

Commentary

Personalised Medicine – Bringing Innovation to the Healthcare System

Denis Horgan^a Mary Baker^b Peter Riegman^c Chiara Bernini^a

^aEuropean Alliance for Personalised Medicine, and ^bEuropean Brain Council, Brussels, Belgium; ^cErasmus MC Tissue Bank, Rotterdam, The Netherlands

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Abstract

Healthcare innovation has never been more prevalent than it is today. But these innovations are only very slowly being embedded into Europe's healthcare systems. There is a huge capacity here in the EU to improve the health and quality of life of all citizens, but the extent to which it is happening is far from optimal. What is ringing out like a bell is that there is a clear need for better focus from policy makers, as this article explains. A policy bridge is required and a conscious decision among the powers-that-be in Europe needs to find a way to harmonise multiple strands of activity and responsibility in the health arena. The end goal will be for the EU to more effectively integrate the incredible advances in science into healthcare systems, for the benefit of all patients.

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Responding to Challenges

There's a huge gap in fulfilling Europe's potential for healthcare innovation [1].

Europe has no difficulty in generating innovations in health. Its universities, research centres and companies are among the world's leading pioneers.

So why isn't innovation actually happening in Europe's healthcare?

The regrettable reality is that the policy environment just isn't capable of moving fast enough or smartly enough to keep pace with Europe's innovators [2].

Denis Horgan
European Alliance for Personalised Medicine (EAPM)
Avenue de l'Armée 10
BE-1040 Brussels (Belgium)
E-Mail denishorgan@euapm.eu

The problem here is not any lack of innovation. It's a lack of focus, and of the ability to focus.

The evidence is all around us.

The capacity for innovation is demonstrated day after day and month after month in breakthroughs such as vaccines, molecular diagnostics, immunotherapies, drug delivery systems, robotic surgery, medical devices and procedures, data analytic systems. The domain of personalised medicine, in particular, is overflowing with possibilities for innovation [3].

The policy rhetoric is often even more evident.

"Innovation can help make the healthcare sector more sustainable and find new cures for health conditions," says the EU's own health department.

The EU's Innovation Union "aims to maximise the EU's capacity for innovation and research," and "the European Commission's aim is to make Europe a world-leader in developing innovative ways to promote active and healthy ageing" [4].

The EU's Digital Agenda includes plans to improve the quality of care, and reduce medical costs, and envisages recommendations on minimum common sets of data and EU-wide standards, interoperability testing and certification of eHealth [5].

The Innovative Medicine Initiative aims to speed up the development of better and safer medicines, through better success rates in clinical trials, faster drug development, and new biological markers to diagnose diseases and assess treatments [6].

But despite all the innovation, and all the rhetoric, the results are taking far too long to get to the citizens. Years, even decades, and sometimes never. The level of time lost is huge.

Why is there a lack of focus on these opportunities? There are too many distractions and a lack of vision on where the real priorities lie [7].

The level of distraction for policymakers is admittedly high. Europe is subject to political and economic turbulence. The EU itself faces new questions about its identity, its purpose and its future. And the wider world is under threat from climate change, shaken by geopolitical insecurities and the consequences of population growth [8].

But the existence of distractions is no justification for inaction. Every generation is fated to confront new uncertainties, and finds ways of responding to these diverse challenges. One obvious value that is common to everyone: the transcendent importance of health. Today's political leaders have an unprecedented opportunity to harness innovation for the benefit of people's health. All they need is the courage to recognise these opportunities and put in place the context that will allow those benefits to reach its citizens.

For the political class in Europe, decisive action on health would provide a more effective antidote to disenchantment and populism than any amount of communications strategies and PR spin. Improved health policy could deliver something so tangible for Europeans that these EU policy makers could legitimately and credibly claim that they are a force for good in their effort to improve the quality of its citizens' lives.

Policy Bridge for Innovation

What sort of action is required to turn Europe's innumerable opportunities in healthcare into a reality?

The answer is surprisingly simple. Innovation is already present especially in the context of an ageing population and groaning healthcare systems. All that is needed is a policy bridge across that gap [9].

Above all, a conscious decision at a high political level needs to be prioritised to harmonise the multiple strands of activity and responsibility in health. Defining a clear objective would be to mobilise the existing resources, to exploit the emerging possibilities, to incentivise all

stakeholders to surmount any traditional barriers that unnecessarily impede their progress, and to link them more effectively in pursuit of a common goal.

The barriers facilitating access to PM including to CDx lie mainly in the areas of (1) stakeholder involvement, (2) standardisation, (3) interoperable infrastructure, (4) healthcare system, (5) data and research, (6) funding, and (7) policy making [10].

A concrete example of how the approach might work would be to elevate initiatives such as Genomics England to the European level, as a way to connect the distinct national and regional genomics initiatives. Similarly, European-level action on registries, exposure, biomarkers, defining high-risk populations or extracting clinical insights using advance data analytics from healthcare databases.

Of course, all these ambitions have to consider political realities – such as the EU countries' sacrosanct national sovereignty, or the impending withdrawal of the UK from the EU. But since the fulfilment of these ambitions would have their effects at the most personal level of citizens' lives, a new hierarchy could see the interests of people predominate over matters of state.

If the objective is fixed and agreed at an appropriately high level, attaining it can take priority over the technical considerations of trade rules or national barriers or budgets that rightly apply to drier aspects of international affairs [11].

But policymakers will move only if the evidence is overwhelming that change will bring real benefits. For that, the innovation community has first to function together more closely to ensure its message to policymakers is irresistibly compelling.

Listening to Messages, Passing Them on and Facilitating Action...

