

Cancer Screening Forum Session 29th November 2022, 11:00-12:30 (CET) - on Zoom Summary note

Participants

Ivana Cattaneo, Novartis Oncology (MODERATOR)

Rebecca Fitzgerald, University of Cambridge & Chair of the SAPEA Board on Cancer Screening

Gian Paolo Morgano, Joint Research Centre (JRC), European Commission

Peter Jepsen, The European Association for the Study of the Liver (EASL)

Claire Albano, Bristol Myers Squibb

Sarah Cook, Cancer Research UK (CRUK)

Alice Brookes, Cancer Research UK (CRUK)

Samantha Harrison, Cancer Research (CRUK)

Ricardo Moschetti, European Cancer Organisation (ECO)

Richard Price, European Cancer Organisation (ECO)

Yoanna Nedelcheva, The European Association for the Study of the Liver (EASL)

Torsten Gerriet Blum, European Respiratory Society (ERS)

Laura Williams, Cancer Research (CRUK)

Sarah Collen, European Association of Urology (EAU)

Hendrik Van Poppel, KU Leuven

George Griffin, Immediate Past President of FEAM/ UK Academy of Medical Sciences

Hannah Whittle, FEAM Scientific Policy Officer

Laure Guillevic, FEAM Policy Officer

Ruben Castro, FEAM Communication Officer

Patrick Hurst, FEAM Junior Policy Officer

Elisa Corritore, FEAM Forum Scientific Policy Manager

Welcoming remarks

George Griffin, Immediate Past President of <u>FEAM</u>, provided some opening remarks. He stressed the importance of the topic of cancer screening and welcomed its central focus in the discussion today. Whilst there have been huge scientific advances in cancer screening, he noted that the EU guidance still dated back to 2003. Therefore, he welcomed the recent <u>SAPEA</u> project on cancer screening in the EU, culminating in a <u>report</u> which closely informed the <u>European Commission's proposal</u> on updating cancer screening guidelines. George Griffin noted that the proposal is currently being reviewed by the Council and he eagerly anticipated the outcome in early December. Ivana Cattaneo, <u>Novartis</u>, also warmly welcomed the audience and noted that the discussion would focus on the SAPEA cancer screening report and the European Commission's perspective, followed by a Q&A and then an update on the multi-cancer early detection landscape.

Presentation by Rebecca Fitzgerald on the recent SAPEA Cancer Screening report, entitled 'Improving Cancer Screening in the European Union'

Rebecca Fitzgerald started her intervention by highlighting the necessity of the <u>SAPEA report</u> on cancer screening. Whilst the survival rate for patients diagnosed with late-stage cancer (stage 3 & 4) is around 26 percent, the survival rate for early-stage cancer (stage 1 & 2) is considerably higher, around 81 percent. Unfortunately, 50 percent of all cancer cases are diagnosed at the late stage. Rebecca Fitzgerald noted that 2.7 million people in the EU were diagnosed with cancer in 2020 and 1.3 million died. In this context, the importance of early and accurate cancer detection is clear.

Rebecca Fitzgerald then stated that a triage concept should be applied for screening and early detection. Ideally, this means that only people with the target condition will be identified as high-risk, and therefore they will be exclusively screened. She then outlined the process of the SAPEA project on cancer screening, which began with evidence gathering and synthesis. There were three separate workshops, all assembling a team of experts, with the aim of answering the three following questions:

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

These workshops culminated in the report on cancer screening. Rebecca Fitzgerald noted that there were three main recommendations which emerged: 1) Ensure that existing screening programmes for cervical, colorectal, and breast cancer integrate state-of-the-art scientific knowledge, 2) Extend population-screening programmes to additional cancers with evidence for a good harm-benefit ratio, cost-efficiency, and feasibility throughout the union, 3) Take advantage of rapidly developing technologies to optimise early diagnosis and risk-based cancer screening in the future.

