



Making Hope Reality – Action on Treatment and Care for Metastatic Cancer Patients

Action Report

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Executive Summary

- This meeting brought together leading policymakers, politicians, oncology experts, and patient advocates to assess the present status of care for patients with metastatic cancer, their particular needs, the policy challenges and the opportunities for improvement.
- The meeting also discussed the implementation of Europe's Beating Cancer Plan and Cancer Mission, as well as other EU policy developments, considering their potential implication and application for enhancing the quality of cancer care received by patients with metastatic cancer.
- The Roundtable provided an opportunity to present the results of a survey of healthcare professionals in Europe and the United States, focused on unmet needs of non-small cell lung cancer (NSCLC) patients with brain metastases.
- Key highlights from this research included that as much as 40% of healthcare providers specialised in caring for NSCLC patients feel less than well equipped to do so.
- Policy challenges were highlighted by experts in respect to metastatic breast, prostate, and lung cancer.
- Among the key recommendations for action that emerged from the conversation were:
 1. Patients with metastatic cancer have particular needs in respect to treatment, care and symptom management. This should be reflected in specific policy to better address these needs.
 2. Patient organisations should be supported within health systems to address the information and care needs of patients with metastatic cancer.
 3. A cultural change is required within political and health systems in respect of metastatic cancer. Hope is under-emphasised, yet treatment and care innovations often provide reason for it.
 4. Improvements in genetic testing of cancer can help in the provision of better treatments, including in respect of patients with metastatic cancer.
 5. Too many cancer patients in Europe do not benefit from biomarker testing. This is a significant source of cancer inequality which should be encompassed within the EU agenda on cancer inequalities.
 6. Patient awareness and understanding about biomarker testing should also be improved. There is an important role in this respect for patient organisations, which should be supported by healthcare systems.
 7. Clinical trials are not sufficiently including cancer patients with metastases. This imbalance should be addressed, including via more realistic trial inclusion and exclusion criteria.
 8. Our oncology data approaches in Europe are deficient when it comes to metastatic cancer. A prime example relates to registries, which are not adequately recording metastatic cancer and cancer recurrence. In the context of Europe's Beating Cancer Plan, the EU Mission on Cancer and the establishment of the European Health Data Space, this deficiency should be addressed. The European Cancer Organisation's Digital Health Network has recommended political targets on registry interoperability as one means to support this.

It is intended that the outcomes of this Roundtable, the evidence shared, and recommendations within discussions, can be brought forward in the present policy environment to help ensure the needs of metastatic cancer care are better reflected in the implementation of European and national cancer policies.

Foreword

By Matti Aapro, President of the European Cancer Organisation (ECO), and Kathy Oliver, Co-Chair of the ECO Patient Advisory Committee

We were delighted to recently welcome leading policymakers, oncology experts, patient advocates, and industry partners to a special Community 365 Roundtable Meeting on Metastatic Cancer. We were united by a shared sense that, too often, the particular needs of patients with metastatic cancer are not fully appreciated when we drive forward new cancer policy initiatives. We also perceive a landscape of opportunity in this sector of cancer care. New technologies and treatment strategies are offering chances for better prognosis and quality of life for our metastatic cancer patients. But to attain these, we must understand the barriers that remain in respect to implementing these improved forms of care, and take action accordingly. That was the underlying motif that can be discerned from the contributions at the Roundtable and that is represented in this report of the proceedings, *Making Hope Reality: Action on Treatment and Care for Metastatic Cancer Patients*.

The meeting opened with the publication of startling and thought-provoking results from a Survey on Unmet Needs of Non-Small Cell Lung Cancer (NSCLC) Patients with Brain Metastases.¹ This reminded us all of precisely the kind of double burden a patient with metastatic cancer can face - the symptoms associated with two or more tumours. Physicians and healthcare professionals may not always feel fully equipped to respond to the particular needs of a metastatic cancer patient, including in respect of supportive care and information. The survey by Ipsos Mori called on all of us to do better.

In addition to metastatic lung cancer, our Roundtable also focused attention on other real-life case studies involving metastatic breast and prostate cancer. We also heard of new ways to provide more opportunities for metastatic cancer patients, including the way in which biomarkers can be used in each case to improve treatment outcomes, survival, and quality of life.

NSCLC patients with brain metastases often experience multiple neurological, physical, cognitive and psychological side effects, and therefore the coordination of care of this particular patient group is often challenging. NSCLC patients with metastases (and their caregivers) also experience quality of life issues and often lack the required support services needed to tackle them. Gaps exist in the information available to NSCLC patients with brain metastases and their caregivers, which prevents optimal treatment and progress. Discrepancies in lung cancer treatment rates across Europe, late diagnoses, a high symptom burden, and the need for accurate tumour subtyping are all specific features of metastatic lung cancer, and require a multidisciplinary approach to maximise treatment outcomes.

There is a need to exploit the full potential of biomarkers and testing in metastatic cancer. In the context of relevant EU policy initiatives, such as the establishment of a Cancer Inequalities Registry, opportunities should be taken to address inequalities in access to, (and quality of), biomarkers and testing in metastatic cancer across Europe. Furthermore, there are also opportunities to improve awareness, education, and information to patients in this respect.

In metastatic breast cancer, there is a need for improved access to data, better treatments, better support and better quality of life for women of all ages, education, and income levels. Successful consensus-building and policy initiatives in the metastatic breast cancer field are therefore required.

In the context of the dramatic impact of Covid-19 on cancer across Europe, a collaborative approach is needed between healthcare professionals, patients, and other stakeholders to tackle the challenges posed to men's health as well, and in particular, to metastatic prostate cancer patients. The crucial importance of multidisciplinary cancer care and the central role of nurses, as well as the need for better pan-European data on prostate cancer, should all be recognised and utilised to address these challenges.

Overall, the Roundtable, and its report, are well timed in order to influence the implementation of Europe's Beating Cancer Plan, the EU Mission on Cancer, the development of the European Health Data Space, and future reforms to the pharmaceuticals regulatory landscape. All of these initiatives offer opportunities to contribute to the creation of an improved policy environment for metastatic cancer care. We hope our report makes it clear that these opportunities should not be missed.

