



From left: Prof Sir John Burn, European Hereditary Tumour Group (EHTG); Prof Crispin Hiley, Francis Crick Institute; Prof Peter Schirmacher, European Society of Pathology (ESP); Dr Matti Aapro, ECCO President-Elect

Bringing molecular tumour diagnostics into real-life daily practice

Molecular tumour diagnostics have great potential to improve oncology care performance. But embedding them in Europe's health systems presents a range of challenges that policy makers need to understand and address. These issues were at the core of the discussions in this Summit session.

Molecular tumour diagnostics are bringing unprecedented levels of precision to cancer identification and care, and with this, fundamental changes to the oncology profession. These technologies analyse a person's genetic code, allowing healthcare professionals to deliver personalised therapies that work best for the individual patient – that are specific to their tumour type and condition.

For patients molecular diagnostics bring clear answers to questions such as: “Do I have cancer or am I at increased risk? What type of cancer do I have?” For oncologists and other medical professionals, these tools inform choice of the most effective medication per patient, and help determine how a cancer is likely to respond to it. They also help to indicate dosage levels and measure if a cancer is under control, or has returned.

Should molecular technologies be an essential requirement of cancer care? Presenters and panellists said yes. But they cautioned that many of today's health systems are not yet prepared to integrate

KEY MESSAGE

There is a lot of talk that the latest technologies can revolutionise cancer care. But this is not a revolution if most of the patient population is not reached – which is currently the case for molecular diagnostics. How can we create a situation where more people have access?

them. To make this a reality, countries need to better inform and educate their medical professionals on molecular approaches, embed new skill sets, and encourage a new data management and sharing culture in healthcare organisations.

Then there is the issue of cost: where patient advocates in this session cautioned against molecular diagnostics becoming a ‘supermodel’ option – that ‘... is lovely to look at, very costly, accessible only to a few, and with no real value to many.’

HIGHLIGHTS OF THE SESSION'S EXCHANGES:

How molecular diagnostics will change the health systems landscape

The power of next-generation sequencing needs molecular genetics to harness these technologies. It is clear, said some discussants, that the dialogue on next-generation sequencing needs to move out of academic forums and into the medical service world. Medical practitioners need to be better informed of these technologies, of what is available today and how medical professionals need to organise to tap their potential.

The presentations highlighted that some oncologists have not embraced molecular diagnostics simply because they do not know about these technologies. One participant commented that some oncologists are not necessarily thinking of molecular biology as they are unaware of the benefits it provides. Likewise, many of today's medical professionals are unaware of how fundamentally molecular diagnostics will change the way they work and improve diagnosis and treatment. So more effort is needed to inform them of the technologies available and the changing landscape.

These technologies will generate a flood of new data, which will only be useful if the skills and infrastructure are in place to manage and interpret it. It is likely that for health services, the value of molecular diagnostics will be defined by how rapidly and accurately they can interpret the data they generate.

The data challenge goes beyond skills and infrastructure. A cultural shift is needed in health systems to make data sharing standard practice. The example was given of a multi-country group that organised the sharing of 45,000 data sets on different cancer types. In addition to the complexity of managing and interpreting it, the partners took 18 months to reach a data sharing agreement. Cases like this illustrate that innovation in diagnostics relies on innovation in process simplification at different levels in the health system.

Just as the medical professional needs to adapt, regulators also need to be brought up to speed with the changing landscape that molecular diagnostics and personalised medicine are bringing. Here, key questions are: what are the implications of these changes for the health system, and how does it need to evolve to handle them?

For regulators, the question is how to make guidelines integrate these new diagnostics into the health system most effectively. For the European Union, the European Medicines Agency (EMA) has developed a new focus on companion diagnostics. It specifies how diagnostics are used in tandem with a drug to determine how it applies to a specific person, their type and condition. Where the US FDA licences specific tests required for this process, the EU framework does not regulate diagnostics or systems. Its 'guideline' approach describes the results to be achieved and requires that the tests used are described in the reporting.

An EMA concept paper was the starting point for a consultation on the development and lifecycle of personalised medicines and companion diagnostics, to assess the most likely response to a specific treatment. <http://bit.ly/2DAKxk7>

Hereditary cancer diagnosis

Participants also heard perspectives on hereditary cancer and how molecular diagnostics can improve the situation for patients at risk of inherited oncological conditions. GENTURIS is the European Reference Network on hereditary cancers. It serves all patients affected by one of the rare genetic tumour risk syndromes, needing specific treatment and follow-up. <http://bit.ly/2DCraaE>

Given the hereditary nature of these conditions, ERN-GENTURIS takes a family-based approach. It focuses on the patient and their relatives who may also be at risk. Its services focus on improved identification of people living with a genetic tumour risk syndrome; developing evidence-based clinical guidelines; and providing access to a range of resources and information.

Dr Matti Aapro, ECCO President-Elect and Board Member of the European School of Oncology (ESO)





Patients: opening equitable access to molecular diagnostics

The patient perspective was a recurring theme in these discussions. Patient advocates commented that there is much talk about new technologies that are revolutionising cancer care and patient experience. But this cannot be called a revolution if the technology does not reach most of the patient population. Which is currently the case for molecular diagnostics.

How to make molecular tumour diagnostics a reality for all patients? Panellists see that the European situation for progressing access to molecular tumour diagnostics is on a good path – thinking and practice are moving toward recognition of high-performance personalised medicine. It also helps that molecular testing is well-established in other cancer areas such as Chronic Myeloid Leukemia (CML) – which has 20 years of experience to share.

CML can be a model for other areas of cancer diagnostics. It has a broad patient population that has equitable access to these technologies. Today CML patients benefit from frequent testing, that allows detailed tracking of their illness. This means that 25% of CML patients are identified as in remission and can be off treatment and be closely monitored with molecular diagnostics for changes in their condition.

As these technologies become more integrated in oncology practice, the good news is that their cost is expected to plummet. One delegate put this in a practical context, commenting that, even as costs fall, one aspect will continue to remain prohibitively expensive – misdiagnosis. This is an area where molecular approaches are likely to bring improvements to health systems.

Molecular tumour diagnostics in cancer care: should they be an essential requirement?

Co-led by the European CanCER Organisation (ECCO) and the European Society of Pathology (ESP)

Prof Peter Schirmacher, European Society of Pathology (ESP): Molecular tumour diagnostics potential, needs and challenges

Jan Geissler, CML Advocates Network and ECCO Patient Advisory Committee: Molecular tumour diagnostics in cancer care: should it be an essential requirement? A patients' perspective

Prof Koen Norga, European Medicines Agency (EMA): Regulatory framework for companion diagnostics and medical devices

Panel discussion perspectives:

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Prof Crispin Hiley, Radiation Oncology Consultant & Associate, Francis Crick Institute, UK

Prof Fatima Carneiro, University of Porto

Moderators:

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Anne-Marie Baird, ECCO Patient Advisory Committee and Lung Cancer Europe (LuCE)