European Alliance for Personalised Medicine

UPCOMING EVENTS

EAPM
7th Annual Conference
BRUSSELS
8–9 April 2019

4th EAPM Summer School
19–22 June 2019 // Leuven

EAPM
3rd Annual Congress
BRUSSELS
18–20 November 2019
Introduction

Welcome to this, our 2018 post-Congress report.

Those of you who joined us in Milan at the end of November will know what a great success the event was, following on from our presidency conference earlier in the year in Brussels and 2017’s inaugural Congress in Belfast.

More than 700 Life Sciences thought-leaders convened at the Congress, which brought together key speakers and attendees who all contributed to the vast programme content and cutting-edge knowledge exchange.

Among us were large numbers of industry professionals, government regulators, patients, researchers, academia, healthcare professionals, and journalists who aim to drive their various valuable insights to action.

Given the topics and the expertise gathered in the Lombardy regional capital, it’s clear that Congress was a true melting pot of ideas and skill sets - a melting pot rich with innovative plans that will have solid results as personalised medicine continues to develop and deliver.

EAPM and its partners will take these innovative plans to policymakers in a period that is becoming ever-more important, with Brexit looming, the European Parliament elections coming up in May next year, and a new Commission not long after that.

So, more than ever this year, a focus was on those politicians tasked with devising and implementing regulatory frameworks in all areas, including certain aspects of health.

More than 700 MEPS will be elected next summer and the Commission will also have a new president as Jean-Claude Juncker steps down at the end of his five-year term.

One of the goals of Congress is always to engage politicians and lawmakers in our fast-growing field, and deliver political asks through our consensus-based process.

Down the line, we all have a responsibility to make sure that personalised medicine is properly embedded into the EU’s often disparate healthcare systems, so we were delighted to see a true cross-section of representatives from various disciplines coming together under one roof, joined of course by ministers from various Member States.

We all have a stake in the health of citizens in our Union and a great deal of our job at such a one-stop-shop as Congress is always to strive to find ways to facilitate change, not least through on-the-ground efforts to deliver the necessary paradigm shifts at national and regional levels.

Europe needs to grasp the fact that health equals wealth and that investment in research and innovation, alongside developing laws and rules that are fit-for-purpose and reflect the swiftly changing world of medicine.

There needs to be encouragement and incentives for those looking to invest and innovate in Europe. We have the skills and facilities within the bloc but currently lack an ideal environment that will ensure better access to treatment for patients.

Innovation and the incentives for it are vital to health and wealth in the current EU-28 (and will be even more important after the UK leaves next year). It also encourages investment from outside of the EU, clearly good for business and jobs.

Once again, Congress allowed a broad airing of views prior to our delivering key aspects to decision makers at European, national and regional levels. This will effectively allow for a bridge to representatives in various policy areas.

Hence our continued interaction with MEPS, Commissioners and Member State health leaders.

David Byrne - EAPM Co-chair
Gordon McVie - EAPM Co-chair
Denis Horgan - EAPM Executive Director
Time to ‘innovate our innovation’

Among key topics covered at the Milan Congress was a two-day track on what many are calling the MEGA initiative. The initiative is gaining considerable traction.

MEGA stands for Million European Genomes Alliance and the joint declaration by a coalition of willing Member States in April indicated political support for linking existing and future genomic databanks, on a voluntary basis, in order to reach a cohort of one million sequenced genomes accessible in the EU by 2022.

Also up for discussion at the event was a multitude of disease areas, the ongoing debate on HTA, men’s health and a plethora of other relevant topics – all under the umbrella of facilitating innovation.

During a bustling first day at Congress, Ciaran Nicholl, of the Research Centre Ispra at the European Commission, told attendees: “We already know that, this year in Europe, there will be 3.9 new cancer patients, and 1.9 million will die.”

Nicholl also told the audience in the presidential session Advancing Europe’s Healthcare - Patients and Economy that inequalities in healthcare across Member States are “unacceptable”, adding that “Europe is not good enough at unleashing the power and potential of the Big Data that we have.”

During the same session, Ernst Hafen, of ETH Zurich, said that: “We are ready to pay for a cup of coffee, no sweat. We have to realise that we have to pay for digital services.”

On stage at the same time, Robert Johnstone, former board member of the European Patient Forum, told attendees: “We have these wonderful science-based systems, but 20% of patients don’t take the medicine they are prescribed, ever. And within a year, 50% stop taking it.”

He also said that we assume that prevention is only for people who are not sick, “but prevention is an ongoing process. However, we are not educating or empowering people” in this.

“We have to start with the young people, we have to start with education,” Johnstone added.

Forward as One: Europe as a Global Player

In an earlier session, the undersecretary of state at Poland’s Ministry of Health, Marcin Czech, (above) told attendees that: “Poland belongs to the fastest ageing societies of the EU. Compulsory health insurance covers 98% of the population, and guarantees access to a broad range of health services.”

The minister added that personalised medicine should be an important element of an effective, patient-orientated healthcare system, and that its wider usage “is perfectly in line with patient care”.

And Christine Chomienne, of INCa in France, said that: “To move forward, we have to innovate our innovation.”

In the same session, Michael Zaiac of Novartis told the audience: “The age of stratified medicine is well underway,” adding that the outcomes for patients have been encouraging.

“But we need to do more, and increase awareness with all stakeholders,” he said, conceding that there are varying rates of adoption of innovation across Europe.

The main topics covered Europe as a global player, plus patients and the economics of healthcare in the 21st century.

Congress heard that in the first instance, improved healthcare supports economic activity.