The Challenges of Brain Metastases: Presentation of Survey Results on Unmet Needs of Non-Small Cell Lung Cancer Patients with Brain Metastases

The first session presenting the survey results on Unmet Needs of NSCLC Patients with Brain Metastases was chaired by Kathy Oliver, Co-Chair, Patient Advisory Committee, European Cancer Organisation, and Chair & founding Co-Director, International Brain Tumour Alliance (IBTA), and Hampton Shaddock, Head, Global Affairs, Oncology, Sanofi Genzyme

Kathy Oliver, Co-Chair, Patient Advisory Committee, European Cancer Organisation, and Chair & founding Co-Director, the International Brain Tumour Alliance (IBTA), opened the session by stressing that brain metastases are amongst the most devastating and feared complications of cancer. The spread of cancer from the lungs to the brain is one of the most lethal forms of metastases. Brain metastases can cause substantial side effects such as acute headaches, seizures, paralysis, memory problems, mood swings, changes in personality, and other challenges. These effects are even more significant as they affect so many aspects of what makes us human beings, and who we are as people.

Oliver explained that care, support, information, and policy relating to 'the brain metastases journey' all need to be improved. The session aimed to highlight these, underpinned by the presentation and publication of findings from an Ipsos MORI survey on the unmet needs of non-small cell lung cancer (NSCLC) patients with brain metastases.¹

She underlined how critical the findings of the Ipsos MORI survey are in terms of highlighting how better outcomes for metastatic patients may be achieved. Patient organisations which have historically been highly focused on primary brain tumours, are now increasingly understanding the range of support and information needs for people with metastatic brain tumours that require a fuller response.

A Collaborative Approach as the Gold Standard

Kathy Oliver highlighted that many of these patient

organisations already have huge experience in helping people with primary tumours, and primary and metastatic cancers share many of the same challenges and quality of life issues. As such, a collaborative approach should be encouraged as the gold standard. Ensuring the appropriate support for caregivers of metastatic cancer patients is also an area needing more attention, as revealed by the Ipsos MORI survey.

Hampton Shaddock, Head of Global Affairs Oncology at Sanofi Genzyme, said that for those patients with NSCLC, up to 40% will develop brain tumours.

Survey Results on Unmet Needs of Non-Small Cell Lung Cancer Patients with Brain Metastases

Jemma Reast, Research Manager and Advocate for Patient Voices, at Ipsos, presented the survey results, beginning with an overview of the survey rationale and methodology. On behalf of the Sanofi and Regeneron Alliance, and in collaboration with the European Cancer Organisation, Ipsos conducted an online survey among 350 participants who chose to take part in the survey, (oncologists and respiratory specialists directly involved in treating a minimum of five NSCLC patients a month, of which at least one has/had brain metastasis, and practicing for 3-30 years), across the US (100), UK (50), Germany (50), France (50), Spain (50), and Italy (50), between 3-27 September 2021.

Challenges of Care: NSCLC with Brain Metastases

The survey reveals that patients suffer an array of symptoms linked both to their NSCLC and brain metastases, which leads to physical and psychological deterioration. On average, surveyed physicians identified a range of 17 symptoms that NSCLC patients with brain metastases might experience. Typical NSCLC symptoms are compounded further by symptoms considered most unique to brain metastases. Coordination, speech, memory, and one's state of confusion,

alongside headaches, seizures, and vision changes constituted the top seven symptoms unique to brain metastases, all of which relate to a patient's cognitive function.

This is perhaps the reason why coordination of medical care is acknowledged as a particular challenge for NSCLC patients with brain metastases by physicians.

"It is more challenging to coordinate the medical care of a NSCLC patient with brain metastases compared to NSCLC patients (without brain metastases)"

Three in four survey respondents agreed that coordination of medical care is more challenging for NSCLC patients with brain metastases, compared to those who have NSCLC only (without brain metastases).

When treating NSCLC patients with brain metastases, challenges experienced by physicians are vast and varied. On average, physicians considered seven activities within the management of NSCLC patients with brain metastases to be a challenge. Core challenges highlighted in the research were *lack of time to have a detailed conversation with a patient in the official time allotted for appointments*, and *lack of quality information to share with patients and caregivers*.

Interestingly, access to a survivorship plan was only identified as a priority support service by 5% of the respondents, coming after a variety of support groups.

The Emotional Side of NSCLC with Brain Metastases

In respect to top challenges faced by NSCLC patients with brain metastases according to physicians, the survey results revealed that the top two were *shortened life-expectancy*, and *impact of diseases on independence*. In addition to physical and mental impairment, emotional distress was perceived to be a challenge for patients, with 50% of physicians surveyed selecting it within patients' top seven challenges. Half of all HCPs reported *providing emotional and/or moral support to the patient and their caregivers and family* as challenging.

Physicians viewed themselves as the most useful resource to patients and their caregivers. Two in three ranked *"face to face support with oncologist"*, or *"online support with oncologist"* in 1st, 2nd, or 3rd place as most useful in accessing information about patients' condition. However, many reported challenges with having open conversations with patients and caregivers, with two in five physicians finding it challenging *"being open and honest with the patient if asked difficult questions (e.g., on prognosis, likelihood of recurrence, etc)"*.

40% of HCPs felt less than well equipped ('*somewhat equipped*', '*fairly poorly equipped*', or '*very poorly equipped*') in managing NSCLC patients with brain metastases, with 60% stating they felt *fairly well equipped*, or *very well equipped*.

Support Needs for NSCLC with Brain Metastases

Most physicians acknowledged that patients might want more information on their disease. Particularly, for example, on life expectancy (64% of HCPs), side effect management (52% of HCPs), radiation therapies (52% of HCPs), and end-of-life care (52% of HCPs).

