Title: Rethinking value construction in biomedicine and healthcare.

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Abstract

Despite longstanding attempts to conceptualise and measure value in biomedicine and healthcare, there is no single agreed definition of what value *is*. Instead, and as such, value is often taken as given or constructed in economic terms. In this paper, we argue that taking the meaning of value as given, or reverting to technocratic or economic dimensions of value, obscures the non-technical and societal dimensions of value construction and operationalisation in healthcare and biomedical practices. Through a comparative study of five cases of biomedicine and healthcare, we aim to bring out the socioeconomic and political processes that makes a thing valuable for society and its implications. Our contention is that a clearer understanding of what makes something valuable (or not) is the first step towards what socially reflexive and responsible valuing of biomedicine and healthcare *ought to be*.

Keywords: Value; Genomics; Artificial Intelligence; Health Technology Assessment; Vaccination; Value-Based Healthcare.

Introduction

Attempts to conceptualise and measure value in biomedicine and healthcare are not new (Birch and Tyfield, 2013; Dussauge *et al*, 2015; Gray, 1983; Novas, 2006; Porter and Teisberg, 2006; Rajan, 2005; Rose, 2001; Waldby and Cooper, 2008). Yet, there is no agreed definition of what value is (EXPH, 2019, p. 4), and as such, value is often taken as given, or understood in economic terms. In this paper, we argue that by taking value as given, or by reverting only to economic-based models of value, we miss the opportunity to explore and understand the processes that make things and processes valuable. Drawing on valuation studies (Dussauge et al 2015; Lee & Helgesson 2019) we suggest that the meaning of value is not to be found in the object that is being referred to, nor in the actors articulating it, but that it emerges from the practices in which this object is being referred to or valued. Using a case-study approach, we illuminate these (socioeconomic, political, social) processes to draw attention to the systemic and societal dimensions of value construction, as well as its enactment and operationalisation in healthcare and biomedical practices across specific contexts. The aim is not to (re)define what value *is*, or to construct precise measures of health to inform policy. Rather, our aim is to provide a clearer understanding of the value construction processes that makes a thing valuable (or not) for society as the first step towards what socially reflexive and responsible understanding of value in biomedicine and healthcare *ought to be*.

We believe that it is neither possible nor desirable to draw a hard line between facts and values, between description and evaluation (e.g. Polanyi 1962, Putnam 2002; see also Friese

& Prainsack, 2020). In this paper, our exploration of how things are made valuable is thus always also a question about the norms that are articulated within and through these practices of (e)valuation (with Sayer (2011: 153-4) we hold that "'norms' tend to be at least as much the products, or ex-post rationalizations, of practices as their determinants") (see also Cook & Wagenaar 2012). At the same time, we are conscious that our very own descriptions are evaluative. We believe that a world in which material and other resources are distributed in a fair and transparent manner, and in a way that enhances people's capabilities (Nussbaum 2000; 2011; Tengland 2020), is preferable to a different one. This normative stance is the tacit sub text to our own descriptions.

Value in Biomedicine and Healthcare: emerging and established spheres

When exploring the nature of value in the context of health, one may easily argue that health *is*, in itself, the highest value, and that the value of any practice, intervention or technology should be established according to the extent to which it protects, promotes or reinstates health[1]. Yet, even this definition would leave us with the question of how to define and operationalise health to inform population-level and resource-allocative policies (Hausman, 2015). At the same time, it would also need to consider individual subjectivities and collective needs (e.g. Datta, 2018) where demarcations between different health states, relative outcomes, and their respective value (Kieslich, 2019) are complex and contingent. Furthermore, beyond these complexities of individual subjectivities, the operationalisation of the meaning of value in medicine and healthcare also tends to differ (at times substantially) based on whether the spheres of value construction are emerging or established. While *emerging spheres* of value construction are based on future expectations of innovative biomedicine and biotechnology, *established spheres* encapsulate the comparatively more

formalised practices of assessing value (e.g. metrical valuation methods) in healthcare systems and are discussed next.

For emerging biomedical innovation, future-oriented expectations create *speculative value* in the present by promising future societal benefit (Brown and Michael, 2003; Callon, 1998; Mackenzie, 2006). This speculative value, enacted through promissory discourses, derive some of its power by promising to address in the future what is seen to be valuable in the present. This in turn, helps to justify public and private funding in the present; at the same time it helps create the infrastructures needed to realise promised goals and improve public health (Birch, 2013; Birch and Tyfield, 2013; Novas, 2006). However, promissory discourses promoting socio-technical future imaginaries (Jasanoff and Kim, 2009) tend to be largely based on the visions of experts, such as scientists, technology developers and policymakers or activists (e.g. rare disease activism in post-genomics and personalised medicine). Patient activists and caregivers have also played a prominent role in both the economic valorisation of biomedicine, as well as the re-valuation of non-economic social dimensions of value through partnerships, networks and engagement (see e.g. AIDS activism in Epstein, 1996). Despite this, macro-technologically focused visions can often miss what other stakeholders, such as the health professionals, and/or publics, perceive as valuable e.g. non-technical values such as fear of job loss, social interactions, and various other social determinants of health(care) (Greenhalgh *et al*, 2017).

Even in the more *established and institutionalised spheres* of value construction, such as priority-setting processes like Health Technology Assessment (HTA), these moral, economic and social issues are also increasingly salient and highly context specific. Within HTA, a rich set of measurement metrics, toolkits, and scales has been developed over the last few

decades to address specific value (or valuation)-based challenges in healthcare provision and service delivery. Such metrics range from clinical effectiveness and cost-utility analyses in HTA to outcome-centred metrics that appraise patient experience (see e.g. Caro *et al*, 2019, Squitieri *et al*, 2017) to answering questions whether a drug or technology should be paid for by public healthcare services, or how much a healthcare provider should receive for providing specific interventions. Value, here, is typically operationalised in a technical way: it is defined in terms of health outcomes relative to monetised inputs (Porter, 2010). Missing from these assessments of value, however, is a clear understanding of what value is beyond 'value for money' (see also Mazzucato, 2018).

