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Canada 'strategic in personalised healthcare'

Here we are already at the final day of EAPM's Belfast Congress and you can see some of this afternoon's highlights in brief in the box on this page, and read further detail in the rest of this newsletter.

One top session that took place yesterday was '*Personal Oncology Approaches - reflections from both sides of the pond*,' chaired by Etienne Richer.

Etienne is Associate Director, CIHR Institute of Genetics, Montreal, Canada, and told Congress that: "Since 2012, more than $240 million in research funding for personalised medicine has been announced by the Canadian Institutes of Health Research and over 110 national and international competition and application partners, most prominently Genome Canada.

"To date, CIHR has invested $85 million into the PM Strategic Initiative, with a goal of improving clinical health outcomes by evolving from a reactive 'one size fits all' approach towards a system of predictive, preventive, and precision care."

Etienne added: "There have been major innovations, and there are early signs of implementation in certain areas, most notably some specific cancers and rare diseases. "

Immediately prior to that session Alastair Kent, from Genetic Alliance UK, had chaired presentations and a discussion on '*Is precision medicine the route to a healthy world?*'

Said Kent: "2016 was certainly an interesting year with at least two major political upsets, namely Brexit and the US presidential election result. Uncertainty has followed us throughout 2017."

"Civic unrest, hate crimes, denial, the blame game and more ensued. For many people, these testing times are offering up more fear than they are hope, despite great leaps in technology as well as more involved, knowledgable and, thus, empowered patients," he said.

Congress heard that there is still much discrimination in healthcare (on both sides of the Atlantic) and there is a real need to ensure inclusivity and make certain that technology is integrated to allow for the right treatment for the right patient at the right time.

Also during day three of the event, key speakers got to grips with precision medicine.

Today's highlights at a glance

- **Every prostate cancer is unique: diagnosis and management**
- **Diabetes: A personalised health epidemic**
- **The value of innovation from the cancer patient perspective**
- **Closing of conference: Keeping the promise and preparing for the future**

Top: Karen McCloskey talked about the Athena Swan Initiative, accompanied by (below) Christine Chomienne. Photo by Simon Pugh Photography

Defined as a medical model that proposes the customisation of health care, with medical decisions, practices, or products being tailored to the individual patient, precision medicine is often employed for selecting appropriate and optimal therapies based on the context of a patient's genetic content or other molecular or cellular analysis.

Tools employed in precision medicine can include molecular diagnostics, imaging, and analytics.

James N'Dow, chairman of the Guidelines Office Board at the European Association of Urology in the Netherlands, was clear about what he felt needed to be done: "We have more than enough data in the medical world, but we don't share enough of this data. We must align stakeholders' interests with our common goal, namely the very best health care that can be provided," he said.

Mary Baker, a former president of the UK's European Brain Council, said: "We need to look at the broader needs of society. A more sustainable approach is to look at prevention. We need to start concentrating seriously on prevention, where pharma has a huge role to play and has had great success with vaccination programmes."

And later yesterday), professor Karen McCloskey of the Centre for Cancer Research and Cell Biology at Queens University Belfast took to the floor to explain the excellent work being achieved by the Athena Swan Charter for Gender Equality.

McCloskey said: "The Athena SWAN Charter was established in 2005 to encourage and recognise commitment to advancing the careers of women in science, technology, engineering, maths and medicine (STEMM) employment in higher education and research.

"In May 2015 the charter was expanded to recognise work undertaken in arts, humanities, social sciences, business and law and in professional and support roles, and for trans staff and students. The charter now recognises work undertaken to address gender equality more broadly, and not just barriers to progression that affect women."

