European Alliance for Personalised Medicine

EAPM Roundtable: "Bringing innovation into EU healthcare systems"

ESMO Congress
27 September, 2019, Barcelona

- Report -

European Alliance for Personalised Medicine

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

EAPM at ESMO 2019

For the 4th year in succession, EAPM hosted a satellite meeting as part of the ESMO Congress. Similar to our own recent events, the focus was on bringing innovation into healthcare systems, but with very specific items on the Alliance agenda.

The drivers of personalised medicine are clear: for patients (and physicians) they mean more options, durable clinical benefit, reduced exposure to non-effective drugs and potential to leverage current scientific and technological advances, while for the pharmaceutical and molecular diagnostics industries they offer the potential to tackle core challenges in discovering and developing more effective medicines, to reduce rates of attrition in drug development, and to reduce the associated escalating costs which are central to a more sustainable future and delivery for healthcare needs.

Meanwhile, for healthcare systems and payers, the drivers are improved efficiency through the provision of efficacious and cost-effective care through the avoidance of ineffective and redundant interventions, are again key to a more sustainable and deliverable future system.

The debate has focussed to a large extent on the cost of 'doing something' – the spiralling cost of developing drugs, the extra cost of providing innovative diagnostics, the hidden costs of supportive care. But what about the cost of *not* doing something?

If we ration healthcare we must do so in a logical way. This will mean making tough decisions, but these decisions must be made on rational evaluation of an evidence base that evaluates both cost and value. We need to prioritise approaches that will deliver cost-effective quality care that will improve the lives of European citizens and societies. While we need to reward innovation in this context, it must be innovation that gives value to patients.

Diagnostic and therapeutic innovation must be implemented in a structured cost-effective approach that emphasises measurable improvements in outcome for the patient in the personalised healthcare era. Resourcing and pricing issues must be addressed in a tangible and transparent fashion to ensure best value in the delivery of optimal quality care for patients.

What is abundantly clear is the urgent need to address the cost/value axis associated with personalised healthcare and develop financially viable but effective solutions.

Just as many patients may require a combination of treatments (surgery, radiotherapy, medicines, targeted therapies) and supportive care to achieve long-term cure, so the healthcare policy solutions that evolve must reflect the need to address all stages of this cancer continuum.

The different sessions in Barcelona dealth with various aspects of this in the context of the oncology arena from our now-usual multistakeholder perspective.

So, what emerged?

It is necessary to formulate a personalised healthcare strategy strategy involving medical specialists, decision makers and regulators in the arena of oncology public health, to enable the EU and Member States to contribute to integrating personalised healthcare into clinical practice while enabling much-greater access for patients.

In order to provide a clear focus and to devote sufficient space to analysis, discussions concentrated on how:

- *To assess and address obstacles to the integration of personalised healthcare into Europe's healthcare systems*

- *To identify best practices and their added value*

- *To outline the potential benefits of personalised medicine on public health and its impact on policymaking in the EU*

Please find details of the sessions on the following pages.

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Session One: Oncology and real-world evidence

The first session heard that further investment in the development of methodologies and a European repository for evaluation methods and evidence of digital health services should be encouraged.

It emphasised the importance (as has the European Commission) of data interoperability, particularly in the context of collecting, sharing, and manipulation of data and recommended the use and development of international classifications and terminologies to increase interoperability.

Attendees also heard that Member State governments could play a more active role in the further optimisation both of the process of decision-making (both at the central and decentralised level) and the related outcomes.

The meeting heard that the EU has revised several regulations that have an impact on personalised medicine, such as the General Data Protection Regulation, In Vitro Diagnostics, HTA and Clinical Trials.

So far so good, but these are isolated regulations and Europe needs a clear framework for personalised medicine to enhance Member States cooperation.

EAPM has successfully launched several initiatives in that direction. One of the most significant achievements is the Million European Genome Alliance initiative, or MEGA (now MEGA+), which led to the signing of the Declaration "*Towards access to at least 1 Million Genomes in the EU by 2022*" by more-than 20 Member States.

