Introduction

How Many Chances Has Europe Got?

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Abstract
The European Union has, as one of its core values, the central ideal of equality and a strong way to measure success in this goal is through the well-being of all citizens. As part of that well-being, one key aspect is health. Politicians will tell you that, if you ask any citizen, health and healthcare will be high on the agenda – and as we live longer that will become more the case, rather than less. In the area of health much progress is being made scientifically, with breakthroughs in, for example, the way we can diagnose and treat rare diseases. New technologies are developing swiftly and coming more-and-more to the fore, while the potential value of Big Data cannot be underestimated. It is incumbent upon all stakeholders in the realm of healthcare – and especially the policymakers and legislators – to ensure that every citizen of Europe has the same rights and access to the same high quality care as his neighbour.

Healthcare: Europe’s Challenge

Creating European unity, a journey that started 60 years ago, continues to be an ambitious and forward-looking endeavours. The European Union started as a dream of few and became the hope of many. The EU’s four fundamental freedoms – a distant dream and goal in 1957 – are now functioning and accepted as self-evident. Europeans have been living together in peace for longer than ever before. European citizens and companies enjoy unprecedented freedoms and prosper across the globe. It is inconceivable that a continent capable of so much should not be capable too of extending the benefits of innovative health policy to its citizens.

In just the same way that the world is hovering on the brink with climate change, with the stakes so high that getting it wrong this time round may spell disaster, Europe’s hesitancy
over healthcare reforms risks leading to irremediable meltdown of health systems – and of Europeans’ health.

Getting it right the next time round may no longer be an option for Europe. For healthcare, as for other major challenges of our time, there may not be a “next time.”

The Case of AMR

The challenge of anti-microbial resistance offers a compelling example. Here, very clearly, the healthcare gains made by decades of successful medicines are threatened in the near future with a frightening reversal if antibiotic prescribing and usage patterns are not drastically changed, and if imaginative new development and funding models are not put in place to incentivise research and reward real innovation.

Equally compellingly, it is now widely recognised that tackling AMR depends on radical new approaches to multi-stakeholder partnership involving many sectors, from public health and food safety to the environment, from research and innovation to animal health, and from prescribing physicians and dispensing pharmacists to the general public. As EU Health Commissioner Vytenis Andriukaitis puts it: “We know a great deal about how to reduce anti-microbial resistance. But to do so requires courage, dedication and decisive and collective action across Europe and indeed the entire world” [1].

Whether Europe – and the world – can deliver that sort of courageous collective action is an open question. The underlying question is the same, whether for arresting global warming, or bringing greater equality to an increasingly divided society, or extending peace and security into Europe’s neighbourhood, or addressing the challenges of mass-migration, or countering organised crime or terrorism, or embracing new approaches to health.

A Capacity for Change?

Do we, as a society, have the capacity to tackle such big questions adequately? Do frameworks exist to cope with the inevitable scale and complexity of such issues? Are they apt to cope with the speed of evolution that sees the EU currently under the presidency of a country that was part of the Soviet bloc a generation ago – and a country that is leading Europe on digital technology, too!

The demonstrations of the capacity for change are all around in many aspects of our lives today: civil rights have moved forward in many ways and places; The US elected an Afro-American US President; Eminem, a white man, is among the world’s most popular rappers; and a Conservative government in the UK introduced gay marriage.

Certainly, in terms of healthcare, Europe is currently not displaying the boldness that would enable it to grasp success from what looks like getting closer and closer to the jaws of failure. A clock is remorselessly ticking as Europe merely toys with the edges of the multiple challenges of the ever-rising demands for care, ever more fragile resources, and the manifest inequalities in opportunity, access, and outcome across Europe’s countries, regions, and social groups.

The EU lacks a framework for collective reflection, decision-making, and action in healthcare. Consequently, the problems proliferate, and more and more of them go unsolved, and the opportunities for solving them are overlooked.

Without a change in mindset, an openness among all stakeholders to working together to systematically identify and deploy the best available solutions, the prospects for the health of Europeans are grim.
Innovation Needs Momentum

At present, the sort of scrupulous self-appraisal and radical re-thinking that would allow for such openness remains largely taboo. There has been plenty of talking around the obvious issues that must be faced, but this is too often no more than a facsimile of activity. There is a lack of momentum in bringing innovation into healthcare thinking and into healthcare systems, despite countless task forces and conferences and reports that have pointed to the possibilities of improvement, to the barriers that need to be removed and to the silos that need to be broken down.

