



European Alliance for Personalised Medicine

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Next EAPM events

Wednesday, February 3rd, 2021, 09.30 - 11.00 CET

Recruiting serology to the long fight ahead against pandemics

March, 2021

9th EU Presidency Conference, *'Forward together with innovation: The why, what and how of tackling the Implementation Gap for healthcare'*

Welcome, health colleagues, to the European Alliance for Personalised Medicine (EAPM) January Newsletter. The big news at the moment is the imminent (3 February) formal launch and publication of the Europe Beating Cancer Plan - for EAPM, which also has a round table on the same date, the focus will very much be on personalised medicine, of course, but with a particular emphasis on lung cancer, which still has the highest mortality rate of any cancer across the EU.

Pandemic or panic-demic? Focus on lung cancer

The fight against lung cancer, for many years one of the most intractable healthcare challenges, and still a major killer, is on the threshold of new victories. Rapid advances in disease understanding, supported by the emergence of comprehensive genomic tumour profiling and the development of targeted treatments provide unique opportunities for a personalized treatment approach with significant improvements in outcome.

Europe's Beating Cancer Plan and national cancer plans across European countries will be vital to capitalize on the opportunities for relieving the burden of lung cancer through personalized treatment regimens. Initially, new standards and improvements will come in the context of clinical centres of excellence that have the necessary infrastructure for NGS testing, MTBs, MGTOs.

But these account for only a fraction of lung cancer patients, and ways must be found of integrating and monitoring patient care from more remote centres. This will require nationwide networks and registry infra-structures to include all patients and standardize treatment across larger patient groups - and the European Reference Networks, the European Health Data Space and Europe's Beating Cancer Plan have a crucial role here.

It is vital that European and national policy frameworks, national infrastructure and funding mechanisms keep adapting to latest scientific insights and clinical advances. With the correct application of new technologies and methods, the principal beneficiaries will be today's - and still more, tomorrow's - patients and their caregivers and entourage. And correctly implemented, these technologies could allow healthcare spending and even national economics to gain from a reduction in the consequences and incidence of lung cancer.

Improvements in outcomes are within reach but depend heavily on:

- A more uniform approach to national risk based screening programs to identify patients early and decrease the rate of patients diagnosed in advanced/metastatic stages;
- early access to comprehensive genomic profiling;
- the identification of most appropriate treatment pathways based on the patient's tumour genetics through multi-disciplinary molecular tumour boards;
- fast and broad access to most beneficial treatment options and access to clinical studies;
- adequate monitoring of patients including patient reported outcomes that will allow for targeted interventions, and;
- the integration of patient data to gain further insights for research, validity of clinical treatment

Beating blood cancers lest we forget!!

Over the years, the EAPM has worked extensively with its members, particularly the European Haematology Association as well as the relevant patient organizations focus on the need for continual work towards reducing and combating the prevalence of blood cancer. Such cancers (hematological malignancies (HMs) to give them their correct moniker) are frequently overlooked and, following recent discussions, it is understood that that may not be as prominently covered as they should be.

HMs are a heterogeneous group of diseases of diverse incidence, and prognosis, and comparison of HM incidence across regions and over time is complicated by the existence of different disease classification systems. Obviously, incidence is one of the biggest and best measures of burden in a population, serving as a vital guide to the allocation of resources.

Statistics suggest that healthcare costs for each patient with blood cancer reach twice the figure compared to average cancer costs. The total cost of blood disorders to the European economy was in the region of €23 billion in 2012 and is only increasing.

Blood cancers are in the top ten of the most common forms of cancer and are responsible for approximately 100,000 deaths in Europe every year. Some of the most critical cancers are Multiple Myeloma, Acute Myeloid Leukemia, Acute Lymphoblastic Leukemia, Chronic Lymphocytic Leukemia, Non-Hodgkin's Lymphoma, Myelodysplastic Syndrome, and Pediatric Hematological Malignancies.

