

## A new social contract for medical innovation

Despite burgeoning knowledge about the origins of disease founded on scientific advances, there are increasing public concerns that medical innovation is not helping patients in need fast enough. In the UK, Lord Saatchi's proposal for a Medical Innovation Bill<sup>1</sup> is one manifestation of this concern, while the Minister for Life Sciences' current Innovative Medicines and Medical Technologies Review is another.<sup>2</sup> A review of medical innovation is timely; it is not just the time taken for research, but the rising cost of drug development that demand attention. The adoption and diffusion of new technologies and medicines of marginal incremental benefit is one of the biggest drivers of cost in health systems, and contributes to their unsustainability.<sup>3</sup> Although the pharmaceutical industry understandably seeks to recover the costs of drug development, commissioners of health services adopt policies and processes that effectively ration the availability of new products. Recent analyses highlight that in a universal health system such as the UK's National Health Service (NHS) with a finite budget, money spent on expensive drugs could achieve more health benefit if directed elsewhere.<sup>4</sup>

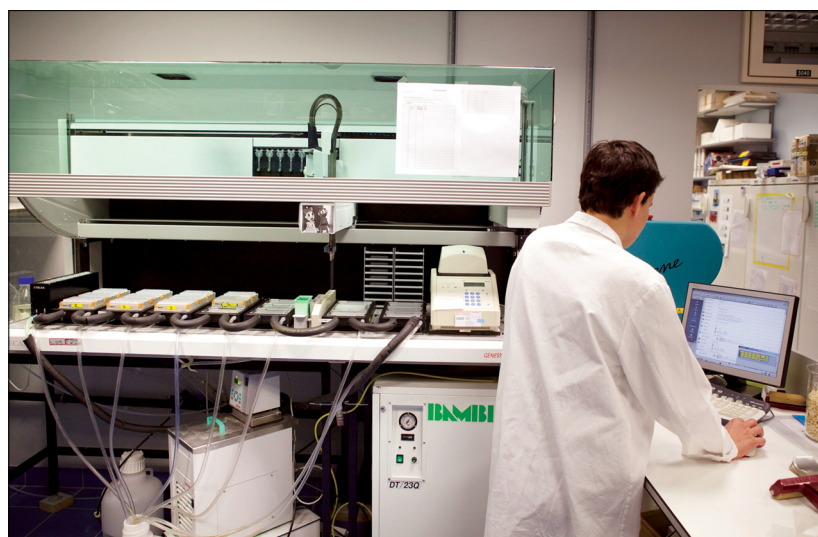
Any revision to the medical innovation process needs to embrace advances in genomics, data analytics, and e-health technologies, which have the potential to transform health and health care. We will soon be able to use population data to inform interventions that improve the health of individuals. Unlike the "one size fits all" population-based strategy that delivered the blockbuster drugs of the past, the future of medicine is likely to be shaped by 4P medicine that is predictive, pre-emptive, personalised, and participatory.<sup>5</sup> Such an approach has the potential to tackle the rising tide of chronic diseases and transform health care from disease-orientated provision to a true health maintenance service.<sup>6</sup>

But are we ready for the revolution? Moving to 4P medicine will require the engagement of patients, health professionals, health-care organisations, regulatory agencies, and commissioners with alignment of their respective interests and imperatives. This process is unlikely to occur if left to chance. Rather, we must address fundamental questions about the economic, social, and behavioural factors that determine the capability and willingness of individuals, organisations, and society to finance and adopt medical

innovations. Such understanding should lead to a review of the social contract between the health system and the citizen that sets a policy framework to guide the adoption of medical advances.

Consideration should be given to the discrete market size for personalised therapies and the complex ways to value and pay for such innovation, which include informing those who invest in innovation earlier in the process and assuring developers of the likely market. Another economic challenge is to ensure that inequality of access to 4P medicine does not follow from wealth inequity. In high-income countries, life expectancy is increasing as the birth rate falls. The rising costs of care for older people fall on a shrinking workforce. How will this change affect our capacity and willingness to fund 4P medicine? Since wealthier people are more willing to invest in preventive health care, future health outcomes in old age could become even more dependent on wealth, and exacerbate inequalities and conflicts about financing because the heaviest users of health services will be the poor.<sup>7</sup> Moreover, health inequalities between countries will be exacerbated if pharmaceutical investment prioritises precision medicine at the expense of research tailored to the needs of poorer nations.

Technological advances require parallel progress in the communication of value, risk, and uncertainty to the public in ways that foster trust and enable informed choice and optimum engagement. It is also important to recognise that people with unmet clinical need



interpret risk and benefit differently from those who are well or whose needs are met. The track record of responding to these challenges is unimpressive. About half the medicines prescribed for long-term conditions are unused.<sup>8</sup> The causes are complex, but are often rooted in patients' beliefs about illness and treatment and mistrust of pharmaceuticals.<sup>9</sup> We cannot assume that the public will perceive personalised medicine as more valuable and less risky than currently available drugs.<sup>10</sup> Truly personalised medicine must be tailored not just to the genetic and biological status of the individual, but also to the psychosocial factors which affect their motivation and ability to use it.

Combining big data with the new genomics creates the potential to predict future disease—a prerequisite for targeted prevention—but little is known about whether people will want this information or how it will influence behaviour and wellbeing. Furthermore, a pre-emptive approach implies treating people who are currently well. This approach has provoked siren voices claiming that society is being overmedicalised. But has society's view been taken into account? Access to individual data at a population level will be necessary for risk assessment, targeting and repurposing of existing agents, all of which will require intense societal engagement. The debacle over the introduction of NHS England's Care.data<sup>11</sup> highlights the pressing need for better ways to engage the public to ensure that values and expectations are aligned.

Unless these issues are tackled, society could sleepwalk into an even more unsustainable situation as it attempts to take advantage of the new science. We need a medical innovation system that enhances value and reduces waste by enabling service users, health professionals, service providers, and innovators to pull together in the same direction. Such a system requires transformative thinking and a better understanding of how value, risk, and uncertainty are perceived and acted upon by individuals, organisations, and society, including regulatory systems. A transdisciplinary approach will be needed that links medicine and medical science, law, ethics, economics, and behavioural and social sciences. These issues should be addressed in tandem with the development of new treatments and diagnostics. If we tackle now the ethical, behavioural, legal, and economic implications of a system designed to facilitate 4P medicine, the benefits to society are potentially huge.

The forging of a new social contract between health care, the medical innovation system, and society will be key to the development of sustainable health-care systems that take maximum advantage of the power of modern science. In the UK, such work needs to be done in parallel with the current Innovative Medicines and Medical Technologies Review to complement this important initiative and facilitate adoption of resultant recommendations.

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