It frequently looks as if there is deliberate ducking of the real issue, as if fear prevents genuine confrontation with the enormity of an impending debacle. But refusing to acknowledge the existence of a problem allows the problem to continue unchecked. The repeated – almost reflex – invocation of the principle of national sovereignty in healthcare discussions looks increasingly like a polite camouflage for deep-rooted resistance to change, a blank check for carrying on as before, permitting the comfort of the familiar present, and of the tradition of the past. But the consequent inertia is turning into a risk for the future [2].

The logical lesson from the shared nature of the healthcare challenges confronting the countries of Europe is that there is merit in seeking some common responses, some sharing of approaches that can take advantage of innovation, even if that requires also some sharing of sovereignty. Some timorous steps are being taken by health authorities that are beginning to see the enormity of the difficult choices that they will face in the future.

The BeNeLuxA collaboration, for instance, is now starting to cooperate on a joint database for horizon scanning of upcoming therapeutic innovations, since they recognise that they all face the same task in identifying new possibilities.

"By scrutinizing the horizon in a proactive and systematic way together, we can better prepare for the future and adapt policy faster, in the interest of the patient. We can also better budget for future spending," they said. It is a small step, but it is an important signal of some recognition by healthcare authorities of the need to innovate their processes in the light of rapidly changing circumstances driven by innovation [3].

Within the field of health, where innovation is occurring at breathtaking pace in so many scientific, technological and business domains, personalised medicine offers not only one of the most opportunity-rich options for innovative approaches. It also offers a ready-made test-bed for health systems to develop their capacity to re-engineer thinking about common problems. Personalised medicine par excellence requires collaboration among so many distinct strands and responsibilities, and among so many partners.

The adventurous shifts in thinking and readiness to cooperate that are necessary to implement personalised medicine are precisely the same adventurous shifts that are needed to give Europe a better chance of solving the many other large-scale challenges it faces. In effect, healthcare reform offers a reality check as to whether it is possible for European society to move from the politics of low expectation and sectional interests, and lock into higher ambitions and wider coherence.

Where Is the Collaboration?

Amid all the European Union’s official 2017 reflections on what it should be doing in the years ahead, improved mechanisms for collaboration have been conspicuously missing.

The notion of sovereignty has been largely neglected in discussions initiated by the European Commission’s paper on The Future of Europe. The options it sets out are timid in this respect; they simply do not go far enough to provoke a radical review. As a result they do not
penetrate to the heart of the weaknesses of EU governance – the uncompromising attachment to the local and partial view, the persistent failure to perceive the bigger picture, and the consequent inability to conceive solutions that are equal to the challenges Europe faces.

But if solutions are to be found, the EU is unquestionably where the search should be concentrated.

**Questions, Questions…**

Taking healthcare as our case study, what possibilities are there for the EU to step up and pioneer far-reaching policies that are adequate to the challenges of today and tomorrow? If the need for healthcare reform is indeed as much of a priority as it is widely and frequently considered to be, then what is impeding the response at the national and EU level? Is it the sheer complexity of the issue, or a lack of ability? Is it multiple disagreements among parties leading to paralysis? Is it the multiplicity of diverse local actions, or the repetition of the same old partial solutions?

Or is the real issue the deficiencies in the mechanisms used to reach decisions? Are our policy forums and decision-making centres simply not able to look far enough beyond their own narrow confines? Are they unable to take account of the scale of the task, of the pace of progress, of the advances in technologies, of the rapid growth of opportunities?

Because opportunities there are, and in abundance. This EAPM conference, and this special issue, make that clear, with their highlights of real evidence-based progress and possibilities.

Diagnosis and treatment techniques exist that can transform healthcare, not only for the individual patient, but for healthcare systems themselves. The opportunities are within reach if that collective courage can be found to overcome defensiveness, to combine forces effectively, and to look head-on at the real issues.

There may be an instructive lesson in the ancient Chinese medicine concept that you paid the doctor only as long as your regular visits kept you well. If you got sick you stopped paying, because the doctor hadn’t done his job of keeping you healthy. The doctor then treated you for free until you were well again.

