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INTRODUCTION
The value of transnational medical research

Ann H. Kelly and P. Wenzel Geissler

Introduction

What is the value of medical research? The question initially provokes an ethical response: the worth of a clinical trial is generally understood in terms of the impact of its outcomes on patient populations. The evaluation of human subjects research raises normative questions of values – the future well-being of society in relation to the risk experimental procedures entail for participants. However, biomedical facts also circulate within national systems of healthcare, global policy organizations, property regimes and pharmaceutical markets. The current dominance of public-private partnerships under the rubric of ‘global health’, the uptake of pro-market strategies by governmental and philanthropic organizations, the bankrolling of the WHO by private individuals, suggest the extent to which the value of both therapeutic products and public health practices have been appropriated by a logic of profit. Clinical trials engage with and generate multiple orders of value; they straddle the world of commodities and public goods, of fiscal costs and moral virtues (Stark 2009).

The papers in this special issue probe the different systems of value that exist between scientific ends, public goods, and lucrative commodities. Taking inspiration from recent ethnographic studies of finance in practice (e.g. Roitman 2005) and economic sociology (e.g. Çalışkan & Callon 2009), they explore how value is variously worked through material, socio-technical relations, institutions, and research practice. To discern the value of research ethnographically, a common starting point of these papers is the work of medical research, including volunteered participation, contracted employment, scientific analysis or ethical oversight. In drawing attention to the modalities of intellectual, practical, and affective labour that drive a clinical trial, this special issue situates the production of medical knowledge with respect to other forms of productive activity. In so doing, we seek to nuance perspectives on the significance of clinical research to the welfare of societies.

What follows is a selective overview of social scientific research that explores the linkages between clinical trials, pharmaceutical markets and global health inequities. We suggest that this scholarship can be roughly characterized by two distinct critical aims. The first concerns the political economy of medical research and the structural conditions under which health becomes a resource for wealth. The value of medical research is analysed through an investigation of medical markets as networks of knowledge production, therapeutic consumption, and capital accumulation. The second interrogates the ethical significance of transnational clinical experimentation. In these studies, value is elaborated as a negotiation between the interests of communities, the protocols of science, the priorities of global health; it indicates access to life saving therapies, the
equitable distribution of research benefits, and the means and terms of engagement afforded by a research project.

Though articulated in different registers, we suggest that both these approaches to value demarcate the ‘social’ from the ‘economic’ dimensions of clinical research. Studies that explore the sociological consequences of the commercialization of medical research and those that seek to strengthen the moral traction of experimental procedures both analyse value as a structuring and systematic logic. We take an alternative track. Concerned with how the material practices of medical research intersect with everyday ways of living, we propose a more promiscuous approach to the question of value, one that is acutely aware of the diverse valuable materials and manifold processes of valuation attendant to medical experimentation. The purpose of drawing upon categories of value theory, such as ‘labour’, ‘production’, and ‘circulation’, is to open up these variables to ethnographic scrutiny (Graeber 2001). Rather than warn against economic incursions into medical knowledge and health practice, or, alternatively, the reduction of local experience to the standards of bioethics, we hope to illuminate the array of practices, knowledges, and techniques through which the value of medical research is brought into being.

Political Economy of Clinical Research

The financial resources and scale of operations of contemporary pharmaceutical research have laid bare the contradictions between the economic and therapeutic value of biomedical production. The multi-billion dollar quest for new pharmaceutical products reveals the strange alchemy whereby marginalized populations in desperate need of healthcare come to sustain the research efforts of an industry dedicated to the needs of affluent populations. For the most part, the social sciences have explored these conflicts by examining the institutional contexts of research, such as regulatory and intellectual property arrangements, and tracing the public health contours of the pharmaceutical industry’s transnational reach. These investigations consider the clinical trial as the dominant mode of medical knowledge production and analyse its value in relation to capitalist system of commodity production.

The rise of the pharmaceutical industry hinges upon the standardization of an evaluative method, the randomized control trial (RCT). The RCT provides a statistical framework to interpret the merits of new drugs against the biases of patients and doctors. As Marks (1997) notes, though the method can be understood as part of a general epistemic shift across the sciences to practices that privilege objectivity and disinterestedness, the particular objectivity of the RCT is defined by the needs of the market place. Clinical trials not only enabled consumers to distinguish between the medicine and snake oil but also, by testing novel products on large group of patients, allowed drugs to be produced on an industrial scale.