This is now called EU1MG, and acknowledges that it is paramount to agree on technical specifications for access and exchange of health data for research and public health purposes, addressing, for example, health data collection, storage, compression, processing and access across the EU.

A key goal is, therefore, to create a governance framework to allow Member States to collaborate, to mutualise capacity, avoid duplicity, at the same time as sharing data and good practices.

A Coordinating Support Action (CSA) has begun at EU level, built upon the Council Conclusions on patient access to personalised medicine adopted in 2015. It focuses on:

- *Circumstances impacting evidence standards, such as different disease stages, goals of treatment, degree of unmet need, breadth of target population, and more*

- *The need to facilitate proactive and constructive dialogue between stakeholders*

At the session on real-world evidence, **Stefan Foser**, Head of PHC Medical Market Development, Global Pharma Development Medical Affairs at F. Hoffmann-La Roche AG, said that the main issue is to define a framework that can work across countries and to raise awareness among the medical committees at the first level, then raise awareness at policy-maker level.

Paolo Casali, who heads the Adult Mesenchymal Tumour Medical Oncology Unit, Istituto Nazionale Tumori, in Milan, Italy, told attendees that: "There are a lot of efforts to generate clinical registries, and networking is crucial to improve this. Unfortunately, when it comes to the legislative framework, there are a lot of uncertainties that prevent an effective use of real-world evidence in Europe.

Paulo said the interpretation of the the GDPR seems

to be very restrictive in practice, and that significantly hampers data sharing.

Fabien Calvo, who is Chief Scientific Officer at Cancer Core Europe, pointed out that, in western Europe, we have seen important changes in mentality and practice that have allowed impressive improvement in treatment outcomes. This, he said, is linked to clinical research, early diagnosis, screening programmes, as well as back-up communication by governments.

Stefan Gissels, meanwhile, of Digestive Cancers Europe, said: "We need better centralisation and better channels between patients and centres."

On that point, Fabien noted: "I think there should be an intermediary way, with a degree of centralisation and a network of smaller centres for a better efficiency", while **Nuria Malats,** Head, Genetic and Molecular Epidemiology Group, CNIO, said that: "This requires the involvement of patients at all level. If we take pancreatic cancer - which is one of the deadliest cancers - 65% of the European population doesn't know about it. So how can they identify symptoms and go to these specialised centres? There is a lot to do to raise awareness about cancer."

Ralf Herold, Scientific Officer, Pediatric Medicines, at the European Medicines Agency (EMA) gave a personal input, saying: "We need to think of real-word evidence in oncology as an opportunity. It is about managing a high level of complexity, and data sharing is only one of these complexities…but they are already being tackled, we are going one step after the other."

He pointed out that the EMA does have an evidence framework (for RWE). The developers know all the details - it is about the demonstration of favourable effects, it should be identifiable, isolatable, quantifiable.

"But we don't have a threshold in that framework," he said. "The understanding of the beneficial effects depends on how we receive the effect vis-a-vis the variability, and this is a big question for personalised medicine. So, I don't think we want a threshold for RWE."

William Cross, of Leeds Teaching Hospitals NHS Trust, said: "I think there's a risk if we centralised certain care, because patients are not aware of where it is. It is important to know that a hospital is part of a network that brings evidence that is translated in a routine for care. We need more education, and dissemination of information about care in hospitals to patients."

He added that: "We need RWE that shows the results and puts them together. There are research centres that write papers together, so why are they using RWE differently? Is that a problem of resources allocation or a problem of organisation within the network?"

He emphasised that what is important is the patient outcomes, and this can be maximised only if the network is organised and patient-centred. One hospital can be more adequate for diagnostics, another one for surgery, and so on. It is important that patients know that when they start the clinical pathway, that a hospital is part of a network that is going to deliver the optimal care."

John Dowling, of Europa Uomo, said that the private sector doesn't seem to have the same evaluations, comparison, and results publications that happen in the publicly funded services.