Caregivers to those with brain metastases become even more involved in care management, and also require support, with 72% of those surveyed agreeing that *"Caregivers of NSCLC patients with brain metastases are more stressed than caregivers of NSCLC patients without brain metastases"*. Additionally, oncologists and support groups with other patients with NSCLC and / or brain metastases, were found to be important in providing information.

"How satisfied are physicians with the information that is available?"

The majority of physicians claimed to be satisfied with the amount of information available to patients and caregivers, however a quarter were dissatisfied. When asked what materials they have at their disposal to offer patients, there was a large number who referred them to online resources. In addition to this, close to 1 in 5 responding physicians did not know what materials they could offer to their patients, or had none available.

It is important to recognise that HCPs usually provide information to their patients in generic form, whereas support groups (which also play an important role), can provide information specific to patients with brain metastases. However, it is also worth noting that, whilst support groups are deemed valuable in this study, there doesn't appear to be specific support groups in any of the countries surveyed for NSCLC patients with brain metastases.

Psycho-Social Support Services

Csaba L. Dégi, Director, International Psycho-Oncology Society (IPOS), and Board Member, European Cancer Organisation, provided a reaction to the survey from the quality-of-life perspective. Dégi called upon policymakers to improve psycho-social support services for cancer patients with metastases. The burden of cancer distress becomes more and more multi-layered as metastases progress. In terms of long-term survivorship, patients with metastases have several unmet needs. There is often a connection "between lung and brains", which is associated with the stigma of smoking as a cause for cancer, and the ensuing metastases. Dégi stated that this is a much-neglected part of the cancer patient journey and can be prevented. Dégi also highlighted the need for the collection of data to close the gap between the reality of the patient, and the resources they can access. Addressing the psycho-social

aspects of metastases and survival is known to help improve the patient situation, including aspects of quality of life. Finally, Dégi called for psycho-oncologists to be included as part of the oncology team.

Applying Lessons Learnt from Primary Cancers

Kathy Oliver, providing the closing remarks of the session, said that it is critical to have emotional and peer support during the metastatic cancer patient journey. Patient organisations focusing on primary cancers are now realising that they need to offer support to patients, carers, and families with metastases. We need to address and improve support for the psycho-social aspects of metastases, through a collaborative approach. Oliver cited an example from the US, where the American Brain Tumor Association established a 'Metastatic Brain Tumor Initiative' to inform, support, and empower patients with metastatic brain tumours. The needs of caregivers should also be better addressed, as 72% of those surveyed agreed that *"Caregivers of NSCLC patients with brain metastases are more stressed than caregivers of NSCLC patients without brain metastases."* Lessons learnt from providing support to caregivers of metastatic patients could be taken from the extensive body of experience from caregivers of people with primary cancers.

Policy Recommendations

- Patients with metastatic cancer have particular needs in respect to treatment, care and symptom management. This should be reflected in specific policy to better address these needs.
- Latest survey evidence from Ipsos-MORI, focusing on unmet needs of non-small cell lung cancer patients with brain metastases, suggests supportive care needs are still not adequately addressed for this group of patients. Physicians need more support in providing this aspect of care to patients, including via the stronger inclusion of psycho-oncology within the multi-professional team providing care to the patient.
- Patient organisations should be supported within health systems to address the particular information and care needs of patients with metastatic cancer.

Treatment Challenges in Metastatic Lung Cancer

The Metastatic Lung Cancer session was chaired by Rudolf Huber, Past-Chair, Lung Cancer Group, Thoracic Oncology Assembly, European Respiratory Society (ERS) and Klaus Feldman, Vice President and Head of Marketing Oncology, Europe and Canada, MSD.

The Burden of Symptoms Is Often High

Rudolf Huber kicked-off the second session by underlining that about half of patients with lung cancer have metastatic disease at the time of diagnosis, and that the burden of symptoms is often high. Even patients with localised lung cancer have, depending on the exact stage and histology, a high probability of systemic relapse.²

Apart from the distinction of small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC), a subtyping of NSCLC (squamous cell carcinoma, adenocarcinoma, large cell carcinoma) is essential. Rudolf Huber stated that, in NSCLC, genetic testing for at least the specifically treatable driver mutations, and testing of the PD-L1 status, should be mandatory.

Huber reminded all that, globally, lung cancer is the most common cause of cancer death worldwide. In terms of metastatic lung cancer, about 80% of SCLC cases are 'stage IV' at the time of diagnosis, and about 50% of NSCLC cases are 'stage IV' at the time of diagnosis. In NSCLC, there is a need to discriminate between M1a (intrathoracic spread), M1b (single extrathoracic spread), and M1c types (multiple extrathoracic spread).¹

Median survival for M1a/b stage IVA is 11.5 months, with a five-year survival rate of 10%, whereas for M1c stage IVB, median survival is six months, with a five-year survival rate of zero.¹

Treatment options include systemic therapy (immune-chemotherapy, immune-mono-therapy, targeted therapy, and chemotherapy), local therapy (palliative, radical therapy for oligometastatic disease), and best supportive care, the latter of which is almost always relevant for all patients. In systemic therapy, genetic analysis of tumour tissue allows targeted immunotherapy (for example, using biomarkers such as PD-L1), leading to prolonged survival times.

Huber reminded the audience that smoking avoidance and smoking cessation can avoid a lot of lung cancers. There is also some evidence that treatment is better tolerated, and there are higher rates of quality of life and survival, in non-smokers.

Klaus Feldman, Vice President and Head of Marketing Oncology, Europe and Canada, MSD, stressed the need to remain committed to research and development for new treatment options for early-stage patients, and working with national authorities to find innovative solutions for ensuring access to these. Additionally, understanding tumour biology better to identify biomarkers, and therefore subsequently permitting individualised treatment, is another important action that is needed to overcome the challenge.

Diagnosed with NSCLC But Not Treated

Thomas Hofmarcher, Health Economist, Swedish Institute for Health Economics (IHE), presented the results of an ongoing research project on treatment rates among patients with advanced NSCLC, entitled "Diagnosed with non-small cell lung cancer but not treated",³ covering the period 2014-2020.