The soaring costs of pharmaceutical research and development have amplified the tension between the methodological purposes of the RCT and its pragmatic orientation as a marketing device. Sociological attention to the marketing of pharmaceuticals has revealed the range of industry tactics used to boost sales, such as financing disease awareness campaigns, ghost-writing scientific articles, developing partnerships with leading medical professionals, and even, auditing physicians’ prescription practices (Sismondo 2009). However, these efforts are secondary to the need to persuade regulatory agencies of a drug’s efficacy. That pressure to gain approval has increased the number of
‘safe’ copycat or recycled and retooled drugs (Mirowski & Van Horn 2005). More worrying is the ever more common practice of assuring the efficacy of experimental entities through the selection of homogeneous patient populations, the exclusion of ‘placebo-responders’, statistically massaging data and concealing negative outcomes (Lakoff 2005).

The first conclusion of these studies is that industry-sponsored clinical trials often fail to generate innovative, or indeed necessary, therapies. The second is that, owing to the clandestine nature of privatized science, clinical trials do not necessarily produce valid scientific information. Appropriated by commercial imperatives, the clinical trial is regularly reduced to what Michael Power describes as a ritual verification – a technique to produce public confidence in the absence of empirical content (Power 1994). Their primary purpose is to provide an interface between the industry and practitioners, widening a prescribing base to introduce experimental entities into circulation. In-depth investigations of regulatory decision-making practices have further illuminated the government’s complicity in permitting risky and ineffectual products into the market place (McGoey 2007). The interpenetration of private and public institutions has reconfigured the standards of regulatory science around the commercial interests of the drug manufacturer as opposed to the interests of patients.

The second critical argument is that the global proliferation of pharmaceuticals has reconfigured the economic value of health. As possible consumers of therapies, patients are exploited for their ‘surplus health’; their healthiness provides not the basis for a workforce but rather for pharmaceutical capital (Sunder Rajan 2002). The abstraction of the patient’s well-being into a commodity form is made possible through the exploitation of the experimental subject. Petryna’s (2009) analysis of the outsourcing of clinical trials to contract research organizations (CROs) makes this point clear by showing how situations of health crisis offer opportunities for pharmaceutical companies to circumvent regulatory systems and gain access to research subjects whose lack of education, financial resources or treatment history makes them more likely to produce ‘cleaner results’. The redistribution of biomedical risk tracks other forms of ‘flexible’ industrial production, with its increasing reliance on insecure, casual labour, decentralized governance and the resulting accentuation of North-South inequalities.

These accounts of ‘neoliberal science’ derive from pertinent observations of a capitalist economy, marked by the enclosure of the scientific commons, institutional restructuring and restrictive intellectual property regulations. Ultimately, they:

reveal an emerging ‘values gap’. Its symptoms include the growing division between populations that have access to life-saving drugs and the ability to pay for them, and populations that have neither and must rely on some other form of distribution … human experiences of suffering and its costs of ‘morbidity’ and other indicators configuring social need. (Petryna & Kleinman 2005, p. 6)

Value, in these studies, indexes a scandal – the incommensurability between the calculative logic of profit-maximization and the needs of populations.

Clinical Research Ethics

The second branch of the literature relevant for this special issue elaborates the value of transnational clinical research within an ethical framework. Though, in practice, the backbone of biomedical ethics continues to be informed consent – a rubric that seeks
to insure respect, autonomy, and privacy – it is the social value of research that currently focuses academic debate. In these discussions, value adds specificity the abstract notion of public good. The idiom of value allows ethicists to raise the questions of good for whom, in what form, and critically, at what point; social value speaks to the immediate and concrete benefits associated with the conduct of medical research, such as jobs, training, and health-care services.

Like the sociological work discussed above, the shift in ethical discourse towards a theory of value reflects a concern with changes in the relationship between medical science, industry and public health, and increased attention to vital inequalities within the production of scientific knowledge. The concern here is less directly with the commercialization of science – though the discrepancy between the priorities of industry-sponsored research and global health burden has been widely acknowledged. Rather what is at stake is the gap between experimental outcomes and improvements in health practice, particularly where weak infrastructure prevents research findings from being translated into health practices: between what is possible for those in control of medical research, and what is needed by those who lend their bodies to it.

The Randomized Controlled Clinical Trial (RCT) is a distributive device; the initial justification for the randomization of treatment was to ensure the fair allocation of medicines in short supply. Clinical science and the management of public health are, therefore, intimately connected. The dominance of public private partnerships and the slimming of state-sponsored research, compounded by the collapse of public health institutions and health services, most notably in many eastern European and African nations, have made that connection increasingly tenuous. While big charity and private partnerships often tackle issues of particular relevance for poorer populations, unable to attract enough profit-orientated funding from the pharmaceutical industry, experiments are usually conducted in the absence of significant government incentives, and rarely engender any public health interventions beyond ‘policy advice’.

