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Conflicting values of biomedical innovation?

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Abstract (100 words max)

The term ‘value’ is at the centre of, an increasingly explicit debate in the fields of health and healthcare policy. ‘Value’ is understood in many different ways and diverging interests are being mobilised. How are values in biomedical innovation being expressed, represented, materialised and aligned or contested in different areas of biomedicine? How do values embedded in regulation, public health, economic policies, healthcare provision, technology assessment, producers' strategies, and patient organisation movements shape biomedical innovations? At an ESOF discussion in Toulouse multidisciplinary perspectives on value between panel members and public participants will be explored and possible pathways to common solutions identified that promote socially acceptable biomedical innovation in the European context.

Keywords: Innovation, Biomedicine, Values, Interdisciplinary discussion

Main text (between 500 and 1,000 words)

Introduction

Breakthroughs in biomedicine appear daily in the news media offering hope to patients, profit to companies and reputation to countries and governments. Here, there is news about gene editing (notably CRISPR-CAS 9, enabling ‘easy’ editing of the genome), or gene therapies for severe combined immunodeficiency. Elsewhere, T-Cell immunotherapies for leukaemia, or limbal stem cell transplantation for blindness are praised. We even contemplate 3D bio-printing of entire complex tissues or organs such as the liver or kidney. Such innovations are held up as game-changing transformations in the practice of medicine. Medicines are promised to become more personalised, more precise, more cellular, targeted by better biomarkers and genomic and other ‘omic’ analysis. However, these achievements and visions are driven by stakeholders pursuing different interests, and we have to ask whether this produces optimal scientific and medical innovations for society at large.

What is Biomedical Innovation?

Biomedical Innovation includes bioprinting, regenerative medicine, biomaterials, nanomedicine, gene editing, stem cell therapies and other forms of treatment based on life sciences. These sub-

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domains of Biomedical Innovation are championed as potential cures for many medical conditions. They are also prioritised by governments' life science wealth creation strategies. Many initiatives have been launched to devise strategies for addressing Biomedical Innovation's challenges in Europe.

Value or values, conflict or consensus?

The infamous Stamina Foundation stem cell case in Italy reached the national parliament and later resulted in criminal convictions for fraud, but thankfully not all biomedical innovations are marked by conflict of values as starkly as this. A trade-off between innovation and commerce versus safety and efficacy is a common tension, evident in regulatory and enterprise policymaking. The development of the EU's Advanced Therapy Medicinal Products Regulation (2007) was a good example of an attempt to address this. Other perspectives and claims to value also clamour for attention, for funding and for special policy treatment, such as patient organisations representing rare diseases, 'dread disease' such as cancer, or health economists' concern to maximise health of whole national populations.

In the fields of health and healthcare policy, there is an increasingly explicit debate using the terminology of 'value' itself, with different meanings and interests expressed. However, actors' and organisations' values are not always self-evident. Stakeholders such as academia, regulators, health technology assessment and ethics bodies, trade bodies, charitable and government funders, health professionals, and patient organisations attribute value to innovations from different perspectives, motivated by diverging interests. Many controversies arise. What are the social, economic, ethical and other values being mobilised in biomedical innovation? Key questions in the current biomedical innovation landscape rear their heads:

- Are strengthened risk and safety values diminishing the value accorded the broadest possible range of beneficial biomedical innovation?
- Are proliferating exemptions to established regulation, compassionate use, 'breakthrough' and 'promising' designations, and unmet need incentives, distorting a fair marketplace and fair financial value for new products?
- How are national and global health priorities addressed by government and companies' biomedical research agendas? Are values of prevention (e.g. vaccines, genomics) in conflict with those of treatment and cure (e.g. cell and gene therapy)?
- Would health inequalities be exacerbated or could they be resolved, by the development of biomedical innovation? Producers continually appeal to increasing 'patient access' – does this promote equitable access according to need?
- Are ethical issues influencing the given or perceived values of biomedical innovation? For example, the International Covenant on Economic, Social and Cultural Rights (ICESCR) includes a right for a society 'To enjoy the benefits of scientific progress and its applications'. Is this right being taken seriously? How does it manifest in intellectual property law?

Social scientists can contribute to value debates in three main ways, first by negotiating neutral spaces where stakeholders can come together for debate; second by providing refined techniques

for eliciting values from participants, and scenario development methods; and finally, by promoting an iterative and open dialogue that locates these issues in wider value systems to ask bigger questions about the direction of travel of biomedical innovation

Debate at ESOF

A special panel at ESOF will discuss these issues in Toulouse on July 11th. It aims to explore how values are expressed, represented, materialised and aligned or contested in different contexts of regulation, public health and economic policies, bio-healthcare provision, technology assessment, producers' strategies, patient organisations and other arenas. The panel will highlight in an interactive roundtable how values of biomedical innovation are similar or divergent for specialists in law, sociology, philosophy, economics or patients or Parliament representatives, and open discussion will consider how they might align to those perceived by the public. Discussions will be stimulated between the panel members and the public participants to identify interdisciplinary convergences and divergences of challenges. For this debate, biomedical innovation is defined as an innovative procedure, technique or product based on human or animal biological elements, with a high level of protection of human health and promoting economic competitiveness.

Discussion will consider if new forms of innovation governance might optimise the alignment of different value perspectives in subfields of biomedicine. 'Partnership' has become a buzzword, and we must ask to what extent can stakeholder partnerships overcome mismatching value positions? Speaking at a conference on Advanced Therapies in London in 2017, Magda Papadaki of the British Association of the Pharmaceutical Industry (ABPI) opined that:

‘..we need to all work together to ensure that we can progress the commercialisation of advanced therapies and turn a cottage industry into a robust and growing market. We need integrated development, regulation and commercialisation for advanced medicines’ (ABPI, 2017).

Alongside such views, the high-level European Group on Ethics in New Technology (EGE) in 2015 suggested a broad approach to the governance of values in health innovation by ‘triangulating science, ethics and society’, when it reported on ‘the ethical implications of new health technology and citizen participation’.

The ESOF panel will stimulate debate on these and other crucial governance and social participation scenarios.

The international panel members each bring distinct expertise includes: *Virginie BROS-FACER (Eurordis, rare diseases Europe)*, *Jurgen KUBALL (University Medical Center Utrecht)*, *Laurence LWOFF (Council of Europe)*, *Aurélie MAHALATCHIMY (UMR7318 DICE-CERIC, CNRS-Aix-Marseille Université-Université de Pau et des Pays de l'Adour-Université de Toulon et du Var)*, *Valérie PARIS (Organisation for Economic Co-operation and Development- OECD)*, *Andrew WEBSTER (Science and Technology Studies Unit, University of York)*.

Session managed by Dr Aurelie Mahalatchimy (Law specialist, UMR7318 DICE-CERIC, CNRS-Aix-Marseille Université- Université de Pau et des Pays de l'Adour-Université de Toulon et du Var, Aix-en Provence, France) and Prof Alex Faulkner (Sociologist, Centre for Global Health Policy, School of Global Studies, University of Sussex, United Kingdom)/ Prof Andrew Webster (Sociologist, Science and Technology Studies Unit, University of York, United Kingdom).

The session "The values of biomedical innovation" is planned for 11/07/2018 from 08:45 to 10:00 am.

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