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Article

Leviathan, or the Rudder of Public Health

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Abstract
In the world of modern health, despite the fact that we've been blessed with amazing advances of late – the advent of personalised medicine is just one example – "change" for most citizens seems slow. There are clear discrepancies in availability of the best care for all, the divisions in access from country to country, wealthy to poor, are large. There are even discrepancies between regions of the larger countries, where access often varies alarmingly. Too many Member States (with their competence for healthcare) appear to be clinging stubbornly to the concept of "one-size-fits-all" in healthcare and often stifle advances possible through personalised medicine. Meanwhile, the legislative arena encompassing health has grown big and unwieldy in many respects. And bigger is not always better. The health advances spoken of above, an increased knowledge on the part of patients, the emergence of Big Data and more, are quickly changing the face of healthcare in Europe. But healthcare thinking across the EU isn't changing fast enough. The new technologies will certainly speak for themselves, but only if allowed to do so. Acknowledging that, this article highlights a positive reform agenda, while explaining that new avenues need to be explored.

Why "Bigger" Health Is Not Always "Better" Health

Is public health provision in Europe not big enough, or is it just too big? Certainly its huge size has enabled it to do great things for European citizens for many years. Three generations of western Europeans have enjoyed an increasingly comprehensive range of services that

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have improved the length and quality of life for many, to the extent that such provision has come to be taken very much for granted. And even in the EU's newer member states and its candidate countries, expectations have risen in line with – and often ahead of – growing prosperity and access to more extensive services [1].

But the size that public health policy has attained, together with the consequent complexity, also makes it very difficult to manage, to modify, and above all to rethink. The health system in Europe is indeed a leviathan – and as with supertankers, there are no possibilities for a light touch on the rudder to make quick changes to its course.

The time is coming when some agile navigation may be necessary. There are risks in policy complacency when public health provision is confronted with the massive changes in its context, ranging from demography and scientific advance to new technological possibilities and economic constraints unparalleled since the rise of post-World War II public health thinking.

The depiction of public health provision as the great leveller, the guarantor of a minimum of care for everyone, is a compelling argument for the retention of a standardised, one-size-fits-all approach. But the changes in the conditions governing public health cannot be lightly brushed aside, for to ignore them, and to fail to react to them, might risk the levelling process becoming a levelling down, and convert a minimum level of service into a maximum level.

Negligent watch-keeping on the supertanker's bridge, clumsy hands on the tiller, or indeed reliance on an inadequate or unresponsive tiller, could endanger rather than enhance the general good that public health policy is deemed to protect [2].

Striking the right balance for the common good necessitates taking full account of competing and even conflicting dynamics. An unthinking acceptance that everything is right as it is at present can lead to blindness over emerging risks. Depending on nursery-rhyme reflexes that if "the bough breaks, the cradle will fall" may cause undue attention to be given to just one bough, overlooking both the possibility that cracks may appear over time and the chance that other and younger boughs – or different and more modern technology – may offer equivalent or better support. Unquestioning attachment to the concept of a homogeneous health system could hinder exploitation of opportunities that may arise for local or spontaneous improvements [3].

Comparable risks arise from unreserved elevation of universal public health into a sovereign principle that automatically takes precedence over any other policy area. It can conduce to a dangerous detachment from real world considerations that have equivalent legitimacy, and can lead to a self-deluding sense of superiority and inviolability among public health officials and policymakers.

A conviction of infallibility, a flat refusal to listen to alternative views or to entertain the possibility of hitherto unimagined improvements is the characteristics of policy inertia – and that is never good for the common good [4].

The European Union, as the overarching framework for policy formation in most of Europe, brings an additional complexity to discussions about public health. It is a powerful potential channel for informed reflection, and at its best, the EU could serve as a compass, a lodestone in plotting the voyage. But the search for consensus as the EU's constant operating principle can also stifle original thinking, so that at its worst the EU can obscure the horizon with a self-generated fog, or have the effect of barnacles encrusting the hull below the waterline. Specifically in the health field, the strict limitations on EU competence act as a further confounding factor, with responsibility for public health uncomfortably half in and half out of the realm of coherent planning [5].

