around 200.000 breast cancer cases.

Many parameters must be recorded to calculate the indicators. However, there is no consensus among European countries on data collection methods or the specific data to be collected.

A systematic review titled "Quality Indicators for Breast Cancer Care" (The Breast 2021; 59: 221-231) found that Belgium and EUSOMA reported the QIs most effectively. The review also revealed that no identical QI was found across all the documents analyzed, indicating that only EUSOMA-certified breast centres can be compared across countries. This shows the importance of harmonizing data collection methods across Europe.

Measuring the care provided is important for improving patient outcomes. Quality control is vital not only for the single breast center, but also for the broader scientific community, as the results from different centres are instrumental in updating national and international guidelines. Data collection is also essential for advancing scientific research in general.

In this regard EUSOMA requirements highlight that a Breast Centre must have a data manager in the core team, responsible for overseeing data collection and analysis.

Training and Education for Breast Specialists

By EUSOMA, European Society of Breast Cancer Specialists

Multidisciplinary Team Meetings

Breast cancer care involves multiple specialists, including surgeons, radiologists, oncologists, pathologists, plastic surgeons, radiation oncologists, breast care nurses, psychologists, data manager and others. The treatment pathway typically includes major steps such as diagnosis, loco-regional treatment, systemic treatment such as chemotherapy, anti-estrogen therapy, and immunotherapy, etc. In weekly multidisciplinary team (MDT) meetings, each patient is usually discussed multiple times throughout their treatment pathway. These discussions aim to ensure that patients receive the best possible treatment and adhere to the latest clinical guidelines.

A 2012 United Kingdom observational cohort study (Kesson EM et al., Br Med J 2012; 344: 2178), which evaluated the impact of the multidisciplinary approach on nearly 14,000 women, found that it was associated with an 18% reduction in mortality at five years. EUSOMA emphasizes the critical role of MDT meetings, making them a mandatory component for breast centre certification.

In Europe all women should benefit from MDT discussions both in early and metastatic setting. Currently, not all metastatic breast cancers are discussed in MDT meetings and improvement on this is needed.
EUSOMA is committed in supporting BC in improving MDT meetings and in this regard is developing some projects.

Recommendations on Training and Education for Breast Specialists

The primary objective of training and education across the various disciplines involved in breast cancer care is to improve the standard of care available to all women in Europe. In 2007, EUSOMA published "Guidelines on the Standards for Training of Specialized Health Professionals Dealing with Breast Cancer" (Cataliotti et al., EJC 2007; 43: 660-675). This document provides comprehensive recommendations on training and educating candidates for the title of Breast Specialist in various disciplines, including breast radiologists, breast surgeons, and breast oncologists.

A 2019 survey conducted by ESSO and EUSOMA (Rubio IT et al., Eur J Surg Oncol 2019; 45: 567-572) revealed significant variability in breast cancer surgery training across Europe. The study concluded that developing and implementing quality standards for breast cancer surgery training is imperative. This standardization will ensure that patients receive standardized and certified surgical care, regardless of the country where they are treated.

"High-quality, specialized breast services must be accessible to all women in Europe, with certified breast centres ensuring that patient outcomes drive updates to national and international care guidelines."

Advancing Breast Cancer Research: Calls for Prevention, Patient Empowerment, and EU Collaboration

By Prof. Dr. Sarah-Maria Fendt, KU Leuven Department of Oncology

Breast cancer causes 16% of the cancer-related deaths in women in the WHO Europe Region. The 5-year overall survival of breast cancer patients depends on the progression of the disease ranging from >99% survival in patients with stage I localized disease to <30% in patients with stage IV metastatic disease. Unfortunately, about 25% of breast cancer patients diagnosed with an early stage I-III disease will progress to a terminal metastatic disease despite the recent expansion in targeted therapies.

These facts highlight the continues need for fundamental breast cancer research to better understand the mechanisms of breast cancer initiation and progression. This increase in fundamental knowledge is needed to define innovative and novel approaches to intercept breast cancer at all stages of the disease. It is therefore recommended to fund basic breast cancer research and to provide avenues for the translation of basic research findings into clinical practice.

In addition, it is recommended to intensify the research efforts and patient information on lifestyle (diet, exercise, alcohol…) in combination with approved and new drugs to empower the patient's decision making regarding modifiable risk factors of breast cancer initiation and progression and to provide clinical guidelines on combining drugs with lifestyle interventions. Moreover, environmental risk factors need to be further researched to quantify their contribution to breast cancer incidences, treatment response and the survival of breast cancer patients.

Moreover, an emphasis should be set on prevention trials. Currently, prevention trials to intercept the progression of early-stage breast cancer to a metastatic disease are extremely underrepresented despite the acceptance of metastasis-free-survival as clinical endpoint in 2018 by the FDA.

Consequently, many promising therapeutic strategies defined in pre-clinical research are never entering clinical trial although the impact on patients (quality of life,…) in case of success would be preferred because of the metastasis preventative nature of the treatment.

It is also recommended to improve the efficiency of patient material (tissues, liquids,..) and data exchange within the European Union as it allows scientists to validate the relevance of their research findings for patients. Streamlining the ethics and legal procedures across member states will ensure that donors are adequately informed and that their personal data is protected in compliance with GDPR laws, while minimizing paperwork and associated delays that present serious barriers to fundamental and translational research today.

"To intercept breast cancer at all stages, we must fund fundamental research, translating findings into clinical practice, while empowering patients through lifestyle interventions and targeted treatments."

Breast Cancer in Europe: Challenges, Inequalities, and Recommendations

By Dr. Marilys Corbex, WHO regional office for Europe

World Health Organization

European Region

Descriptive Epidemiology

- With more than 375,000 new case per year, breast cancer is the most frequent cancer in the European Union, even when considering men and women together.
- It is the 3rd killer after lung and CRC cancer with 96,000 deaths per year.
- In the EU, more than 60% of breast cancer occur as interval cancer or among women who are out of the age range for screening (65% in Dk). Therefore the rapidity of diagnosis and treatment of women with symptoms is key, however this differs a lot across EU country.
- In North, central and south Europe the average 5-years survivalis high at 87% while in Eastern Europe itis 79%.
- There are clear inequalities in access to rapid diagnosis and treatments across countries of Europe, but also within countries, across socio-eco status.

Prevention

- The most important risk factor of breast cancer are not modifiable, they include: age, familial history of breast cancer, not or low number of children, late age at 1st pregnancy, early age at menarche, late age at menopause.
- Some risk factor are modifiable, notably alcohol consumption and overweight after menopause. According to countries:
  - between 5 and 10% of breast cancer cases are attributable to alcohol consumption.
  - between 10% and 13% to overweight
  - So almost ¼ breast cancer could be prevented by tackling these 2 factors (commercial availability, promotion, taxes & prices)
- Proven protective factors include: breastfeeding, physical activity notably after menopause, and eating fruit and vegetables.
- •The effect of smoking on risk of developing breast cancer is not very strong, but what is clear is its harmful effect on survival for breast cancer patients.

Screening

- Screening can help reduce mortality if well quality assured. Screening can also harms, the main harms are false positive and overdiagnosis.
- It has been well documented that the general public and GPs generally overestimate the benefit of mammography screening while underestimate its harms.
- To give an idea of these harms and benefits, here are some estimation for a country like Belgium:
  - Let's consider 1000 women 50 to 60 screened every 2 years. After 10 years:
  - –38 will have been diagnosed with BC, of which 5 are dead, despite screening. 33 are still alive, among which only 3 of them thanks to screening.
  - –But 3 of the 38 have been overdiagnosed and overtreated
  - –On each round of screening, 100 women will have a false alert and 15 will have a biopsy (of which 4 will have confirmation of cancer).
- In UK it has been calculated recently that 3 women need to be overdiagnosed and treated for 1 live saved by screening.
- In case quality is not very strictly controlled, the harms of screening increase (more false positive) while the benefit decrease (more false negative so less lives saved).
- Screening programs are demanding in resource and to ensure high quality is challenging, many eastern EU country still struggle to ensure this quality
- For screening, the WHO underline the importance of:
  - ensuring the highest quality to their screening programs
  - providing full and unbiased information to women invited for screening
  - ensuring rapid diagnosis and treatment of symptomatic breast cancer (with focus on equity issues)

Breast Cancer in Europe: Challenges, Inequalities, and Recommendations

By Dr. Marilys Corbex, WHO regional office for Europe

Treatment

- There is a growing concern in the scientific community about both the decreasing value of new cancer drugs and their growing cost:
  - –New cancer drugs now cost on average 200 000 € per year per patient, including the drugs that do not help patients live longer or have better lives.
- Industry investments in marketing are higher than in research. The majority of new drugs put on the market are not better than older ones but are just more expensive. A recent study of 131 new cancer drug showed that in 41% of the cases were they were used, they had no quantifiable effect or negative effects. This is a study among many.
- Industry marketing campaigns and their influence on treatment guidelines result in very significant overuse of cancer drugs with small or negligible benefits. These “drugs are not benign – they cause toxic side effects and financial burdens, negatively impacting patients quality of life.
- For example, the Palbociclib which is beneficial to only a a small proportion of patient but is prescribed now in more than 75% of advanced breast cancer. It is poorly tolerated and can have severe side effects; evaluation by the German HTA agency has repeatedly found it had “only inconveniences” and “a negative value”. It cost around 3000€/month and in 2020 it ranked number 3 in the expenditure for reimbursed pharmaceuticals in Belgium.

Rehabilitation and Palliative care

- To go back to normal life after cancer is challenging, notably at work place.
- Supportive, Rehabilitation and Psychosocial services remain under-developed in most EU countries and are not accessible to all (keeping in mind that socio-economic inequalities exist and must be addressed).
- Supportive and Palliative care that relief symptoms and physical pain as well as psychological suffering is a human right for all cancer patients. It tremendously increase quality of Life
- Palliative care remains too neglected in the world including in the EU. Opiod consumption varies from 520 mg/capita in Austria to around 20mg/capita in Bulgaria, Romania or Estonia.
- It is unfortunate, all the more since at country level, development of Palliative care has been shown to reduce very efficiently overall cancer treatment costs

.

