

The people's prescription

Re-imagining health innovation
to deliver public value

October 2018

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About the UCL Institute for Innovation and Public Purpose

The Institute for Innovation and Public Purpose (IIPP) is a department within University College London (UCL) and part of The Bartlett faculty, known internationally for its radical thinking about space, design and sustainability. IIPP's mission is to change how public value is imagined, created and evaluated to tackle societal challenges and achieve economic growth that is more innovation-led, sustainable and inclusive. Our research and teaching programmes aim to shape a dynamic and bold public sector driven by public purpose. Markets can be shaped by purposeful policy making and by new collaborations between the state, business and civil society. Markets can be designed to deliver public value.

www.ucl.ac.uk/iipp

About Global Justice Now

Global Justice Now campaigns for a world where resources are controlled by the many, not the few. We champion social movements and propose democratic alternatives to corporate power. Our activists and groups around the UK work in solidarity with those impacted by poverty and injustice.

www.globaljustice.org.uk

About Just Treatment

Just Treatment is a patient-led campaign fighting to secure fair and affordable access to medicines on the NHS, and to bring about a medical innovation system that prioritises the lives of patients and public health over the profits of pharmaceutical companies.

www.justtreatment.org

About STOPAIDS

STOPAIDS is a membership network of 70 organisations with a thirty-year history of engagement on international development and HIV and AIDS. We convene and unite UK civil society and shape UK leadership in the global response to HIV and AIDS. Our advocacy work addresses systemic issues critical to that response, including access to affordable medicines.

www.stopaids.org.uk

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Executive summary

A thriving health innovation system should generate new health technologies that improve public health and ensure access to effective treatments for the people who need them.¹ However, our current health innovation system fails to direct innovations towards the greatest health needs, and is fraught with inefficiencies: when innovation happens, it happens more slowly and at great cost.²

Driven by profit rather than public health, the pharmaceutical sector is incentivised to set high prices and deliver short-term returns to shareholders, rather than focus on riskier, longer-term research which leads to critically needed therapeutic advances. The high prices of medicines are causing severe patient access problems worldwide, with damaging consequences for human health and wellbeing.³

These are symptoms of an innovation model that is broken. This report maps the fault lines of this system and sets out principles for a new one. While it does suggest some quick fixes that policymakers can implement in the short term, crucially it proposes concrete policy actions that can be taken in the long term to actively shape and co-create a health system that delivers real public value.

Diagnosis

Continuing with business as usual is not an option, as our current health innovation model is expensive, inefficient and unsustainable. The first step to addressing these problems is to diagnose the problems of the system and outline the principles for how our health innovation system can be better designed to build a health innovation model that delivers public health.

Problems with the current health innovation system

Our current health innovation system is failing on multiple fronts, affecting both the rate and the direction of innovation. Such failings affect patient health, innovation and the economy:

R&D priorities are not determined by public health needs

A wide range of critical health needs are either not being met or are sidelined, in high-income, middle-income and low-income countries alike. A system driven by profits ignores diseases prevalent mostly in the global south, such as tuberculosis which kills millions.⁴ It also incentivises development

of 'me-too' drugs that offer little therapeutic advance and primarily serve to prolong patent protection. Studies have found that more than half of approved medicines in recent years offered no additional medical benefit.^{5,6}

Lack of transparency and stifled collaboration

As the major incentive for innovation in our current system, intellectual property rights (IPR) need to encourage innovation rather than stifle it. The fact that patents have been made increasingly hard to license, much broader than the downstream area of innovation, and too easy to extend, has led to patents blocking learning, diffusion and dynamic collaborations. Additionally, a systemic lack of transparency (and public accountability) in the underlying research data and methods, in both pre-clinical and clinical trial stages, has severe implications not only for the research process, but also for patient health. A 2016 meta-analysis of 28 studies documenting clinical trial results found that unpublished documents were much more likely to report the occurrence of adverse events than published ones.⁷

Out-of-reach drug prices

There are no safeguards within the current R&D model to guarantee that medicines – including those developed with public funding – are affordable for the patients who need them. Patent monopolies negate competition, allowing companies to charge the price the market will bear. High prices put pressure on national health budgets and have led to rationing of treatments, for example on breakthrough medicines for hepatitis C and cancer in the UK.^{8,9} Pharmaceutical companies argue that prices are proportionate to the intrinsic value of drugs – that is, the costs to society if a disease is not treated or is treated with the second-best therapy available (value-based pricing). According to this argument, higher prices represent more value, with health systems willing to pay now for better future health outcomes from a therapeutic advance. However, this argument obscures the key political-economic drivers of higher prices: short-term financial pressures to increase prices, and monopoly power to set prices at the upper limits of what health systems can bear.