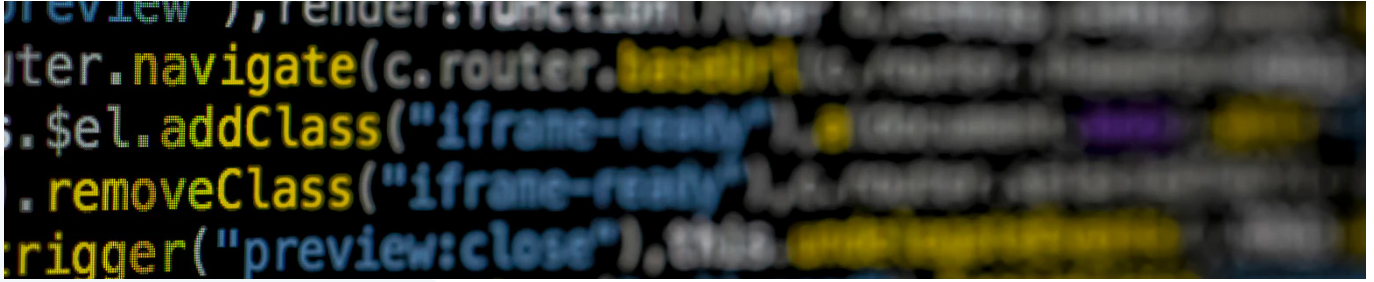
These cancers present a serious medical and financial challenge and account for around 40% of cancer cases in children and one third of overall cancer deaths. However, it has been suggested that the upcoming Europe's Beating Cancer Plan is not as yet paying as much attention to blood cancers as it should.

EAPM and its key stakeholders believe that this is a gap that should be urgently addressed in the upcoming EU Beating Cancer Plan, as blood disorders are not only a burden for patients, but also for society as a whole, with around 80 million people having either malignant or non-malignant haematological disorders. We need to urgently step up how Europe tackles this and the European Beating Cancer Plan can support this common EU effort.

European Council president expresses doubt over vaccinating 70% by summer

Charles Michel, president of the European Council, made his comments as the EU faces scrutiny over its slow rollout of coronavirus vaccines, weeks after Britain set the ball rolling. Speaking on Sunday (24 January), Michel told Europe1 radio: "There are difficulties in the production lines in the coming weeks and that will make the process more complex. But if we manage to mobilize the production lines, we may be able to succeed. It's going to be difficult." The EU has not yet given the go-ahead to the Oxford/AstraZeneca vaccine.

Dutch MEP Groothuis to lead cybersecurity bill



Dutch Liberal member of the European Parliament Bart Groothuis is set to be the lead negotiator on the NIS Directive, which is the first piece of EU-wide legislation on cybersecurity. It provides legal measures to boost the overall level of cybersecurity in the EU. The Directive on security of network and information systems (the NIS Directive) was adopted by the European Parliament on 6 July 2016 and entered into force in August 2016. Member States had to transpose the Directive into their national laws by 9 May 2018 and identify operators of essential services by 9 November 2018.

The NIS Directive provides legal measures to boost the overall level of cybersecurity in the EU by ensuring member states' preparedness by requiring them to be appropriately equipped. Businesses in these sectors that are identified by the member states as operators of essential services will have to take appropriate security measures and to notify serious incidents to the relevant national authority.

Of course, this has an impact on health care, taking into account recent hacking issues relating to approval procedures of COVID-19 vaccines with the aim to sow distrust in vaccines as highlighted by the EU medicines agency.

Recruiting serology to the long fight ahead against pandemics, Wednesday, February 3rd, 2021, 09.30 - 11.00 CET

With adequate, and adequately rigorous, testing in place, it is argued that it will be possible to evaluate without risk of bias different populations being treated with different vaccines across the world. To allow the benefits to accrue from this situation, data will have to be collected and compared from a wide range of studies, and at a truly global scale. This in turn will depend on all stakeholders being ready to operate outside and across the customary siloes that characterise the health community, and to adopt a common language based on a new literacy. But by extension of the EU's new ambition to build a European health union, and taking as a model such international concords as the Paris climate agreement or the UN framework convention on tobacco control, what could and should emerge is a coordinated international response to future health crises of this scale, in an international pandemic treaty.