Benjamin Horbach, Health Systems Strategy Leader - PHC at F. Hoffmann-La Roche AG, highlighted the need for more public health focus, in conjunction with a multi-stakeholder approach, especially in molecular diagnostics, which improve early diagnosis, thus ensuring better treatment and quality of life.

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And **Peter Kapitein**, of Inspire2Live, said: "Patients know nothing about hospital. They are completely lost after just being diagnosed with cancer. They ask their general practitioner who tells them that they think they should go there."

He added that the best units for each cancer should be made public so that patients know. "It is a scandal that in Amsterdam, we have one of the best breast cancer centres in the world, but we send the patient somewhere else," he said.

Caridad Pontes, of Servei Català de la Salut, told the meeting that: "RWE brings us the possibility to share quality data. RWE helps us recognise that we are dealing with a small population that cannot be completely studied during the normal development that we make. We collect additional information and it becomes a medical tool."

Bengt Jonsson, of the Stockholm School of Economics, said that RWE has been talked about for a long time in rare diseases, but nothing happens. "Most registries that we have in Sweden don't include many variables, they are incomplete. And when we have all the data, it is not really used. We have a long way to go."

Benedikt Westphalen, of the University of Munich, said: "The main problem we have when we talk about RWE, especially in precision cancer medicine, is that the testing that we use to identify patients, and treat them, and then generate evidence from that, is not harmonised."

Paul Naish, of AstraZeneca, told the meeting: "Data should be shared, but no one is sure of what we can share since the entry into force of the GDPR. One-time consent is a real fiction there. We need to...lift up this barrier to the use of RWE and data sharing for personalised medicine."

Session Two: Putting personalised medicine into practice: the value of prognostic testing for breast cancer and prostate cancer in Europe

The second session was co-chaired by EAPM's **Denis Horgan**, and **Karen Copeland**, Medical Science Liaison III, at Myriad Genetics.

The duo set the scene with Denis asking what the issues are at national level with respect to bringing prognostic testing into healthcare systems.

Different Member States are running at different speeds, he said, with different regulations, capacity, and reimbursement schemes that hamper innovation. So how can the EU develop a framework to support this, and what actions should be taken at EU and Member State level?

Karen told attendees that promising advances have been made, especially in the last five years. Thanks to new testing techniques, she said, we are not treating the tumour the same way, we bring changes in the way patients are managed and treated. She then offered two examples, one on breast cancer and another on prostate cancer.

Testing advances, Karen told the audience, allow us to answer four pressing questions. These are:

- *Will I get the disease: Risk*
- *Do I have the disease: Diagnostic/Screening*
- *Should I treat the disease: Prognostics*
- *How should I treat the disease: Therapy*

Karen said: "The incidence of communicable diseases has significantly decreased with modern medicine, (and) life expectancy is increasing alongside other diseases such as cancer, which are putting a burden on our healthcare systems.

"We need to address this issue. Personalised medicine and genomics can reduce the pressure on our healthcare systems and allow a better allocation of resources."

"There is an increasing commitment from governments and the European institutions on cancer plans that we need to incorporate into a larger framework for precision medicine to ensure that genomics can be translated into healthcare systems."

Karen pointed out that, in Europe, nearly half-a-million men were diagnosed with prostate cancer in 2018. The disease accounted for 5.5% of all cancer deaths that year, and represents the fourth-highest economic burden for cancer.

Meanwhile, half-a-million new cases of breast cancer were recorded across the same year. Breast cancer represented 7.1% of all cancer deaths, and is the second-highest economic burden for cancer in Europe.

Karen explained that Myriad has developed two prognostic tests for breast and prostate cancer. For women with HR positive, HER2 negative localised breast cancer, "EndoPredict" is the only test to answer three critical questions: the five-, ten- and 15-year risk of breast cancer recurrence after therapy; the patient's individualised benefit of chemotherapy versus the risk associated with chemotherapy; and who is unlikely to benefit from extended endocrine therapy.