A healthier Europe will mean citizens spending less and less time in hospitals under expensive treatment regimes, often at a direct cost to the taxpayer, and it will also mean that people receiving the right treatment at the right time are more able to stay in the workplace, thus generating wealth.

A focus on research into new medicines and cutting-edge treatments will also create jobs – whether they be in research itself, education, design and manufacture of in-vitro products or within the pharmaceutical industry.
Alberto Mantovani, of Humanitas, was among the speakers in the ‘Facilitating access for today’s diseases’ presidential session

The road to better health must have personalised medicine as its destination. With the backing of the European Union, the bloc can work towards building a healthy and wealthy Europe, one worthy of its stated goals for generations to come.

In the second instance, covering the economics of health, personalised healthcare will need to start with prevention to be truly successful and individual. This will see it move from disease management to health management which will change the cost structures and prevent loss of quality life, Congress heard.

The way therapy is approved and subsidised will need significant modernisation. Individual responsibility in risk reduction and cost sharing/insurance is foreseen to develop. The medical structures and citizen involvement will also need development to optimise the best use of new possibilities.

In total, the first day in Milan saw six main topics, or tracks, running in parallel and covering regional matters, diagnostics, education of healthcare professionals, access and genomics plus men’s health - a topic too few talk about.

The latter track covered areas such as lowering the risk and mortality rate of the most frequent cancer in men, setting the framework for political action and tools to realise this, and a multidisciplinary approach of early diagnosis, discussing the way forward. More of that later...

Bridge building

Day two was a busy one in Milan, featuring - among other tracks - two well-attended presidential sessions.

The first of these came under the banner of ‘Facilitating access for today’s diseases’.

Peter Meeus, from Shire, told the audience and panel that rare diseases need to be treated differently from more common diseases, using real-world data.

He said: “There is a need for Member States to invest more in data bases. Rare disease patients are not easy to find to put into a trial.”

Marco Marcello, of DG CONNECT, said in the same session that Europe needs to give citizens better access to their health data everywhere in the EU. This would involve enabling secure access, while empowering patients with digital tools and apps.

Data sharing across borders will lead to better research and personalised healthcare, and: “The Commission is building the bridge,” he said.

Marcello then emphasised that the Commission encourages and supports Member States to adopt interoperable electronic health record systems.

He also spoke about the flagship data-sharing initiative, which now has 19 countries on board, and came on the back of EAPM’s MEGA efforts in concert with Marcello’s DG.

Attendees heard that the signatories met for the first time in September, to try to understand technical, organisational and legal challenges.

It’s a perfect example of cooperation and Jennifer Mills, from Foundation Medicine, said: “If we don’t collaborate, we can actually make more of a divide. Partnership is no longer optional, it’s essential.”

In the same session, Stanimir Hasurdjiev, from PACT, explained that the challenges in his country Bulgaria can easily be seen in every country in Europe and in every disease area.

It’s a common responsibility to make sure nobody lags behind in access and more, he said, adding that the speed at which we move depends on the speed of the slowest country.

Speaking about the upcoming European Parliament elections, he said: “Politicians must understand that there is no Europe without healthy citizens.”

Sitting alongside Hasurdjiev, Alberto Mantovani, from Humanitas, pointed out that sustainability in healthcare is one of the biggest challenges needing to be faced.

From here to 2025: Personalised medicine and healthcare for an immediate future

The second Presidential session of day two featured a dialogue with CEOs.

Elena Bottineli, of San Raffaele Hospital, was first to speak and highlighted the importance of collecting data and using it well. She also focused on archiving, sharing, and AI to help doctors use the data optimally.
“We have to educate our hospital staff. There are many things they need to know, and it will take some time.”

Eva Weinreich-Jensen, European Hospital and Healthcare Federation (HOPE)

“Politicians must understand that there is no Europe without healthy citizens.”

Stanimir Hasurdjievi, PACT

“We assume that prevention is only for people who are not sick. Prevention is an ongoing process. However, we are not educating or empowering people. We have to start with the young people, we have to start with education.”

Robert Johnstone, Former board member, European Patient Forum

“To move forward, we have to innovate our innovation.”

Christine Chomienne, INCa

“Europe is not good enough at unleashing the power and potential of the Big Data that we have.”

Ciaran Nicholl, Research Centre Ispra, European Commission

“Patient access to innovation is a shared responsibility - governments, payers, patients, industry...”

Nicoletta Luppi, MSD Italy
Investment in research, and the education of HCPs (as well as patients), also came under Elena’s scrutiny.

“We really think personalised medicine will improve healthcare for patients,” she said.

Torsten Hoof, of Genomic Health, told attendees that Europe is doing well with regards to life expectancy. Putting a focus on oncology, he said that the promise in personalised medicine is to get better outcomes in cancer patients.

Value-based reimbursement will fuel personalised medicine, he suggested.

Nicoletta Luppi, of MSD Italy, explained that cancer mortality has been declining in the past 40 years, while adding that current patient access to innovative cancer medicines varies in Europe. She highlighted as reasons for this national GDP, but also pointed out that political will is a big factor.

“Patient access to innovation is a shared responsibility - governments, payers, patients, industry…” Nicoletta said.

Maurizio de Cicco, of Roche Italy, illustrated that improved understanding of cancer biology has challenged traditional business models, while Michele Perrino, from Medtronic, told attendees that: “We need to bring technologies that are accessible.”

Connecting technologies to the outside world is vital, he said.

As well as the two Presidential sessions, Tuesday saw tracks on lung-cancer screening, which addressed screening strategies and guidelines, epidemiology and public health.

Congress heard that earlier diagnostics and earlier treatment has many benefits, among them fiscal, as has often been mentioned, because while cost is a major issue better diagnostics will ease the burden on healthcare systems.