In settings where healthcare is often a matter of international and non-governmental intervention, a ‘social value’ framework addresses the fragile links between research, policy, and practice. One important way in which value can be ‘added’ is by ensuring benefits are in place after the conclusion of trials, for instance, through the dissemination of results, the provision of continued access to therapies or the building of ‘capacity’. These measures to entangle the experiment in local clinical contexts represent a shift ethical doctrine towards the empirical, and give precedence to social scientific explorations into community perspectives, traditions, and social practices. Recent scholarship on how communities make sense of research (Geissler & Molyneux 2010) and the centrality of ‘trust’ in community-research relations (Gikonyo et al. 2008) has further pressed ethical discussion beyond what might be added to existing projects, to consider the ways in which local participants might shape the research design. In this sense, the generation of social value has been increasingly tied to mechanisms of ‘public consultation’, ‘community partnership’, or ‘collaborator networks’ that attempt to:

- involve partners in sharing responsibilities for determining the importance of health problem, assessing the value of research, planning, conducting, and overseeing research, and integrating research into the health-care system. (Emanuel et al. 2004, p. 931)

The collectivization of experimental subjects and their transformation into empowered publics has emerged as a salient model in western research contexts. Epstein’s (1996) now
classic discussion of the role of HIV activists in shifting regulatory standards illustrates how clinical trials can provide an interface for lay citizens to impact the orientation, management, and evaluation of medical research. A method whose scientific integrity depends on the representative character of the sample, the clinical trial is also a political resource; it offers occasions for new approaches to the production of knowledge and value that rest on the dynamic collaboration of civil society.

Less sanguine accounts regard these efforts to elicit a ‘public voice’ as a way of displacing local politics. Hayden’s (2007) analysis of benefit-sharing agreements offered by bioprospecting firms, for instance, points to how practices of participation strategically fragment publics into those that can legitimate and facilitate the collections of resources and those that cannot. In the cases she describes, value is not distributed to existing social groups, but rather collectives are configured around the interests of the industry. Other scholars have linked the anti-politics of community-engagement to the emergence of stateless forms of citizenship. In contrast to policy initiatives that emphasize the provision of health services, these critiques suggest that the entanglement of clinical research with the development industry has conflated participation in trials with participatory governance and civic life with therapeutic access (e.g. Nguyen 2005).

Informed by long-term ethnographic engagements with developing world contexts, these critiques remain sceptical of the ability of bioethical inquiry to advance the redistribution of value. However, despite the efforts to address differentials in wealth and power, these studies remain grounded in the specific histories of biomedical research and administrative practice, and committed to the democratic possibilities of that relationship. The idiom of social value preserves a domain of clinical research where normative questions of accountability, representation, publics, and of values can be raised.

**Value at Work**

Considered together, these discussions highlight the two dimensions of the value of clinical trials – one defined by the market valuation of medical commodities and the other characterized by population welfare. Though they draw from distinct empirical material, these two lines of critique share the central premise that the normative and sociological questions of medical research should be held distinct from economic analysis. The papers presented at the workshop from which this special issue derives were given with the intention of transcending dichotomies between the economic and the moral by fostering dialogue with health policy, medical researchers, and patient activists and engendering a more honest consideration of the politics, economics, and pragmatics of conducting clinical trials than those provided by bioethics. In situating the value of clinical research ethnographically, that is by examining the material activities and semiotic forms through which it is mediated, the contributors take inspiration from a Marxian theory of value (e.g. Turner 2008), but refrain from grounding clinical research value in a single circuit of production. Rather they pursue what is perhaps best understood as the ‘material politics’ (Law & Mol 2008) of clinical trials – how, in other words, research value is multiply configured in therapeutic, social, and economic landscapes. In following these terrains, contributors materialize value in relationship with, rather than in opposition to, values (Miller 2007).

Catherine M. Will’s analysis of UK research policy describes the strategic distribution of medical research value through the conduct of clinical trials. Over the past decade, the
UK has promoted its National Health Service (NHS) – with its single pool of patients – as an advantageous site for industry-sponsored research. Will interrogates the ‘multiplication of value’ these trials are expected to bring by tracking the formal and informal ways in which patient benefit is constituted. In particular, she attends to the spaces – the curtains cubicles, Victorian windows and impromptu breakfast tables – where experimental protocols and clinical care, individual health and commercial profit ‘come together in more or less awkward juxtapositions’. Will supports these compelling descriptions of the uncanny atmospheres of clinical research with accounts of the everyday work of carrying out trials, reflecting on how the therapeutic relationship is managed through distributions of clinical practice, research protocols, and expressions of hospitality. She suggests that value multiplies in the moments when these elements come together, and experimental subjects are afforded additional care than that provided by a researcher, or arguably, the NHS.