Conclusion

Commercial determinants are a growing concern in cancer early detection and care.
To learn more read:

- https://eurohealthobservatory.who.int/news-room/events/item/2022/04/27/default-calendar/what-are-the-commercial-determinants-of-cancer-control-policy

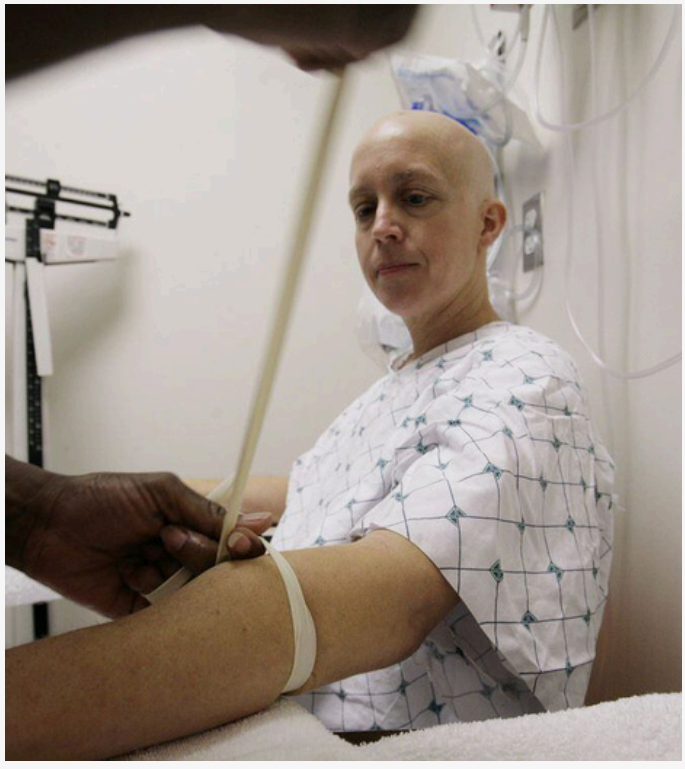
Appendix: WHO work on breast cancer

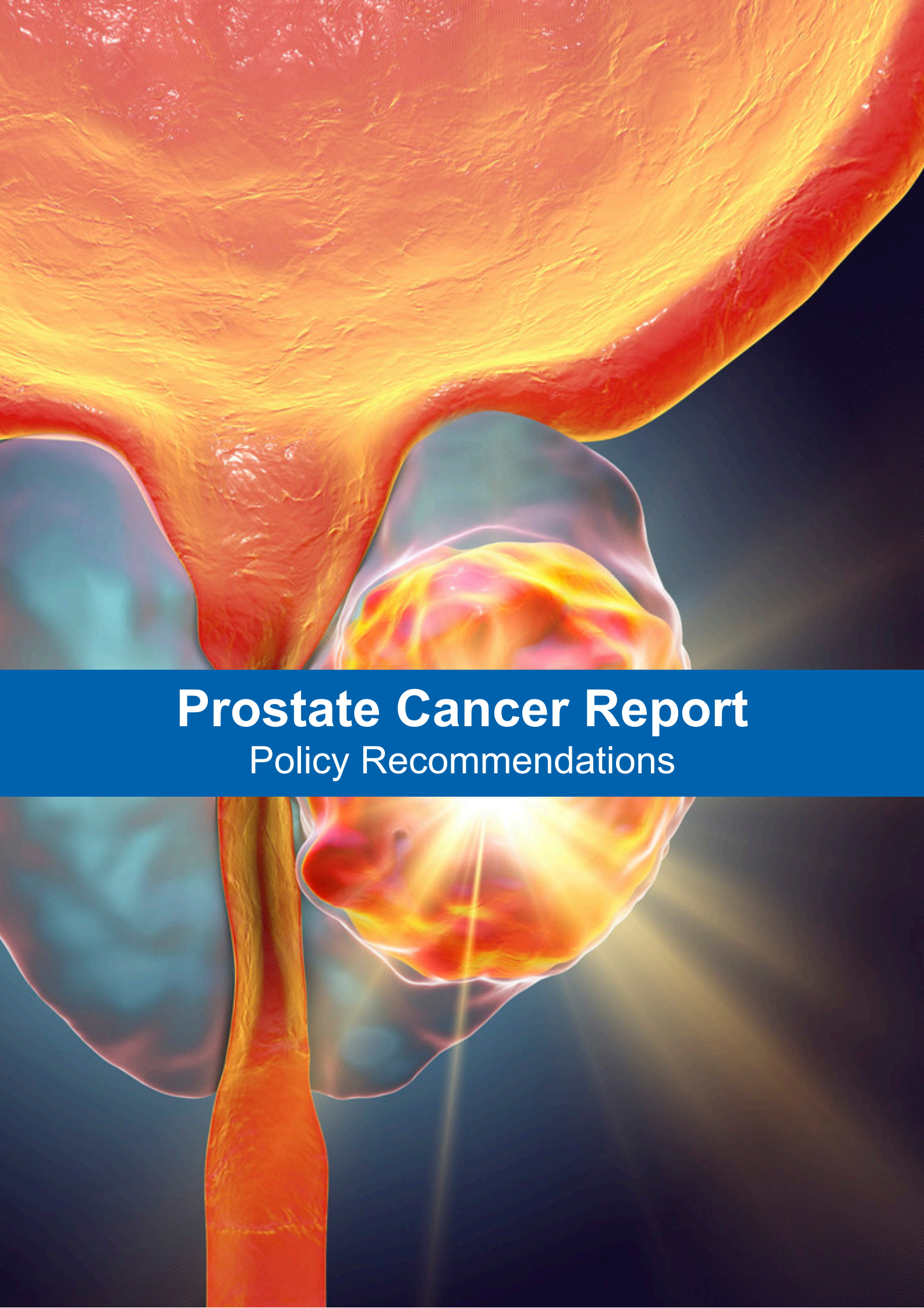
International Agency for Research on Cancer

- Surveillance (incidence, prevalence, mortality, etc.)
- Risk Factors (research, monographs) and early detection (handbook of cancer prevention)

WHO Headquarters, regional and country offices
Assist Ministries of Health in implementing breast cancer control measures :

1. Prevention: healthy life style,
2. Capacities for early diagnosis, screening & treatment
3. Supportive & Palliative care





Prostate Cancer Report

Policy Recommendations

The mutation of prostate cancer screening, an innovation by compassion for the benefit of many, the breakthrough of MRI and its European opportunities

By Dr. Clément ORCZYK, MD PhD DESC(Urol) FRCS MPH for University College London Hospitals

There is now no doubt that the previous detection strategies for prostate cancer, primarily based on PSA testing and random biopsies, have led to overdiagnosis, overtreatment, missed diagnoses, poor disease stratification, and inadequate treatment allocation—an extreme situation for modern medicine at such a large scale. At the same time, prostate cancer continues to claim the lives of tens of thousands of men across Europe each year, with projections indicating this number will double by 2040. However, there are important lessons to be learned: the introduction of new policies and tests has significantly shaped the population-level dynamics of the disease, and treatment has demonstrated a positive impact on mortality rates. These are essential criteria for establishing effective screening programs: the right combination of early detection with appropriate, effective treatment. Some would add, compassionately, that minimizing side effects and harm is equally crucial.

The urology and research communities have responded to these facts, leading to the most significant transformation in prostate cancer care in over 40 years: the introduction of MRI into the diagnostic pathway. For the first time, clinicians can visualize tumors within the prostate gland, revolutionizing the approach to diagnosis. MRI has proven to be vastly superior, with a 100% improvement in identifying patients at risk of prostate cancer compared to previous methods. Not only does it allow for better detection of clinically significant cancers while avoiding unnecessary diagnostic procedures in more than a quarter of patients, but it also enables improved cancer management by establishing a 3D target—a medical object long denied to prostate cancer patients, but standard in other medical disciplines for decades. This breakthrough has been acknowledged in urology guidelines as recently as 2021.

To translate this revolution in care into broader benefits through screening, several critical actions must be taken, and resources allocated at a higher level in terms of information dissemination, equal access, legal frameworks, and innovation in research.

1. Rebranding Prostate Cancer Screening for Public Engagement

Prostate cancer screening requires a rebranding to improve public adherence. It is essential to widely communicate to the general public and general practitioners that recent scientific advances and changes in urological practice now support a simple, yet powerful message: “The aim is to detect only those cancers that would benefit from treatment, using the least invasive methods at each step.”

The widespread skepticism surrounding the potential benefits of screening, which is rooted in concerns about side effects, should not be underestimated. Historic trials have documented low adherence to previous screening strategies, which were based purely on PSA testing. A less invasive pathway—featuring active surveillance, focal therapy, and tailored treatments—is gaining acceptance, particularly in settings where resources are available. Clear communication to the public is paramount for the success of any future screening program.

2. Addressing Inequalities in Access to Quality Care

Inequality in access to high-quality prostate cancer care must be tackled across the EU, particularly access to MRI scanners. Disparities in MRI access of up to tenfold have been observed. MRI is now the cornerstone of any screening or detection strategy, as it reduces overdiagnosis and ensures more accurate diagnoses. An EU initiative could consider investing in MRI scanners, while also addressing the workforce and training needs required for interpreting these images. New methods for digital reporting and standardization should be developed, leveraging Europe's existing expertise in this field. Furthermore, urologists must appropriately utilise MRI findings to reduce overdiagnosis and improve diagnoses through the latest biopsy techniques. Investments in artificial intelligence (AI) development could also enhance this process.

3. Establishing a Legal Framework for Innovation and Data Use

Developing a legal framework to support innovation, data modeling, and AI in healthcare—specifically for prostate cancer—should be a priority. This framework would enable the collection of standardized, high-quality data across EU member states, potentially extending to partners such as the UK. The European Health Data Space offers an opportunity for prostate cancer research to benefit from shared data on a large scale. The secondary use of this data will facilitate new monitoring tools and the emergence of valuable findings on prostate cancer, a disease with a long natural history and relatively low mortality rate. Public involvement is essential to ensure the ethical use of data, given its sensitivity.

4. Investing in Research and Innovation

Significant investment in research is crucial, not only due to the looming health crisis posed by an aging population but also to maintain Europe's leadership in the field and foster a thriving biomedical industry that benefits society. The recent introduction of MRI presents a unique opportunity to investigate the biology of prostate cancer at an early stage, including the precise collection of tissue samples. Europe leads in prostate imaging and biopsy, having pioneered this concept.