"A considerable proportion of diagnosed patients with advanced NSCLC across Europe remain untreated with cancer drugs despite a clinical recommendation to receive cancer drug treatment."

Hofmarcher described an example of treatment discrepancy between Portugal (where 80% of patients receive optimal drug treatment), and the UK (where only 40% of patients receive optimal drug treatment, as defined according to guidelines from the European Society of Medical Oncology (ESMO) and medicines approval from the European Medicines Agency (EMA)). Hofmarcher explained that the IHE study aims to uncover why such a difference exists, why patients are not receiving any drug treatment, and why they receive outdated treatment options.

The study included a quantitative element, looking into national cancer registries, and national sales data of EMA approved therapies, and a qualitative element, exploring the reasons why patients were not treated optimally.

According to ESMO guidelines, systemic therapy is recommended for all first-line patients with European Cooperative Oncology Group (ECOG) PS 0-2 (which should be around 80%).⁴ However, in this study, four main observations were made:

- Overall, treatment rates have improved in all countries over the study period, but most miss the ESMO benchmark
- There are very large differences in treatment rates across countries
- There is no correlation between wealthy and less wealthy countries in overall treatment
- The composition of treatment rates has changed profoundly

“Many patients with advanced NSCLC who do receive cancer drug treatment are treated with outdated treatment options.”

The study also revealed that chemotherapy has been replaced with immunotherapy and targeted therapy, thanks to developments in genomics and genomic benchmarks. However, we are still far away from the benchmark outlined in the ESMO guidelines. The main barriers of treatment rates in Europe result from patients remaining untreated, or receiving outdated treatment.

Identified underlying reasons for patients receiving outdated treatment options or remaining untreated included:

- Poor performance status at diagnosis
- High prevalence of co-morbidities
- Inadequate clinical guidelines
- Narrow clinical eligibility criteria
- Treatment refusal by patients
- Insufficient financial resources, human resources, infrastructure
- Long delays in time to treatment, from weeks to months, with long delays meaning more progression (and therefore making patients less suitable for treatment)
- Low use of modern cancer drugs, due to slow reimbursement, on average taking two years from authorisation to reimbursement
- Limited continuing medical education
- Country-specific barriers, (for example, differences between district hospitals and university hospitals)

- Barriers to diagnostic testing (slowing down personalised medicine)

Overcoming the Barriers to Treatment

Hofmarcher suggested that countries need to start measuring patient access to cancer drugs through a treatment rate-metric. Some countries, such as the Netherlands, Norway, and the UK, have already started to measure treatment rates based on patient-level data from national registries. In countries where national registries do not exist or are of lower quality, insurance claims data from national health insurance funds could be used instead.

The spotlight needs to be put on patients who, for some reason, do not receive treatment despite being diagnosed. Analysing the kind of treatment received, (of those who do receive treatment), would need to be the second step.

Hofmarcher reminded the audience that there is no single solution to improve drug treatment rates and access to modern cancer drugs. Low treatment rates could mainly be improved by earlier diagnosis, by faster time to treatment upon diagnosis, by broadening and harmonising the clinical eligibility criteria to receive drug treatment, and by convincing patients of the benefits of receiving (modern) drug treatment. The use of outdated treatment options could mainly be improved by faster local reimbursement of new drugs which are recommended as standard-of-care, by higher public drug budgets, by greater resources to improve testing capacity, and by ensuring continuing medical education.

Anne-Marie Baird, President, Lung Cancer Europe, provided a reaction from the patient perspective, stating that there are huge unmet needs for NSCLC patients with brain metastases. With this in mind, we cannot forget about the other cohort of lung cancer patients (patients with SCLC), as we often also don't hear about their high unmet needs.

Increasing Education and Raising Awareness

Baird then offered several recommendations for policy. To facilitate early diagnosis, we need to increase education and raise awareness of risk factors and symptoms in the general public. Policies should be put in place to ensure that lung cancer screening can be widely implemented across

Europe. In order to provide information, encourage networking, and enable peer-to-peer support, policies should be put in place that recognise and support patient associations. Additionally, more signposting from treating centres to patient support groups is needed.

Clinical trial inclusion and exclusion criteria should better reflect the population. For example, older patients, and those with NSCLC with metastases should be more routinely included in trials. More work is needed in basic and translational lung-cancer research, to understand the links to metastatic disease.

Additionally, Baird recommended a number of health system changes. For instance, ensuring adequate and up to date clinical guidelines are implemented as part of quality cancer care programmes. Baird went on to recommend rapid access to biomarker testing where needed, timely access and reimbursement to drugs, and ensuring

the psycho-social needs for patients with lung cancer with metastases are incorporated into the multidisciplinary care pathway. Addressing caregiver's needs, ensuring adequate information is available to patients and carers, and facilitating person-centred care and shared decision-making are also essential for better treatment outcomes.

Prevention, Screening and Access

In closing the session, Rudolf Huber stated that we have to raise awareness about lung cancer's specificities, including in respect of metastases. We need better screening and early diagnosis. There is also a need to focus on prevention, not only on smoking, but on other causes, such as pollution (which amounts to up to 20% of the lung cancer risk). Additionally, more comprehensive quality measures are needed, with tailored psycho-social support for patients and support for caregivers. Klaus Feldman added that in addition to these factors, timely access is also needed.

Policy Recommendations

- Improvements in genetic testing of cancer can help in the provision of better treatment, including in respect of patients with metastatic cancer.
- Further research in understanding tumour biology to identify new biomarkers is also promoted.
- Evidence suggests that, in too many parts of Europe, outdated treatment for metastatic lung cancer patients remains common. Treatment rate metrics should be developed and used as part of a response to this challenge.
- Improved treatment of metastatic lung cancer is intrinsically linked to the need for earlier detection, for which there are new policy options for health systems, including risk stratified lung cancer screening programmes.
- Clinical trials are not sufficiently including cancer patients with metastases. This imbalance should be addressed, including via more sensitive trial inclusion and exclusion criteria.