For men with localised prostate cancer, she said, "Prolaris" is the only test to answer three critical questions. These are: The 10-year risk of disease-specific mortality in conservatively managed patients; the 10-year risk of metastasis after radical prostatectomy or radiation therapy and; who can safely pursue active surveillance.

Karen explained that, for these two cancers, thanks to these prognostic tests, outcomes for patients have improved dramatically over the last few years. It is not only a matter of who do we need to treat, she said, but how do we identify the patients with the most aggressive diseases and give them the best treatment, as well as identifying the patients with the least aggressive diseases allowing us to avoid unnecessary treatment?

Europa Uomo's John Dowling told the meeting: "We need a major change in the way prostate cancer has been diagnosed and treated. We are looking for a systematised strategic population screening of men, starting with a very early PSA baseline test so that you can identify, even at the age of 45, the people who are the most at risk of developing a prostate cancer.

"We think that would be a most effective way of stopping the over-treatment of men that has been going on over the last 30 years, reducing the number of dangerous biopsies and prostatectomies."

Stefan Gissels, of Digestive Cancers Europe, said: "We really need to stratify the risks to avoid over-treatments, but also under-treatments of men who believe they are not at risk. More screening is required. And I think we also need to talk more about men with breast cancer."

John acknowledged this last point saying that there are more men dying of breast cancer than men dying of testicular cancer in North America. That should be taken into account. And men don't test for this, he said.

Stefan then asked Myriad's Karen: "Do you think we need a

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different framework for each cancer, or would a general framework be enough to encourage the uptake of prognostic tests?"

Karen replied saying: "I think a general framework on prognostics makes sense, which allows for flexibility within it to adapt to different diseases.

"But when we look at the various types of laboratory tests, these are not regulated well in Europe, and in the US, the FDA does not regulate at all. So, I think, as part of this framework there should be a regulatory agency, an independent organisation to evaluate how tests are elaborated."

Frederique Penault-Llorca, Director, Centre de Lutte Contre le Cancer de Clermont-Ferrand, then explained that biomarkers can help guide clinical decisions and help predict the patient's response to therapy.

We have three categories of biomarkers, she said, and they are:

• *Predictive biomarkers identifying the likelihood of favourable/ unfavourable treatment response*

• *Prognostic biomarkers identifying the risk of clinical events, independent from therapy*

• *Pharmacodynamics markers identifying the occurrence of a biologic response following a treatment*

Frederique told attendees that breast is the most frequent cancer in women. She said: "We realise that chemotherapy is clearly over used. Thanks to prognostic biomarkers, we can figure out whether chemotherapy is beneficial or not for a patient with breast cancer.

"We ran the test on 200 patients affected with breast cancer, she said, and in 28.5%, chemotherapy was avoided."

The French paradox

Frederique told the meeting that breast cancer gene expression tests are now recommended by several guidelines (including ESMO's) in the EU, but not yet in France - nor in the Netherlands. In light of inadequate and/or lack of clinical data respectively found in first and second generation tests, the French health authority considers it to be premature to recommend routine use of the tests in early breast cancer, and does not recommend reimbursement by national health insurance.

She described this as "a terrible decision".

In France, molecular tests are run by 28 molecular genetics platforms, she said, sponsored either by the National Institute for Cancer (INCa) or the health ministry. In parallel, she said, we have oncogenetic labs.

"There is an administrative supervision by the ministry of health and INCa. Before 2016, molecular tests were free for all patients, and this system allowed equality of treatment over the territory and better treatment for cancer - 91% of patients asking for the test benefited from it - it was unique in Europe."

However, she said, there was a change in the funding mechanism in 2016-2017, and the situation is deteriorating. Now, only 54% of the cost is funded for the test; the rest is paid by the prescribers and the patients.

Among other things, this is driving inequality in access to molecular tests in France, which is not acceptable in 2019.

"This is a very good example of terrible decision making for personalised medicine and the outcomes of treatment for patients with breast cancer," Frederique said.