In this sense, the recent push towards making new interventions in biomedicine and healthcare more 'valuable' by involving patients and the public in research and in decision-making processes in a more systematic way is heartening. If organised in the spirit of democratic empowerment (Prainsack, 2017) - namely to broaden the range of voices and perspectives who define stakes, solutions, and criteria to measure what counts as a success - this involvement also serves the purpose of drawing attention to the ethical, symbolic, epistemic, and societal and political dimensions of value as we do here. In other instances, patient involvement can also take a tokenistic or instrumental form, serving the purpose of legitimising decisions already made by experts, or creating value for corporate actors (see also Filipe *et al*, 2017). Notwithstanding, these attempts to consider the perspectives and experiences of patients more systematically in various domains of healthcare and biomedicine reflect a positive development towards a more inclusive debate about value.

In the following section we provide insights into the different ways value is currently understood, constructed and operationalised in specific biomedical and healthcare contexts. We selected five case studies across speculative and established value systems in the

European and North American context of biomedicine and healthcare. Each case study was selected to elicit a variety of conceptual and practical implications of value practices. Specific questions explored included (i) how interventions and processes in biomedicine and healthcare are made valuable, (ii) through which social practices, and (iii) underpinned by which ethical, moral, and economic norms. Thus, we move away from showing the lessons learnt in any single health domain - to illuminating the common issues across seemingly disparate domains. Indeed, that the same theme(s) emerge across a diversity of the empirical material is the crucial finding here. In other words - that seemingly incommensurable empirical circumstances become commensurable by the same challenge (what socially reflexive and responsible valuing of biomedicine and healthcare *ought to be*) - is the unique contribution of this paper and the justification of its methodological choice.

Methods

Our case studies drew on different data sources. For the UK 100,000 Genomes Project, we explored data based on 20 interviews with individuals who worked at or were associated with Genomics England (i.e. the company delivering the project), plus policy documents and media articles related to the project. The case study on hepatitis C medication is based on an analysis of appraisal documents of HTA organisations, and a selection of media articles. The vaccination case study presents the current value paradigms in which policy is typically developed by national governments, drawing upon desk research as well as expert interviews with epidemiologists and public health officials in Austria and the Netherlands, and experts at the World Health Organisation (WHO). The case of artificial intelligence (AI) in clinical practice builds on systematic review of grey literature and discussions with scientists and researchers undertaken as part of a three-year engagement with the Ethics and Society subproject of the Horizon 2020 funded Human Brain Project. Finally, for the value-based

pricing case, we reviewed publicly available documents of Medicare and Medicaid services in the United States.

Rethinking speculative value

Valuing genomic data

Reflecting on the UK's 100,000 Genomes Project (100 kGP), this case study highlights how the construction of speculative value in genomics is built on the promise of potential translational research into clinical practice. This itself depends on a particular set of data-centred social practices and values.

100 kGP, promoted and delivered by the Department of Health-owned Genomics England Limited (GEL), was an innovative venture that sequenced 100,000 genomes from UK National Health Service (NHS) patients and their families who have a rare disease, cancer, or an infectious disease (Gov.uk, 2012). The initiative, which ran between 2014-2018, was a clinical-research hybrid project because of its dual research and clinical aims (Dheensa et al, 2018) to incentivise the transformation of UK clinical care so that genome sequencing became routine diagnostic practice within the NHS; and to provide genomic and affiliated health data for scientific discovery and future patient benefit. These aims sat alongside an economic goal to drive the development of a UK genomics industry and to bring opportunities to foster the development of new market niches, for example, genomic diagnostic toolkits, particularly in the commercial biotechnology industry.

100kGP, like so many other genomics-based personalised medicine initiatives, was premised on the decreasing cost and accelerating pace of genomic sequencing which paved the way to accruing massive genomic datasets for research and analysis. The availability of 'big data' in

genomics was key to realising the benefit that 100kGP would bring to society. In fact, the 100,000 genomes data and affiliated collected health information is considered by GEL to be where the worth of the project lies, and the medium through which 100kGP's value will be realised. So important is this dataset, that GEL described it in the UK 2018 Science and Technology committee report, *Genomics and Gene Editing in the NHS*, as the "significant concentration of 100kGP's value" and the "best data resource for genomic medicine in the world".[2]

Starting from its core resource - the genomic data and affiliated health information - 100kGP was promoted to patients and the public as delivering speculative data-driven value in a number of ways. First, 100kGP was sold as a project which, through the collection of genomes and affiliated health data, would bring health and economic benefit to UK patients and citizens. Health benefit was constructed as being delivered both now (in terms of a possible clinical diagnosis), and in the future (in terms of benefits from the research endeavour) (Samuel & Farsides, 2017). The expectation that such health benefits would be realised was delivered to the UK public as a certainty: For example, during the launch of 100kGP it was claimed by the UK Government that the project "will transform how diseases are diagnosed and treated"[3]. In addition, GEL states explicitly on its website that "we can be certain of benefits such as new medicines and diagnostic tests"[4]*;* and associated news articles reporting on the project have basked in the excitement of the "bold" and "mammoth" initiative, which continues on the back of human genome sequencing – "one of the greatest feats in medicine"[5].

In terms of economic benefits, these were portrayed on GEL's website in optimistic storytelling by drawing an analogy between 100kGP to the introduction of the railways in the

Victorian era. GEL painted a picture of "unexpected economic benefits" and "undiscovered technologies" which could potentially emerge from the genomic data and affiliated health information, just as the Victorian railways triggered an unexpected economic boom in holiday resorts, postcards and travel guides[6]. Such future-orientated visions and promises of health and wealth describe a collectively imagined vision of an attainable future which allows the realisation of the "Genomic Dream" (Davies, 2017, p. 161), implicitly prescribing a genomic future that is morally good, of value to society, and ought to be attained (Jasanoff and Kim, 2009). In other words, this promotion of speculative value, via promissory discourses, left little space for explicit discussions about what the value of the genomic project *is*. Moreover, because promissory discourses are performative, being mobilised in the present to obtain further investment (Brown and Michael, 2003), promissory discourses generated data-accumulation, which acted as a valuable asset in the present to be mobilised for research or rented out to other researchers' - data became a revenue-generating and tradable resource (Birch, 2013) that created economic value in the present. Economic value in the present was further secured through specific access schemes for commercial partners, for example, the Genetics Expert Network for Enterprises (GENE)), which ensured that the data produced by GEL aligned with industry needs (see Minari et al 2018).