Research should focus on understanding the cancer's trajectory from its early stages, enabling refined stratification tools and the development of new approaches based on molecular biology and advanced imaging analysis. Identifying individuals at risk of progression or requiring treatment at an early progression will be key to reducing overtreatment. MRI also supports selective approaches, such as focal therapy, which significantly reduce treatment-related side effects, a factor that aligns with patients' preferences and must be part of the discussion. A deeper understanding of the disease will pave the way for new therapies—including immunotherapies—and much-needed prevention strategies.

To address the limitations of PSA testing and the shortage of MRI scanners, the development and validation of new biomarkers to detect the MRI phenotype of the disease should be prioritized. These biomarkers must be affordable, widely accessible, reproducible, and capable of reducing reliance on MRI without compromising diagnostic accuracy.

Conclusion: Building a Sustainable Future for Prostate Cancer Screening in Europe

Investing in these four key areas will enable the establishment of a robust, future-proof prostate cancer screening program that addresses urgent needs. The major breakthrough of incorporating MRI into patient care has already occurred; now, it must be fully supported to benefit as many people as possible. To identifty better, to diagnose better, to treat better those in needs for the wider impact under European leadership.

"The major breakthrough of incorporating MRI into prostate cancer care has transformed detection and diagnosis—now, we must fully support this to benefit as many people as possible."

Enhancing Prostate Cancer Outcomes: Key Strategies for Screening and Surgery

By Dr. Giovanni Lughezzani, Humanitas Research Hospital, Milan, Italy

Prostate cancer screening and early diagnosis

While our ability to accurately diagnose prostate cancer (PCa) has improved dramatically in recent years thanks to advances in imaging and fusion biopsy technologies, there are still several areas that we should work on in the European Community to improve the early diagnosis of PCa.

First, PSA alone as a screening strategy is not accurate enough to stratify the risk of harbouring PCa. This has been shown in several studies (e.g. ReImagine from UCL and Probase). The use of alternative more accurate biomarkers (e.g. PHI or 4K panel) and/or risk calculators incorporating these alternative biomarkers should be further evaluated at a population level. Similarly, as the large-scale use of tests such as multiparametric MRI in screening is extremely difficult to justify (for both cost and availability reasons), alternative, readily available, cheaper and faster imaging modalities should also be investigated.

Secondly, access to multiparametric MRI should be facilitated for EU patients with suspected PCa. The quality of MRI and MRI interpretation should also be standardised and guaranteed, which could probably be achieved by adequate training of GU radiologists and by centralising prostate imaging in high-volume centres.

Thirdly, when MRI is not available or not feasible (patients with contraindications to MRI), microultrasound could be an easy-to-use tool with similar sensitivity and negative predictive value to MRI.

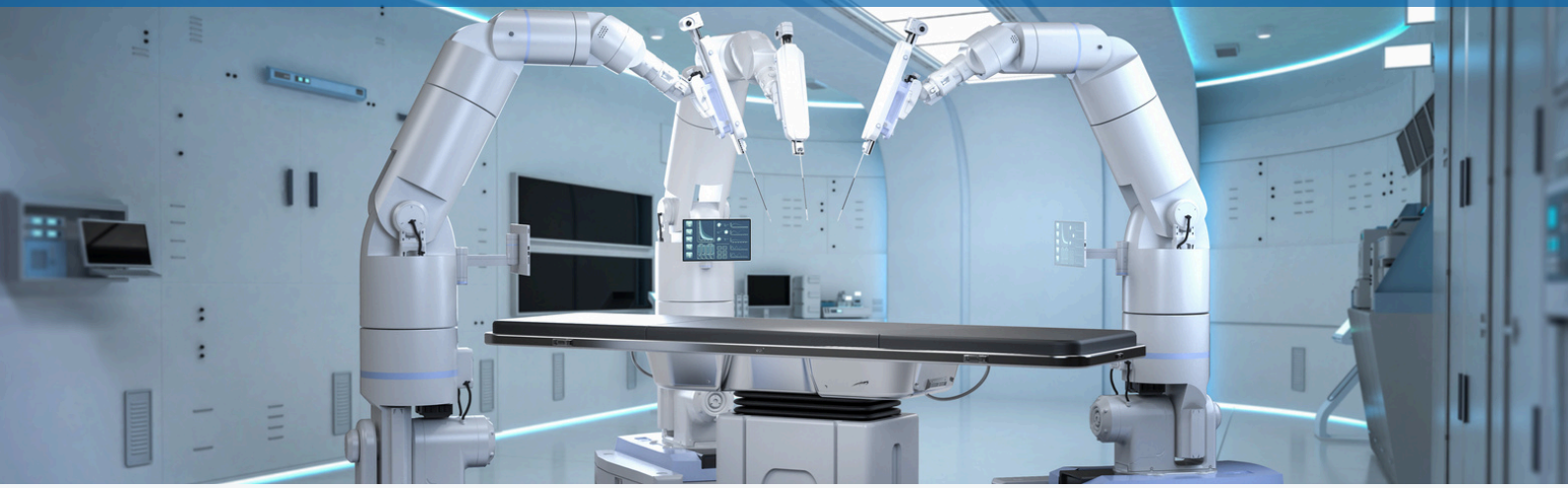
Prostate cancer surgery

Optimal outcomes of PCa surgery, regardless of the type of approach (open/laparoscopic/robotic), should also be ensured. Prostate cancer surgery should only be performed in high-volume centres. Centre/surgeon-specific oncological and functional outcomes should be carefully monitored and made publicly available.

"While our ability to diagnose prostate cancer has improved dramatically, we must enhance access to advanced imaging and develop alternative, cost-effective screening options across Europe."

Robot-Assisted Prostate Cancer Surgery

By Dr. Justin Collins, MBChB, MD, FRCS (Urol), Associate Medical Director for CMR Surgical



Robot-assisted radical prostatectomy (RARP) is increasingly adopted by urologists IN the EU as the gold standard approach. There is evidence of inherent risks of utilising new technologies that are unfamiliar early in the learning curve. The development of standardised and validated training programmes is crucial to deliver safe introduction and mitigate these risks. It is recognised that errors are more common early in the surgeons learning curve and the combination of simultaneously learning about both technology and technique, on patients, has inherent patient safety risks if training is not optimised.

The first validated robotic training curriculum was published in 2015, this was for RARP. This validated curriculum is the current gold standard and has been replicated by several societies in multiple specialties. The standardised structure describes staged training commencing with a baseline evaluation, e-learning and operating-room (OR) observation. With modules of simulation training, including wet-laboratory training in cadavers, pigs and other animal models. However, centralised wet-laboratory training centres are expensive and limit access. Another key issue is the level of competence that the trainee has when they commence operations on patients. Expertise from more experienced surgeons may not be available locally, requiring travelling preceptors, with additional cost and an impact on access. Weaknesses in individual's training and subsequent performance can be missed if training is not objectively assessed, benchmarked and quality assured. In other high-risk industries such as aviation, there are international training standards that are benchmarked and quality assured. Proficiency in performance must be shown before the pilot is allowed to fly a plane with passengers onboard. The same rigorous approach to surgical training has not yet been applied.

To improve surgical training, we need awareness of weaknesses, quality assured standards and access to affordable training that are integrated with job planning. The combination of systems thinking with a proficiency-based progression (PBP) approach to training has been shown to be highly successful in reducing errors in aviation training, whereas surgical training has historically been an apprentice model, with variabilities in the trainer's skills as both a surgeon and educator. Ultimately, all stages of training will benefit from digitalisation and automated data collection related to surgeon performance.

Although international agreed gold standard metrics with benchmark have been achieved in the aviation industry it is unrealistic to propose that one set of metrics can be achieved in RARP without retraining the whole of the current workforce. There are several recognised approaches to RARP such as Retzius sparing RARP and various steps of the standard procedure that are not universal, such as bladder neck sparing approaches and anterior and posterior reconstruction sutures. The phases of the operation can also be completed in different order, for example either commencing with a posterior approach or anterior approach.

Our recommendation is for a metrics-based approach to training that is benchmarked (and freely available?). Metric selection should prioritise agreement between the appointed expert trainer and their trainee (local gold standard) over a singular global gold standard approach. Metrics should be transparent and benchmarked to enable personalised performance feedback. Credentialling should be given by the organisation/body that has legal responsibility for the patients' welfare.

"A metrics-based, benchmarked approach to surgical training is essential for enhancing safety and proficiency in robotic prostate surgeries, ensuring patient welfare across the EU."

Prostate Cancer Screening in Europe: Milestones and Insights from the PRAISE-U Project

By Dr. Renée C.A. Leenen, M.D. PhD Candidate, Erasmus MC Cancer institute, Rotterdam.

Background

In 2022, the European Council updated its recommendation on cancer screening in Europe, emphasizing the importance of a stepwise approach involving pilot programs and further research to assess the feasibility and effectiveness of organized prostate cancer (PCa) screening programmes. In response to the recommendation, the PRAISE-U (PRostate cancer Awareness and Initiative for Screening in the European Union) project (https://uroweb.org/praise-u) was initiated.

PRAISE-U Project Overview

In direct partnership with a consortium network including 25 institutions across 12 countries, PRAISE-U works to encourage early detection and diagnosis of PCa through customised and risk-based screening programmes. By doing so, PRAISE-U moves from trials to the implementation of population-based and modern (i.e., individualized and risk-based) screening pilots in EU member states (MSs) (1). The project started on April 1, 2023, and will run for three years. To evaluate the functionality, feasibility, sustainability and cost-effectiveness of the implementation of a risk-based algorithm, the consortium will work with five pilot sites in four MSs; Poland, Lithuania, Ireland, and 2 regions in Spain (1).

Year 1 Achievements

Living State-of-Play Document

In the first year of the project, several key deliverables were completed:

- Cost-effectiveness: this systematic review (SR) provides a contemporary overview of the costs and benefits of PCa screening programmes. The SR indicates that screening programmes incorporating a risk-based approach and MRI have the potential to be cost effective (2).
- Policies, guidelines and opportunistic screening: this SR reviewed the policy, medical guideline recommendations, and the current level of opportunistic screening in EU MSs. The review suggests that current early detection policies are not fit for purpose. High levels of opportunistic screening and overdiagnosis persist, prompting policy recommendations for standardised guidelines, informed decision making, and increased awareness to improve efficiency and effectiveness in early detection of PCa (3).
- Early detection of PCa in the EU and UK: this comprehensive SR of contemporary SRs provides a complete overview of the current evidence, covering different aspects; 1) Invitation; 2) Decision making; 3) Acceptance; 4) Screening test and algorithm; 5) Harms and benefits; 6) Future of screening. By identifying consistent and conflicting evidence, this review highlights the evidence-based foundations that can be built upon, as well as areas requiring further research and improvement (4).