Sign of the times: more attendees in Belfast

We have, top left, Brasanna Kumar and Lakshmi Santhosh, top right is Dimitar Georgiev. In the centre we have Nadia Pellanda Jandl with Tom Lillie to the right. The bottom row features Vladimir Ljubicic and Daniel Schneider. *Photos by Simon Pugh Photography*

Canada's Etienne Richer and Francoise Meunier of Brussels. Photo by Simon Pugh Photography

ECU's Athena SWAN charter and gender equality charter mark was brought together in April 2015, then expanded the following year to include arts, humanities, social science, business and law departments alongside the current science, technology, engineering, mathematics and medicine disciplines.

Processes are currently being developed and aligned to ensure the expansion is effective and meets the needs of current Athena SWAN members, the institutions that took part in the gender equality charter mark trial, and those who are considering joining either charter.

The society is also continuing to consult with a number of key stakeholders, including funders, learned societies and the Department for Business, Innovation and Skills on the future shape and direction of charter marks.

During the session on the Charter, Karen was joined by Christine Chomienne, of INCa in France, and Francoise Meunier, from the European Association for the Research and Treatment of Cancer in Brussels. EAPM co-chair Gordon McVie presided over the session.

Coming up today

Molecular Diagnostics – Enabling the Personalised Medicine Revolution

The Regulations for the approval of in vitro diagnostic kits (IVDs) in Europe have been completely revised and replaced with a modern, risk-based system.

However, the new rules are far more complex and burdensome, and there is a lack of capacity and expertise on both the regulatory and the industry sides.

As all existing IVDs must be re-certified under the new regulations, there is a danger of 'mass extinction' of existing IVDs when the derogation period runs out.

This would be a huge set-back for the progress of personalised medicine. IVD manufacturers and regulators need to act now to avert such a scenario.

Every prostate cancer is unique: Personalised prostate cancer diagnosis and management

Prostate cancer is the second-leading cause of cancer, and accounts for almost one-in-ten cancer deaths among European males. There is an ongoing debate of the benefits of screening,

Quotes from the sessions

"The Canadian Institutes of Health Research are glad to contribute to this event in order to strengthen the links between Canada and Europe in the area of personalised medicine."

Etienne Richer,
CIHR Institute of Genetics

"Pilot data from qualitative interviews suggest some problems of burnout and distress affecting the ethos of some trials."

Joshua Hordern,
University of Oxford

"Society is living longer, it is an incredible achievement, but in the wake of this achievement come challenges, and I believe precision medicine can really lead to a healthier world."

Mary Baker,
Past President European Brain Council

"One of the solutions to mitigate concerns and risks as regards the misuse of genetic data lays in the adoption of non-discrimination laws."

Denis Horgan,
EAPM Executive Director

"We need large data sets and data sharing in order to detect biomarkers that predict response to treatment."

Fabien Calvo
Cancer Core Europe

"The EU-AIMS Project will be the first biological EU-led randomised trial in autism"

Declan Murphy,
Kings College London

The nurse's story

A 49-year-old nurse KP, who lives and works in Poland, says that one of the worst aspects of her job - which she generally loves - is having to explain to her patients in hospital that providing access to clinical trials is difficult and providing the most modern medicines is often impossible due to a lack of resources.

"It is very frustrating and often confusing for a patient. They cannot understand why they are being denied a particular treatment, even though they may know about it - or their families may know about it - through the mainstream media or the internet," she told EAPM.

"We strive to make all necessary decisions together, but sometimes the options just don't really exist."

IMI's Pierre Meulien discussing personalised medicine through open innovation at one of this morning's sessions. Photo by Simon Pugh Photography

meanwhile, that needs resolving and acting upon swiftly.

Given the EU's ageing population, the burden on society due to prostate cancer is expected to increase dramatically. In this context, it is perhaps surprising that the research funding available is below other killer cancers. This means that progress in the area is slow.

A further issue is that EU Member States have large disparities in how often prostate cancer happens, and the survival rates vary alarmingly from country-to-country.

Given the amount of medical data theoretically available, in the case of prostate cancer there is not enough information on risk factors or patient characteristics. Arguably, the data is out there, as is the genetic information, but it is not being used in the most efficient ways possible.