Promissory discourses associated with 100kGP were reinforced through narratives of altruism, trust and ethics. First, as has been seen in other publicly-funded health research projects (Tutton & Prainsack, 2011), GEL called upon the vested interests of potential participants for better health - both for themselves and for society - through the use of rhetoric, which rallied them to this common cause (Woods, 2016).[7] Woods and others argue that this rhetoric emphasised the need for citizens to endorse and potentially participate in the project (Sterckx, 2018; Woods, 2016), creating social reciprocity and imagined community

through the data, and establishing social ties and communities of indebtedness between fellow citizens (Titmuss, 1997; Waldby, 2002). This was also achieved through a sense of promoting national imaginaries and identities in terms of participating in a UK genomic endeavour (Felt, 2015). Beyond rhetoric, GEL's governance framework resonated with notions of altruism e.g. in its broad approach to consent whereby participants needed to agree to their data being used for a range of possibly unspecified research projects maximising the chance of societal benefit. Studies have argued that seeking consent for individual studies could slow down research, which could otherwise ultimately have social value (Sterckx, 2018; Woods, 2016).

Second, data-driven promises were further legitimised by GEL's alignment with the NHS - GEL capitalised on the public's trust in the NHS, to gain trust in the project. Such narratives of trust developed because of 100kGP's delivery through the NHS – patients were first introduced to the project through their NHS clinician, and an NHS member of staff walked patients through the consent process and took their blood/tumour sample. However, alignment with the NHS was more than this: the brand *Genomics England*, as well as the 100kGP, were actively and knowingly promoted as closely affiliated with the institution because of the realisation that this would add trust, and ultimately social value to the project (Samuel & Farsides, 2017). In this way, the interests of GEL and their stakeholders were brought into practice through social values and well-established platforms provided by the trustworthy NHS system.

Third, GEL promoted their data-driven activities as being 'ethical, valuable, and serv[ing] a public good' (Gardner, 2017). This is a well-acknowledged approach for many biomedical research institutions seeking reassurance and acceptance from the public (Wienroth, 2019;

Hoeyer, 2012) and is discussed extensively elsewhere (see e.g. Samuel & Farsides, 2018). Promoting such a model of ethics and data governance reinforced the project's socially legitimate ethical value (Petersen, 2005; Jasanoff, 2005; Hoeyer, 2012; Samuel & Farsides, 2018).

In sum, the discourse of 100kGP constructs a promise that the data will be implicitly valuable in providing health and wealth benefit. These promises are reinforced through discourses of altruism, trust and ethics. These promises act performatively to render genomic data and its affiliated health information economically valuable in the present. We argue that constructing value in this way is limited to seeing value only in terms of the value data can produce. Questions of value, however, should be more far-reaching. In the context of genomics, and 100kGP in particular, a better way to construct questions of value would be to flip them around: rather than asking what value can come from data (data-driven value), what we should be asking is what we find valuable in society, and how we can get there. If health is a key goal, using and analysing genomic data (could) provide one approach to delivering better health for some patients, but there are many other ways that better health can be realised, including low- or high-cost innovations and interventions which address a whole range of social and medical determinants of health. The less lucrative key goals of care and support for well-being may also be deemed as valuable for the lives of genomic medicine patients and the public (Warren and Addison 2020). While investment in genomics remains underpinned by a politic-economic commitment that prioritises investment in technologies with market potential, health policymakers risk missing opportunities to consider questions of health and care that, while not associated with new market opportunities, may be deemed more valuable to patients.

Valuing AI in Clinical Practice

Attempts to routinise AI-enabled health in clinical practice provide a cautionary example of the misunderstandings and disappointments that are likely to setback realisation of what is likely to make AI valuable for society. As AI-enabled healthcare focuses on machine learning algorithms, we use the lens of machine learning-based clinical prediction models (CPMs) to illustrate how sidelining (or ignoring) processes of speculative value construction deters realisation of what value in biomedicine *ought to be*.

CPMs aim to link and analyse vast amounts of patient data, medical records, scans, tests etc for delivering disease-specific diagnostic or prognostic predictions for individuals but have historically low clinical adoption rates (Shah *et al*, 2018; Wessler *et al*, 2018). For many, low-adoption rates suggest 'implementation' challenges of routinising research into clinical practice (Zheng *et al*, 2005; see 'implementation science' in Bauer *et al*, 2015). Undeniably, implementation issues play a role in weakening CPM adoption, but the ways in which the AI-component's value is perceived among clinical staff exacerbate implementation struggles.

Consider e.g. the recent market withdrawal of Johnson & Johnson's (J&J) automated anaesthesiologist Sedasys (a type of CPM) for administering the anaesthesia drug Propofol to patients undergoing surgical procedures. At launch, the construction of Sedasys' value for health (care) systems (by its developer J&J's (2013)) was highly technical, centered on its AI-enabled advanced technical ability to "empower health care facilities to more effectively use their limited resources to deliver greater value in the increasingly resource-constrained U.S. health care environment." Yet, this technocratic articulation of the value of Sedasys was not inaccurate as Sedasys was proven to deliver anaesthesia at a tenth of current costs (Rockoff, 2016). Yet, within three years of its launch, Sedasys was withdrawn from the

market after strong 'resistance from doctors and nurses' amid widespread fears of job loss from AI-based automation (Simonite, 2016; Rockoff, 2016). In the language of this paper, Sedasys' market withdrawal would suggest that it was not found to be valuable by society despite J&J's high valuation of its technological offering and cost savings for health systems.