The **objective** of this roundtable is to assess the factors, understand the need and frame the discussion for Serology testing for SARS-CoV-2 at a country level by engaging with experts.

A **key target audience** is decision making (public health professionals, public health institutes, medical authorities as WHO Europe, and EMA) so as to understand the barriers and enablers so that serology testing in vaccination surveillance systems can be adopted.

Questions to be addressed:

- Testing strategies: restricted vs. systematic - Is there a need to revise earlier recommendations?
- Should approaches to testing adapt to different types of vaccines, also in view of progressively lifting containment measures?
- What is the state of play of serological testing? Could/should we anticipate recommendations before it becomes accessible?

Please find the link to register [here](#) and the agenda [here](#).

Stop finger-pointing over vaccination and get to work, says Commission

“We are racing against time, not against each other,” Health Commissioner Stella Kyriakides said on Tuesday (19 January). “On the contrary, it is a race that we in the EU are running together, as a team and in unity. As a team, it is important to set clear and ambitious targets.”

And the Commission has set vaccination goals for March and the summer, and backed a bare-bones vaccine certificate. Vice President Margaritis Schinas left the door open to using them later for travel.

Portuguese EU Presidency puts emphasis on coronavirus vaccines

Portuguese Deputy permanent representative, Ambassador Pedro Lourtie, said: “What is important ... is to be able to co-ordinate, to share information, and make sure the purchase of vaccine[s] that was made through the joint contracts [is] being fulfilled. And in that sense the European Commission will be giving us regular information.”

Council President Charles Michel has said he wants to coordinate the rollout “with the heads of state and government in a regular way,” Lourtie said. “We will maintain this coordination in accordance, of course, with the national competencies.”

In addition to vaccinations, the Portuguese presidency also has several other health ambitions, such as improving access to medicines, reinforcing the EU’s ability to respond to crises and championing digital health.

Vaccine union



On Wednesday (13 January), the EPP held its online “Towards a European Health Union” conference, with three heads of major mRNA-based coronavirus vaccine companies and three commissioners. Commission Vice President Margaritis Schinas used the opportunity to declare the EPP

“the health party of the European Union”, and Schinas stood by the EU’s joint purchase of coronavirus vaccines, saying: “This is a small miracle happening at the European level: For the first time, a European health union is tangible, emerging reality — not just a soundbite, not just a slogan, not just a clip. It is happening.”

COVID-19 unlikely to strike twice but guidance should be followed, according to study

Researchers conclude that reinfection is uncommon but still possible and say people must continue to follow current guidance, whether they have had antibodies or not. Scientists from Hong Kong recently reported on the case of a young, healthy man who recovered from a bout of Covid-19 only to be reinfected more than four months later.

Using genome sequencing of the virus, they could prove he caught it twice because the virus strains were different. Experts say reinfection isn’t surprising, but it’s likely to be rare, and larger studies are needed to understand why this might happen. Researchers found that those who had already been infected once had 83 percent lower odds of infection compared to those who had never been infected based on both probable and possible positive COVID-19 test results. If restricted to only positive results — where there is a high viral load and symptoms — that number rises to 99 percent.

Monoclonal antibodies



A study in US nursing homes has shown for the first time that monoclonal antibodies, mass-produced in a laboratory, can protect people from developing symptomatic COVID-19. Their manufacturer, Eli Lilly, hopes these antibodies will provide an additional way to protect people at risk of serious disease from the pandemic coronavirus. But given the success of COVID-19 vaccines and their increasing availability, it’s not clear that the expensive and somewhat cumbersome intervention will be widely used.

Both Eli Lilly’s monoclonal antibody and a similar two-antibody cocktail from Regeneron Pharmaceuticals—famously used to treat former US President Donald Trump in October 2020—have already received emergency use authorization (EUA) as a therapeutic for those who have become infected and are at high risk of developing severe COVID-19. So far, they are not widely used because they must be given early in infection and infused in a hospital or clinic. But now that they appear effective at preventing even mild disease, Eli Lilly plans to ask the US Food and Drug Administration to expand the EUA to include use as a preventive.