Potential of Biomarkers and Testing to Achieve Improvement in Metastatic Cancer

The session on the Potential of Biomarkers and Testing was chaired by Aleš Ryška, President, European Society of Pathology (ESP) and Rodney Berzoini Smith, Head, Oncology Medical Affairs Europe, Daiichi Sankyo.

Ryška introduced the session by stating that not many areas of medicine are developing as fast as in the area of biomarkers. That said, there are major challenges in biomarker testing in cancer, with the number of eligible therapies for patients rapidly increasing. A bottleneck exists, either with availability, or with lack of reimbursement of molecular testing.

Ryška referred to the results of the Central European Cooperative Oncology Group (CECOG) survey from 2018,⁵ which demonstrated a significant variation in practice between Central and Eastern European countries. Many patients are not being tested because the tests are not available.

Tissue Is an Issue

Ryška described the single versus multigene (Next Generation Sequencing, NGS) approaches. There is a complex nexus between the tissue sample, the pathologist, and expectations, moreover, there is a limited amount of tissue available or accessible. NGS approaches can test for all biomarkers at once, but NGS has some downsides, such as reduced availability in some regions of Europe. There are significant variations in access to both drugs and tests, as well as test quality across Europe (with Eastern Europe affected more). Ryška stressed the need to establish test reimbursement mechanisms before thinking about making the related therapies available.

Rodney Berzoini Smith spoke about the DESTINY-Gastric02 Study, an open-label, multicentre phase two study in Western patients with HER2+ gastric or GEJ cancer.⁶ With standard endpoints, a 38% overall response rate was seen in change of tumour size from baseline. Whereas, in the DESTINY-Lung01 Study, (a multicentre, international, two-cohort phase two trial, with the same investigational compound),⁷ by deploying an additional exploratory endpoint

(biomarkers of response), a 50% ORR was seen. To conclude, Berzoini Smith stated that by not using NGS, we will miss potential groups of patients that could benefit from treatment.

Raising the Awareness, Importance and Impact of Biomarker Testing

Zorana Maravic, Chief Executive of Digestive Cancers Europe (DiCE) stated that:

“As a molecular biologist by education, and having previously worked in the pharmaceutical industry, I was naively thinking that by now, we would have solved this problem.”

In a recent survey of 800 patients living with metastatic colorectal cancer, only 22% of those surveyed said that they were tested, and 50% of patients were not aware, or did not understand what the testing was. On this basis, Maravic highlighted that all patients should be tested, and actions are needed to ensure this.

Maravic went on to highlight two studies (one in metastatic colorectal cancer, and the other in metastatic gastric cancer), exploring the situations across European countries. These studies also explore the improvements needed in healthcare professional and patient education on testing, as well as to improve communication between patients and healthcare professionals.

Maravic then made several recommendations for policy, starting with calling for all patients to have biomarker testing performed once the diagnosis has been made, in order to identify the best treatment for the patient, and such testing to be repeated if necessary, depending on the cancer type. There should be simultaneous approval of medicines with tests, and as soon as a drug is reimbursed and available, there should also be a dedicated budget allocated to allow access to testing. Furthermore, it is important for the laboratories performing the tests to undergo regular quality assurance procedures.

In order to achieve sufficient efficiency and cost savings, development of regional testing centres

should be encouraged. All stakeholders should be aware of the relevant guidelines, for example, the ESMO guidelines, in order to provide adequate testing and to anticipate future developments. All the data that is gathered through the testing process should be collected and analysed to help us better understand the role of genomic alterations in driving cancer, and it is important to set up mechanisms to anticipate future testing needs and funding requirements. For some cancers, comprehensive testing should become the standard (e.g., pancreatic cancer).

Finally, Maravic stated that we should increase the level of awareness and knowledge among patient populations on the importance of biomarkers, facilitate communication between HCPs and patients, and encourage active patient involvement in their treatment by shared decision-making.

Addressing Disparities in Access to Testing Across Europe

Patrick Michl, European Pancreatic Club (EPC), and Chair, Gastroenterology (W3), Martin Luther University Halle-Wittenberg spoke about biomarker testing challenges in gastrointestinal (GI) cancers. Michl stated that in gastrointestinal tumours, the number of biomarker-guided therapies is increasing, mainly in colorectal, gastric, biliary, and pancreatic cancer. However, there are currently disparities across Europe, for example, current standard biomarker testing and resulting targeted therapies are not readily available across many European countries, especially in Eastern Europe.

Other challenges include the genetic heterogeneity in GI cancers, for example, in pancreatic cancer. The future challenge to identify more biomarker-driven therapeutic options for gastrointestinal cancers lies, at least in part, in the high genetic heterogeneity of these tumours, with possible molecular key drivers being prevalent in only small subgroups of patients. What we really need, said Michl, are novel trial designs for the evaluation of multiple biomarkers, i.e., “Basket trials” and “Umbrella trials”. Basket trials include subjects with multiple diseases being treated by a common targeted intervention, whereas umbrella trials comprise subjects with a single disease with multiple targeted interventions.

We are moving towards a highly flexible, highly adaptive platform trial design in order to keep up with new biomarker discoveries. The challenge

related to this, is the complexity of “-omics biomarkers”. We are moving towards multiple “-omics” (genomics, epigenomics, transcriptomics, proteomics), and in the future, these multiple liquid biopsies will place a high technical and resource demand on health systems.

Michl then listed several challenges and potential facilitators for biomarker-driven therapies across Europe, for instance, that there is an urgent need to increase availability of biomarker testing and biomarker-guided therapies. Combining suitable panels of multi -omics biomarkers (protein, miRNA, lncRNA, ctDNA, circulating tumour cells) could increase predictive accuracy, on a large, multinational scale. There is an urgent need for innovative clinical trial designs including basket or umbrella studies, as well as highly adaptive platform trials to evaluate emerging therapeutic options for molecularly defined small subgroups of patients. We need to increase our efforts to identify novel, potentially therapy-guiding biomarkers using multi-omics technologies integrating AI-algorithms, and we should be validating promising candidate biomarkers in large, multinational platform trials with adaptive designs. Ultimately, this all requires multi-stakeholder partnerships from industry, academia, and politics on a European level.