Discussion Groups and Country Profile Fact Sheets

To provide a comprehensive description of screening activities in the MSs, discussion groups were conducted at the 2023 EAU national societies meeting, and collaboration with WONCA Europe was established to retrieve a primary care perspective. Findings for each MS were incorporated into country profile fact sheets, which include all relevant information regarding PCa early detection for each MS.

Prostate Cancer Screening in Europe: Milestones and Insights from the PRAISE-U Project

By Dr. Renée C.A. Leenen, M.D. PhD Candidate, Erasmus MC Cancer institute, Rotterdam.

Needs Assessment Analysis

A needs assessment analysis was performed to understand the current practice towards early detection in the EU MSs, the barriers to implementing or planning population-based screening programmes, and potential solutions to overcome these barriers. The Barriers to Effective Screening Tool (BEST) survey was adapted to the PCa context, translated into all spoken languages in the EU27, and disseminated to different stakeholders across the EU (5).

- **Support:** across Europe, participants have noted the presence of opportunistic screening, and particularly urologists and patient representatives expressed their support for the establishment of a population-based PCa screening programme.
- **Barriers:** nevertheless, successful implementation is complex; it requires political and medical society support, operational resources and capacity, awareness campaigns, as well as the development of protocols, guidelines, and legal frameworks.

Clinical Performance Indicators and Pilot Protocols:

Clinical performance indicators of screening effectiveness and pilot specific study protocols were established. Each pilot site has been carefully selected to represent different health care systems across Europe. While these protocols will follow a standardized risk-based algorithm, it will also allow to be tailored to align with the current health care system in each MS.

Current Activities: Year 2

In the second year of the project, the five pilots will start. This year, all pilots will begin sending invitations. The pilots will run for 12 months, aiming to invite between 5,600 (in the Galicia region of Spain) and 30,000 (in Poland) men.

Upcoming Plans: Year 3

In the third year, the effectiveness and feasibility of the pilots will be evaluated. Additionally, psychosocial outcomes will be assessed to understand the broader impact on men's well-being, alongside a cost-effectiveness analysis to ensure the sustainability of the proposed screening algorithm. The evidence and data gathered will be shared on a freely accessible living Knowledge Hub (https://uroweb.org/praise-u/results) to foster collaboration and continuous improvement of PCa screening practices in Europe.

Future Perspectives

Following the significant changes enabled by the European Commission in 2022, we have moved from trials to implementing population-based and modern screening pilots. However, continuous effort is required to sustain this progress and to potentially transition from trials to the implementation of tailored national screening programs.

Objectives for the MEPS:

- **Enhance Collaboration:** Foster collaboration among EU member states to share best practices and improve screening strategies.
- **Establish Standardized Practice and Equality:** Develop and implementation of standardized guidelines, so that all EU member states can offer individualized approaches to achieve timely PCa detection in men who can benefit from early treatment.
- **Promote Awareness:** Every man in the EU needs to be aware of the pros and cons of early detection for PCa.
- **Continue our Process of Knowledge Acquisition:** Continuation of the ongoing PRAISE-U pilot studies will not only enable further use of the major investments so far, but will provide invaluable knowledge on long(er) term compliance and effect of population based PCa screening.

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An urgent call to allow the benefits of prostate cancer screening to European men

By Dr. Roderick van den Bergh, Urologist – Erasmus MC, Rotterdam, The Netherlands

Prostate cancer is a major health concern in Europe, increasing due to the aging population. The perspective below illustrates how screening for prostate cancer may significantly reduce the burden of this impactful disease among men in Europe. With 335,000 cases per year, it is the most frequent type of cancer diagnosed in men and causes death in 75,000 men annually. Many more patients do not die of the disease but develop metastases, leading to prolonged illness and requiring treatment with hormonal therapy, which greatly impacts quality of life and mental health by causing metabolic changes and depression. The challenge in prostate cancer diagnosis is to timely find and treat cancers that could cause harm if left undiagnosed while leaving undetected the smaller cancers that have a favorable natural outcome when untreated.

The blood test for the protein PSA (prostate-specific antigen) is a marker for prostate cancer and can be used for early diagnosis of the disease. Large studies initiated in the early 1990s have found that organized screening using PSA reduces death due to prostate cancer by 20%, even though not all men invited to participate accepted, and some had already undergone a previous PSA check before participating in the study. When compensating for these limitations, the true mortality reduction using PSA may be as high as 50% for the motivated individual compared to never checking PSA. However, the implementation of PSA screening may also have side effects, the main one being overdiagnosis. Overdiagnosis means finding small tumors that would never have led to symptoms during a lifetime due to their indolent behavior. Overdiagnosis could lead to overtreatment when, despite the limited harm of these small abnormalities, radical treatment is elected, risking side effects such as incontinence and sexual dysfunction. Therefore, the implementation of screening should be well considered.

In the last three decades, unorganized PSA testing has become widespread. PSA is often requested actively by men who are anxious about developing prostate cancer, or it is checked in men who have problems passing urine, which is actually mainly a symptom of prostate enlargement and not prostate cancer. This unorganized use of PSA is called opportunistic screening. Opportunistic screening is unwanted, as it only has a limited impact on reducing mortality due to the disease while leading to the highest overdiagnosis rates. If PSA is used, it should be used correctly. This means that the right ages of men should be subjected to PSA testing (starting relatively early and stopping in the elderly), the thresholds for further diagnostic evaluation after PSA should be well followed, and the repeat PSA testing interval should be risk-based (e.g., every two years for PSA 2-3, every five years for PSA <1). There is an unwanted inequality in PSA testing between men from different socioeconomic statuses, education levels, and ethnic backgrounds. It has been found that screening initiatives have a higher benefit in these groups.

Coincidentally, the diagnostic algorithm for prostate cancer has also modernized and improved in the past ten years. The main improvements include the better indication for biopsy after an elevated PSA, whereas in the past this was followed by a direct biopsy. This is achieved by interposing risk calculators and MRI imaging of the prostate to decide on a prostate biopsy. These algorithms have a significant favorable effect on unnecessary biopsy rates and the detection of insignificant disease, reducing this by ±75%. Different more recent studies have already included MRI in prospective screening protocols, and the ratio between significant and insignificant disease is much more favorable than in classic screening studies using PSA only. This stepwise, risk-based approach to screening reduces the side effects of screening while maintaining the advantages.

An urgent call to allow the benefits of prostate cancer screening to European men

By Dr. Roderick van den Bergh, Urologist – Erasmus MC, Rotterdam, The Netherlands

By implementing modern risk-based organized screening for prostate cancer, the European Commission serves two important advantages for all men in Europe and their families:

- The favorable effect of screening is brought to all men, reducing prostate cancer mortality by at least 20% and having an even larger impact on the risk of developing metastases. Screening is also introduced to those men who otherwise would not be subjected to PSA, even though they often have an above-average risk of prostate cancer. The inequalities in access to men's health care will thus be reduced. The screening initiative should be combined with awareness of the disease and focus on men between 40-50, to prepare them for deciding on screening when they are invited at the age of 50.

- Screening directs existing opportunistic PSA testing in the right direction, avoiding inefficient application. Men requesting PSA can be redirected to existing European screening programs, with optimized decision-making and frequency of screening for prostate cancer, reducing side effects.

In summary, organized modern risk-based screening for prostate cancer has enormous potential to reduce mortality due to prostate cancer, with even larger downstream improvements in quality of life and mental health. Further action is therefore urgently required to implement screening for prostate cancer to all men in Europe.

"Organized, risk-based screening for prostate cancer has enormous potential to reduce mortality, improve quality of life, and address healthcare inequalities across Europe."

Optimizing Prostate Cancer Care: A European Strategy for Robotic Surgery Excellence

By Dr. Ruben De Groote, MD, FEBU for OLV Hospital Aalst, Belgium

During the ICPS EU Prostate cancer discussion, stake holders within the field of urology and surgical sciences discussed how to optimize the care for prostate cancer patients and how to optimally implement a European screening strategy.

As a urologist, specialized uro-oncology and robotic surgery, my main focus is how to deliver the best surgical treatment possible for patients with localized prostate cancer. To reach this goal the urology department of the Onze Lieve Vrouw Hospital Aalst in Belgium has pioneered by offering robotic surgery to its patients since 2001. Robotic surgery offers the best of minimally invasive surgery and open surgery. It allows the surgeon to do maximal surgery with minimal impact for the patient. Therefore, surgical robotics are the future of surgical prostate cancer treatment. However, quality of the surgery is still determined by the quality of the surgeon using the robot. “A fool with a tool is still a fool”. Therefore, a European strategy must be developed to optimally use robotic surgery in the field of prostate cancer. This strategy should contain the following keypoints:

1. Centralization

High level robotic surgery should be offered in high volume centers of excellence as there is a direct link between the volume of robotic procedures and the quality-assured outcomes. Moreover, this will lead to a more cost-productive implementation of these highly expensive hardware systems.

2. Training

Surgeons who perform robotic surgery should be trained accordingly. Having a robotic system does not guarantee surgical quality. Therefore, dedicated and validated training curricula should become integral part of a European strategy to optimize surgical care for prostate cancer patients. Proficiency Based Progression training has shown to significantly improve technical skills and to significantly decrease intra-operative errors which could compromise patient safety. By reaching quantitively defined benchmarks, progression through surgical training can be monitored. Procedure-specific operative metrics, defining the different steps and errors of the procedure, serve as a guiding training and assessment tool. Incorporation of models (virtual models, dry lab and wet lab) in dedicated training centra should prevent junior trainees/surgeons from starting their learning curve on real life patients and thus compromising patient safety.