From the first workshop, a couple of general suggestions emerged: improve the participation of citizens in existing cancer screening programmes by making access to screening easily, and ensure that best practices and standards are developed and applied. Specifically, regarding breast cancer, Rebecca Fitzgerald noted the proposal for a Council recommendation, which suggests extending breast cancer screening for women between 45 and 74 years of age. Regarding cervical cancer, the GCSA recommendation was to prioritise screening by testing for human papilloma virus (HPV) and support

its eradication through the uptake of vaccination against HPV below 15 years of age. Furthermore, regarding Colorectal cancer, it was recommended to use faecal immunochemical testing (FIT) as the preferred triage tests for individuals for follow-up colonoscopy.

The second workshop examined the feasibility of extending screening programmes to other cancers, such as lung, prostate and gastric cancers. Rebecca Fitzgerald noted the GCSA recommendation for lung cancer, which is to extend screening programmes to lung cancer using low-dose computed tomography for current and ex-smokers. The recommendation was issued due to the strength of the evidence showing a reduction in cancer mortality for smokers and ex-smokers aged 50 to 80 years, when given low dose CT scanning (LDCT). Regarding prostate cancer, Rebecca Fitzgerald stated that the recommendation was to extend screening programmes to prostate cancer using prostate specific antigen (PSA)-based cancer screening. Finally, Rebecca Fitzgerald outlined the GCSA recommendation for gastric cancer, which is population-based screen and treat programmes for Helicobacter pylori in regions with intermediate to high gastric cancer incidence.

Rebecca Fitzgerald closed her presentation by reiterating that there are crucial opportunities available to the EU Commission member states to optimize existing breast, cervical and colorectal cancer screening programmes. She noted that the promising emerging tests and novel multi-cancer screening technologies have the potential to make a real impact in ensuring uniformity, quality and equity in cancer screening across the EU.

Ivana Cattaneo thanked Rebecca Fitzgerald for her interesting overview and praised the report for being based on firm scientific evidence and for containing practical and useful recommendations.

Presentation by Gian Paolo Morgano, JRC Healthcare Quality, on the European Commission perspective

Gian Paolo Morgano provided an update from the <u>European Commission</u> perspective. He began by outlining the background of the EU cancer screening legislative progress. In 2003, there was a <u>Council recommendation</u> for national population screening programmes for breast, colorectal and cervical cancer, followed by the European Parliament and the Council asking the European Commission to develop new guidelines based on scientific directives and quality assurance scheme for screening and care. In light of this request, the European Commission has created three initiatives on breast, colorectal and cervical cancer. Gian Paolo Morgano noted that the aim of each initiative is to improve the quality of cancer prevention, screening and care and contribute to reduce inequalities in accessing cancer services across Europe. There are two main components to these initiatives: 1) evidence-based guidelines recommendations on cancer prevention, screening and diagnosis, 2) quality assurance schemes covering the entire cancer care pathway.

Firstly, the <u>European commission initiative on Breast cancer (ECIBC)</u> was launched in 2015. Gian Paolo Morgano stated that there had been 76 recommendations on screening and diagnosis, as well as 18 plain language summaries tailored for women and patients and 4 good practice statements. Gian Paolo Morgano also noted that the guidelines are regularly updated every three years. In the latest update, 2 new recommendations were issued, including the use of AI in mammography reading, and 7 recommendations were updated. It was noted that a new update of the guidelines will commence soon.

Secondly, the <u>European Commission Initiative on Colorectal Cancer (ECICC)</u> was launched in 2022. This initiative follows a new methodological framework for a guideline-based quality assurance scheme development. Gian Paolo Morgano noted that a multidisciplinary working group of 15 members was

quickly assembled, including representatives from patients' groups. He also noted that the initiative is currently in the preparation phase and the development phase will begin soon, followed by the updating phase from 2025 onwards. Furthermore, Gian Paolo Morgano stated that 50 healthcare questions on primary prevention and screening have been prioritized and will be likely included in the European Colorectal Cancer guidelines. Gian Paolo Morgano also noted that the ongoing stakeholder's consultation on the prioritization of additional healthcare questions will be published by the end of 2022, and the first set of recommendations is expected in the first half of 2023.