Moving Past the “One-Size-Fits-All” Approach

Berzoni Smith stated that we are long past the one-size fits all approach for treatment, and this goes for trial designs too. There are still large barriers to optimal biomarker testing, and we still need to ensure new drugs find the right patient.

Drawing the session to a close, Ryška stated that multidisciplinary collaboration is needed, with oncologists, surgeons, and pathologists, given the vast and increasing number of biomarkers we now have. Ryška also called for molecular tumour boards, with all specialities represented, as, even if we test all the markers, the message could be “lost in translation”.

Pressure is needed on decision makers to understand how important biomarker testing is, and to understand its expected higher costs. Finally, decision-makers need to understand that the higher initial outlay in costs for the testing, will give payback to health systems many times over in the future.

Policy Recommendations

- Too many cancer patients in Europe do not benefit from biomarker testing. This is a significant source of cancer inequality which should be encompassed within the EU agenda on cancer inequalities. One means of addressing this access challenge could be for reimbursement agencies to simultaneously assign budget for a new treatment with budget for testing.
- Patient awareness and understanding about biomarker testing should also be improved. There is an important role in this respect for patient organisations, that should be supported by healthcare systems.
- The era of 'omics' also requires further innovation in clinical trial designs, including 'basket trials' and the integration of AI algorithms.
- The deployment of molecular tumour boards was also raised as a prospective means to increase the quality of treatment and care in this field.

Opportunities for Progress in Metastatic Breast Cancer

The session on Metastatic Breast Cancer was co-chaired by Tanja Spanic, President, Europa Donna, Fatima Cardoso, President, ABC Global Alliance and Matti Aapro, President, European Cancer Organisation

The Need for Multidisciplinary Treatment Approaches

Tanja Spanic, President of Europa Donna, introduced the session from the patient perspective. All breast cancer patients, including those with metastases, need optimal care as part of multidisciplinary treatment approaches. Patient information and education is also important, because when patients are involved in treatment choices, this has been shown to help improve outcomes. When starting anti-cancer therapies, patients want to be able to maintain a good quality of life. Quality of life, by definition, can vary from patient to patient, and is based on various factors. For example, patients may be facing significant uncertainty, and therefore have specific needs. Patients may also be facing other difficulties in their lives, or be experiencing stigma. Finally, Spanic reminded the audience that these patients are our mothers, daughters, sisters, and friends.

A Focus on Hope

Fatima Cardoso, President, ABC Global Alliance, provided an overview of current issues in breast cancer. Cardoso explained that the ABC Global Alliance focuses on metastatic breast cancer; however, policymakers need to be educated on the fact that metastatic cancer is not “the end”, but the focus should be on “hope” instead. Cardoso went on to state that there is a lack of data, for example, in registries, which could potentially be resolved by appropriate policies, such as European-wide data cooperation, to pick-up on cancer patients who have recurrences.

In order to set the context for the discussion, and remind all of the real-life human stories that emphasise the urgency of this issue, a film⁸ of metastatic breast cancer patient stories was screened to the Roundtable.

Key messages from the video included:

- *“A price has been put on our lives, which is unfair”*
- *“They just look at you as a walking corpse”*
- *“I am living their worst nightmare”*
- *“I am treated like a curse”*
- *“I can’t understand that there is no happy ending”*
- *“There is no need for treatment, as she will die anyway”*
- *“Thinking about my kids is difficult”*
- *“I am advanced breast cancer”*
- *“Be the change”*

Cardoso explained the differences between metastatic breast cancer (MBC) and advanced breast cancer (ABC), which is broader and includes both metastatic breast cancer, which has spread to distant sites of the patient’s body, and inoperable locally advanced breast cancer, which despite not having spread cannot be cured in the majority of cases. Screening in breast cancer has resulted in a steep decrease (30%) in mortality since the 1990s, however, in the 2005–2015 decade, there has only been a 2% improvement in 5-year survival rates for metastatic breast cancer, highlighting why attention is needed to achieve progress in this category of patients. Until recently, the median survival rate for MBC is three years, and three out of four metastatic breast cancer patients die within five years from the time of diagnosis.⁹

However, there is some light at the end of the tunnel, as better treatment options can increase median survival in MBC from three to five years, when MBC is diagnosed directly at its metastatic stage, rather than it resulting from a cancer relapse. In addition, these last two years have seen an increase in median survival to about five years for two out of the three breast cancer subtypes (ER+ and HER2+ subtypes). The psychological impact of a virtually incurable disease is significant, and can include feelings of abandonment, feeling lost, stigma, and frustration from not being invited to trials.¹⁰

The Key to Change Is Collaboration, Sharing Resources and Knowledge

Cardoso asked the panel and audience: “*What lessons can we learn from managing patients with early breast cancer?*”

We know that treating patients according to guidelines improves survival and quality of life. And we know that multidisciplinary care is indispensable for all stages of breast cancer.

A significant aspect of improving care involves integrating the patient’s perspective. For example:

- Defining priorities together
- Defining goals of treatment, including the delicate balance between quantity and quality of life in metastatic diseases, which is a very personal preference
- The acceptable level of toxicity should be defined by the patient
- Defining together which endpoints truly matter
- Defining together what “meaningful benefit” means
- Communication
- Awareness, education, and fighting stigma

Cardoso explained that when defining the goals of patient-centred treatment in ABC, this should be to achieve a balance of efficacy and toxicity. Specific goals include improving survival, delaying disease progression, prolonging duration of response, palliating symptoms, improving, or maintaining quality of life, and in the near future, transforming it into a chronic disease. There exists however, the major problem of tumour resistance to therapy. Therefore, we need access to several lines or types of treatment.