A key reason for this, we suggest, was that what CPMs value *ought to be* could not be fully realised without the iterative processes of social interaction that makes a technology (here Sedasys in particular and CPMs in general) valuable and embeds it within society. *Social interaction* here refers to the interaction between technology and the social norms and values that makes a biomedical artefact valuable to various end-users and society.

For end-users such as clinicians and clinical staff, the value of CPM adoption in clinical practice was inseparable from their "personal or professional reasons [values] to resist or reject [CPMs] …[based on] concerns about threats to their scope of practice or to the safety and welfare of the patient—and even, in some cases, about a fear of job loss" (Greenhalgh *et al*, 2017, p. 13). Despite this, a reflexive consideration by J&J of these personal and professional values (valuable to Sedasys' end-users) were missing at the time of Sedasys' launch e.g. as reflected in a statement by a J&J executive "...[that having Sedasys means] there doesn't need to be an anaesthesiologist participating anymore" (Frankel, 2015). On the face of it, this statement suggests a technocratic value construction by a global giant (J&J) with little consideration for non-technical issues and tensions. Yet, a closer look suggests a pervasive supply-side affinity for technocratic value construction that largely misses the social, economic and moral imperatives that makes a technology valuable to end-users (Datta Burton et al, 2021) or the implications when otherwise dominant technocratic rationalities inadvertently conflict with end-users who represent a relatively powerful set of actors

(clinicians and clinical staff) (Ulucanlar *et al*, 2013). This affinity is particularly evident in the early years of CPM (and AI) development when technocratic fixes such as 'better training' of clinicians and clinical staff were overwhelmingly recommended by scientific expertise for improving CPM adoption (e.g. Mann *et al*, 2011). However, this approach has since been challenged by recent evidence showing that approaching the problem of low CPM adoption rates as a training issue not only erroneously assumes clinicians' aversion to computerised decision support (Liberati *et al*, 2017) but also obscures the underlying non-technical socioeconomic, moral, professional and epistemological dimensions at the heart of the issue (Allegaert *et al*, 2012).

Yet, these non-technical dimensions matter especially when they are entangled with and contingent on personal concerns such as job loss from automation (Prainsack & Buyx, 2018; Rockoff, 2016). Moreover, as the rejection of Sedasys showed, these personal concerns not only trump professional appreciation of technical benefits offered by AI-enabled health and CPMs, but also reinforce implementation challenges around technical concerns (Liao and Mark, 2003). For instance, technical concerns around the lack of a clear perception of risk (to patient safety and efficacy) when using CPMs in clinical decision-making (as evidenced and reinforced by the widely acknowledged issues[8] of machine learning itself) became a key 'concern' used by the clinical staff to reject Sedasys. Sedasys' clinical stakeholders (the American Anathesiologist's Association (AAA)) - a relatively powerful set of actors - lobbied the US government for years to prevent its FDA approval and after approval urged its 50,000 members to record adverse safety issues possibly to build a case for revoking the approval (ibid). This, despite the fact that Sedasys' clinical trial recorded no adverse events in 1700 patients initially tested and promised cost savings, suggests the salience of non-technical personal, moral, economic and social issues that makes a biomedical artefact

valuable. At the same time, it also suggests the salience of understanding the nuanced (non-technical) underpinnings of the different, and potentially competing, array of stakeholders' (e)valuations of an emerging technology (Ulucanlar *et al*, 2013).

This salience is highlighted by recent industry-wide acknowledgement (among AI-enabled health (care) developers) for the need of socially reflexive, responsible and responsive AI development focused on *augmenting instead of replacing* human-led decision-making. In an op-ed contribution to the *New York Times* in 2018, Fei-Fei Li, Chief Scientist of Google AI, legitimised the salience of personal concerns over job loss by acknowledging that,

> ...no amount of ingenuity, however, will fully eliminate the threat of job displacement. Addressing this concern is the third goal of human-centered AI: ensuring that the development of this technology is guided, at each step, by concern for its effect on humans ...[as] machines don't have to be our competitors, but partners in securing our well-being (Li, 2018).

Such acknowledgements legitimises personal concerns of clinical staff around job loss (see e.g. Davenport and Glover, 2018 in NEJM) and are undeniably a step in the right direction, but are yet to improve CPM adoption rates. A key reason for this lack of improvement is thought to be public scepticism around corporate 'statements of concern' for non-technical and social issues typically perceived as "hypocritical" reputation management unsubstantiated by meaningful action (Cherry, 2013; Arli *et al*, 2019). Indeed, general public scepticism of corporate social responsibility (CSR) plans reinforced by increasing public distrust of tech-giants such as Google[9] or Facebook[10] fed by a continuous drip of adverse revelations around transparency and trust issues[9,10] tarnishes trust in tech-firms developing

AI-enabled healthcare as well. While critical scholarship urging clinical staff to become "critical user[s] of these [CPM] models", and "[applying] the same rules of evidence and scepticism ...as for all health care interventions" bolster healthy scepticism (Harris, 2019).

Yet, these non-technical issues of trust and transparency taken together with the more personal moral, economic and social dimensions of CPM usership suggest a complexity of value construction processes well beyond the technology-centric fixes proposed by implementation science to improve CPM adoption. This is unsurprising for these non-technical dimensions remain at the heart of the iterative processes of social interaction (between technology and society) that speculative value must traverse to become socially embedded, create public as well as personal value and eventually crystallise into formalised systems of valuation. Technocratic ways of valuation that tend to leave out or sideline these non-technical issues and tensions or underestimate the salience of social interactions and is likely to setback socioeconomic and political processes that make things and processes *valuable*. As the next section will illustrate, these processes of social interaction remain ever relevant in health value construction, dynamically shaping even the more formalised valuation spheres of HTA, vaccines and value-based health outcomes.

Rethinking established spheres of value

Valuing New Antivirals

In 2013, new direct-acting antiviral (DAA) medicines to treat hepatitis C – sofosbuvir, simeprevir and daclatasvir – entered the market. They are considered medical breakthroughs because they offer a cure from a chronically debilitating, and eventually life-threatening,

disease that infects the liver and can result in liver cirrhosis, liver cancer and/or necessitate liver transplants. These medicines are the first treatments that attack the hepatitis C virus directly resulting in a sustained virological response (SVR), a clinical outcome used to measure if the virus is still detectable in the blood after certain points during the course of treatment.