She went on to explain that the French government wants to support the creation of 12 Super NGS platforms for human genome sequencing. Two platforms are already there and the tests have started this year.

"But this ambitious programme raises a lot of questions, she said: We don't know what the role of these platforms in cancer will be. What will the future of INCa academic platforms be? Are they going to disappear because there is now a lot of competition with private and public platforms?"

It is not the role of a public entity to cut the cost, she said. "We do research, not business. We don't know the future and how this fits with the goal of equal access to healthcare for patients."

She added that: "Hospitals have to cover almost half of the cost of testing, it is not reimbursed 100%. This is a schizophrenic situation: we have drugs that can be very effective but also very expensive, which is completely covered in France on one hand, but on the other hand, the molecular tests that are helping you identify who can benefit from it will not be covered.

"We are trying to save money on the test, and as a result we are losing money on treatments."

She said that a massive programme of sequencing in cancer is useless - a large panel with 500 genes is probably sufficient. Meanwhile, for treatment, we need a panel with 40-50 genes.

William Cross, of Leeds Teaching Hospitals NHS Trust, Department of Urology, took the topic of prostate cancer, telling the attendees that it is the most common cancer in men in the UK, with 47,000 new cases every year. One-in-six men will be effected, he said.

Incidence of prostate cancer has increased 44% since the 1990s, which is when PSA (Prostate Specific Antigen) emerged in routine clinical practise.

That's how most men are diagnosed with prostate cancer, William said, adding that early prostate cancer doesn't show symptoms. But men are just doing opportunistic screening, as there is no prostate cancer screening programme in the UK.

He said that patients want to know their personal risk and to understand the treatment decision. This is a very difficult decision to make. A patient doesn't want to miss the chance of treatment, and he doesn't want unnecessary treatment either.

That's why we developed a *PERSONAL* study: *Prolaris Enhanced Risk Stratification – an ecONomic and clinicAL evaluation*, he said.

During the clinical pathway, after a diagnostic and MRI/biopsy, we conduct the Prolaris test on a patient. This test allows us to classify the cancer - localised, locally advanced, metastatic - stratify the risk (such as low/intermediate/high) and determine treatment accordingly (whether that be active surveillance, monitoring or radical treatment).

This allows patients to better understand their risk, and be more active in treatment decisions. For the clinician, it enables a more focused treatment counselling and avoids invasive treatment. And it is more cost-efficient for society while also helping to reach the goal on equal access.

But, William added, what we haven't looked at is how patients interpret this additional information. He said a lot of work could be done in this area and that we should conduct a study on how

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patients react to stratification and how it impacts treatment decisions.

"When it comes to policy makers", he added, "to draw a framework, we need to deliver high-quality research information so they can also make an informed choice in terms of what healthcare pathway they want to financially support."

John Dowling told attendees that the best treatment can be no treatment at all. But there is a cultural pressure: cancer is this thing that we need to take down.

"Patients want treatment even if practitioners don't recommend it", he said. "They don't understand that this is something we can live with, like diabetes. Families are putting pressure on patients on active surveillance, too."

Stefan Gissels said that this is one of the first roles of patient organisations, to help patients and their families understand the disease before any treatment decision is made.

Fabien Calvo, of Cancer Core Europe, said: "I think the real challenge here is to convince health authorities, we have to offer some proof on the effectiveness of the test.

"Costs are decreasing", he said, "so we can expand the size of the tests. We also have a problem with available drugs, we don't have a lot of effective drugs. And, then, we have to demonstrate the benefit for patients, a benefit in using the drug or a benefit in not using the drug."

Finally Benedikt Westphalen, of the University of Munich, said: "We are trying to figure out how valuable the test is, so maybe one could analyse the number of patients needed to be tested to gain benefit from the test."