It is a principle that might find its place, mutatis mutandis, in meeting the challenges of switching contemporary healthcare towards a more sustainable model of preventive medicine. But it is also powerfully illustrative of the type of radical thinking that alone can guide European healthcare out of the impasse it is finding itself in as resources shrink for meeting soaring demands.

**Engaging All Partners**

What the EU needs is a framework that can shift its approach to healthcare so that it promotes rather than restricts access to the benefits of innovation and of innovative thinking. This would be a new form of partnership in which all stakeholders are engaged and all can find their place as contributors towards a shared goal.

It would have to be capable of absorbing distinct inputs and building on their dynamics to construct a view of the whole, rather than seeing common approaches frustrated by a cacophony of ideas or resistance from stakeholders determined to defend a particular local vested interest. It would need the integrative capacity and adaptability of the jazz musician, and a structure resembling the delicate complexity of a snowflake rather than a blunt monolithic block of ice, to be capable of responding to innovation and translating it into healthcare.

It would have to be able to ween partners away from unthinking and entrenched traditionalism, to make them comfortable with innovation and the technology that makes it
possible. Resistance can arise from lack of understanding – but reflex resistance can be overcome. Not everyone is familiar with the technology underlying emails, unlike the familiar process of traditional mail: but for all the intrinsic complexity of email, all but the most extreme Luddites now routinely use it.

Moving with the Times

In areas central to healthcare innovation, this platform would have to reconcile protective instincts towards society with recognition of the new autonomy that individuals can now enjoy as a result of innovation. The general public routinely buy flight tickets online, check in and choose their seats online, make payments and get bank loans and mortgages online... In many areas of technological innovation, regulatory authorities and policy makers have accepted, adapted to and facilitated its integration into daily practice – often boosting efficiency, widening choice, and reducing costs, too.

But in healthcare, red flags are so often raised when the possibility arises of speeding up systems, bringing in efficiencies, or empowering patients, and this can act as an impediment to improvements.

Concern for protection of the patient can easily overlap with patronising the patient, in contrast to so many other areas where notional associated risks for the citizens do not prevent the grant of a degree of autonomy: driving a car or rearing a family are also challenging and potentially hazardous, but regulation and individual rights have managed to secure some equilibrium.

In addition, the overprotective instinct can generate misunderstandings. Innovators in healthcare are occasionally accused of ignoring patients’ interests, but there are issues too about the representativity of the accusers or the justification for their arguments.

Demanding that every trial subject should fully understand the trial and the science behind it can err on the side of excess. For many patients, anxious for treatment, the understanding of the potential risks of the trial may well take second place to the much more acute understanding that without treatment, the result will be death.

Again, which patients with a terminal disease have ever said that they do not want their data shared so as to benefit future patients? But spokespeople claiming to represent patients frequently caution regulators and politicians against laxity on protection of privacy, informed consent, or sharing of data.

They question whether screening or genetic testing should take place, because of the alleged risks of overtreatment. And ethics and demands for total safety are often brandished as reasons for delaying treatment or blocking innovative procedures – ignoring the equivalent ethical dilemma posed by withholding existing diagnostics or treatments from patients who could benefit.

There is a risk that overprotection can backfire, can have unintended consequences of operating ultimately against the interests of patients. The same applies to bringing innovation to healthcare systems. Excessive caution can harm rather than help healthcare.

Universal Need for Quality

Discussions of the health of EU citizens often also provoke a hardening of defensive national positions, driven by concerns that joint approaches will trample distinct and particular social interests and group or individual values and identities. But the reality of providing quality of life for citizens is no different whether they come from Taormina in Italy,
Kerry in Ireland, Varna in Bulgaria or Kaunas in Lithuania. The needs for quality of healthcare remain similar. An innovation that brings an increased quality life in one geography can bring the same quality of life in another.

So, the need for a neutral multi-stakeholder platform is inescapable – somewhere where institutions at EU and national and local level, and all partners, can interact in confidence, safe in the knowledge that the views of all sides are being taken into consideration in constructing an equitable and overarching view of the whole.