That is the purpose of the EAPM actions. We are bringing together all the expertise from the many disciplines and domains – research, science, industry – in a one-stop shop environment. We are already aware of our own areas of expertise, but we aim to take account of all the underlying issues, to hone and refine our arguments, and to translate them into proposals that will lead to policy changes, to adequate regulatory and funding frameworks, and to collaborations that will ensure the chances are seized.

We are looking for a radical shift from the current piecemeal approach that limits itself to individual actions taken in isolation, without any overarching vision or concept. The traditional European approach of revising pieces of legislation – such as on data protection or clinical trials or intellectual property – without first establishing a comprehensive overview of strategic objectives is a certain recipe for incoherence, contradiction, and confusion.

It condemns everyone working in the field of healthcare innovation to pick their way through a patchwork of ad hoc constraints that hamper progress, waste time, energy and resources, dampen the sense of adventure on which innovation depends, and discourage commitment and investment [12].

The US under Obama took a deep breath and launched a top-level plan to link the multiple dimensions of healthcare innovation through the 21st Century Cures initiative. While its fate remains at present undecided, the scope of the thinking behind it is a powerful demonstration of what can be done – and what might be done in Europe too, if policymakers are alerted to the potential.

The pace and productivity of innovation can be boosted by promoting closer integration or cross-fertilisation among parallel disciplines – pharmacology, genetics, epidemiology, digital technology, diagnostics, environmental science, even humanities and economics. But this demands a new readiness to take a wider, a more strategic, view [13].

The merits of changed perspectives can sometimes be less than obvious for experts working in their chosen field – the familiar challenge of getting people to work outside their comfort zones. And the challenge is all the greater in enticing policymakers to function outside their own comfort zones.

Health ministers do not always carry much weight with industry ministers, and research ministers tend to live in constant tension with finance ministers. At a more technical level, national and regional regulators across Europe have made progress in collaboration over recent decades, but are still fiercely independent. And even within countries, regulators and other stakeholders – payers, patients, publics – frequently have only limited contacts and communication.

Look at the painstaking – and painfully slow – progress in agreeing common approaches across Europe’s 50-plus organisations responsible for health technology assessment, or the heroic attempts by the European Medicines Agency to construct effective coalitions for early-stage discussion and advice on innovative therapies. The picture is far from encouraging [14].

Putting the Science into Healthcare

If Europe can become more effective in integrating the rich output of its science into its healthcare system, it will make a tangible change for its citizens – and potentially for citizens of the wider world too. And a step-change in the delivery of innovations could feed a virtuous circle that would improve the perception of innovation and of science in health, at the level of public policy and even at the level of the public. As a result, the healthcare community would no longer be on the back foot in discussions of policy, of the provision of funding, or of the practical value of incentives [15].

The sort of transformation envisaged will not happen by accident or just goodwill alone.

A health information technology infrastructure that offers interoperability and the possibility for integrating data from personal health devices, patient collaborative networks and social media, along with environmental, demographic and genomic data, will be created and used only if conditions are conducive – and that will depend on whether there are incentives for data-owners to contribute data, and for researchers or practitioners to access data.

Moving promising products across the Valley of Death requires more than a leap of faith. It needs funding measures to reach the next step in translational research. The introduction of safe new diagnostics and therapies by validating biomarkers, for instance, is fraught with failure along the development pipeline or in immediately demonstrating sufficient health benefits. Additional funding for clinical implementation and real-world assessment can effectively incentivise progress and avert waste [16].

Bringing new approaches across the entire healthcare value chain, which is central to advanced healthcare innovation, does not come for free either. Research in close collaboration with regulatory bodies, healthcare providers, policy-makers, ethical, legal and social experts and patient organisations is a necessary aspect of healthcare innovation, but makes new demands for communication and cooperation requirements that have a cost.

Similarly, developing greater inter-disciplinary work demands novel mechanisms, which also have their cost. Research funders and decision-makers will need to adapt to operating beyond classical schemes, to support training modules, outreach activities, and cross-sectoral projects. Funding will also be needed to include specialists from big data and information and communication technologies, to push forward data sharing and integration, or from public health and regulatory affairs. Even public health specialists and smaller research-intensive but administration-light firms may provide new incentives or support to become fully involved in the way that progress requires [17].

More immediately, there is a clear need for greater coordination within the EU institutions themselves, both at policy level and at the level of officials – because the EU remains the great motor of Europe, even in its current phase of self-doubt.

The early stirrings of seeing health as a major rather than a minor issue have already occurred with reflections in the European Council on the simple budgetary imperative to make healthcare more efficient and sustainable. But still the implications are slow to be realised. EU health ministers are still little more than bit-part players in EU policy formation – their input is channelled only through other organs. The EU-sponsored actions that have been taken – in cancer, for instance, or rare disease, or e-health – continue to operate in isolation of an overall policy, and persistent timidity over member state sensitivities restricts their impact. And the division of responsibility for aspects of health between Commission departments – notably DG SANTE, DG RESEARCH, DG GROW and DG CONNECT – handicap rather than help coherent policy formation. Coherence does not require everyone to move at the same speed – but it does require everyone to permit progress to take place.

Bridging those gaps needs firm action at senior level – from a powerful European Commission President convinced of the merits of the case, from a Council President clear about the advantages of working together on health innovation, from a European Parliament where consensus reigns on the need to join up the dots in supporting innovation in a field of primary importance for the electorate it represent. And above all, it requires a sense of urgency among the political leaders of the member states, so that they can, at European Council level, take a lead for the whole of Europe in advancing an agenda that will allow all its citizens to become beneficiaries of healthcare innovation [18].

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Funding Sources

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