Other tracks covered diabetes and hospitals, while Congress heard that digital health technologies have the potential to play a significant part in improving health services. Advances in robotics, AI and personalised medicine mean patients can benefit from improved health outcomes.

Congress also heard that patient empowerment is fundamental to unlocking the potential that exists to free up vital resources within healthcare allowing them to be used where they are needed most.

Elsewhere on day two, regional track attendees heard that a revolution in technology has exponentially reduced the costs of and increased the ease and availability of genome sequencing, such that this knowledge can now be used to benefit everyone.

Also taking place on the second day in Milan were a genetics track, and the winter school for healthcare professionals.

Day three lives up to its billing

The third and final day of Congress in Milan summed up the whole event - excellent presentations and discussions, plus plenty of interaction and networking.

As usual, the day saw two key Presidential sessions, this time on ‘Interfacing with Public Policy Makers’ and the closing session, ‘Who is to do What?’ - which comes up later, for obvious reasons.

The first presidential session had Congress hear that the evidence of the merits of personalised medicine is already ample and the potential is huge.

The benefits are there for the taking for patients, citizens and society, and will bring new levels of satisfaction to professionals working in the health domain.

But, attendees were asked, why is its development and exploitation so slow, particularly in Europe?
Warm welcomes...and chilled cocktails

Speakers and delegates gathered for a reception at the headquarters of the Lombardy Region in Milan, at the end of the first day of EAPM's second annual Congress. Also held during the three-day Congress was a lively presidential dinner on the 39th floor.

All Congress pictures by Simon Pugh Photography
The session gave attendees the viewpoint that the innovative quality of personalised care demands links to other areas of innovation.

Eva Weinreich-Jensen, European Hospital and Healthcare Federation (HOPE), said: “We have to educate our hospital staff. There are many things they need to know, and it will take some time.”

Aside from this, “We need the politicians to be careful with the lawmaking,” she said.

Eva added that politicians have to go out and talk to people, as well as discuss ethical dilemmas.

And Gaetano Guglielmi, IRCCS, Italian Ministry of Health, agreed with Eva that: “The training of the healthcare professionals is very relevant.”

Chairing the session, Antoni Montserrat, (above) formerly of the European Commission’s DG Public Health, said: “Things are changing in the field of personalised medicine”, and reminded attendees that: “We will change the political panorama next year, with the European elections. We will have new instruments, Horizon Europe and the European Social Fund Plus.”

And Francesco De Lorenzo, of the European Cancer Patient Coalition, told the audience: “There is no personalised medicine if there is no innovation.”

On patient-organisation empowerment, he said: “There is no innovation without patients,” but added that: “There are problems sometimes to get accepted (in some Member States).”

Meanwhile, Mary Harney, former Irish health minister, told Congress that: “The best innovation happens when it’s widely diffused,” and added that: “Healthcare systems tend to be slow at embracing innovations.”

Mary, who is the current chancellor of the University of Limerick, also spoke about the need to look seriously at the sustainability of healthcare, adding that the debate should be a value one - on results - rather than a volume debate.

“At the moment we’re often paying for things that don’t deliver value,” she said.

Francesco Scopesi, of Shire Italy, focused on rare diseases and told attendees that it’s highly challenging to develop new medicines and more effective approaches for patients.

“Speed matters for people with rare diseases,” he said. “We need to be quick!”

On access, Francesco reminded policy-makers that: “Bureaucracy shouldn’t be a barrier or hurdle to patient access to orphan drugs.”

Also taking place during day three were additions to the regional track, a dedicated patient track, the third day of the winter school, rare diseases and translational research.

On top of this was the launch of Regions4PerMed, on the 39th floor of the Lombardy Region headquarters - EAPM’s hosts for the event.

More of that below…

Other Congress highlights

Regarding lung-cancer screening, the major topics addressed in this track were screening strategies, epidemiology and public health.

Congress was hardly surprised to hear that lung cancer is the biggest killer of all cancers, responsible for almost 270,000 annual deaths in Europe.

When it comes to this disease, Europe is looking at risk prediction models to identify patients for screening, plus how many annual screening rounds is enough.
This is not before time.

Undoubtedly, tobacco smoking is the major risk factor for lung cancer, although passive smoking, and a family history of lung, head and neck cancer are, among other factors, also important.

Figures show that lung cancer causes almost 1.4 million deaths each year worldwide, representing almost one-fifth of all cancer deaths, yet the biggest cancer killer of all does not have a solid set of screening guidelines across Europe, Congress was told.

Certainly, lung cancer screening implementation in Europe has been debated in the scientific community and with politicians at national and European level for a long time.

Different members of the European Parliament and most experts in the field have agreed that Europe’s health systems need to adapt quickly to allow patients and citizens benefit early diagnosis of lung cancer and thus reducing mortality for this lethal disease.

The recently released results of the NELSON survey, the second-biggest of its kind into the disease, showed that computed tomography, or CT, screening for lung cancer reduces lung cancer deaths by 26% in high-risk asymptomatic men.

It also suggests that with screening the results could be even better in women.

The trial included almost 16,000 people, and findings show that CT screenings are effective, often lead to detection of suspicious nodules, and can greatly increase the chances of cure.

It has shown beyond doubt that screening has the potential to detect lung cancer at an early stage, and such a result is impossible to ignore.

So, findings Europe (and in the US) strongly suggest that lung cancer screening works. There is hard evidence, although debate continues about the best way to implement screening of this kind, and even how to properly evaluate cost effectiveness.

Of course, guidelines could help to tether costs, by bringing in improvements to the efficiency of screening methodologies and, thus, programmes themselves.