3. Benchmarking

Key to centralization and training are the definition of validated and objective benchmarks. Surgical volume alone is not sufficient to define a center of excellence. Quantitively defined benchmarks allow to objectively assess surgical quality. Tumor-stage specific surgical outcome benchmarks take into that a certain level of quality musty be reached to get certified as center of excellence.

4. Collaboration with scientific societies

Scientific societies are the driving factor of scientific endorsement of clinical practice. It is through scientific research that surgery will improve over time. Therefore, a strong collaboration between EU and scientific societies as EAU (European Association of Urology) and ERUS (EAU Robotic Urology Section) is mandatory to move forward for the sake of our patients

Prostate Cancer Detection and Patient-Centered Care in Europe

By Guenther Carl for Europa UOMO

Europa UOMO have these main suggestions for the forthcoming future:

a) As it is not European wide available we need a proper structured early detection system for Prostate cancer.

This must consist out of https://uroweb.org/praise-u a pilot project between EAU and the EU commission targeting early detection within 3 years on a fixed algorithm in 5 regions of Europa. Deciding on this pilots is, that we use same level of age to start, same values of PSA at age 45 and higher, same decision to image by MRI and to follow up by risk calculator and fusion guided biopsy if possible.

b) This is in line with the German PROBASE trial

https://www.dkfz.de/de/presse/pressemitteilungen/2022/dkfz-pm-22-20-PROBASE-Weltweit-erste-Studie-zu-risikoangepasstem-Screening-soll-die-Frueherkennung-von-Prostatakrebs-verbessern.php where 50000 men at age 45 (50%) and age 50 (50%) are recruited, following the same PSA formula as above mentioned, where first tentative results for age 45 are available, stating close to 90% PSA below 1 ng/ml PSA.

Means next measurement after 5 years and close to 9% PSA below 3 ng/ml consequently next measurement after 2 years. Summary between 1 and 2% are showing a PSA above the intervention level and the next figures will show the necessary clinical intervention.

As a side effect in about 6000 cases a DRE was done with a negative result regarding detection, thus it is planned to get DRE out of the guide lines for early detection.

c) Within Sweden the OPT region based early detection system is introduced the necessary basic documents are attached.

We hope with this way of handling the necessary program to identify clinical significant prostate cancer early enough for intervention and to make sure that nearly all indolent cancer is sorted out will get implemented to the benefit of men allover Europe

We additionally refer to shared decision making in the EU, where we have not only marginal differences within the member states.

Within the EUPROMS surveys (carried out by EuropaUOMO) https://www.europa-uomo.org/resources/. We could find out that a not so small number of patients report that they feel no properly involved in the decision of their treatment whether it was invasive for palliative. We urge all involved HCP's to follow this remark and to involve patients more directly when it comes to decision about treatment. Es specially when the situation becomes palliative and there are not many options about hat to do, the information about possible side effects is crucial and if not properly done might trigger decision regret. To get more details EuropaUOMO will carry out an online survey towards the end of 2024 solely targeting shared decision making and getting the voice of patients here.

EAU: Advancing Risk-Based Prostate Cancer Screening Across Europe

By Dr. Hendrik Van Poppel, Vera Vasilyeva, Sarah Collen for European Association of Urology, Arnhem, The Netherlands

Prostate cancer is the most frequent male cancer in European Union, with about 335,000 Europeans diagnosed every year, but it can often go unnoticed. A further complexity comes from the fact that only a proportion of prostate cancer cases manifest into serious disease, hence regarded as high-risk cancers, while other cases develop so slowly that they would never cause harm in men's lifetime. To improve the chances of detecting high-risk cancers early, modern prostate cancer screening programmes are increasingly incorporating the risk-based strategy, in order to decrease prostate cancer mortality, the mostly second cause of male cancer death in the EU.

A risk-based strategy implies that screened men undergo several rounds of risk stratification, diagnostic procedures, that help profile them into different risk groups. The ultimate aim is to filter out the men with high-risk prostate cancer and offer them an appropriate treatment. Those individuals with low- or medium-risk disease remain on regular monitoring. The risk-based strategy for early detection of prostate cancer was developed and published by the European Association of Urology. This strategy was ratified by the Science Advice for Policy by European Academies (SAPEA) and by the European Commission, and contributed to a wider Beating Cancer Plan. The theoretical basis for risk-based strategy is widely endorsed by clinicians, however the practical, country-wide implementation presents a potential challenge. While not utilising any new medical technology, introduction of region or country-wide risk-stratified screening requires appropriate reorganization of medical resources, and establishment of dedicated screening patient pathways within a country.

Building on the risk stratified strategy developed by the European Association of Urology, in 2022 the EU Council published updated cancer screening recommendations to bring attention to this matter in EU countries. These recommendations incorporated prostate cancer screening into the programs aligned with European guidelines and quality assurance for cancer sites. Seeing that establishment of risk-based strategy is not trivial, the EU-suggested approach for prostate cancer screening involves a stepwise implementation, including piloting and further research to assess the feasibility and effectiveness of organised programmes based on systematic invitation.

In alignment with the EU Council guidelines, the European Association of Urology together with a consortium of 25 institutions has launched a pan-European project PRAISE-U (Prostate cancer Awareness and Initiative for Screening in the European Union). This currently ongoing project created standardised key performance indicators and a protocol for quality-assured population-based screening as well as to test its implementation in 5 European sites: Poland, Ireland, Lithuania, region Galicia in Spain, and the city of Manresa in Spain. The analysis of the future pilot results will consider the performance of the risk-based strategy in regard to screening effectiveness, clinical, psycho-social, and cost-effectiveness outcomes.

Praise u
SMART EARLY DETECTION OF PROSTATE CANCER

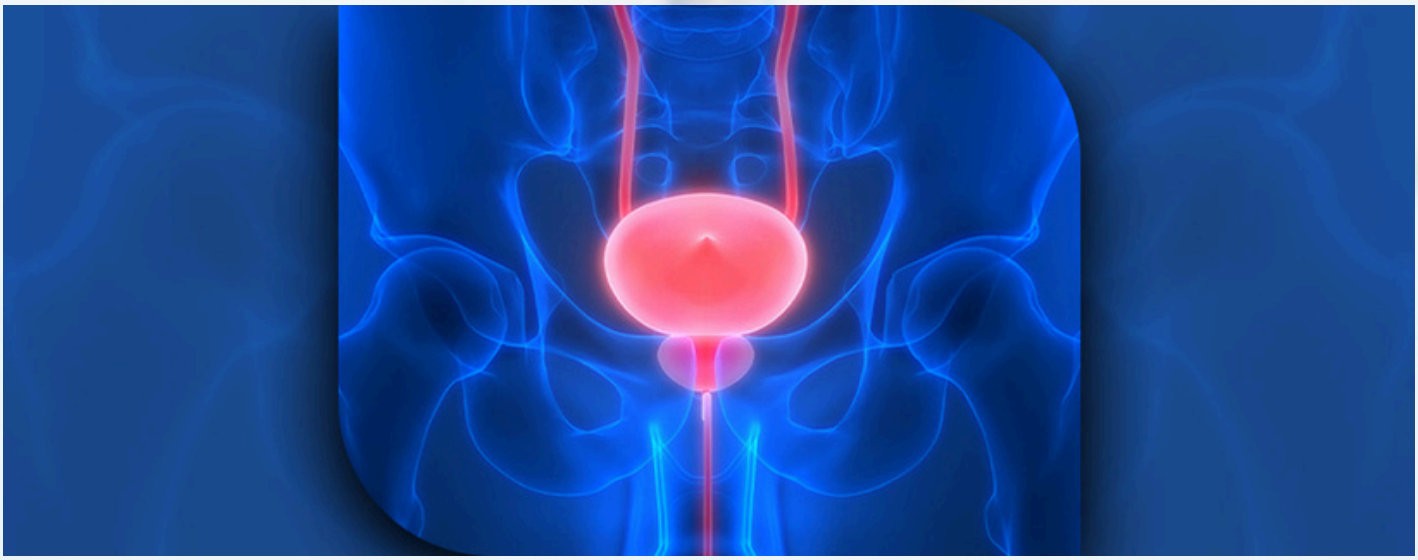
EAU: Advancing Risk-Based Prostate Cancer Screening Across Europe

By Dr. Hendrik Van Poppel, Vera Vasilyeva, Sarah Collen for European Association of Urology, Arnhem, The Netherlands

PRAISE-U was initiated in April 2023 and will last for three years in total. Throughout its first year of operation, the consortium teams have developed a solid theoretical rationale, specifically establishing a living state-of-play document for prostate cancer screening, developing key performance indicators and a codebook for assessment of pilot results, as well as country-specific protocols for implementation of risk-based screening and accompanying participant information materials. This body of knowledge has been converted into a piloting package which is being promoted to external collaborators within EU who have interest in establishment of screening programmes within their countries. PRAISE-U project is now entering its second year which focuses on start-up implementation of the pilot sites. Having received ethical approval, all 5 pilot sites are initiating invitations and participant flows within Q3 of 2024.

Within a bigger EU4Health programme, PRAISE-U assesses the implementation of risk-based strategy for early detection of prostate cancer, while its 'sister projects' TOGAS and SOLACE are addressing developments in the screening of gastric and lung cancers respectively. PRAISE-U, TOGAS and SOLACE are working towards further advancement of implementation of EU Council Cancer Screening Recommendations and have a joint vision for follow-up funding in the forthcoming EU4Health 2025 programme. These efforts, together with EU Joint Action initiative can take the achievements of the current projects to the next level towards full implementation of lung, prostate and gastric cancer screening in Europe.

"The PRAISE-U project pioneers a risk-based strategy for prostate cancer screening across Europe, aiming to improve early detection and provide high-risk patients with timely, appropriate care."



Prostate cancer care in Germany

By Prof. Dr. Igor Tsaur for Eberhard Karls University of Tübingen

Diagnosis

In Germany, men with a compulsory health insurance aged 45 or older are authorized to undergo an annual check-up encompassing medical history, examination of the external genital organs and lymph nodes as well as digital rectal examination. Critical issues include absent general reimbursement of PSA testing for screening purposes (30-40 €) and of prostate MRI (700-900 €) for males with a statutory health insurance mediating inappropriate diagnostic flow particularly in men with a low income.