So, knowing which patients are safe in the short term, and which will have the best outcomes via targeted treatment, is a lot harder than it should be. As with many modern-day healthcare breakthroughs, new knowledge is taking too long to be put to effective use on the ground.

Such inefficiency has an obvious effect on safety and on economics, too.

The above issues and challenges can only be solved by key stakeholders, including patients, coming together and collaborating.

Prostate cancer incidence is set to rise and we have to act now, every stakeholder. There is no time to be lost, but we need agreed guidelines.

Key points include:

- *Guidelines (on screening and more) may well be the way forward, given that they potentially have less rigidity and therefore more flexibility (within strict standards of safety and ethics).*

- *Innovation has brought about a greater need for adaptation through appropriate frameworks that must be designed by experts, in consensus - albeit with necessary input from regulatory bodies.*

The Netherlands' Peter Sterk at an innovation session today. Photo by Simon Pugh Photography

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● *It is vital to ensure that any and all agreed standards can be met down the line. These include ethical considerations, patient safety, certainty within timeframes and facilitation of advancements for the benefit of Europe's patients and society in general.*

● *Screening needs to be continuously reassessed, with guidelines updated when applicable. Despite arguments of over-treatment and issues of cost, it is one of the most potent preventative tools available to us today.*

Diabetes: A Personalised Health Epidemic

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood sugar.

Hyperglycaemia, or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels.

According to the World Health Organization (WHO) the number of people with diabetes rose from 108 million in 1980 to 422 million in 2014. It is a major cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation.

In 2015, an estimated 1.6 million deaths were directly caused by diabetes. It is an epidemic of truly global proportions.

Healthy diet, regular physical activity, maintaining a normal body weight and avoiding tobacco use are ways to prevent or delay the onset of type 2 diabetes, for example, and these are clearly lifestyle choices in most cases.

The WHO adds that the disease can be treated and its consequences avoided or delayed with diet, physical activity, medication and regular screening and treatment for complications.

Closing of conference: Keeping the promise and preparing for the future

As we try to look forward in terms of personalised medicine there is certainly a long way to go to fully integrate it into healthcare systems across Europe.

For example, as discussed elsewhere in the Congress, stakeholders need to leave their silos and cooperate, both within countries and across borders. Fortunately, there are clear signs that this is happening more and more.

New technologies can only help, and sensible data protection legislation that safeguards the rights of individuals, while also allowing for the necessary use of vital data in medical research, will be a key driver of long-term success in this area.

The European Alliance for Personalised Medicine, in its STEPs campaign, set out the following key goals:

● STEP 1: Ensuring a regulatory environment that allows early patient access to novel and efficacious personalised medicine

● STEP 2: Increasing R&D for personalised medicine, while also recognising its value

● STEP 3: Improving the education and training of health care professionals

● STEP 4: Supporting new approaches to reimbursement and HTA, required for patient access to personalised medicine

The above aims reflect the current barriers to full integration of personalised medicine, not least of which is patient access.

It is clear that Europe's health policies need to recognise and tackle the inherent health system vulnerabilities faced, specifically, by smaller countries and in the regions of the larger ones. The Alliance therefore introduced its SMART approach.

'SMART' stands for *Smaller Member states And Regions Together* and already the idea has been a great success, involving medicines bodies, national health ministers and cross-sectional stakeholders, all working to move personalised medicine to the next level of integration.

Declan Murphy, of King's College London, (above) joined Barbara Baggiani, Silicon Biosystems, in the session on innovation today. Photos: Simon Pugh Photography

Alastair Kent, Genetic Alliance UK, and Kaisa Immonen, of the European Patient Forum, addressing attendees on Wednesday. Photos by Simon Pugh Photography

Twitter hashtag for this Congress:
@eapm2017

European Alliance for Personalised Medicine

In close collaboration with our partners:

Platinum partners:

Gold partners:

Silver partners:

Bronze partners:

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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