Congress heard that, when it comes to lung-cancer screening, much can be achieved with consensus-based guidelines to ensure that all stakeholders are aware of acceptable standards and are effectively all singing from the same hymn sheet.

Guidelines must be put in place to allow countries to set-up quality assured early detection programmes for lung cancer, possibly through increased public-private partnerships.

Congress were told of the a need for greater efforts, backed up by collaboration between countries and professional, organisational and scientific support for those seeking to implement or improve population-based screening programmes.

Overall, it is clear than any further delay to the implementation of the best form of lung cancer screening will mean many more unnecessary lives lost.

Congress heard that earlier diagnostics and earlier treatment has many benefits, among them fiscal, as has often been mentioned, because while cost is a major issue better diagnostics will ease the burden on healthcare systems.

**Diagnostics**

Congress heard that IVDs, specifically companion diagnostics, play an essential role in personalised medicine and the patient-healthcare pathway.

As non-invasive tests used for diagnosis, screening, assessing predisposition and monitoring, IVDs do not treat patients; instead, they rely on biological samples, including blood, urine or tissue, to provide a specific set of data regarding an individual’s health status.

Congress heard that there are certain intrinsic characteristics of IVDs that distinguish them from medical devices and pharmaceuticals.

While they are a unique group within the broader
medical device sector, there are also differences among IVDs.

The afore-mentioned companion diagnostics, for example, are highly innovative and precise tools, which necessitate special consideration that accounts for their integral role in the further development of personalised medicine.

Companion diagnostics are rapidly growing in importance in this field. They provide the potential of more effectively treating patients by targeting their therapy and avoiding ineffective treatments that may harm the patient.

This was duly noted by the Commission and the European Parliament that saw a number of amendments to relatively recent legislation, including many put forward by EAPM and its stakeholders.

Congress called for continued collaboration with the academic community to ensure that innovation in personalised healthcare is incentivised and continues to develop, as well as a true stakeholder platform to allow a space for a regular exchange of information and developments in the area.

Attendees heard that ongoing research and development of new therapies, diagnostic tools, and mobile technologies offer new opportunities, bringing faster and more accurate diagnosis, allowing patients to go home sooner, helping healthcare professionals to monitor conditions more accurately, and improving patient outcomes.

**Genomics**

Where genomics in health stands today - and its incredible potential through Next Generation Sequencing and more - still requires the development of a high-level plan for advancement in this crucial and swiftly moving area.

Discussions have looked at improving treatment selection in cancer, maximising success of diagnosis in rare diseases, and what regulatory framework is best to support innovation in genomics.

There is still a need to inform European Union and Member State policy makers in order to shape the landscape for the successful implementation of genomics and related technologies in the healthcare arena.

Genomics is the foundation that enables the vast potential of personalised medicine to be realised, much of it preventative, Congress heard.

With rising healthcare costs and individual health systems being increasingly challenged, genomics has the potential to impact the health of all of us and provide diagnostic, economic and efficiency benefits, ensuring that patients receive the right information and the right treatment at the right time.

This will ease the burden on healthcare systems and lead to a healthier and, thus, wealthier, Europe. The potential for bettering the health of EU citizens is huge.

Yet, while genome sequencing has progressed rapidly in clinical and translational research with the development of multiple tools and methods, there is a need to define standards to ensure consistency of clinical testing.

This will also greatly further research by facilitating greater comparability of the increasing number of sequences being performed, Congress heard.

Genomics is starting to be implemented across a number of clinical areas in different geographies. Europe must ensure that models of best practice for clinical implementation and application are shared across these.

And from an education point of view, the majority of current clinicians have not trained in the ‘genomic era’ and have little experience of using such information in healthcare.

**Access, ‘value’ and HTA**

In healthcare systems that are becoming increasing tough to finance, how do we decide what constitutes ‘value’?

Congress heard that one must understand a product and/or treatment while considering what it can provide, weighed

Ernst Hafen, of ETH Zurich, told attendees: “We are ready to pay for a cup of coffee, no sweat. We have to realise that we have to pay for digital services.”
against cost and other considerations, for the benefit of the patient.

How do we assess that benefit? We can talk about extended lifespans, better quality of life, treatment that is purely palliative and more. But if the medicine, for example, is highly expensive and gives only an extra few weeks of life, or makes the sufferer only marginally more comfortable, is there really much value?

Congress heard that, from a humanitarian point of view, many would argue that the answer should be ‘yes’, but that flies in the face of spiralling costs and, sometimes, a lack of proof that a treatment achieves very much.

Today, when medical innovations are increasingly prevalent but those under-pressure healthcare budgets are tightening all the time, it is important to find ways to optimise equitable access to healthcare systems and treatments.

HTA bodies are very useful but, in a Europe that sees a lack of equitable access to the best treatments in many of the EU's Member States, a lack of alignment and agreed definitions of value lead to a clear imbalance between richer and poorer countries as well as, often, between different regions within single states, Congress heard.

The European Commission's recent moves to bring in obligatory joint action on health technology assessment has been welcomed by many stakeholders and the European Parliament, although certain Member States remain resistant, arguing that the Commission is over-stepping its mandate in an arena that sees member countries have competence under the Treaties.

The patient at the centre

Research has shown that patient-centred care models are cost-effective and lead to better outcomes and patient satisfaction. Patient empowerment can be a vital element of high-quality, sustainable, equitable and cost-effective health systems.

Congress heard the view that there is a strong argument that the concept of ‘value’ should always be seen from the ‘customer’s’ point of view, in this case, the patient.

The Alliance's co-chair and cancer specialist Gordon McVie said: “Healthcare should start with the patient. As should the concept of value.