It was concluded that what is required going forward is:

- *Education and awareness on the benefit of these tests*
- *Case studies in terms of economic value*
- *A policy framework to bring this into healthcare systems*

Session Three: Biomarkers and Value

The lively biomarkers and value session aimed to facilitate patient access to biomarkers and molecular diagnostic technologies, through the development of a policy framework with input from expert, multi-stakeholder viewpoints.

The scope of this framework would be:

- *To guide Member States across the EU and facilitate consistent decision making in order that molecular diagnostics and biomarkers can be integrated into healthcare systems*
- *To focus on divergent standards, lack of uptake in healthcare systems, patient understanding and a subsequent decision-making framework of this information*
- *To guide Member States by proposing standards required for the uptake of biomarkers, encourage consistency across disease areas, and identify potential efficiencies with the ultimate aim of faster patient and citizen access companion/molecular diagnostics*

Among other matters, the session examined the current and evolving landscape, variations in national processes and procedural requirements, and developments in regions outside the EU.

When it comes to the value of molecular diagnostics, the

meeting heard that, for patients, this lies in safer and more effective therapies, as well as increased confidence and certainty in their treatment decisions.

Physicians, meanwhile, would be better informed to make the best possible individual treatment decision for their patients, and payers would see more cost-effective healthcare and better budget allocation.

Setting the scene, **Joe Clune**, Diagnostic Director, Immuno Oncology at Astra Zeneca, posed the questions of what could Member States and the EU do to improve access to testing? What policy framework should we build to facilitate patient access to biomarkers and molecular diagnostic technologies?

To answer these questions, he said, we need expert discussions like this one today. "We will have virtual meetings of expert working group to craft policy asks, such as the ECPC's priorities and a policy paper defining the problem statement."

He added that: "We will develop action plans to promote guidance to Member States," pointing out that there will be the EAPM Congress in December in Brussels, other advocacy summits and follow up activities.

"The idea is to start a movement for testing in Member States and in the EU," he said.

Joe added that patients and physicians want information to guide treatment decisions for safer and more effective therapies. Testing helps increase confidence and certainty.

Biomarkers and molecular diagnostic technologies are an opportunity to achieve a more cost-effective healthcare, he said.

He went on to emphasise that "the big challenge" is to ensure that patients have access to the right testing at the right moment, and that this is not given enough attention in the EU debate.

He added that Europe is behind the US in testing. "Advances can't reach a patient who isn't tested. We need to fill this gap."

Joe finished his scene setting by saying: "We should prepare guidelines on what Member States should do, so that molecular diagnostic and biomarkers can be integrated into healthcare systems.

"We have imagined three domains of actions to tackle in a testing access policy framework: one on 'Availability', which is a space for approval and capacity; one on 'Access', to reimbursement and to create pathways, and one on 'Attitudes'.

"And we think the question is not what the EU can do itself, but rather what can the EU can do to enable the countries, a sort of persuasion power," he added.

Benedikt Westphalen, of the University of Munich, told the meeting that: "There are countries in the EU that do not have access to the WHO300 and oncology drugs that are needed…We need to push for a better implementation of biomarkers across the board."

Mark Lawler, Scientific Director, DATA-CAN, said that in every country, there should be guaranteed basic training of the workforce.

"Then, there is the question of cancer screening," he said. "We should not think of diagnostic tests in isolation because, sometimes, the reason why people are not taking on diagnostic

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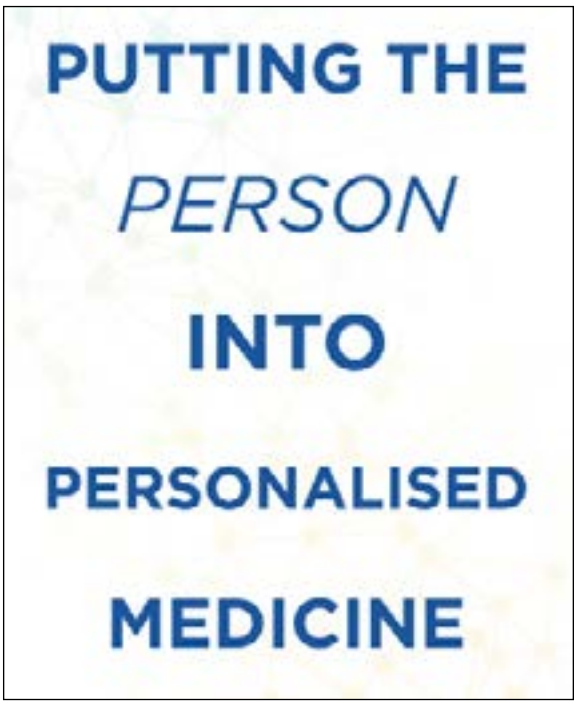