In addition to the new mode of action, there are several other characteristics that have led the medical community to label these medicines as innovative breakthroughs. First, they are effective in the majority of hepatitis C virus types, so-called genotypes, thereby significantly lowering the need for type-specific diagnostics and treatment. Second, in some cases, they can reduce the treatment length from 48 to 12 weeks. Third, they are associated with significantly fewer side effects than previous treatment regimes which were both harder to endure for patients and had less prospects of being successful, leading to low rates of treatment adherence. Finally, they are administered as pills rather than injections thus reducing the need for clinic visits and related costs (Kieslich et al, 2016).

Yet, Sofosbuvir's high cost at introduction confounded health care payers. For example, in the United States the estimated price for a 12-week treatment was US$84,000, leading it to be labelled the '1,000-dollar' pill (McCarthy, 2015). In England the estimated price was £35,300, leading to additional costs of £700m to the National Health System (NHS), depending on the volume of patients expected to be treated. Despite their apparent clinical value, state and private health care payers alike were overwhelmed by the cost implications of reimbursing these new medicines. The problem was that the price attached to a cure, arguably the highest form of value in health care, did not seem to match up with available budgetary resources. So how do health system actors normally decide what makes new treatments *valuable*, let alone valuable enough for their price?

The way in which health care systems decide whether to reimburse a new drug differs from country to country. Many countries have set up so-called health technology assessment (HTA) agencies to evaluate the effectiveness, benefits, risks and costs of new treatments. Based on appraisals of clinical evidence and health economic analyses, these agencies provide reimbursement recommendations for state or private insurance payers. HTAs are very technical in that they rely on health economic methods to evaluate the long-term benefits, side effects, opportunity costs and cost effectiveness of treatments. The underlying assumption of many health economic models is that a patient will be taking a given medicine, or benefit from a given procedure, over the course of his/her lifetime. In other words, the length of time (eg. lifespan) and the quality of life gained by treating a patient with a particular drug are important considerations in health economic evaluations, which partially explains why curative drugs such as the DAAs for hepatitis C can be challenging to appraise under current HTA metrics because the point at which one can collect data on the effect of the drug ends with patients being cured. In the case of the DAAs, however, this was not a challenge; HTA organisations such as the National Institute for Health and Care Excellence (NICE) in England found them to be highly cost effective, and determined their cost effectiveness ratio measured against quality-adjusted life years (QALY) gained was well below NICE's threshold of £30,000 per QALY.

Ultimately, health systems found ways to provide access to the DAAs, albeit by restricting access to certain patient groups in some cases. NHS England (NHSE), the commissioner of most health services in the NHS, restricted access to the sickest patients, i.e. the ones already showing signs of advanced liver disease. A similar route was taken by several health care payers in the US, whereas other countries, especially in the global South, negotiated lower prices with pharmaceutical manufacturers. While these approaches offer one solution to high prices, they also raise difficult ethical questions: Can it be ethically justified to treat only the

sickest patients even though treating all patients could prevent many from advancing to more serious stages of the disease? If pharmaceutical manufacturers are able to provide medicines at a lower cost in some countries, why not provide them at a lower cost in most countries? A detailed analysis of these questions is beyond the scope of this paper, however, the questions point to the complexity of deciding what makes new treatments valuable.

The case of new hepatitis C medicines suggests different notions of value need to be balanced against each other when making reimbursement decisions. It is not just 'value for money', the idea that the clinical benefits of an intervention need to be proportionate to its costs, that plays a role in making reimbursement decisions. For patients and doctors, the significance of the prospect of a cure cannot be overstated. Moreover, the fact that the DAAs are administered orally rather than through injections was valued highly by patients and clinicians alike, something that is not adequately captured in current HTA metrics. Even if we agreed, however, that the highest form of value in health care is to be cured of a disease, then governments and health care payers still have to balance the value of one set of medicines against another to adhere to distributive and equity principles in a welfare state. Of course, one could argue that the dilemma of high drug prices could be resolved if the pharmaceutical manufacturers lowered their prices. In this instance, however, this argument is too simple. Even at the high prices at initial market entry, which have since then been lowered in most countries, the drugs 'passed' cost effectiveness and other thresholds to demonstrate value; under current HTA frameworks, pharmaceutical manufacturers cannot necessarily be faulted for setting the prices they did. Sadly, what became apparent was that in drug development we have become so used to incremental advances that the prospect of curing a disease brought unexpected challenges.

The crux of the problem in cases such as the DAAs for hepatitis C seems to be that the current way of measuring and demonstrating value based on HTAs does not draw meaningful distinctions between clinical value or benefit, value for patients, value for money and affordability (Charlton et al., 2017). Formalised and institutionalised methods such as HTAs allow the assessment of value on the basis of pre-defined criteria, but these criteria may not be meaningful or helpful for the policy-makers and decision-makers who have to decide how to spend a given pot of money.

The policy debates that followed the introduction of hepatitis C medicines underline that medicine assessments are never just technical judgements (Clark and Weale, 2012). Faced with the question of whether health systems could afford to pay for the high-priced drugs, judgements had to be made outside of the technical world of HTA. This shows that technical decision-making is not likely to replace the need for political decision-making that involves value judgements (Landwehr, 2009). Value only becomes meaningful in relation to something (Lee, 2006), and this 'something' depends on the context. What is valuable through the lens of HTA metrics is not by default seen as valuable or 'doable' by other stakeholders. Whilst the cost effectiveness of DAAs could not be denied, their price became meaningful when decision-makers realised that significant shares of health care budgets would be needed to reimburse them. This led to situations in which the value of a cure competed with existing commitments. This is common in public policy where ideas and commitments are in constant competition. The struggle over the value of new drugs, however, is exacerbated by concerns that the majority of new drugs, especially new cancer drugs, are reimbursed despite only demonstrating marginal benefits (Wieseler *et al*, 2019), which means the justification for restricting access to medicines such as DAAs is not straightforward.