Treatment

Nationwide adoption and comprehensive distribution of robotic systems leads to the claim of their maximal utilization level aiming to decrease case-based operating expenses. Coupled with minimally required annual treatment procedure numbers for certification maintenance as “prostate center” (50 treated prostate cancer cases per year), a precarious situation emerges for those centres compelling them to perform as many surgical procedures as possible. This might eventually result in an inadequate indication policy for prostate cancer surgery subjecting even low-risk cases to prostatectomy, thus representing a superfluous overtreatment. Unmet need exists for a statutory proportion of patients with low-risk cancer per centre which have to be included in active surveillance programs in order to counteract this tilt.

Another alarming aspect is a higher reimbursement for radical prostatectomy in combination with pelvic lymph node dissection as compared to that without. This absurdity fosters some surgeons to perform lymph node dissection in every case even if the risk of lymph node metastasis is neglectable and the hazard of potential complications of this procedure by far outdoes its potential life-saving benefits. This might be overcome by alignment of the reimbursement for prostatectomy with or without lymphadenectomy.

Moreover, economic pressure might further impel surgeons to perform the so-called “berry picking” resecting only a small amount of lymph nodes instead of the oncologically appropriate extended pelvic lymph node dissection which is recommended by guidelines but is more time-consuming. Thus, lymph node dissection extending the procedure of prostatectomy potentially endangers subsequent surgical cases scheduled on the same day to drop out and be postponed to another day representing a low cost-effectiveness from the economic standpoint in such a system.

In addition, there is a shortage of psycho-oncological and outpatient pain management service. This ends up in long waiting times to make an appointment which are often inappropriate for males with a limited life expectancy.

"Economic pressures and inadequate reimbursement structures risk overtreatment and hinder optimal care in prostate cancer, highlighting the urgent need for balanced healthcare policies."

Saving Progress in Cancer Care

By Dr. Aleksandra Filipovic, MD, PhD for SPCC - Sharing Progress in Cancer Care (Switzerland)

Reconnecting Body and Mind in Oncology

Our clinical reality in oncology spanning from prevention, screening, diagnosis, treatment and support in post-treatment settings, calls for an integrated and holistic approach. Somewhere between a blood test, a scan and a procedure, there is a whole person. Oncology has made and will continue to make tremendous scientific/clinical strides and improvements in detecting cancers earlier, treating to significantly extend survival while minimizing side effects, and making many previously lethal cancers, now manageable chronic conditions.

We have zoomed far in to see genomes at a granular level, we have ushered AI to mine datasets that exceed human computational capacity. And now it is time to usher the human connection back into oncology. To support procedurally, financially and systemically, that interventions and initiatives that address the body-mind connection, impact of stress, personality patterns, mental states, somatic memory of trauma etc., are recommended in our official oncology guidelines alongside standard of care.

These modalities include: Compassionate Inquiry, Internal Family Systems (IFS), Somatic Experiencing, Neurocircuitry pain reprocessing, Cranial Nerve Integration. We also call for organized support and initiatives for more clinical trials in holistic integrative oncology to expand the evidence base for these approaches in oncology care. A dedicated steering committee could be instated to oversee standardization, operationalizing, monitoring and governance related to holistic integrative oncology education, training and practice.

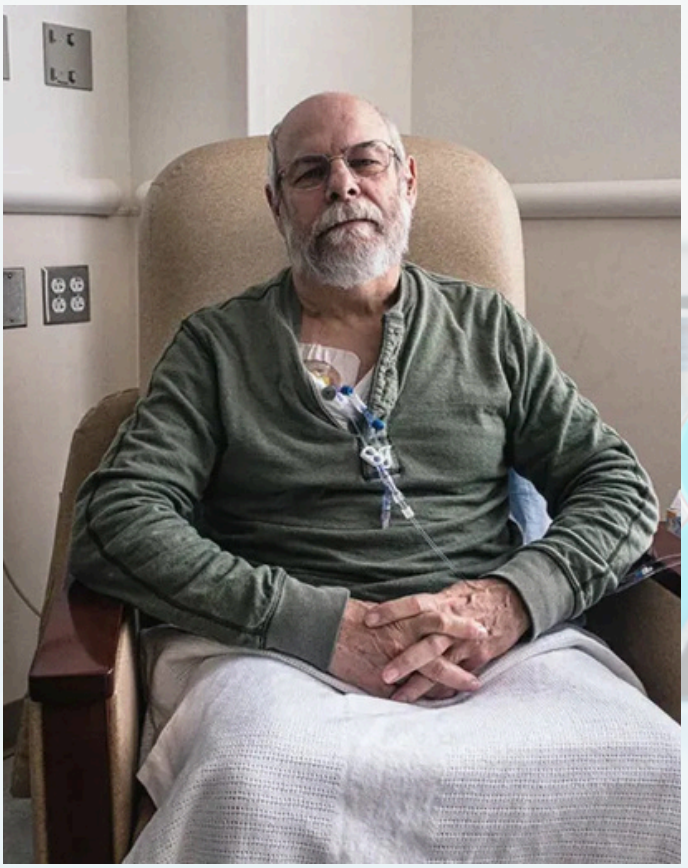
A New Narrative for Oncology Communication

Words are bio-symbols and medical narrative is one of the oldest mediums of healing. We advocate an investment into a curriculum/program, which would offer oncologists and oncology care team members broadly, a way to reframe narrative we have gotten so accustomed to using in clinic. Examples: the patient progressed/ instead of: the tumor grew and therefore clinically we call this disease progression; Patient failed treatment/instead of: treatment was not effective to induce reduction in tumor size; in clinical trial narratives patients are often referred to as subjects; etc. By having a dedicated medical narrative initiative, the words we use to speak to patients and about patients will shift and become a treatment in their own way, one that serves, supports and heals on a human level their whole being, while honoring all medical truths too.

Saving Progress in Cancer Care

By Dr. Aleksandra Filipovic, MD, PhD for SPCC - Sharing Progress in Cancer Care (Switzerland)

"Somewhere between a blood test, a scan, and a procedure, there is a whole person. It's time to bring the human connection back into oncology, integrating mind-body care alongside standard treatments."



Building Collaborative Bridges Between Academia and Industry

An open dialogue is key to discovering novel treatments and paradigm shifting breakthroughs. This requires academia and industry to come together more so in the coming years than ever. There is a wealth of untapped science in academic institutions globally and we call for initiatives that bring scientist, innovators and entrepreneurs at the same table with industry leaders, in a very tangible way.

We have witnessed the pendulum in oncology swinging from chemotherapy, to targeted agents, to immunotherapies, to anybody drug conjugates, radiopharmaceuticals and cell-based therapies, to name some major categories. Some, like chemotherapy, targeted drugs and ADCs are characterized by faster time to response, while immunotherapies that harness body's own immune system for anti-cancer effects, often require longer to elicit a clinical response. Patterns of response therefore, both in the form of time to response, nature of response, depth of response and duration of response can be unique in the immunotherapy setting.

Protracted time in excess of 18-24 months, as opposed to 6-12 months, to reading out a potentially clinically meaningful endpoint, especially in early phase clinical trials, has been known to minimize interest in investing into certain programs. With this culture of: it is too long to wait for patients to actually survive, we are turning our backs to treatments that could be the next anti-PD-1.

A call to revising pendulum swings when it comes to investment trends in oncology drug development are highly encouraged and having everyone represented from academia to industry leaders would be crucial in re-establishing values in drug development with patients' benefit over time to return of investment at the forefront.

Universal screening for prostate cancer to secure early detection and diagnosis

By The Swedish Prostate Cancer Association

All men with a medical or genetic risk of prostate cancer should be offered a PSA test and information about the advantages and disadvantages, considering the recommended time intervals.

All men aged between 50 and 75 years are entitled to PSA testing at the recommended intervals. This applies regardless of whether the region concerned participates in the Organized Prostate Testing OPT project.

Overdiagnosis should be avoided by patients with a well-founded suspicion of prostate cancer being investigated in the next step with bpMRI or as a second step after the Sthlm3 risk calculator. Biopsies should be performed transperineally for better precision and less risk of infection.

All patients should, in connection with the diagnosis, receive customized and repeated written and oral information about the disease, treatment options, effects and side effects, time perspective, rehabilitation and the possibility of choosing a healthcare provider and/or new medical assessment, as well as information about the Prostate Cancer Association and the local patient association. Partners and family members should be offered the opportunity to participate.

All patients who are diagnosed must be offered a named contact nurse. The contact nurse must always be present at meetings with and about the patient. The contact nurse is responsible for ensuring that the patient receives an individual care plan, digitally and/or in print, and that the plan is continuously updated.

Uro-oncology clinic. All patients should see both a urologist and an oncologist, individually or in the form of a joint clinic, before choosing treatment.

All patients with diagnosed prostate cancer should be discussed at a Multidisciplinary conference where interdisciplinary assessment can take place.

The patient must always be informed of the possibility of a completely new medical assessment (second opinion) in their own or another region.

The choice of treatment should not be based on age but on an assessment of health status and life expectancy. The patient's own wishes should always be given priority.

Surgery shall only be performed at quality assured and level structured clinics. The clinics must be able to openly report their activities and results, including PROM data.

Hydrogel Spacer should be used in all radiotherapy to avoid damage to the bowel.

PSMA-Pet should always be used in case of relapse after radical treatment. This also applies to early stage suspected metastatic cancer.

Approved medicines should be introduced quickly and used equally throughout the country. Prescriptions must be based solely on medical need and the patient's other circumstances. The Prostate Cancer Association also demands regulation of non-preferred drugs, such as potency drugs, to achieve a minimum and common pricing in the country.

Rehabilitation planning should begin at diagnosis, needs should be identified on an ongoing basis, and interventions should not be provided as an option but should be integrated into regular activities. For patients with more extensive problems of a medical, social or psychological nature, the necessary specialist treatment must be arranged, including rehab weeks.

HIV Report

Policy Recommendations

Ending AIDS in Europe and beyond: the urgency of now

By Eamonn Murphy, UNAIDS Regional Director for Asia Pacific and Eastern Europe and Central Asia regions

Ending AIDS in Europe and beyond: the urgency of now

Today, progress in the fight against AIDS is endangered by global turmoil, including wars, rising anti-rights movements, and funding cuts. The human and financial costs of a resurgent pandemic are unaffordable.

But ending AIDS as a public health threat is possible. The path is proven. The European Union can lead both internally and externally, driving progress across the entire European continent—and beyond—toward ending the AIDS pandemic.