tests is because they only pay for what the diagnostic test will tell them. So sometimes it is not just about the test itself, but rather about what the test will mean in terms of resources."

Stefan Gissels, of Digestive Cancers Europe, explained that the context is different in every country. But survival rates are increasing in many eastern EU countries, such as Lithuania.

"In these countries, top players are emerging, so there is a need to train and recruit people, this has to be enforced," he added.

EAPM's Denis Horgan said: "What we want to do first is to identify what are the key issues, identify the understanding, the attitude of people, patients, policy makers, draw on this and then elaborate a policy framework to address these issues and link it to what the European institutions can do."

"The problem is," said Denis, "that a lot of people are trying to solve the issues without defining the problem that they want to solve, which creates a lot of uncertainties in terms of policy and legislation."

Max Schravendeel, Health & Research Officer, ECPC, spoke about a survey undertaken by the Coalition and EAPM, which showed that 30% of patients don't know what biomarkers are.

Meanwhile, 60% of patients were not proposed a biomarker test, so whether or not testing is implemented in healthcare systems doesn't mean that it is offered to the patients.

On top of this, 70% of patients said they didn't receive sufficient information regarding biomarkers. "This is not only about informing our patients, but also about informing future patients," he said.

Max added that educating the public about personalised medicine is very difficult…but this is doable, he said, "and our patient groups do take up on our awareness month and our initiatives".

CNIO's Nuria Malats said that patients are contributing to raising awareness on disease, diagnostics and treatment.

"From the research point of view, the purpose of biomarkers is not only for diagnostic but also for education and prevention," she said. "How do we identify a population that has a high risk of develop a cancer? By using testing, biomarkers."

Myriad Genetics' Benjamin Gannon said: "Regarding cancer prevention, has anybody looked at what the reasons are for the differences between the US and the EU?

"In 2017, we launched a testing programme for women with a family history of breast cancer and we were able to deliver a risk stratification and clinical decisions were taken on this basis.

"But you have nothing like that in Europe," he said. "So, I would suggest we look at how it was launched in the US, how it became so popular among the population, and how we managed to test 400,000 patients.""

Nuria responded by saying that, in the US, policy makers have adopted a more preventive attitude, not only in terms of prevention programmes, but also in the way they are funding research projects.

Bengt Jonsson pointed out that the EU that doesn't have a European healthcare system, but national healthcare systems. "It is a matter of definition, but it is also a matter of economics. In the research arena, we can do joint projects, but we cannot do anything if there is no money," he said.

Mark Lawler took up the theme: "If we look at the different Member States, and the difference in biomarkers and molecular diagnostic uses across the EU, it is only a question of money.

"This is less cost-effective than in the US. We spend twice as much in the EU than in the US, because medicine is twice as expensive. We need to have a look at the price discrimination…It is not affordable because this is not cost effective."

Fabien Calvo said: "There is a huge discrepancy between the amount of money invested per patient across EU countries, especially between the east and the west, we have to take this into account."

Nuria pointed out that it is not only between Member States, it is also within them.

And Stefan Gissels added that: "We should demonstrate the value of testing, the barriers to it and the consequence of the barriers. But the actual translation into how we would work should be discussed at national level."