Valuing Vaccines

The above case studies have broadly explored the questions that arise as we try to ascertain the value of new technologies when considering their implementation into the health system. In contrast, the value of vaccination to all stakeholders, including government officials, clinicians, and the public at large has typically been presumed as given by policymakers. Yet the recent decline of vaccine uptake in high and middle-income countries (Larson *et al*, 2016) indicates that even this 'established' value remains open to contestation. The purpose of this case is to open up the very notion of value with regard to vaccination, and to show how different value positions frame value in a specific way. First, we discuss the assemblage and use of national vaccination rates as a specific political framing of value; second, similar to the Hepatitis C treatment discussed above, we point to the economic mode of valuation in the form of the HTA of new vaccines. We argue that both modes of vaccine valuation are reductionist and tend to conceal different value perspectives.

First, vaccination policy typically revolves around numerical values expressed in indicators and targets. These tropes clearly mark health policy at the level of states, at the level of supranational (EU) and global (WHO) authorities, as well as other transnational global health actors (see Adams, 2016; Reubi, 2018). Public health actors typically measure the value of vaccination in the form vaccination rates - the percentage of the eligible population that has received a particular vaccine. Yet these measurements are not only imprecise (Edelstein, 2017), but can be tinkered with for political purposes: by modifying criteria eligibility, vaccination rates can appear higher, for example, if migration data is not aligned with vaccination data, then the eligible population may *de facto* have decreased. This is particularly pertinent for intergovernmental settings in which vaccination rates become political performance indicators: as stipulated in the International Health Regulation (IHR)

of the WHO, member states report their vaccination rates to the WHO on an annual basis. When the (measurement of) value of vaccination is thus reduced to vaccination rates, this can have important implications for the allocation of political and financial resources. As Adams (2016, p. 9) notes, such "metrical forms of accountability" can effect policy action and bring about health, but they also confer political allegiance and secure funding. What the specific metric of coverage rates leaves out, however, is detailed and local knowledge on just distribution and access to vaccines, and the impact of socio-economic inequalities on vaccine uptake (Tur-Sinai *et al*, 2019). Moreover, such metrics can reveal little about the societal, ethical and personal value dimensions, as these tend to escape quantification and thus remain un(ac)counted for. This reflects a more general tension between modes of valuing in public health, where interventions are valued at population level outcomes, in contrast to clinical assessments of value for individual patients, as described in Lowy (2015) and Morrison (2019)

Second, in health economics and the specific discipline of HTA, there appears to be increasing recognition that, first, the value of a given technology is assessed and perceived in different ways across cultures (Henshall and Schuller, 2013), and second, that conventional modes of health economic conceptions define value too narrowly by valuing vaccine benefits based on a small subset of benefits, primarily on averted healthcare spending (Bärnighausen *et al*, 2014) and ensuring workforce productivity. In response to this rethinking, some commentators have tried to grasp the social value of vaccination more broadly, going beyond the principle of cost effectiveness (Luyten and Beutels, 2016), which has predominantly shaped decision-making on vaccines in public health programs. In a similar move towards a broader perspective on value, HTA experts have called for streamlining definitions of value-based decision-making by drawing on different value perspectives – that of health systems,

patients, the wider public, and industry. The recognition that value assessments "cannot be replaced by mathematical approaches" (Henshall and Schuller, 2013, p. 353) is instructive, yet most work in this discipline remains wedded to a utilitarian notion of value even when including "wider societal benefits" and community health and economic externalities, such as reduced antibiotic intake or making a given region more attractive for tourism and foreign direct investment.

Such an economic mode of valuing becomes evident in the discussion of the sustainable development goals (SDGs), for example. While equality of access ("leaving no one behind") has been a driving norm at the level of the WHO, and the SDGs strongly draw on this language, these ethical norms are inseparably linked with economic notions of value: the Global Alliance for Vaccines (GAVI) frames vaccination as "one of the best buys in global health" for achieving the SDGs (GAVI, 2018, p. 1), and in GAVI's approach to the SGDs, promoting immunization becomes linked to a diverse set of values, from equality to innovation (such as in the fast-tracked Ebola vaccine), to a more productive workforce (based on improved health), and more effectively mitigating climate change by way of making people more resilient. The focus on innovation here is interesting and somewhat reminiscent of the importance of the promissory value articulated in our first case (100k genomes): HTA scholars seem to be concerned that the future value ("promise of technology") is difficult to gauge which may lead to an undervaluation of new vaccines and thus a delay in their introduction in national immunization programs.

The two specific modes of valuing discussed in this case study are shaped by different, but also overlapping sets of social norms and values. Yet the transnational, all-encompassing theory of value we see in GAVI's discourse offers little towards such a societal grounding

and instead injects a strong economic notion of valuing in this policy area - even if we see the very notion of value being expanded in HTA. It also offers little instruction as to how context matters to valuation. From a health systems perspective, HTA is useful, but mainstream methodologies foreground *countable expressions of value,* and leave broader ethical, social, and political notions of value implicit and unexplored. While these forms of value are quantified in proxy values (e.g. in the notion that life years gained are of societal and shared ethical value), they clearly deserve more empirical, and qualitative attention in an era where vaccination practices have become a platform for politics. This would also elucidate the different perspectives on value, and different forms and repertoires of valuation (Sharon, 2018; Boltanski and Thevenot, 2006 [1991]). The growing importance of vaccine hesitancy (Dubé *et al*, 2013) shows that the value of vaccination cannot be presumed to be shared – and that these different value positions may simply be incommensurable. Examining value practices empirically, as we do in this paper, may then form part of what we may call a "policy valuography" (Paul, 2019). In turn, such an approach would help create a level playing field where social agents are able to discuss and make explicit their different, but also shared value positions.