Tackle stigma and discrimination

Despite the progress made in the HIV response[1] more than half of HIV diagnoses across Europe occur late, at advanced stages, highlighting the urgent need to address stigma as a barrier preventing people from seeking HIV services.[2]

A report by the European Centre for Disease Prevention and Control (ECDC) and the European AIDS Clinical Society (EACS) revealed gaps in HIV knowledge among healthcare workers in Europe and Central Asia, contributing to increased stigma: 39% were unaware that "Undetectable equals Untransmittable" (U=U), i.e. that people on treatment with an undetectable viral load cannot sexually transmit the virus. 44% lacked knowledge of post-exposure prophylaxis (PEP) for preventing HIV after potential exposure, and nearly 60% were unfamiliar with pre-exposure prophylaxis (PrEP), a daily medication for those at higher risk.

Educating healthcare workers about these tools will help reduce stigma, foster trust, promote early testing, and improve treatment.

Another driver of stigma is discriminatory punitive laws that target key populations at risk of HIV. The criminalisation of same-sex relations, sex work, or possession of small amounts of drugs for personal use, push people who are criminalized by those laws away from accessing vital health services.[3]

Across the European continent there is an urgent need for decriminalisation to facilitate public health.

Eliminating all forms of HIV-related stigma and discrimination is essential to ending the AIDS epidemic. The Global Partnership for Action to Eliminate All Forms of HIV-related Stigma and Discrimination helps countries develop practical interventions to protect the rights of people living with HIV and key populations.

This initiative targets six key areas: healthcare, education, the workplace, legal systems, communities, and humanitarian settings. Recent commitments from Germany, Luxembourg, Spain, and several Eastern European nations reflect a growing momentum across Europe to tackle HIV-related stigma.

Enable access to new health technologies

While global new HIV infections have fallen by 39% since 2010, 37 of 49 countries in the European region reported an increase in new cases in 2022. Most diagnoses—over 70% (79,144 cases)—occurred in Eastern Europe, with 20% (22,397) in Western Europe and 8% (8,945) in Central Europe.[4]

New diagnoses are especially growing amongst younger key populations, including LGBTQ+ people, sex workers, and people who use drugs.

Ending AIDS in Europe and beyond: the urgency of now

By Eamonn Murphy, UNAIDS Regional Director for Asia Pacific and Eastern Europe and Central Asia regions

Europe can help reduce the vulnerabilities of these groups by ensuring access to new and emerging health technologies, like long-acting injections for prevention and treatment. The introduction of HIV medication requiring only one injection every six months holds promise as a game-changer, particularly for key populations.

To maximize the impact of this breakthrough, it is essential to ensure access for everyone who would benefit. This requires ensuring that the price from manufacturers is affordable, which includes enabling generic production for all low- and middle-income countries, including in the European region.

Leave no one behind

Migrants, refugees, and other mobile populations face legal, social, and economic barriers that limit access to health services, including testing and treatment. This exacerbates their vulnerability to HIV.

Migrant-sensitive HIV services—enabling cost-free, fear-free, access to prevention including condoms and pre-exposure prophylaxis (PrEP), to testing, and to rapid linkage to treatment and care for those living with HIV—are crucial for protecting their health and for maintaining progress towards ending AIDS in Europe.

Address the HIV funding crisis for Eastern Europe and Central Asia

In 2023, global HIV resources fell to USD 19.8 billion, a 5% decline from 2022. There is a nearly USD 10 billion funding gap for programs in low- and middle-income countries to meet the 2025 targets. [5]This decline particularly harms Eastern Europe and Central Asia, where ongoing war, humanitarian crises, and restrictions on civic space are driving a rising epidemic.

Since 2010, Eastern Europe and Central Asia has seen a 20% rise in new HIV infections and a 34% increase in AIDS-related deaths, and only half of the 2.1 million people living with HIV are receiving treatment.

Community-led organizations are a lifeline for many affected, but lack of resources and restrictive systems hinder their efforts.

In Ukraine, facing one of the largest HIV epidemics in Europe, the government and community organisations are working to sustain their AIDS response despite the challenges of war, providing essential prevention and treatment services under extremely difficult conditions.

International solidarity is crucial.

We can end AIDS across Europe – together.

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"Ending AIDS as a public health threat is possible. The path is proven, and the European Union can lead both internally and beyond its borders to eliminate the AIDS pandemic."

Building a Robust HIV Policy Framework in the EU: Data, Equity, and Sustainable Solutions

By Dr. Alessandro Gallina, Phd for European Public Health Alliance

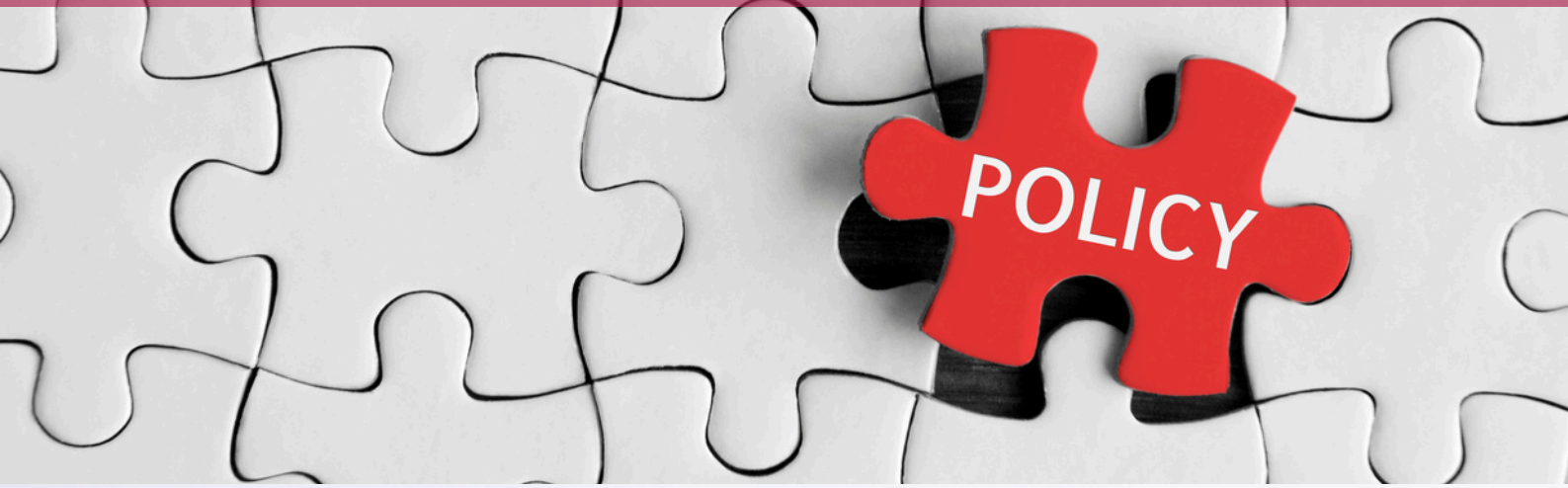
Highlighting a few important points:

- Data Availability, Quality, and Consistency within the EU: These are crucial for informed decision-making and effective policy development.
- Co-Creation as a Tool for Equitable Policies: Utilizing co-creation can lead to more sustainable and comprehensive approaches, particularly in reaching marginalized or vulnerable populations.
- Availability and Pricing of Medicines: We must continue to address the commercial determinants of health in HIV and other STIs, maintaining them as a priority.
- Caution Against Superficial Solutions: We should be wary of investing in "easy" products, like new apps, which often consume resources without delivering substantial benefits to the populations they serve.
- Comprehensive Health Vision: It is crucial to keep health high on the policy agenda, learning from past crises and advocating against budget cuts in health funding, such as the recent 20% redeployment from EU4Health.
- Regarding the potential for calling for a new Joint Action between member states, although I remain sceptical about its effectiveness due to past experiences, the clear willingness to learn from each other and share best practices was reiterated during our discussion and should be considered further. Hence, I am not excluding it a priority.

"Utilizing co-creation in policy-making fosters more equitable, sustainable solutions, especially in reaching marginalized populations and advancing comprehensive health equity."

Toward an Inclusive and Holistic HIV Policy: Bridging Health, Education, Social Services, and Justice in the EU

By Dr. Roman Winkler, MMSc



Need for HIV-policy approach taking into account a holistic public health perspective

1. Adressing the health sector

- No health without equality -> sexual health plus gender equality
- access to PrEP for all across the EU (breaking down barriers)
- establishment and support of innovative care settings, such as „evening clinics“ etc.
- focusing on vulnerable groups such as homeless people -> need for public health community centres
- establishing care settings for the elderly living with HIV
- need for multi-disciplinary care teams (public health case managers)

2. Adressing the educational sector

- sexual education throughout the educational cycle of children and adolescents
- making sexual health a general topic in schools, universities etc.