After more than 60 years of EU integration, a degree of closeness exists among member states in a wide range of areas. Innovation is readily accepted across the EU in many sectors, with joint efforts driving forward everything from space technology to cross-border rail operation or defence cooperation. The rare disease community, low in the number of individuals with each disease, but high in numbers taken as group across Europe, has shown a way forward in this, in increasing access to treatment as well as in incentivising and embracing innovation.

The EU’s genesis in the aftermath of the Second World War is still eloquent testimony to collective will to rise above divisions – even in its most conflictive form. The EU has brought together warring factions with long memories to reach collaboration on a range of issues.

If the EU has been able to build bridges across such a deep gulf, is it really possible that it cannot find the will and the means to function more effectively with a joint approach to harness the benefits of innovation in healthcare? These historical issues cannot be more complicated than differences on the development of science.

**Education Is Key**

Unqualified EU adherence to the principle of precaution – the philosophy of measure twice and cut once – is not always appropriate, and can be a serious impediment to taking on board innovations that can provide better solutions.

A more refined sense of nuance has to be brought into the evaluation of policies, and this imposes a duty on all partners to adopt a more self-questioning approach to their views and their actions and their choices. That process can be stimulated and promoted by a form of education, at all levels, from the top of the EU down to local physicians – and the important role of physicians cannot be overstated in effecting change.

The educational process has to engage individual patients too – all the more so since at times of sickness, the natural temptation is to fall back on the familiar and the traditional. People feel vulnerable when they are ill, and they revert to what they know and trust. That is understandable, but it does not mean that it should be accepted as the default approach.

**The Flexibility Principle**

At the level of member states, exaggerated protectiveness can block innovation, sometimes driven by pressure groups whose own agenda may not give pride of place to the interests of patients. But it is important, if the benefits of innovation are to flow to Europe – and to European patients, that adequate platforms promote flexibility to provide for adequate reconciliation of diverse attitudes, and permit adoption of valuable innovations.

This is a crucial moment for the EU, facing the departure of a key member state in 2019, and preparing a mid-2018 proposal for profound changes to the multiannual financial framework of the EU of 27.
As it adapts to the future, the EU is the organisation that can still command respect and provide a degree of confidence among many stakeholders. But if it is to continue to do so, it will have to recognise the importance of innovation and the complexity of integrating it into its policy formation.

And in Europe, with all its complexities, the impetus cannot be expected to come from just one point. The sort of change that is necessary requires wide engagement, which presupposes wide understanding, and which in turn presupposes a change in thinking about innovation.

The need is pressing for a multi-stakeholder forum to act as a disinterested platform for the many stakeholders as they juggle the many issues of integrating innovation into healthcare. An organisation such as EAPM, which already has the confidence of partners from right across the healthcare landscape, could play an invaluable role here [4].

Innovation exists, in abundance. But the chance for exploiting it is not permanently on offer. Can Europe find a way of seizing it for healthcare – or will it let it slip through its fingers?

**The Strength of Europe**

There is every reason to believe that Europe can summon its strengths to grasp the opportunity. Some of those strengths put it in a uniquely advantageous position, even though they are often dismissed as weaknesses. Its mixed legal heritage, combining elements of common law and a civil law framework, can sometimes make for complications – but at the same time this allows it to provide a degree of certainty over safety, incentives, and individual rights.

It also allows Europe to be pragmatic in its policy formation – which can provide the space for integrating innovation. Even Europe's oft-criticised caution on transferring data can be interpreted more positively as a demonstration that the EU is a strong defender of international data security – something appreciated by both stakeholders and investors. And the intricate patchwork of its regions that can sometimes impede standardisation has the merit of offering a series of testing grounds for different approaches to problem-solving [5].

Nor should it ever be forgotten that with the EU, this continent with its all-too-recent history of internecine warfare has managed for more than two generations to settle disagreements – whether over fishing grounds or tractor rollover bars or macro-economic strategy – by discussions in committee rooms.

This shows how deep the understanding is among Europe's countries of the need for collaboration and cooperation. This is what, in the health field, has allowed the work of the European Medicines Agency to develop so substantially, or public and private partners to create and expand the Innovative Medicines Initiative, or for the drug industry and health ministers to sit around a table to discuss how to ease access to medicine.

With so much to be gained by working together, whatever reservations may persist are eventually likely to be overcome.

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**Funding Sources**

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