“Our viewpoint and strategy is reflected in the landmark Luxembourg Council Conclusions on personalised medicine which stated that the EU-28 should take into account, ‘inter alia, added value from the patient’s perspective as well as enhanced cooperation and exchange of best practices’.”

McVie added: “Since then, EAPM has been following up on the Council Conclusions and will continue to do so into the future, not least through conferences and Congress such as this.”

Mens's Health

Congress heard that one-in-five men die before the age of 65 - before they have time to enjoy retirement. That’s an astonishing statistic.

Men are also more likely to respond to stress by taking risks such as misusing alcohol, and are less likely to have a positive view of talking therapies. At the same time they are around one-third less inclined to access psychological therapies than women are.

It’s a given that men don’t want to talk about things such as the potential killer that is prostate cancer, for example, and are unlikely to want to visit the doctor for check-ups because they find it embarrassing and hide behind the ‘I can’t afford the time off work’ argument.

In fact, more than half say they think that their boss would think worse of them for heading to the doctor.

“Apart from anything else, men’s health is a political issue, or should be,” said Hendrik Van Poppel, EAU Adjunct Secretary General - Education, EAU.

“Men make up roughly half of every population in the EU...
Member States and, of course, the ones who do make it past retirement age still get to go out and vote.

“At that age, even men start to care more-and-more about their own health,” he said, adding: “Would-be MEPs in next year’s European elections would do well to remember this.”

Congress heard that working men create wealth, and healthy male retirees stay out of hospital. The mathematics are simple, and it is time to act.

Prostate cancer on the march

Meanwhile, the number of men being diagnosed with prostate cancer across Europe has increased over recent years. This is thought to be mainly down to men becoming more aware and having tests to detect very early prostate cancers as well, of course, as the ageing population that leaves more-older men in society.

Despite significant advances in treatment, it is a growing problem that has a major impact on men’s health. In 2008 some 70,000 men died of this disease in Europe, which accounts for in the region of 10% of all male cancer deaths.

The vast majority (92%) of these deaths occurred in the oldest age group, which is made up of 65-year-olds and over.

Today, some three million European men are living with prostate cancer and the number will grow due to the EU’s ageing population.

There are in the region of 105.5 new cases per 100,000 men across the European Union each year. But there are significant differences between Member States with, for example, as many as 123 cases per 100,000 in Ireland.

Congress heard that the actual causes of prostate cancer are still unknown, but some factors such as age, as mentioned, and a family history of the disease increase the chances of developing it.

In fact age has been identified as the strongest risk factor, with men under 50 having a very low risk. However, those reaching the age of 80 or more will have an 80% risk of developing the disease.

Also, those men with close relatives (such as a father, a brother, a grandfather or even an uncle) who have contracted the disease in the past, are slightly more likely to develop it themselves.

Despite the best efforts of scientists, no specific gene has so far been identified with a direct link to prostate cancer, although research has flagged up that faulty genes linked to a higher risk of breast cancer could also increase the risk of getting the disease.

Nothing, however, is certain right now - although eating a healthy balanced diet which is high in fibre and low in fat and sugars may reduce the risk.

As mentioned above, there is no doubt that more research is needed into a disease that not only will not go away, but will actually increase as our population ages.

It is important to note that prostate cancers often have no
early symptoms. One problem with the disease had been over screening, which identified too many non-life threatening prostate cancer cases.

This in turn led to a great deal of unnecessary treatment and brought with it long-term side effects. A result of this has been some Member States deciding against national screening programmes for the disease.

Despite this reluctance, the problem of prostate cancer will only worsen, with projections suggesting that, by 2060, there will be an increase of around 32 million in the number of men aged over 65.

**Diabetes**

According to the World Health Organisation (WHO), there are some 60 million people with diabetes in Europe, which equates to around 10.3% of men and 9.6% of women aged 25 years and above.

In every age group, however, diabetes is on the up. And this rise is due mainly to people being overweight and obese, eating unhealthy diets and having a lack of physical activity.

Congress heard that WHO projects that, worldwide, diabetes deaths will have doubled from 2005 levels by 2030.

We live in an ageing population and the older a person is, the greater their risk of diabetes. But the really bad news is that type 2 diabetes (T2D) is increasing in all age groups, including children and adolescents.

Half of people with diabetes die of cardiovascular disease (primarily heart disease and stroke), and 10-20% of people with diabetes die of kidney failure. Blindness is also an issue, as is nerve damage.

Congress heard that the overall risk of dying among people with diabetes is at least double the risk of those without it, and that diabetes is a truly worldwide problem.

It should be as hot a topic as cancer, but it is not, attendees were told.

Meanwhile, it is a fact that many if not most patients stop taking their prescribed medication after between 6-12 months. This means they quickly lose most of the clinical benefit. Adherence is critical, but the figures are damning.

On top of this, deaths from missed diagnoses of T1D are still happening. And with T2D, consistent and timely diagnosis remains suboptimal, with evidence showing an average period of more than six years from onset to diagnosis.

As mentioned earlier, blindness and kidney disease can be a direct result of T1D, so people with the condition must have access to groundbreaking innovations to benefit from them.

Congress heard that work to improve healthcare access for the T1D community has three main areas of focus – coverage, affordability and choice.

Work to improve healthcare access for the T1D community has three main areas of focus – coverage, affordability and choice.

Congress heard that there is a clear aim to raise awareness of the impact that diabetes has, while promoting management, care, prevention and education of the disease.

Diabetes has been compared to a wildfire raging through the globe, attendees were told, yet the disease and healthcare costs are not being dealt with by the world’s nations, including those in Europe.