One central observation of Will’s chapter is that appeals to clinical research value cut across different imaginaries of collective and individual benefit. As the UK’s share of pharmaceutical research increases, the boundary between the research and the clinic becomes more convoluted, and the risks and impacts of research harder to trace. In his account of ‘Kurtis Pharmaceuticals’ and ‘Williams Pharmaceuticals’ drug donation programs in West Africa, Ari Samsky extends Will’s concern with the rhetoric of ‘mutual benefit’ to the provision of drugs to control river blindness (onchocerciasis), a now high-profile, ‘Neglected Tropical Disease’. Samsky’s analysis relocates industry practices within a gift economy, juxtaposing the expectations of the medical-scientific architects of the donation programs with the disappointments of the Tanzanian farmers receiving the drug. Like Will, Samsky explores the concrete practices through which research value links corporate boardrooms to rural African villages. Samsky situates the work of drug distribution – obscured by the rhetoric of the gift – within the local labour system. His ethnographic task evokes further questions about the contradictions that underpin Big Pharma’s efforts to demonstrate corporate responsibility. Together, Will and Samsky convey the networks of responsibility that characterize pharmaceutical research and highlight the points at which obligations are cut. Resisting the temptation to read the dominance of Big Pharma in scientific research as reducing the value of knowledge to logic of profit, Will and Samsky demonstrate the interference of different value-producing activities and the hidden costs these entanglements entail.

For P. Wenzel Geissler, it is precisely the invisibility – or rather, unintelligibility – of material exchanges in the context of the experimental activity that is of interest. Geissler analyses what would seem a particularly trivial evidence of clinical research value: small monetary payments, so called ‘transport reimbursements’, made by transnational public health research organizations to research subjects undergoing clinical procedures, providing information or biological specimens, or contributing in other ways to scientific production. From ethnographic work with an HIV trial in western Kenya, Geissler argues that these small reimbursements are generally understood as a transfer of value (rather than zero-sum ‘reimbursement’). Though central to research work, these transactions are obviated by bioethics, which remains focused on the value of individual autonomy and regards exchanges across extreme economic disparity as potentially violent and coercive. This ‘unknowing’ of material value in the everyday conduct of scientific production is at best confusing and possibly politically problematic. But rather than embrace a unitary model of exchange to replace the bioethical insistence on giving, Geissler’s stresses the complex interplay of value these vital transactions entail – reimbursements not only...
provide the means to buy food and survive but are also linked to the experience of belonging and the promise of care. The calculative logic is embedded in the conviviality of trial relations; the ‘gift’, he reminds us, has never been free.

The connection between the individual activities and collective imaginaries of research is an analytical concern Ann H. Kelly shares. Her paper focuses on a malaria control trial in Dar es Salaam and interrogates the scientific, political, and economic significance of the pain-staking work of monitoring the movements of mosquitoes. Kelly’s analysis begins from the collective body of voluntary mosquito collectors and the ways in which that collective is inter-articulated by the protocols of scientific research, the post-socialist politics of Tanzania and the economics of global health. She is particularly drawn to the presence of these workers – fixed points in the inter-circulations of capital, fact, and disease. Kelly contrasts this immobile work to the fluid and sporadic modes of productivity engendered by the experimental project. Her ethnography illustrates how the former anchors the latter, linking scientific research to social progress.

Finally, Melinda Cooper reads the development of the large-scale clinical trial against the organizational logic of Fordist industrial production, a genealogy that reframes the risks entailed by the human subject as consistent with those belonging to the industrial workplace and underwritten by the welfare state. In light of her analysis, informed consent, stripped of any of the broader protections afforded to a worker who might fall and suffer an industrial accident, seems a rather flimsy form of protection for the experimental subject. However, like Geissler, Cooper is not convinced that the labour model offers much in the way of an alternative – the standard wage for unskilled labourers is, in fact, much lower than the compensations received by the average trial subjects, at least in the North. Instead, the connections Cooper draws between the history of the clinical trial and that of labour reforms, reveals the constitutive role of the clinical trial in conceptualizing the public. Cooper argues that the welfare state was subtended by actuarial logic – welfare could only provided once it was capable of calculating the effectives of interventions on the populace. The clinical trial made this calculation possible, by subjecting the few to the accidents of the experiment. As opposed to the uniform national collective imagined by Titmuss (1970), Cooper exposes the forms of marginalization that create the conditions for a coherent social body.

Like other contributors in this special issue, Cooper explores the ways in which the research value is shaped by governmental rationality and generates new languages of contestation. Should volunteers in research be compensated in the same ways that local fieldworkers are paid to gather data? What are the terms of collaboration between health researchers, governments, and free enterprise? How is research value best pursued, by securing health, reducing inequality, growing the economy or sustaining employment? This special issue raises these questions through an exploration of how research is actually done – the practical alignments of institutions, actors, resources, objects, and interests. These empirical engagements with the intersection of values and values will provide, we hope, new conceptual resources to guide ethical and social scientific inquiries into the links between science and the public good.

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