Benedikt was clear that access to testing cannot wait. "Now, as oncologists, we are facing the emergence of next-generation sequencing…Good quality molecular testing is already here, and we need to find a way to make it accessible," he said. He added that the question is: who sets the standards?

"Is it going to be the pharmaceutical companies, based on the trials on which the drugs were approved? Does it have to come from the EU to create a biobank to run tests on? Someone who is independent of a financial interest has to run these tests," he said.

EAPM's Denis Horgan finished up by saying that, first, "we need to agree on definitions, and then define our objective. Based on this, we could elaborate a strategy of actions to implement in the coming three years to promote a political framework".

Next steps on biomarkers will be:

- *Organise two conference calls in October and November to discuss key outcomes*

- *Second face-to -ace meeting targeted for 3 December, 2019 at the EAPM Congress*

- *Policy paper one "Draft problem statement: solutions and challenges for uptake of biomarkers in the healthcare system" due in December, 2019*

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Session Four: Translating policy into practice

The fourth and final session at EAPM's ESMO event was entitled: "*Translating policy into practice - The value of personalised medicine for public health, its impact on EU health policy, and its global dimension*".

The key questions here were what are the requirements for a country to be able to move towards personalised healthcare? And how can this be tracked?

Three perspectives were offered up:

• *Translational Research Perspective - Denis Lacombe, Director General, EORTC*

• *Economic Perspective - Bengt Jönsson, Professor emeritus at Department of Economics, Stockholm School of Economics*

• *Patient Perspective - Peter Kapitein, Inspire2Live*

Denis Lacombe told attendees that trials, a registry, and testing are required for treatment optimisation, but it is becoming more-and-more difficult to run independent trials.

He explained that EORTC presented a manifesto about the need to facilitate an "optimisation treatment strategy" to the European Parliament, to open this dialogue at the EU level.

Clinicians, industry, representatives, regulators, HTA bodies and patients were all invited to give their views on providing evidence-generated data to define optimal access to treatments.

Currently there is no central point in Europe - it is all very complex. But, of course, the power is in the hands of Member States when it comes to health issues, Denis said.

Bengt Jönsson, meanwhile, explained that economics is essentially about choosing - choosing where we put the money. There are three barriers to personalised medicine, he said, and these are reimbursement, reimbursement, and reimbursement. Someone needs to pay, and the payment is borne by the healthcare system, hence by society.

For a medicine, it is quite easy to measure the value, cost and benefit. But when it comes to testing, it is very hard.

Bengt said that one of the most pressing challenges to the take up of personalised medicine is the question of how to make personalised medicine valuable.

Inspire2Live's Peter Kapitein first of all asked: "How do we implement personalised medicine?"

He said that evidence is important but it's not enough. We have proved a lot already, but we have not implemented much, he said, adding that "It is a scandal that we don't implement what we know."

He said that there is no simple solution for the implementation of personalised medicine, but then gave the example of the IBAN system being created despite the reluctance of banks.

"It works," he said, "because the coalition of people who built it knew that it was going to be good for Europe... So we need to build a strong coalition".

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In the room for EAPM in Barcelona

All Congress pictures in this report by Simon Pugh Photography

European Alliance for Personalised Medicine

About EAPM

The European Alliance for Personalised Medicine was launched in March 2012, with the aim of improving patient care by speeding development, delivery and uptake of personalised medicine and earlier diagnostics, through consensus.

EAPM began as a response to the need for a wider understanding of priorities in personalised medicine and a more integrated approach among stakeholders. It continues to fulfil that role, often via regular major events and media interaction.

Our stakeholders focus not just on the delivery of the right treatment for the right patient at the right time, but also on the right preventative measures to ensure reliable and sustainable healthcare.

The mix of EAPM members and its broader outreach, provides extensive scientific, clinical, caring and training expertise in personalised medicine and diagnostics, across patient groups, academia, health professionals and industry.

Relevant departments of the European Commission have observer status, as does the EMA, and our engagement with MEPs and Member State health ministries in key policy areas is a crucial part of our ongoing work.

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