**Hospitals**

Congress heard that university hospitals play an important role as front-runners in and catalysts for innovation, as well as
promoting best practices and contributing to the development of strong local, regional and national economies.

Attendees also heard that personalised medicine has the potential to respond to the increasing burden of co-morbidities and enhance the sustainability of healthcare systems.

It is crucial to demonstrate the benefit of large scale deployment of personalised medicine to citizens and these healthcare systems.

Up for discussion was how digital technologies and the wider use of health data are changing our lives and their applications in healthcare, especially in the light of the General Data Protection Regulation and a need to improve the interoperability of electronic health records.

But while research is all around us in hospitals and elsewhere, Congress heard that there is a need for value-based indicators to measure the impact of research into clinical practice.

Meanwhile, patient empowerment is fundamental to unlocking the potential that exists to free up vital resources within healthcare to be used where they are needed most.

Regions

Congress heard that a revolution in technology has exponentially reduced the costs of and increased the ease and availability of genome sequencing, such that this knowledge can now be used to benefit everyone.

But although sequencing is starting to be introduced to clinical care, improving diagnosis and care of patients with rare genetic diseases and starting to impact on cancer diagnosis and stratification of therapies, there remain a number of key challenges to ensure genomics and related technologies are applied such that over the next few years we can fully realise the potential of personalised medicine. So, how can this be achieved?

Congress heard that there are workable solutions already being found.

In the Nordic countries (namely Denmark, Iceland, Norway, Sweden and Finland), each one has independently deployed personalised health programmes that converge towards genomics-based and data-driven cure-and-care.

They are coordinated, united in strategy and are striving to be consistent in the quality and level of data, as well as in their organisational structure.

Such a cooperation-based strategy, and the involvement of both the public and private sectors, should form a vital building block underpinning the EU’s position as a frontrunner in innovative healthcare.

Meanwhile, Congress heard that in central European countries there is a focus on the use of technology and Internet connectivity, which provides new methods for utilising and improving public health services.

Attendees learned meanwhile that the eastern European region is currently facing serious problems with coordination, system disintegration and lack of control over the market environment, especially in the area of medicines.

As for regional innovation in Mediterranean countries, Congress heard that there is a heightened focus on personalised healthcare among relevant stakeholders across the area.

However, an effective strategy for bringing about the necessary policy modifications and practical shifts requires an understanding of the personalised healthcare landscape.

Other discussions and presentations on the regional track saw the topic of best practice in sharing data from a regional perspective.

Congress heard that modern healthcare is based on evidence and that this evidence comes from data.
Therefore, data relating to individuals are fundamental to modern health research, while the processing of personal data is vital for clinical trials and observational research performed in industry and academia.

These considerations are even more pertinent with regards to personalised medicine.

Regions4PerMed

Continuing the regional theme, for the launch of Regions4PerMed in Milan attendees heard that there is an urgent need to start restructuring care delivery, fuelled by factors such as chronic diseases, Europe’s ageing population and health workforce shortages.

To tackle the challenges, new care models are needed and their implementation requires essential investments and related strategies.

The involvement of a broad range of public and private partners and investors is required, with a combination of bottom-up and top-down approaches to realise these necessary new care models.

When it comes to implementation of these, two underlying principles are, as ever, collaboration and partnerships.

Said Maurizio Bersani, of DG Welfare, Lombardy Region: “When all of the concerned stakeholders, be they politicians, care authorities, care professionals, citizens and patients, service providers, technology providers and investors, are committed to working together, this should create a favourable environment for the design and deployment of new care models.”

Coordinating regional policies and innovation programmes in personalised medicine is an urgent need.

And, as personalised medicine develops, a number of good practices are emerging, not least regionally, which, individually and collectively, offer insights into how to design and implement successful new models.

Patients

During this track Congress heard that with the rapid evolution of genetic and genomic technologies revolutionising our approach to prognosis, screening and targeting of therapies, the age of personalised and predictive medicine has not only defined how clinical practice is evolving today, but also shows how it will be practiced in the future.

Personalised medicine is underpinned by the clinical molecular testing of biomarkers, which can be prognostic, predictive, pharmacodynamic or diagnostic.

Pharmacodynamic biomarkers measure the effect of a medicine on a disease, whereas diagnostic biomarkers are used to establish the particular disease that is present in the patient sample.

Attendees were told that in oncology, for example, the success stories of clinically useful pharmacogenetic predictive biomarkers have so far come mostly from retrospective analyses of clinical trial data and impromptu genetic analyses.

A systematic prospective approach with current technologies available is defining how biomarker discoveries are made in tandem with drug development.

A variety of high-throughput approaches, including the use of parallel next-generation sequencing, single nucleotide polymorphism analysis and transcript profiling by microarray have been used to discover new predictive biomarkers.

Biomarkers are clearly a big deal, yet Congress heard that they are still largely unknown or understood by cancer patients and are insufficiently used by physicians.

Healthcare professionals use diagnostic tests to clarify and support their clinical decision making but poor patient knowledge, difficulties in reimbursement and a lack of existing biomarkers in some European countries are an obstacle to improving cancer patients’ clinical outcomes.

This is obviously a far from optimal situation.
Under the spotlight here were an explanation of what biomarkers actually are, and how to get this information to the patients through increasing biomarker literacy.

This came on top of the inevitable need to adapt the regulatory framework - a common theme at Congress - the improvement of access, and recommendations for policy makers.

Later, a discussion was held on ensuring that patient preferences are valued when assessing new treatments, and attendees heard that several challenges must be managed in order for personalised medicine to be realised.

Congress heard that in addition to scientific tasks it will be critical to address the major gap in perception and knowledge between the scientific community and the public regarding pharmaceutical development and innovation.