Valuing Health Outcomes

Our final case study moves towards the question of how value is operationalised at the level of hospital care. Specifically, it opens up questions of how value is measured for the purpose of paying hospitals for services provided to patients (i.e. "pricing" their services). Within the larger shift towards value-based healthcare – namely the idea that healthcare providers should be paid for specific outcomes that they achieve, rather than for the volume of interventions they perform, this sub-field of value-based pricing seeks to change financial

incentives in favour of value v. volume. Value-based pricing includes assessments, which consider value for patients (often measured via patient outcomes), as well as other results (Porter and Teisberg, 2006).[11]

The idea of value-based pricing can also drive the purchasing rules for hospitals. The example that we are looking at here in more detail is the Hospital Value-Based Purchasing (VBP) Programme of U.S. Medicare[12]. The VBP, however, which was introduced as part of the Affordable Care Act 2010 (Section 3001a), does not pay hospitals *purely* on the basis of outcomes. It retains a small percentage of the funds that hospitals would normally be paid and distribute the money according to how well specific hospitals do in terms of (a) performance achievement and (b) performance improvement. Performance achievement refers to the absolute level of their performance, whereas performance improvement measures the relative positive change of performance over a time period (see below). A hospital that does particularly well in these two categories receives a larger share of the retained funds than a hospital that did less well in terms of performance and improvement, even if both provided the same volume and type of interventions.

VBP is one element of a much larger programme within the Centers for Medicare & Medicaid Services (CMS) - the part of the U.S. Department of Health and Human Services that oversees Medicare and Medicaid - and the Affordable Care Act more broadly, to shift reimbursement from *volume* (number and kind of interventions) to *value* (e.g. Berger, 2011). Unlike other value-centred programmes,[13] the hospital VBP is mandatory for all acute care, general medical and surgical hospitals in the country (see also Dupree *et al*, 2014).

The Hospital VBP Programme defines value as patient outcomes by dollar spent. It seeks to do this by achieving five main goals: eliminating or reducing adverse events (through errors or other reasons), adopting evidence-based care standards and protocols that have been proven to improve outcomes, changing hospital processes to improve care experience, increasing care transparency for consumers, and rewarding hospitals that provide high-quality care at a lower cost to Medicare (CMS, 2018). This happens in the following way: VBP first withholds Medicare payments to participating hospitals by a certain percentage,[14] and then distributes funds according to indicators of quality of performance.[15] Each participating hospital receives up to two scores on each performance measure, one for achievement and one for improvement of performance. Whatever score of the two is higher gets on the hospital's score sheet. In an additional step, the score is adjusted to how well that hospital's performance compares to all other hospitals that participate in the programme, and how much their performance has improved. The so-called total performance score determines a value-based incentive payment adjustment factor for each eligible hospital.

Several studies have assessed the effect of VBP on various aspects of performance. Some of the limitations of the VBP programme identified by this work include reporting time delay, meaning that improvements are only captured about two years after they are made, by which time performance measures may have changed. Another issue is the size of the payment incentive, which diverts attention of hospitals towards other programmes within CMS with higher financial rewards, and clinical indicator overlap (Ramirez *et al,* 2016). Moreover, the focus on clinical outcomes captured in VBP have been argued to incentivise hospitals to neglect other, unmeasured outcomes (ibid). For example, in a study comparing how well hospitals with different business plans fare within VBP, Ramirez *et al*, (2016) found that measures within VBP tend to lean towards patient satisfaction (which is arguably a very thin

understanding of value). A 2014 study found no correlation between hospitals' total performance score and reduction of Hospital Acquired Conditions, which is seen arguably a very important aspect of a hospital's performance. Their finding brought these authors to call for incentive programmes that *directly* correspond to improvements in care, rather than measuring the quality of performance of services (Spaulding *et al*, 2014). Another study (Dupree *et al*, 2014: 5) found that "public hospitals are at the greatest risk for poor performance on the surgical measures" compared to private hospitals, which the authors hypothesise to be strongly related to resource availability.[16] If this finding were a more general trend, then performance-related payment models such as VBP would exacerbate the divide between public and private hospitals. Although it is not yet clear whether or not there is such a wider trend, Dupree and colleagues' findings seem to corroborate those of other studies on the impact of "Pay for Performance" (P4P) programmes more broadly, which have been in place in many different forms and contexts in the U.S. and whose effects on quality and value have remained "frustratingly elusive" (Ryan and Damberg, 2013, p 42) (see also Rosenthal and Dudley, 2007; van Herck *et al*, 2010).

From our perspective, the VBP illustrates Pressman and Wildavsky's (1973) statement that the more complex a policy measure, the more problems it creates in its implementation. The administrative burden of VBP seems to be considerable, and the steering effect has not been shown to be very significant. Moreover, the finding that VBP rewards hospitals that are already better resourced than others indicate the presence of a Matthew effect that, given increasing health disparities in the United States, are particularly problematic. Most importantly, VBP seems to suffer from the lack of attention to systemic justice and equity considerations - an aspect that EXPH (2019, p. 5) have criticised as a shortcoming of contemporary understandings of value-based healthcare more broadly:

> Currently, ‘value’ in the context of healthcare is often discussed as ‘health outcomes relative to monetized inputs’, aiming at increasing cost-effectiveness. This interpretation of ‘value’ is perceived by the EXPH as too narrow and the notion of ‘valueS-based healthcare’ seems more suitable in conveying the guiding principle underlying solidarity-based healthcare systems.

We echo this suggestion. If VBP in the hospital sector – and in fact, value-based healthcare more broadly, is to reduce waste, reducing harm, and increasing equity, instead of being just another metric to be gamed by an increasingly profit-driven hospital sector, then it is necessary to systematically explore the meaning of value for key actors within the institutions whose practice is meant to be changed by the incentive (Ulucanlar et al, 2013). What does it mean to a hospital manager, a nurse, a resident, a patient, a family member, to provide or receive high-value care? And how can value in their understanding be enhanced within hospital care? What financial instruments, metrics, practices, and organisational changes need to be (developed and) adopted to support such value?

Discussion: from valuation to valuing

The five case studies sought to illuminate processes of value construction in biomedicine and healthcare across different levels of speculative and established health spheres - interventions, implementation, care, prevention, systems. We explored how, across different contexts and value systems, different meanings of value are presumed by the ways value is mobilised, measured and assessed. Taking value as given we argued, conceal different value repertoires (Sharon, 2018; Dussauge *et al*, 2015), and specifically, the social practices,

institutions and infrastructures through which health values are constructed and operationalised; whether top-down or bottom up.