Finally, Gian Paolo Morgano outlined that the European Commission Initiative on Cervical Cancer (ECICvC) is not yet operational, but it will soon be launched. It will benefit from the support of the International Agency for Research on Cancer (IARC) and it will closely mirror the methodological approach of the other 2 initiatives.

Q&A session 1

Ivana Cattaneo thanked both speakers for their interesting presentations. After discussing the scientific and political dimension of cancer screening guidelines, she inquired if they were satisfied with the current situation. Gian Paolo Morgano provided a brief reflection, stating that he had reviewed the draft Council recommendations and noted that, in line with ECIBC, the <u>draft Council recommendations</u> suggest breast cancer screening between the ages of 45 and 74. Rebecca Fitzgerald asked Gian Paolo Morgano for further information about the use of AI in mammography, given that this was a new recommendation that emerged from the <u>European commission initiative on Breast cancer (ECIBC)</u>. Gian Paolo Morgano explained that the recommendation is to use AI in a supporting role for radiologists, but never to fully replace human involvement, due to the increased risk of false positives. Furthermore, Richard Price, from the <u>European Cancer Organisation (ECO)</u>, noted that the <u>European Commission Initiative on Colorectal Cancer (ECICC)</u> was mentioned as having an impact on the EU and beyond, and asked for further clarification. Gian Paolo Morgano explained that the idea is to make products that may be useful for other countries as well, outside of the EU member states. Other third countries can make a request to use the Commission's systematic reviews in order to inform their guidelines.

Peter Jepsen, from the European Association for the Study of the Liver (EASL), directed a question to Rebecca Fitzgerald about the absence of mention of other high incidence cancers in her report, such as liver and bladder cancer. Rebecca Fitzgerald stated that they considered the prevalence of the types of cancer and the strength of evidence, before making their decision. She added that it was imperative to determine whether the risks outweigh the potential benefits, thus decisions were taken on the basis of robust, prospective evidence. Furthermore Torsten Blum, from the European Respiratory Society (ERS), raised two points. Firstly, he expressed concern about the rumoured EU Council recommendations in relation to lung cancer screening, stating that the SAPEA report recommendations had been watered down. Secondly, he noted that his consortium for lung cancer has received a grant from the EU4Health programme to propose comprehensive lung cancer guidelines, and he required assistance in aligning the guidelines. Gian Paolo Morgano agreed to reach out to Torsten Blum via email after this session and coordinate on this.

Hendrik Van Poppel, <u>KU Leuven</u>, and Sarah Collen, <u>European Association of Urology (EAU)</u>, asked about the Council recommendations due to be published on the 9th December. Furthermore, they inquired whether prostate cancer would be included in the recommendations and, if so, would there

be a European Commission prostate cancer initiative, as there is for breast, colorectal and cervical cancer. Gian Paolo Morgano was uncertain but assumed that if prostate cancer is included, there would be an initiative on prostate cancer as well. Additionally, Claire Albano intervened on behalf of Bristol Myers Squibb. She expressed her support for the Beating Cancer Plan, as it has created a prioritization of a specific disease. Claire Albano also stressed that good policy making should always rely on evidence and she welcomed the cancer screening guidelines as a solid first step. She added that an ambitious screening programme will be cost-effective in the long term.

Finally, George Griffin, Immediate Past President of FEAM, mentioned a project called <u>EU-TOPIA-EAST</u>, coordinated by Harry de Koning, who is a Professor of Public Health and Screening Evaluation at <u>Erasmus MC University</u>, <u>Rotterdam</u>. This project aims to implement effective screening programmes for breast, cervical and colorectal cancer in three exemplary Middle-Income Countries (MICs) in Eastern Europe. Rebecca Fitzgerald added a comment, calling for the final Council recommendations to be evidence based and flexible.