Well-informed patients and their professional carers will play a key role in the implementation of personalised medicine, attendees were assured.

This will happen in terms of developing an understanding among the public, and also at an individual patient level, ensuring that people know how to use medicines targeted to patient sub-groups in a safe and effective manner.

Also flagged-up to Congress was the need for education and training opportunities that are easily accessible for patients and healthcare professionals, better information for patients, the need for recognition of the complex nature of pharmaceutical benefit-to-risk information, and the need for ethical management of potentially conflicting interests associated with genotyping of individuals.

Electronic health records were discussed at length in the patient track, too, while Congress heard that as broader data sets are accessed, specific patterns could be discovered that better guide clinical decisions.

These tools can be used to confirm that findings are relevant to individual patients before initiating new diagnostics or therapeutic interventions.

Congress then discussed how the tools can be implemented and what training would be required for the adoption of these technologies.

**Rare diseases**

The question has been asked regarding why Europe should take a lead in this area.

Congress heard that the emergence of ‘omics’ and Big Data has revolutionised healthcare, and the personalised medicine approach is already being successfully applied in different healthcare areas such as oncology, cardiology, nutrition and also for rare diseases.

But health systems across the EU are often still promoting the ‘one-size-fits-all’ approach, even if it is known that patients do greatly vary in their molecular characteristics and response to medicines and other interventions.

Several challenges need to be addressed in all areas affecting personalised medicine, such as the integration of Big Data, patient empowerment, translation of basic to clinical research, bringing innovation to the market and shaping sustainable healthcare systems.

As part of this track, pancreatic cancer was a specific topic. Pancreatic cancer is the eighth most common cancer among men in the Western world (ninth in women), and has arguably the lowest survival rate of any.

There are no identifiable symptoms at an early stage and it is, therefore, currently hard to detect.

By the time symptoms appear, the cancer is often already advanced and it is too late for surgery in many cases.
Mortality of pancreatic cancer is expected to keep increasing in Europe in the long term, overtaking the mortality rates of other long-recognised deadly cancers.

Congress heard that pancreatic cancer is more common in people aged 45 and above, and its exact cause is unknown. It is usually fatal, not only because of generally late detection, but partly because it tends to resist chemotherapy. And when it comes to surgery, only about 15-20% of patients have tumours which are considered able to be removed by this method.

Overall five-year survival rate remains low (around 6%), and there have been no significant improvements in survival over the last decade, although outcomes are slightly better for the small percentage of patients whose disease is discovered early.

Attendees heard that Congress aimed to appeal to policymakers, legislators and regulators to encourage innovation and to broaden access to treatment, and to all stakeholders to work more closely together to reduce the burden of pancreatic cancer on patients and on society.

Even with personalised medicine aspects of testing, there is still a long way to go before research can provide a reliable and fool-proof test for the early detection of pancreatic cancer.

More research is desperately needed into a disease that will not only not go away, but will become a bigger problem in a European Union with an ageing population. Action is needed at the highest level, and it is needed now, attendees heard.

**Translational research**

As we all know, European researchers have been at the forefront of major scientific healthcare discoveries in areas such as cancer, cardiovascular disease, genetic disorders, and infectious disease.

The challenge facing us now, Congress heard, is how we best translate this knowledge and expertise into medical advances that improve outcomes and enhance well-being for European patients.

The EU is certainly working on it, as Horizon Europe is an ambitious €100 billion research and innovation programme that will succeed Horizon 2020. It will incorporate policy missions to ensure the effectiveness of research and innovation funding by pursuing clearly defined targets.

The Commission has talked to policy experts in order to develop studies, case studies and reports on how a mission-oriented policy approach will work.

The plan is that it will provide coordination to close research gaps and stimulate innovation.

The vision of a knowledge-based economy is one of its core components, although this has not really happened over the past decade. And there's still a gap between the western Member States and others, which means inequalities in both the funding and the amount of research being undertaken.

As it stands, Congress heard, there needs to be reform. Clearly, translational research is a key enabler of research efforts and could be an even bigger one. It represents the conduit through which European discovery science can be converted into new diagnostics, treatments, products and approaches that benefit European citizens and society, not least through personalised medicine.

The latter is already delivering benefit for European patients. In cancer, targeted approaches have led to practice-changing clinical management in these diseases. Personalised medicine is also shaping the development of new preventative and therapeutic approaches, attendees heard.

Although personalised medicine can be seen as the evolution of medicine, rather than a revolution, it brings new challenges in terms of the delivery and understanding of the results. This is not only true for patients, who need to understand complex genomic results, but also for medical professionals who often
haven't been exposed to this type of information before.

It's all about increasing the efficacy of personalised medicine approaches, yet unfortunately the translation of these into Europe's healthcare systems hasn't happened at the anticipated pace, attendees heard.

Winter school for HCPs

Congress hosted the Alliance's first Winter School for young healthcare professionals, or HCPs, in the wake of three previous successful summer editions. A fourth will take place in 2019.

For the school, EAPM and its stakeholders once again drew young delegates from all over Europe and these were again representative of the new generation of HCPs.

Attendees from a multitude of countries across the EU gathered for the three days, and the faculty put in place by the Alliance and its stakeholders also had a similar EU-wide spread.

The school was once again entitled 'TEACH', which stands for Training and Education for Advanced Clinicians and HCPs, and the goal is and has always been to bring young, front-line professionals up-to-speed with fast-moving developments in the field.

Aimed at age-range 25-40, TEACH has always held to the thesis that, if personalised medicine is to be in line with the EU and Member State principle of universal and equal access to high-quality healthcare, then clearly it must be made available to many more citizens than is currently the case.