The ABC Global Charter lays out ten goals for the current decade, and is calling for a comprehensive needs assessment to define the most urgent and actionable goals, with involvement of all the stakeholders for ABC. Cardoso highlighted two of these ten goals, no. 2: *enhance our understanding about ABC by increasing the collection of high-quality data*, and no. 10: *help patients with ABC continue to work by implementing legislation that protects their rights to work and ensure flexible and accommodating workplace environments.*¹¹

Regarding goal no. 2, Cardoso stressed the point that cancer registries do not register relapses, and that we need to be able to track the patient, have a minimum dataset collected, harmonise definitions, and determine the prevalence of ABC. Regarding goal no. 10, the indirect costs of cancer, such as loss of productivity, financial burden, and psychological burden, can be reduced by workplace flexibility. In fact, a major lesson from the Covid-19 pandemic is that flexible working practices are possible.

Treatment is Only Efficacious if It Is Accessible

There are disparities in cancer outcomes (i.e., survival) across Europe, and they are directly linked to inequalities in access to care, with Eastern Europe affected in particular.¹² Disparities also exist within countries themselves.

Cardoso asserted that we must define together what “meaningful benefit” is, and that there are tools that can help with this. For example, the ESMO Magnitude of Clinical Benefit Scale.¹³ Cardoso went on to state that not every therapy that is approved has meaningful benefit. Furthermore, Cardoso stated that not every ‘positive’ trial is a true step forward, that new therapies are not always better than old ones, that costs should be linked to benefits, and that we should all be responsible in our decisions.

Cardoso concluded her intervention by stating that reimbursement rules are hurting metastatic breast cancer patients, as in many countries, the current rules do not facilitate oral, less toxic treatments, nor do they facilitate shorter treatments of radiotherapy.

Outcomes Should Not Depend on Patient Education and Income

Olivia Pagani, Breast Cancer Programme Coordinator, European School of Oncology (ESO), and Breast Cancer Consultant, Hopital Riviera-Chablais, Rennaz, Vaud, provided an intervention on advanced breast cancer in young women. Pagani highlighted that young women with breast cancer are a minority, typically classified as women of less than 40 years old, but also including pre-menopausal women.

Recent data from France showed that young women with metastatic breast cancer at diagnosis constituted 7.5% of the sample. Although such

cancer is usually associated with more aggressive presentations, the overall survival of young women with MBC was not worse than older women in the cohort. There are however, in-country variations in treatment and outcomes. Whilst stage-specific survival has improved in young breast cancer patients since 2000, this has not been seen equally throughout the population. Treatment outcomes vary depending on patient education and income, with those with lower income and lower educational levels seeing poorer outcomes.^{14,15}

Pagani recommended that every young breast cancer patient should have access to optimal treatment and supportive care, irrespective of social status. Further research is needed on patients from diverse backgrounds, non-nuclear families, co-parent settings, and parent and caregiver settings.

Data Is Critical

Isabelle Soerjomataram, Deputy Branch Head, Cancer Surveillance, International Agency for Research on Cancer (IARC), provided an intervention on the need for better data in metastatic breast cancer. Soerjomataram said that in 2020, half a

million cases of breast cancer were diagnosed in Europe, and there were 142,000 breast cancer deaths. Despite there being a significant improvement of data completeness over time, there is however a variation in diagnoses across Europe, and the completeness of this data is often not reported.

Regarding metastatic breast cancer data in Europe, most countries don't have population-based data, and where there is data, it is often not complete. Soerjomataram stated that if there is no data (for example, on metastatic breast cancer), there is often no action taken in the area. Soerjomataram emphasised that in order to improve this situation, we need international projects and collaborations to set international standards, and the use and implementation of different tools to monitor, measure and report progress.

Good News from Portugal

Matti Aapro highlighted a recent success in Portugal, and stated that he was delighted to share news that from next year, Portugal will be the fifth country in Europe to implement the Right to be Forgotten for cancer survivors.

Policy Recommendations

- A cultural change is required within political and health systems in respect of metastatic cancer. Hope is under-emphasised, yet treatment and care innovations often provide reason for it.
- Our oncology data approaches in Europe are deficient when it comes to metastatic cancer. A prime example relates to registries, which are not adequately recording metastatic cancer and cancer recurrence. In the context of Europe's Beating Cancer Plan, the EU Mission on Cancer and the establishment of the European Health Data Space, this deficiency should be addressed. The European Cancer Organisation's Digital Health Network has recommended political targets on registry interoperability as one means to support this.
- Treatment reimbursement strategies in Europe should better reflect patient preferences for their treatment, including reduced toxicities, shorter treatment and more convenient forms of treatment, such as treatment delivered at home.

Perspectives in Metastatic Prostate Cancer

The Metastatic Prostate Cancer session was chaired by Arnulf Stenzl, Adjunct Secretary General, European Association of Urology (EAU) and Board Member, European Cancer Organisation and Andrew Cavey, Global Program Head, Prostate Cancer, Advanced Accelerator Applications (AAA)/ Novartis.

Prostate Cancer Is the Most Frequently Seen Cancer in Men

Arnulf Stenzl, Adjunct Secretary General, European Association of Urology (EAU) and Board Member, European Cancer Organisation introduced the session by providing the current state-of-play in metastatic prostate cancer treatment.

Stenzl reported that prostate cancer is the most frequently seen cancer in men. There is an association between systemic therapy and overall survival in early detected, low-volume hormone sensitive prostate cancer (mHSPC).¹⁶ Stenzl added that in addition to the existing treatment options, there are also more drugs on the horizon.