France to impose COVID testing on EU travellers

France’s President Emmanuel Macron has announced new coronavirus rules for travellers from the EU, with the country requiring European visitors as well as those from outside the bloc to have a negative Covid-19 test performed less than three days before they enter the country.

The new restrictive measures, to come into effect from Sunday morning (24 January), were announced by the Elysée Palace late on Thursday and follow an EU summit by video conference at which leaders discussed measures to control the pandemic with continuing vaccination programmes and controls on free movement. Until now, Macron had sought to maintain freedom of movement within Europe, but pressure on hospitals and the spread of new, more infectious variants of the virus have convinced him

‘More deadly’ UK variant claim played down by scientists

Scientists say signs a new coronavirus variant is more deadly than the earlier version should not be a “game changer” in the UK’s response to the pandemic. UK Prime Minister Boris Johnson has said there is “some evidence” the variant may be associated with “a higher degree of mortality”. But the co-author of the study the PM was referring to said the variant’s deadliness remained an “open question”. Another adviser said he was surprised Mr Johnson had shared the findings when the data was “not particularly strong”. A third top medic said it was “too early” to be “absolutely clear”.

Brazilian variant raises concerns

Paul Hunter, professor in Medicine at the University of East Anglia, said he believed it’s likely that the Brazilian variant will also show increased resistance to antibodies. “We are likely to see gradual accumulation of variants that are more and more able to escape vaccine induced immunity and indeed naturally induced immunity,” Hunter said.

Commission proposes tougher coronavirus travel restrictions



The European Commission has proposed ramping up coronavirus re-strictions for travelers within the bloc as well as those coming from third countries. On Monday, Justice Commissioner Didier Reynders said: “There’s an urgent need to reduce the risk of travel-related infections to lessen the burden on overstretched health systems.”

EU ready to provide Ukraine with coronavirus vaccines

The Ministry of Foreign Affairs of Ukraine is negotiating with EU countries on the possibility of purchasing COVID-19 vaccines or receiving them as humanitarian aid. “The Foreign Ministry instructed ambassadors in all European capitals to discuss support options for surplus vaccines (either on a paid basis or as part of humanitarian aid) so that we can start vaccinating health workers and people at risk...We have already received certain positive signals from some EU countries that they can transfer or sell surpluses to us,” Deputy Foreign Minister of Ukraine Vasyl Bodnar said in an interview with Ukrinform. The diplomat noted that President of Ukraine Volodymyr Zelensky raised the issue of vaccines in a phone conversation with Chancellor Angela Merkel. The fight against the pandemic was also discussed during political consultations between the ministries of foreign affairs of Ukraine and Germany in Berlin last Monday. The Health Ministry plays a key role in this matter, and the Ministry of Foreign Affairs provides assistance in establishing contacts, Bodnar added. The deputy minister assured that the Foreign Ministry is working very actively to ensure that the vaccine appears in Ukraine as soon as possible to start mass vaccination.

UK spending on COVID vaccines hits nearly £12billion



The UK's push to secure and administer hundreds of millions of doses of coronavirus vaccines is estimated to have cost up to £11.7 billion so far, according to the public spending watchdog. The government has signed deals for five vaccines providing up to 267 million doses at an expected cost of £2.9bn, with non-binding agreements with two other companies set to bring total provision to 357m doses, the National Audit Office said.

Additional costs including those associated with sponsoring trials, distributing and administering the vaccines lifted the total spend to £11.7bn. In negotiating with the EU, drugmakers pursued a similar approach. Both the UK and the EU rejected requests for complete immunity.