The EU attachment to equality – as most recently enshrined in its approach to social affairs and its bill of rights – is laudable as a philosophy, but can run into problems in such a diverse organisation, where national conditions vary so widely across the bloc. This raises the

question as to what is the appropriate role for the EU, and whether its espousal of a generalisation so simplistic as the common good of EU citizens constitutes a route-map for the best service in public health. There is a risk in ready-made slogans, particularly in areas of great complexity, significance and sensitivity [6].

Certainly the adoption of a mantra approach blatantly ignores the evident intricacies of differing national circumstances and the galloping development of science. And in the area of healthcare, it can act as a blinker, obscuring the 360° 24/7 vision that is necessary if all the opportunities for advances and synergies are to be perceived – and if all the reefs and shoals are to be avoided. Failing to detect the rapid changes or to recognise some of the emerging interconnections that influence health policy can lead to strategic flaws in planning [7].

Exploring New Possibilities

Without a clear vision of all the possibilities, complacency can infect the capacity for response to change, and a fragmentary approach can lead to unexpected and accidental conflicts between policies.

Take, for instance, the negative impact on health research of an unqualified resistance to sharing of data that was inspired not by concerns over health, but by unrelated fears that social media giants would abuse personal privacy. The limitations arising from data protection legislation are well-intentioned, but consent requirements that are protective of individuals in the context of Facebook can be excessive if they result in the irretrievable locking up of vast amounts of measurements that could advance the understanding of disease.

What has happened here is that ICT policy has had a determining say on areas where public health considerations should have been dominant. DG Connect's influence over health applications and Big Data and cloud computing means that it is dictating the narrative and leaving health to cope downstream with whatever the impact may be, relegating health in effect to a subordinate role.

Or take the equal – and paradoxical – attachment to transparency, almost reaching fanatical proportions on occasions: again, well-intentioned legislation that may ensure probity in governance or financial controls can have negative effects on innovation when it triggers demands for unlimited access to commercially-confidential research findings [8].

Optimising Selectivity in Modern Healthcare

So the undeniably admirable concern for public health needs some nuance to translate the ideal into practice, both to avoid it being used too bluntly and to prevent it being overshadowed by other policies. A balance difficult enough at national level. In the European context, a more selective approach to policy design may be even more necessary to keep public health policy finely attuned to real public good [9].

It is not certain that the EU has practiced that selectivity optimally. It has exercised some choices, and some of those choices have worked out better than others. The ban on smoking in public places resulted more from the issue of protection of workers than directly from public health policy. The effect has been beneficial, but it is striking that an obviously valuable public health policy came about uniquely through the exercise of a completely different policy competence. Similarly, EU action to bring some order to cross-border healthcare and to citizens' rights to treatment and reimbursement was the consequence not of policy planning but of judgements in the European Court of Justice. There are plenty of other examples of selectivity in process and procedure: healthcare was not included in the EU's services directive;

regulation of clinical trials still leaves wide scope for national decisions; and the provision of treatments remains entirely within the competence of individual member states [10].

The sheer diversity of approach confirms that there is no underlying logic or overarching perspective for making EU policy decisions on public health. Policy is often the result of random factors, a consequence sometimes of caprice more than of coherence. There is, for instance, a manifest reluctance by some in the healthcare community to make use of emerging technologies, to harvest the fruits of scientific research in new health applications that can treat the patients or the broader public. Just take the example of patients contributing to earlier diagnosis of melanoma by using their own smartphones [11], making the condition easier to treat – and then just look at how widely that is endorsed and supported across the member states.

Member State Competence and Inaction

As the stakes rise in ensuring sustainable health systems, the time is coming when a more sophisticated rationale will be needed to guide public health policy effectively – a more soundly based social contract to move forward, above all at EU level. Retaining public health as a sovereign member-state competence demonstrably has had adverse unintended consequences, and continues to do so. Most obviously, it has handed each member state an effective veto on any EU-wide joint approaches, because any country can simply invoke the sovereignty clause to bring any common action to a juddering halt. Time and time again, this has prevented realising the potential of healthcare at the EU level, leaving policy prey to vociferous arguments against change so as to defend limited or local vested interests or unquestioned traditions and assumptions, without any recognition of the interests or benefits of citizens [12].