Short-termism and financialisation

Pharmaceutical companies are increasingly focused on maximising short-term financial returns to shareholders. A common tactic is companies buying back their own shares to boost the value of the remaining ones, hence also boosting the value of stock options. From 2007 to 2016, the 19 pharmaceutical companies included in the S&P 500 Index in January 2017 spent US\$297 billion repurchasing their own shares, equivalent to 61% of their combined R&D expenditures over this period.¹⁰ The use of these funds to boost shares and options, rather than investing in technology and production, leads to value capture by shareholders at the expense of health advances in the public interest.

Principles for a health innovation model that delivers public value

Recognising the deep dysfunctionality of the current model, we have drawn up core principles that could nurture a better health innovation ecosystem:

Directed innovation and mission setting

Innovation should be directed towards public health outcomes. This means designing an incentive structure that rewards public health advances rather than market return. This can be achieved through a 'mission-oriented' approach, in which public actors set the directions for innovation aimed at key public health milestones, and policy levers are used to welcome bottom-up experimentation to achieve those goals. Indeed, these are the processes that got us to the moon!¹¹

Collaboration and transparency

Tackling public health needs requires a collaborative environment where actors – public, private and civil society – work together and share knowledge in new and dynamic ways to accelerate innovation. This requires transparency as well as an intellectual property system that incentivises innovation rather than blocking it (eg, the use of narrow patents that are easily licensed).

Affordability and access

Affordable and accessible medicines are fundamental to the realisation of the human right to health.¹² There is also a clear socio-economic case for supporting these actions in terms of securing a healthy workforce and the positive ripple effects on the economy as well as tax revenues.

Long-term horizons and patient finance

Innovation is uncertain and can take time; public and private actors thus need to commit to long-term goals. It is also necessary to identify forms of finance that are 'patient' and capable of providing reliable funding to sustain the innovation process, allowing collective learning to accumulate over time while at the same time bearing high risks and inevitable failures.

Remedies

Solutions to the problems of the current system cannot all be implemented overnight. While some can be implemented almost immediately, others require a more radical transformation of the system. The latter can be based on existing experiments worldwide, which at scale could be used to foster system change.

Immediate policy actions: Getting better prices today

In the short term, immediate actions are needed to address the ongoing crises of access to medicines. Governments should urgently implement pricing strategies and measures based on managing intellectual property rights (IPR) to improve the affordability of vital medicines. These include pooled and volume-based procurement, and increasing transparency around prices – both these measures can improve the bargaining power of public buyers. Policy makers can also make intellectual property work for public health by ensuring that stringent patentability criteria are applied to prevent overly broad patents,¹³ as well as making information on patents accessible to increase transparency. Governments can also negotiate agreements around voluntary licenses to improve access to affordable medicines. When this is not possible, compulsory licenses (and government or Crown use) should be actively used. Governments should not implement intellectual property rules that go beyond what is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹⁴

Transformational change: Re-imagining our health innovation system to deliver public value

In the longer term, governments must do more than simply treat the symptoms of this fundamentally flawed system, and should instead adopt transformative approaches aimed at a radical shift in the innovation ecosystem to better serve public needs. The transformative proposals listed below are built on the principles of how innovation flourishes.