Said Christine Chomienne, of INCa, France: “One of the key goals in the personalised medicine era is to improve communication between front-line HCPs and their patients. The latter should have an equal role in any decisions made about their treatment, and this requires them to be able to input vital information, such as lifestyle and work circumstances, as well as to be properly informed from the other side.”

“It is great to see some young and up-and-coming stars at the school, and I think that the younger generation will have a different view on treatment of patients. I think the dialogue between the physician and the patient will change in the future,” she added.

Christine went on to say: “I expected the school to be very good, but it was even better than I anticipated. The attendees came from many different countries and different specialities. It’s been very trans-disciplinary, very European.”

During the week-long track attendees heard about electronic health records (EHRs), among a plethora of other topics relevant to medicine today.

Students learned that as EHRs become better integrated into healthcare systems, access to high quality data should improve. This development should enable new tools that leverage artificial intelligence that will complement each physician's clinical skills.

As broader data sets are accessed, specific patterns could be discovered that better guide clinical decisions.

Attendees at the school heard that general and family practitioners are ideally situated to manage these tools to confirm that the findings are relevant to individual patients before initiating new diagnostics or therapeutic interventions.

Therefore, the school took a long, hard look at how these tools can be implemented and what training would be required to support these HCPs in the adoption of such technologies, using real world examples.

Attendees at the winter school also heard about tools to individualise clinical decisions for HCPs in this time of greater co-morbidities and survivorship.

Due to effective and improving medical care, they were told, there are growing number of survivors who suffered from a myocardial infarctions, cancer, or other life-threatening diseases. This group represents a new generation of patients that must manage their past conditions as a chronic condition.

It is important that GPs and family practitioners understand the specific care required for these patients as they are typically responsible for these patients' long-term care.

Students also learned from experts about some of the most exciting medical advances of the past year, with speakers giving a brief overview of technologies and what factors led to the innovations.
Among topics addressed were CAR-T therapies, artificial pancreases and gene editing and gene therapy.

At the end of proceedings Denis Horgan, executive director of EAPM said: “Over the three days, the school has been centred around the concept of personalised medicine, and was designed to provide a forum for presenting new data and sharing ideas for innovation.”

“It allowed its attendees to enhance their knowledge of evidence-based approaches on diagnosis and treatment, let them access the latest results on clinical and translational research, and brought them up-to-speed on emerging innovative techniques, diagnostic tools and more.”

“In the changing world of health care in Europe, the education of healthcare professionals is under-emphasised,” Horgan said. “Hopefully, we can help to remedy this situation. So far so good…”

**So, who is to do what?**

EAPM’s executive director also closed the Congress. Denis Horgan told attendees that: “Personalised medicine is the test-case for how far health systems are capable of a rational and reasoned response to opportunity.

“It is also a test-case for how far the supporters of personalised medicine are able and willing to come together in a joint effort to drive the process that can induce constructive change. Innovation is key.”

The wrap-up session heard that, in some areas, the EU has had a strongly supportive role in healthcare. The resulting coordination, to develop science, to translate innovation, to systemise marketing authorisation requirements for medicines and to facilitate quality testing and trials has shown a positive aspect of the EU, and should serve as inspiration and encouragement for more joined-up approaches to tackle new challenges.

Key going forward there will be, for example, an understanding of the potential for personalised medicine to deliver improved outcomes for European citizens, the challenges that it presents to traditional health systems and the barriers that currently exist.

Attendees heard that there needs to be a strategy that raises awareness and delivers a personalised medicine educational toolkit, tailored for its participating stakeholders.

The winter school is an ideal example of the work of EAPM and others in this regard, Horgan emphasised.

Also, Congress was told, there needs to be put in place the infrastructure and tools to deliver a personalised medicine-enhanced health systems landscape that empowers translation of exciting discovery science into new diagnostic, therapeutic and preventative approaches that help preserve the health of our citizens.

Cooperation and the abandoning of silo thinking is essential.

Horgan said: “If the will to work together on personalised medicine can be found, a new horizon for health in Europe can be reached. The journey can reach its destination by 2025. But the benefits can accrue as from today.”

“Milan has been excellent all round and it’s time to thank all speakers, panel members and attendees for being here this week in the Lombardy capital. Also, a special thanks go to our hosts, the Lombardy Region.

“We look forward to seeing you at both our seventh conference and our third annual Congress in Brussels in 2019,” he said.
"There is no personalised medicine if there is no innovation. There is no innovation without patients."

Francesco De Lorenzo,
European Cancer Patient Coalition

“The best innovation happens when it’s widely diffused.”

Mary Harney,
Former Irish health minister

"Speed matters for people with rare diseases. We need to be quick!"

Francesco Scopesi,
Shire Italy

"There is a need for Member States to invest more in data bases. Rare disease patients are not easy to find to put into a trial."

Peter Meeus,
Shire

"Data sharing across borders will lead to better research and personalised healthcare. The Commission is building the bridge."

Marco Marcello
DG CONNECT

"If we don’t collaborate, we can actually make more of a divide. Partnership is no longer optional, it’s essential."

Jennifer Mills,
Foundation Medicine
About EAPM

The European Alliance for Personalised Medicine (EAPM), launched in March 2012, brings together European healthcare experts and patient advocates involved with major chronic diseases. The aim is to improve patient care by accelerating the development, delivery and uptake of personalised medicine and diagnostics, through consensus.

As the European discussion on personalised medicine gathers pace, EAPM is a response to the need for wider understanding of priorities and a more integrated approach among distinct lay and professional stakeholders.

The mix of EAPM members 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. EAPM is funded by its members.

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