A key finding, across speculative and established value spheres, was the context-dependency embedded in the social practices of valuing, shaped by various social and ethical norms and stakeholder (policymakers, practitioners patients and publics) subjectivities. For instance, while personal concerns over job loss among clinicians and clinical staff defined the struggle to routinise AI in clinical practice, national interest defined the struggle over genomic data (to develop a thriving UK genomics industry via the GEL-100kGP). Likewise, imperatives of health services provisioning agencies, especially affinities for quantified measures of value defined the struggle over reimbursing new DAAs, socialising vaccines and delivering performance-based reforms of hospital purchasing.

Given this heterogeneity in value construction, a key finding was that existing one-size-fits-all-stakeholders approaches in institutionalised value systems (such as current HTA methods, vaccination coverage or emerging VBP strategies) struggle to reconcile existing value conceptions with what is considered valuable by actors and stakeholders. Albeit not surprising to those who have studied, or worked within, the healthcare sector, this has profound implications. A key cause of this struggle was a preference (or rather, dependence) for easily quantifiable and monetised inputs in value construction processes. This, in turn, tended to sideline non- or poorly-quantifiable variables that structurally disadvantaged some stakeholders over others and at times rendered them and their needs systemically invisible. Moreover, these structural invisibilities led the disaffected (i.e. those rendered structurally invisible) to seek visibility in localised contexts through public resistance against the state for perceived injustices (e.g. in VBP, AI and vaccination). We argue that if these blind spots in institutionalised practices and metrics of valuation are not addressed, then attempts to

measure and enhance health value are likely to perpetuate existing inequalities and possibly also create new ones.

In turn, processes of speculative value construction (cases of AI and genomics studied here) as precursors of the more formalised spheres of value construction, show how the advantaging of some stakeholders over others in discourses related to value construction sets the stage for the embedding of structural biases in value construction processes as they become formalised over time. Specifically, the overwhelming representation of mostly supply-side stakeholder (policymakers and technology developers) perspectives in overly optimistic promissory discourse, at the expense of representing diverse multi-stakeholder value perspectives, discursively advantaged some instead of others. This discursive advantaging exacerbated rather than revealed, acknowledged and remedied structural biases.

Conclusion

Our aim was to illuminate the socioeconomic and political processes that make biomedicine and healthcare *valuable* (or not) as the first step towards what socially reflexive and responsible valuing of biomedicine and healthcare *ought to be*. What emerged across the first four cases of speculative and established value construction was a need for reflexive context specificity and stakeholder inclusivity as the basis for a more responsible approach to what value *ought to be*. On the face of it, the VBP case challenges this approach; showing that context-specific and inclusive policies may also be counterproductive. Yet, a closer look suggests that context-specific policies administered within existing narrow 'value-for-money-based' value systems, as the VBP case concludes, is the likely culprit for VBP's underwhelming success. This suggests that what is needed is a value framework (of 'what value ought to be') that is broad enough to provide the flexibilities required for reflexive and context-specific approaches to shape future biomedicine and healthcare. Moreover, rather

than seeking to squeeze the breath and multivalence of different forms and practices of valuation into uniform metrics, it may be more fruitful to operate with different repertoires of valuation that is made commensurable by human interpretation and deliberation, than computed by machines.

Endnotes

[1] See other definitions of value in Dussauge *et al*, 2015; Birch, 2017.

[2]https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/349/34908.htm#footnote-067

[3]https://www.england.nhs.uk/2014/08/nhs-world-leader/

[4]https://www.genomicsengland.co.uk/about-genomics-england/the-100000-genomes-project/

[5]https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)62453-3/fulltext?showall=true%3D

[6]https://www.genomicsengland.co.uk/about-genomics-england/the-100000-genomes-project/

[7]Woods provides an example of such rhetoric, which appeared on GEL's website: "Genomics England, with the consent of participants and the support of the public, is creating a lasting legacy for patients, the NHS and the UK economy, through the sequencing of 100,000 genomes" (Woods, 2016, p. 177, 229)

[8]Such as model transparency (how an algorithm is constructed), data bias (which data is used or not and how algorithms might change if used), data anonymisation (privacy concerns), calibration (fitting statistical prediction to the risk threshold where patient requires treatment) reduce clear clinical risk perceptions (see e.g. Datta Burton et al, 2021; Shah *et al*, 2018; Wessler *et al*, 2018).

[9]https://www.nature.com/articles/d41586-019-03574-5

[10]https://www.nbcnews.com/business/consumer/trust-facebook-has-dropped-51-percent-cambridge-analytica-scandal-n867011

[11]The full set of principles is that (1) Focus should not only be on lowering costs but also on value for patients; that (2) competitions must be based on results; that (3) competition should revolve around medical conditions and over the full cycle of care; that (4) high-quality care should be less costly; that (5) value must be driven by provider experience, scale, and learning at the medical condition level; (6) competition should be regional and national, not just local; (7) results information to support value-based competition must be widely available; and (8) innovations that increase value must be strongly rewarded (Porter and Teisberg, 2006).

[12]https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing.html

[13]An example for voluntary measures is the establishment of Accountable Care Organizations (ACO).

[14]At the time of its inception, CMS intended for VBP to be budget-neutral for Medicare; "any additional costs associated with quality improvement must be offset by other reduction in cost" (Tompkins *et al*, 2009: w252).

[15]The latter are calculated in, very broadly speaking, the following way: Using selected measures from CMS' Hospital Inpatient Quality Reporting Program, the quality of a hospital's performance on mortality and complications, healthcare-associated infections, patient safety, patient experience, process, and efficiency and cost reduction are assessed.

[16]According to the authors, lower margins of public v. private hospitals mean fewer resources being available to be channeled into quality improvement and maintenance (including teaching, training, tracking and analysing performance, etc.; Dupree *et al*, 2014).

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