COVID-19: Team Europe supports African, Caribbean and Pacific countries to access finance through digital technology

The European Commission, together with the Organisation of African, Caribbean and Pacific States (OACPS), has signed today a new initiative of €14.5 million with the United Nations Capital Development Fund (UNCDF) to unlock the potential of digital finance. This will benefit more than 600,000 women, youth and entrepreneurs across African, Caribbean and Pacific countries. "Today more than ever, digital technologies have a central role to increase access and usage of affordable financial products and services that meet people and business needs as well as accelerate economic recovery from the coronavirus pandemic. This is why, as reflected in our EU Strategy with Africa, we want to join forces with Africa to foster a digital transformation that also helps us close the digital gender divide", said Jutta Urpilainen, Commissioner for International Partnerships. "If we want to achieve the Sustainable Development Goals, digital solutions are key to create more jobs and improve basic services such as health and education", she added. Mobile money is the provision of financial services through mobile technologies. It allows paying bills and transferring money by using mobile apps and creates new opportunities for businesses and individuals. For more details, please consult the press release and the new Digital 4 Development Hub, launched in December by the Commission, aimed at building strong ties across the globe to make the digital revolution an opportunity for everyone.

Greece aims to vaccinate 220,000 by January end

Coronavirus vaccinations will reach a minimum of 220,000 citizens by the end of January, Greek health authorities have now announced. Health Ministry Secretary General for Primary Health Care, Marios Themistokleous, said it is likely that other vaccines, such as the one by pharmaceuticals manufacturer Moderna, will be delivered imminently, thus increasing the number of available vaccines. Greece is faring well within the European average as far as progress with ongoing vaccinations is concerned, he added.

Should you avoid alcohol when getting a coronavirus vaccine?

Drinking alcohol after getting a coronavirus vaccine can significantly blunt the immune response and potentially render the vaccine ineffective, according to a leading Russian scientist. “We strongly recommend refraining from alcohol for three days after each injection,” Alexander Gintsburg, head of the Gamaleya National Center of Epidemiology and Microbiology in Moscow, which is developing the Sputnik V vaccine, told New Scientist. This warning doesn’t just apply to the Sputnik V vaccine, but all COVID-19 vaccines and indeed all other vaccines. “This is quite obvious,” he said. Existing scientific literature on alcohol and the immune system shows that excess alcohol is an immunosuppressant so people who drink a lot are more susceptible to infections. “Heavy drinkers have many problems and poor immune function is one of them,” said immunologist Eleanor Riley at the University of Edinburgh, UK.

And that is all for now, stay safe and well.

In the news

EAPM - Registration open: ‘Recruiting serology to the long fight ahead against pandemics’:

<https://www.eureporter.co/health/personalised-medicine/european-alliance-for-personalised-medicine-personalised-medicine/2021/01/28/eapm-registration-open-recruiting-serology-to-the-long-fight-ahead-against-pandemics/>

EAPM: Big plan on beating cancer set for big launch, coronavirus restrictions tighten

<https://www.eureporter.co/health/personalised-medicine/european-alliance-for-personalised-medicine-personalised-medicine/2021/01/26/eapm-big-plan-on-beating-cancer-set-for-big-launch-coronavirus-restrictions-tighten/>

EAPM: The blood is the life – key work on blood cancers needed with respect to the upcoming European Beating Cancer Plan:

<https://www.eureporter.co/health/personalised-medicine/2021/01/22/eapm-the-blood-is-the-life-key-work-on-blood-cancers-needed-with-respect-to-the-upcoming-european-beating-cancer-plan/>

EAPM makes first focus of 2021 on lung cancer

<https://www.eureporter.co/health/coronavirus/2021/01/19/eapm-makes-first-focus-of-2021-on-lung-cancer/>

EAPM – From cybersecurity to mass extinction, health issues reach critical mass:

<https://www.eureporter.co/health/personalised-medicine/european-alliance-for-personalised-medicine-personalised-medicine/2021/01/15/eapm-from-cybersecurity-to-mass-extinction-health-issues-reach-critical-mass/>

Bilateral vaccine deals in sharp focus, billions spent on vaccines:

<https://www.eureporter.co/health/personalised-medicine/2021/01/12/eapm-bilateral-vaccine-deals-in-sharp-focus-billions-spent-on-vaccines/>

EAPM enters 2021 with confidence and healthy hope for the future:

<https://www.eureporter.co/frontpage/2021/01/07/eapm-enters-2021-with-confidence-and-healthy-hope-for-the-future/>