There are casualties from this approach. And prominent among them is personalised medicine – a field full of potential, but a worldwide field where anything Europe does has to be seen in a worldwide context. And at that level, it doesn't look too good for Europe right now. The Obama initiative on precision medicine in 2015, even amid the many uncertainties of the Trump administration, has promoted growth in related sectors of the US industry.

US industry now holds more than half of the world market for precision medicine, which is currently worth USD 40 billion, but is predicted to almost quadruple between now and 2025. China, Japan and South Korea are also giving strong support to precision medicine. But in Europe, which currently holds only a quarter of the world market, the approach is piecemeal, despite all the burgeoning possibilities for the future. Affirmative action is being taken in only a handful of member states, and that is subject to the background handicap of unhelpful EU legislation on clinical trials, data protection, and incentives [13].

A further handicap in Europe is that new technologies that can bring tangible results are often not allowed to get into the healthcare system. Sometimes this is due to the historic fiefdoms within the healthcare community where, for instance, medical and scientific societies still exercise strong influence over recommendations or guidelines for treatment. Resistance at this level, deliberate or accidental, can delay the endorsement necessary for new technologies to win acceptance and introduction into standard practice. Sometimes it may even be the case that local interests of an existing technology conspire to reject newer competition [14].

Changes Too Slow

The rise in instant international communications is gradually undermining some of these old orders – but the rate of change can be too slow to allow the adoption of innovative technologies and techniques. It is still a serious challenge to promote the sort of change in habits

that would benefit citizens – and harder still to find effective ways of allowing the public argument principle to support the call for change [15].

Some of the methods that could – and should – make a positive contribution include better communication by the EU about the opportunities that innovations present for all citizens if they are integrated into health systems. Under the solidarity principle, there are strong – but so far under-utilised – arguments for ensuring wider access to earlier diagnosis and better treatment. Another approach that could ease the necessary transition would be to create EU-level committees or networks of experts or joint actions on specific diseases. That could offer a countervailing force to entrenched resistance to innovative thinking and innovative products and services. Or existing regulatory and advisory structures could retain their role but with their terms of reference and their objectives modified to encourage adoption and integration of innovation [16].

Let New Technology Prove Its Worth

But the most compelling case for integrating technology into health systems is made by the technology itself, which can demonstrably produce radically better results now and for the future, and which crucially also triggers the radical rethink that public health is in need of to take advantage of the era of personalised healthcare. Innovative personalised medicine technology brings together such a wide range of different strands of the healthcare matrix, provoking new actions and synergies across the entire healthcare community, giving new motivation for re-evaluating how the public health questions are being asked, and answered [17].

It is likely a bumpy road on occasions, because of entrenched interests, because of the inertia that becomes built into large systems, and because people are naturally resistant to change and reform. Even those who stand to benefit from the new order will not necessarily be enthusiastic unless they understand what it can bring.

Until then, they may well be sceptical about an unfamiliar new order holding out promises they are unconvinced of. Personalised medicine in Europe is, as a result, in a form of public health limbo at the moment (not to say a public health purgatory!) – not because of any lack of intrinsic merits, but because of the context in which it is coming to life. This unstable base is all the more unhelpful since if any of the promises made on behalf of personalised medicine do not come true, that will have a generalised knock-on effect on the credibility of this approach, and disappointment may drive some of the converts back into doubt [18].

The comparison with religion may seem far-fetched, but is not altogether inappropriate. Devotees of an all-embracing public health system are being asked, in effect, to accept that reform will bring them still closer to a state of grace. Personalised care can appear to be a new Holy Grail, not so much challenging existing beliefs but intensifying them around a clearer orientation. To that extent, if personalised medicine is to develop fully, it needs to keep health stakeholders on side – or at least a working majority of them [19].

Member State Backing Vital

A persuasive move might come from a group of member states publicly endorsing the personalised approach as a route towards economic, political and social benefit for their citizens. The beginnings of such a move are perceptible in recent actions on big data/e-health/genomics/electronic health records, where Estonia has taken on a pioneering role in leading a coalition of the willing. Hard evidence of concrete advantages flowing from such cooperations to sustain the theory would go even further, of course [20].