Stenzl recommended the following structured early detection of prostate cancer in a cascade:

1. Prostate-specific antigen testing
2. Other urinary and / or serum markers
3. Sophisticated imaging of the prostate (mpMRI, micro-ultrasound) before going to a prostate biopsy

Stenzl then posed several questions to the panellists and audience:

- *“Does earlier or better imaging improve metastatic disease?”*
- *“Does maximal treatment in HSPC improve outcome? And also quality of life?”*
- *“Has personalised genetic classification and associated adjusted treatment arrived with metastatic prostate cancer?”*

“Men Die With It Rather Than of It Is a Misconception”

Andrew Cavey, Global Program Head, Prostate Cancer, Advanced Accelerator Applications / Novartis, provided an intervention on ongoing unmet needs and policy opportunities in metastatic prostate cancer. Cavey stated that

within radio-ligand therapy, the technology exists for genetic profiling, but perhaps the infrastructure does not. Contrary to common belief, men do die of (and not only with) prostate cancer.

Prostate cancer is the second to fourth leading cause of death in men depending on the country. 80% are metastatic at the stage of castration resistance. The main treatment is castration and hormonal interventions, with various levels of tolerability. The good news is, that there are encouraging research and development programs which will bring new treatment options to men with metastatic prostate cancer.

Whilst these new treatments can impact survival and bring advances in quality of life, there are several barriers in policy that need to be overcome. The following recommendations were provided:

- We should establish an EU-wide prostate cancer registry
- We should pursue a comprehensive prostate cancer policy agenda, which goes beyond the topic of early detection, and also includes a focus on advanced disease stages
- A suitable vehicle to advance prostate cancer policy could be a European Commission Initiative on Prostate Cancer (modelled after the EC Initiative on Breast Cancer that already exists)
- Research should go further into the advanced disease stage, using the model of breast cancer
- We should ensure we make the best use of multidisciplinary care teams

Nurses as a Critical Resource and Coordinator for the Patient Journey

Hendrique Reinders-Huisman, Urology Nurse Practitioner, Groningen, the Netherlands, and Scientific Congress Office Member, European Association of Urology Nurses (EAUN), provided an intervention from the nursing perspective. Reinders-Huisman said that prostate cancer patients are a very heterogeneous group, with several sub-groups. However, for all groups, the number of treatments has increased over the years beyond castration, and now includes combination therapy.

In metastatic castration-resistant prostate cancer, sequencing is critical to patient characteristics and genetic testing. The role of urology nurse practitioners has become increasingly important with the increase in treatment options, complexity, and personalised treatment regimens. There is now more and more shared decision-making, provision of information, patient dilemmas, and involvement of various hospital departments. Therefore, a patient-centred approach is even more critical. Nurses can take on this interprofessional role, with a clinical and psycho-social element, and can act as a holistic interlocutor between the physician, urologist, and patient.

Treating the Patient, Not the Disease

Ken Mastris, President, European Cancer Patient Coalition (ECPC) and Past-Chairman, Europa Uomo, provided an intervention from the prostate cancer patient perspective. Mastris explained that there are 450,000 men in Europe diagnosed with prostate cancer each year, with two million currently living with the condition. Mastris called for treatment of the patient, not the disease, because everyone is different.

The incidence of advanced prostate cancer in some countries is likely a reflection of late detection, caused by lack of awareness of the necessity for early detection, or a lack of proper diagnostic tools. We also need to think about comorbidities. Covid-19 has increased the disparities, for example, in the UK, where there is now a backlog of prostate cases.

Patients, GPs, and the broader public should be better informed, in particular GPs. This also relates to the debate about prostate-specific antigen (PSA) testing, and the need to go to a risk-based scenario approach. Advances in biomarkers can help distinguish between different forms of prostate cancer for example, between aggressive and less aggressive types.

Mastris then provided a number of recommendations for policy:

- As the number of prostate cancer survivors is increasing, patients, general practitioners, and the broader public should be better informed about the needs of cancer survivors in order to improve their quality of life
- Patients need to obtain balanced and fair information on the advantages as well as the adverse side effects of their treatment plans
- Patients need to be able to make their own choices and preferences (adapted to their level of acceptance, culture, and societal expectations)
- Therefore, there is a need to promote an interdisciplinary patient-centred approach for specific survivorship research programmes, and to develop and elaborate new tools, in order to facilitate survivorship research, including the assessment of the wellbeing of cancer survivors
- Patient-centric approaches in research, medical education, cancer management, and care delivery are critical to an evolving paradigm in cancer care
- With Europe's Beating Cancer Plan, there is an immense opportunity to reduce the cancer burden in Europe through cancer prevention, early diagnosis, accessible treatment, available innovative medicines, and post-cancer care.

In the ensuing discussion, Reinders-Huisman stated that patient-specific concerns need to be taken into consideration, for example, does the patient use his hands for work? If yes, chemotherapy would be a risk due to the resulting neuropathy. Nurses can guide this process.

Andrew Cavey highlighted the role of the nurse practitioner to reduce the burden of disease, the need to recognise that every patient is different, and that we need to treat the patient, not the disease.

A Risk-Adapted, Population-Based Detection and Screening Approach

In the final part of the session, Hein van Poppel, EAU Adjunct Secretary General for Education, and Co-chair of the European Cancer Organisation Inequalities Network, stated that misconceptions about PSA testing have arisen, leading to avoidable later diagnosis and then higher mortality. In the UK, prostate cancer has now taken over from breast cancer as the number one cancer, and in the US, it is the number two cancer.

It is important to recognise that quality of life for advanced prostate cancer patients is too often of a very low standard. We need a risk-adapted, population-based detection and screening approach. EAU's recommendations should be picked up by Europe's Beating Cancer Plan.

Policy Recommendations

- Prostate cancer policy needs to go beyond the strong focus on early detection to also incorporate realisation of the opportunities to improve treatment of patients with metastatic prostate cancer.
- A European Commission Initiative on Prostate Cancer, similar to that which exists for breast cancer, could be an important policy tool to achieve this broader focus.
- The role of nurses as a critical interlocutor and coordinator of care for patients remains underappreciated. Further inter-specialty and inter-disciplinary understanding on this should be promoted via policy initiatives, including the forthcoming EU inter-specialty cancer training programme.

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As the not-for-profit federation of member organisations working in cancer at a European level, the European Cancer Organisation convenes oncology professionals and patients to agree policy, advocate for positive change and speak up for the European cancer community.

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