Multi-cancer early detection (MCED) landscape update from Alice Brookes, Cancer Research UK (CRUK)

Alice Brookes began her intervention by providing an overview of the multi-cancer early detection tests landscape. She highlighted the <u>CRUK early diagnosis waterfall</u> and remarked that action is required on all fronts to improve cancer survival outcomes. An MCED is a multi-cancer early detection test, which is designed to identify the presence of many types of cancer from one sample. Alice Brookes noted that the potential applications of MCEDs included asymptomatic screening, symptomatic diagnostic pathways, as well as treatment selection and minimal residual disease (MRD) detection. Alice Brookes also reflected on some of the challenges of MCEDs:

Performance

- Can MCEDS detect early-stage cancers with high sensitivity and specificity?
- How will MCEDs perform in a real-world setting?
- How do we ensure overdiagnosis is minimized?

Evaluation

- Do we evaluate MCEDS by cancer site or overall?
- Should filters be applied to tests (to implement for certain cancers)?
- Is stage shift a suitable surrogate endpoint to suggest mortality?

Patients

- How do we ensure the potential benefits outweigh the harms?
- What will patient acceptability and behaviour towards MCEDs be?
- Will MCEDs exacerbate or help address inequalities?

Implementation

- How will MCED implementation impact the workforce?
- How do we ensure effective implementation?
- Will MCEDs be cost effective?

Furthermore, Alice Brookes discussed the predicted timeline for MCEDs. The blood-based multi cancer symptomatic pathways will become fully operational in around 5 years, whereas the blood-based multi cancer asymptomatic screening will become operational after 10 years. Alice Brookes provided the example of the Galleri test, which is a new blood test to detect cancer, currently being trialed in the National Health Service (NHS). She noted that the first results of the asymptomatic screening trial

are expected in 2023 and the results of the symptomatic pathways test are expected very soon. However, Alice Brookes also highlighted that the MCEDs is a busy research space and there are other promising MCEDs in trials as well, in addition to the Galleri test.

Q&A session 2

Ivana Cattaneo asked what lessons the EU can learn from the UK approach, regarding the ongoing NHS trials. Alice Brookes highlighted the importance of designing a trial with clear outputs and end points and collecting accurate evidence in advance. George Griffin inquired about the Galleri test, asking whether there is any evidence that sequential testing is useful in cancer survivorship to help patients who have already been diagnosed with cancer in the past. Alice Brookes noted that this is one of the major areas of research currently. Although there is a great focus on screening for cancer diagnosis, there are also many studies examining post cancer monitoring. Furthermore, Torsten Blum congratulated Alice Brookes on the important work of CRUK and, referencing lung cancer screening, he asked if different signals are found in smokers and non-smokers in genetic testing. Alice Brookes stated that she hadn't seen any evidence of the tests reporting a difference in signals between the two groups, before adding that increasing the accuracy of cancer signal origin prediction is crucial. Peter Jepsen asked about the stage of the cancer and the detection/diagnosis through the MCEDs, and Alice Brookes confirmed that the late stage, aggressive cancers are detected at a higher prevalence. Finally, Ivana Cattaneo asked all three speakers to state the key advice and recommendations they would provide to individual member states. Rebecca Fitzgerald stressed the importance of planning, sustainability and coordination with other member states. Gian Paolo Morgano echoed Rebecca's comments and added that the dissemination of cancer screening guidance is vital. Samantha Harrison, Cancer Research UK (CRUK), intervened and stressed the importance of learning from each other and sharing best practices.

Concluding remarks

George Griffin thanked all the participants for their participation and provided some closing remarks. He stated that the field of cancer screening is witnessing rapid scientific progress, referencing the promise of emerging MCEDs such as the Galleri tests. Furthermore, he reiterated that evidence-based policy and research will be the way forward in navigating this rapid progress. Finally, he remarked that this is not a competition, but a way forus to better serve our communities and individuals.