Some grass-roots activism could also consolidate the prospects for developing personalised medicine. The rare disease community – extensive and influential in Europe – is by its nature sympathetic to the core concept. Pressure from them for specialised focus on diagnosis and therapy for conditions identified in only few patients constantly impels public and political attention towards the need for assessing and responding to health needs at an individual level rather than as standardised treatments delivered in bulk. Other patient associations and charities also drive citizen demand for (and occasionally also supply) investment in research.

More EU Support Required, Not Less

A shift in the EU approach to meeting citizens' needs could strengthen the case for personalised care, too. Currently the EU treaty offers little basis for support, and this Commission has shown little interest in expanding attention to health (apart from some warm words from the health commissioner, which have so far fallen on rather deaf ears among his Commission colleagues).

But within months of this EAPM conference in Belfast, preparations are going to be getting underway for the next European Parliament elections, and for the appointment of a new Commission, so that they can move the EU forward from the beginning of 2020. And the agenda of the EU for that new phase is already under discussion, with the five scenarios that the Commission published earlier in 2017, outlining options for the future ranging from a highly interventionist and engaged EU to a minimum service exercise. These options are under discussion now, and hold out the opportunity for strategic policy input from stakeholders.

Against this background, the question for the advocates of personalised medicine and healthcare is whether they can persuade the policy world of the merits of their avowed mission, and of the need to align public health policy accordingly. Success will depend heavily on how far the conception of public health remains static, or how far it is capable of adapting to changes in the nature of innovation and of society.

One-Size-Fits-All No Longer Fitting

At the heart of this adaptation is the response to the urgent need outlined at the head of this article for some agile navigation of a ponderous vessel. In terms of science, technology, sociology, the time is over for the one-size-fits-all approach in health.

Advances in genetics have made it now the received wisdom that we all vary from one another in constitution, predisposition, susceptibility… But adapting to that reality can be seen by some as questioning the concept of equality in healthcare – virtually a taboo. However, if public health insists on continuing to treat everyone the same way, rather than seeking to treat citizens in the ways most suitable to their different make-ups and needs, it will remain with an outdated and inefficient model that will work against the interests of citizens – of all citizens [21].

To that extent, undiscerning attachment to the traditional view of public health is not acting in the best interest of health. On the contrary, its insistence on equal rights to equal care is doing a disservice to the population. When differentiated treatments are available to improve care, insisting on equal treatment is to deprive of their rights those who might benefit from a treatment custom-made for their particular condition. The same might be said for invoking currently accepted rights – such as the right of a member state to refuse a treatment,

or to withhold funding or incentives for research, or to prevent data being shared, or to prohibit a clinical trial in its territory [22].

There are the seeds of injustice in standing in the way of progress in something so fundamental to each person's rights as healthcare, and there are the seeds of something approaching an undemocratic élitism in brandishing "public health" as a pretext for opposing change. And when the current uneasy status of health policy in the EU leaves action within it vulnerable to veto, then the rights are compromised of many who might wish to embrace change – such as those sharing a genetic characteristic or a rare disease.

Luddite élites sheltering beneath a tattered public health banner bear an uncanny resemblance to the chilling injunction from the huge crumbling statue that Shelley depicted in his "Ozymandias": "Look on my works, ye Mighty, and despair!" [23].

Crossing the Threshold

As far back as 1945, President Truman was advised that basic research was "the pacemaker of technological progress… founded on new principles and new conceptions, which in turn are painstakingly developed by research in the purest realms of science." That advice is as true today as it was then, with the EU on the threshold of seizing the opportunity of personalised care [23].

Crossing the threshold will need an acceptance that the EU can act in a facilitating role, with political endorsement, and with research funding extending beyond short-term projects, and across medical disciplines of radiology, surgery, oncology, engaging the drug and ICT industries. Consistent collection and curation of evidence gathered from real-world data will have to be integrated into healthcare innovation more effectively.

The rudder that once acted to steer public health is no longer adequate for the job, and new thinking is needed to take advantage of opportunities that did not before exist.

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