A mission-oriented approach to improving health outcomes

Governments can set the direction of health innovation by focusing the energy of state, civil society and private sector actors on clearly articulated public health goals. This ‘mission-oriented’ approach has been successful in other areas, driving everything from technological advances in aviation and aerospace to the creation of the internet.¹⁵ We believe the same approach can marshal unprecedented coordination in innovation for health. Government advocacy for long-term targets can also help secure the long-term financial investment required to support complex research and development processes. Mission-driven organisations can also collaborate internationally to address global health challenges. Social movements can play a key role in fostering mission-driven innovation contributing to meeting health challenges.¹⁶

Delinking incentives from high prices

The current incentive system for drug development is failing to deliver optimal health outcomes and must be reformed. A critical first step is to ‘delink’ the cost of R&D from the price of any resulting product. Innovation can instead be supported through grants or subsidies and rewarded by a variety of prizes, including innovation inducement prizes, market entry rewards, or open source dividends. Because these financing options are public in nature, they can be used to reward the achievement of R&D milestones and stipulate that results be made affordable, creating an innovation system driven by agreed health priorities and dedicated to access. The potential savings from this delinked system, in which new medicines enter the market at non-monopoly generic prices, are vast.¹⁷ We propose steps that can help transition health innovation towards such a model.

Achieving public return through conditionality

If value is created collectively through the involvement of different actors, then the rewards should also be shared to ensure sustainable capital and resources for continued innovation. Instead, under the current system, the public sector plays an essential role

in funding the upstream high-risk research, while the downstream profits disproportionately go to the private sector.¹⁸ A more just sharing of rewards needs to be based on a reinvigorated concept of 'public value' – in other words value that is both created *and* shared by the public. This could happen in various ways, including attaching conditions on public funding such as reinvesting profits from innovative products to support future R&D (rather than being hoarded);¹⁹ a commitment to share knowledge and fully disclose data related to R&D, including expenditures and data from failed clinical trials; the possibility of the public retaining a golden share from IPR (and on occasion equity of profits);²⁰ and a requirement that manufacturers supply treatments on reasonable terms.

Changes to corporate governance: Beyond shareholder value

Transforming innovation requires rethinking the role of the public sector beyond its 'market failure' box – acknowledging its role in actively creating markets, not just fixing them. Additionally, the private sector can be better structured. Corporate governance is key. The assumption that companies must maximise shareholder value can be rethought.²¹ We should consider, for example: limiting share buybacks that extract value out of healthcare systems to reward shareholders; tying executive compensation to the delivery of therapeutic advances rather than stock price increases; giving taxpayers and patients a voice on corporate boards at pharmaceutical companies; and promoting alternative governance models such as co-operatives, 'B-Corporations', community interest companies, and other models with an explicit public value orientation.

Conclusions: A practical radical approach

While this report is visionary, its recommendations are not based on fantasies. There are practical experiments around the world that can serve as stepping stones. This report analyses certain key state-directed, mission-oriented initiatives which incorporate the principles set out in this report. The US government's Defense Advanced Research Projects Agency (DARPA) and Biochemical

Advanced Research and Development Authority (BARDA) show how government can set the direction of research and provide risk-tolerant funding to support that direction while working with the existing private ecosystem. DARPA is geared to embrace uncertainty and risk of failure in generating ground-breaking innovations for defense purposes, and BARDA puts the mitigation of health threats at the heart of its mission for the public. Examples from Cuba and Germany highlight contrasting processes in delivering missions: Cuba's state-led, top-down biotech mission illustrates the role the state can play in the creation of an integrated innovation system that ensures access, while Energiewende in Germany shows the importance of combining bottom-up consensus-building and experimentation in civil society with a high-level political agenda in driving mission-led innovation. While governments may differ substantially in how they set about achieving missions, the common lessons in the primacy of the mission-oriented approach in delivering public value resonate across borders.

The report is both radical in its recommendations while also being practical, building on what has worked around the world in health and in other sectors to propose a series of policy recommendations designed to create a more efficient, collaborative, innovative and equitable model for developing effective medicines and ensuring access to them. A key aspect of the proposals is the way they steer and incentivise research investments that deliver public value, through a dynamic network of public, private and non-profit organisations across the entire innovation chain from the supply side to the market-creating demand side (eg, procurement).

As a whole, the report proposes a system of developing and ensuring access to medicines that increases the rate of innovation while also directing it towards health needs, and ultimately creates better value for money than the model we have today. As the number of countries struggling to afford new medicines grows, and patients are increasingly denied access to treatments that could heal them, the question for political leaders and policymakers is not whether they should initiate action to deliver a public-value-centred health innovation model, but when.