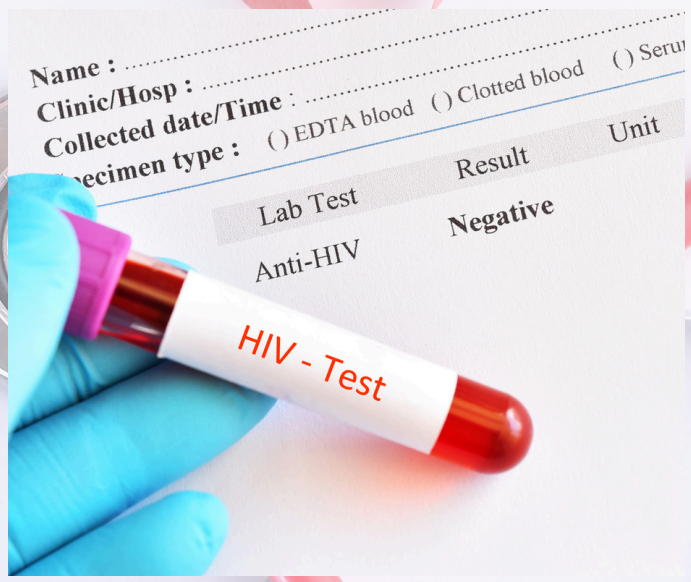
3. Adressing social services and consumer protection

- public awareness campaigns targeting anti-discrimination of HIV, risk groups

4. Adressing the justice system

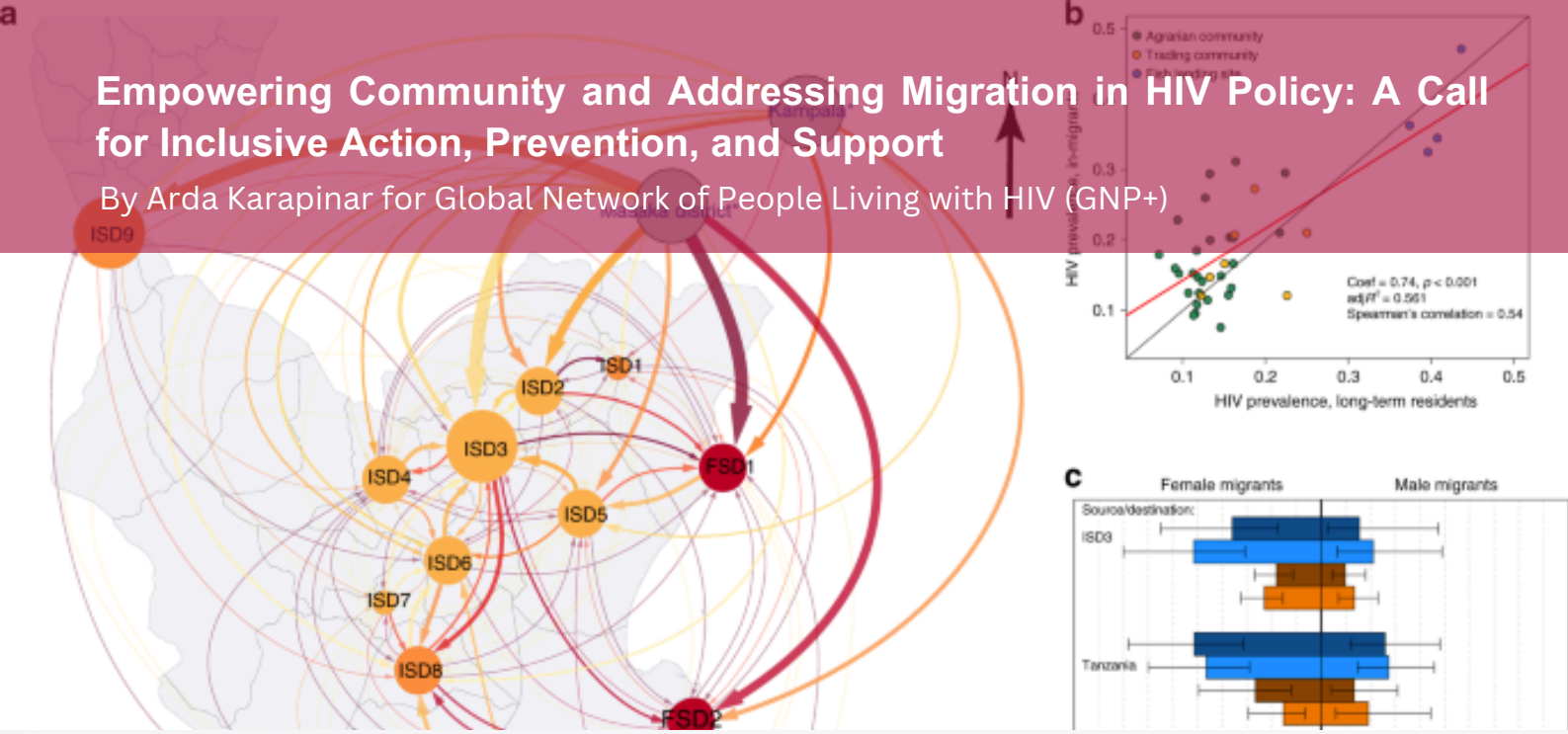
- ensuring comprehensive labour rights, access to medication and HIV-prevention in general

"No health without equality: access to comprehensive HIV care and prevention services across the EU is essential, including innovative settings that address the needs of vulnerable groups."



Empowering Community and Addressing Migration in HIV Policy: A Call for Inclusive Action, Prevention, and Support

By Arda Karapinar for Global Network of People Living with HIV (GNP+)



The first two points that I would like to emphasise again and again are the importance of community involvement in all processes and the emphasis on the importance of #UequalsU, whose impact is scientifically proven, as an essential and absolute public health tool. In particular, emphasising that the community is an equal actor and natural stakeholder and leader in all processes, from the planning phase to the implementation phases of the processes, is really important for shaping policy and decision-making processes. Of course, you know best how to formulate this emphasis in the design of the document.

Another focus should be on PrEP, citing examples of successful countries (e.g. France) and adding studies showing that the money spent on prevention saves other healthcare expenditure in the long term.

Another important focus is of course on regular and irregular migration flows;

Ukrainians and Russians are not treated further for various reasons: Fear of stigmatisation and discrimination, language barrier, unfamiliarity with how the medical system works. Poland is a red rag – the people come in the terminal stage – in poor condition, the government in Poland is very concerned. There is not enough money for the NGOs – they were not prepared to work with so many people.

The health conditions in the refugee camps require special attention. The increase in illnesses and the rising number of suicides are due to the lack of access to medical and psychological care.

Recommendations:

Research needed – health status of refugees.

More funding for NGOs – dedicated funding streams for NGOs to expand their services and help people overcome barriers - overcoming fear of discrimination, language support and navigating the medical system.
There are quite a few refugees from Ukraine and Russia who have been working in the HIV response – they can support efforts but need to be integrated into the systems of countries hosting refugees.

Special assessment of access in refugee camps and special attention is needed there.

"Community involvement at every step is essential; as equal actors in planning and implementation, the community's role shapes policies that address real needs and enhance public health."

Improving the prevention of HIV and the care of patients living with HIV

By Vincent Barvaux for Institute of Tropical Medicine in Antwerp, Belgium

Suggestions with regards to the prevention of HIV and the care of patients living with HIV:

- Promote innovative strategies to encourage testing for HIV in people at risk of HIV infection but not regularly tested (such as women from subsaharian Africa)
- Facilitate free self-testing for HIV; this will require funding for health care centres to take care of patients with HIV/STI detected through this method
- Use social medias to promote testing for HIV
- Provide truly free access to PrEP for people who are at risk of HIV infection
- Better integrate Community Based Organisations into the care provided to patients at risk of HIV infection and patients living with HIV
- Improve the psychological support of patients living with HIV
- Develop holistic approach to ageing patients living with HIV

"Promoting innovative strategies, from free self-testing to holistic support, is crucial in advancing HIV prevention and care for those most at risk."

Healthcare challenges faced by the aging HIV population in Europe

By Prof. Dr. Jaime Vera, MD PhD MRCP DTMH for Brighton and Sussex Medical School, U.K

Due to the success of combination ART, people with HIV are living longer, and it is expected that by 2030, most individuals receiving care for HIV in Europe will be over 50 years old. Evidence from several European cohort studies involving people with HIV over the age of 40 has shown that they have a higher prevalence of comorbidities, geriatric syndromes, and mental health issues compared to the general population. These chronic conditions often present up to ten years earlier in people with HIV.

Currently, infectious disease services are not equipped to address the complex healthcare needs of this aging population, particularly given the limited capacity of clinics. To meet these challenges, innovative, inclusive models of care are needed. Such approaches could not only improve health outcomes for aging people with HIV but also reduce healthcare-associated costs.

Older individuals living with HIV are calling for services and interventions that help prevent and manage the effects of multimorbidity, frailty, and mental health challenges, while also addressing social isolation and the stigma that continues to affect them. There is also a pressing need for comprehensive social care and end-of-life care provisions, including training for social care workers to reduce stigma.

While the HIV treatment cascade in most of Europe is highly effective, with most people aware of their status and engaged in care, the demands of keeping aging individuals on treatment and providing holistic, patient-centered care remain significant. Healthcare providers are urging health commissioners to recognize that, despite the success of treatment, HIV care is far from complete. New services and approaches are needed to ensure people remain engaged in care and maintain a good quality of life. New services and interventions should be co-produced with patients and HIV healthcare providers to ensure they are inclusive, acceptable, and cost-effective for healthcare systems across the region. Eliminating HIV transmission remains an important goal, but equally important is ensuring that those living with HIV receive excellent physical, mental, and social care, free from stigma

"As people with HIV live longer, innovative, inclusive care models are essential to manage aging-related health challenges, reduce stigma, and support a holistic quality of life."

Improving access to care, advanced testing and treatment

By Elske Hoornenborg, MD specialised in Internal medicine and infectious diseases, GGD

Barriers to care

- Give specific attention in policies regarding access to HIV prevention, testing and linkage to care to Transgender communities, sex workers, and mobile populations including asylum seekers, refugees e.g from Ukraine and other migrant groups.
- Stimulate co-creation and cooperation between communities and governmental organisations

Advanced testing and treatment

- Make an EU statement that affordable self-testing should be available
- same for affordable PrEP and PrEP-care
- Make sure that information on services regarding testing and treatment is available and easy to find, in multiple languages, for migrants (e.g like at the website https://www.queersbeyondborders.info/)
- Spread the word about cost-effectiveness of PrEP

Access, Education, and Rights in HIV Prevention and Care

By Veerle Doossche, Policy Officer HIV and STD - SENSOA

Contributions from Sensoa:

- Ensuring access to comprehensive sexuality education for everyone living in the EU
- Making PrEP and hiv-medication accessable and affortable for everyone, with special attention for uninsured people.
- Advocate for a coordinated approach between member states regarding access to PrEP for travelling sex workers.
- Addressing the importance of community-based organisations for HIV prevention (including PrEP), testing and referral to care.
- Involving people living with HIV in policy making -and implementation
- Being attentive to current waves of migration and the impact on the HIV epidemic
- Attention to the ever-growing group of people ageing with HIV and the needs this brings: the need for multidisciplinary care and good coordination of this care by means of a case manager.
- And last but not least: the EU should hold Member States accountable to their international commitments on sexual and reproductive rights. Because discrimination and a hostile legal framework has severe negative impact on both HIV prevention, HIV-testing and access to care.

"The EU must ensure access to comprehensive sexuality education and affordable HIV prevention and care, holding member states accountable for upholding sexual and reproductive rights."

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