

Configuring the patient as clinical research subject in the UK national health service

Mary Adams* and Christopher McKevitt

King's College London, Primary Care and Public Health Research, King's College School of Medicine, Capital House 7th Floor, 42 Weston Street, London SE1 3QD, UK

(Received 17 September 2013; final version received 8 December 2014)

This paper examines a central image in UK academic clinical research – the patient as altruistic research subject – by means of an interpretive review of social science, bioethical and bioscience research and development policy literatures. The review examines this image as it is indicted in discussions about the nature of clinical science; is consolidated in the ethical regulation of this science; and is articulated in recent bioscience research and development government initiatives. Drawing on Strathern's notion of the virtual (public-sector) subject, the review identifies the anticipation of NHS patients as alternatively 'available' or 'entitled' to the expanding translational medicine industry.

Keywords: patients in research; biomedicine; beliefs; UK

Introduction

During a prestigious biomedical research seminar on epigenetics, a professor invited some research subjects to 'take the floor'. We peered down as four women stepped out gingerly and perched themselves on a line of plastic chairs facing us. The professor moved fast, anticipating a new and vexed question for his students: '...can you tell me why you take part in this?' The subjects dutifully spoke into the flashing microphone in turn. One woman replied that she had 'just always done it'; another said that she came along 'to get a good regular MOT really'; and another spoke of a relative with dementia, 'so anything I can do towards a cure for that ... that's worth it'. After the seminar, audience attention turned back to the question of clinical research subjects. When asked by one student about research volunteers' gender ratios the professor now shrugged his shoulders and waved his hands about as he joked, 'Well, we do have more women ... that's because ... well ... they've just got that altruism gene...' (field notes MA November, 2012).

This brief episode from ongoing fieldwork indicates a recent concern in the ordering of clinical research activities in UK universities. This is for viable publically funded research in the biosciences to continue to expand its pool of volunteer subjects and to anticipate the motives and availability of necessary volunteer populations. The 'why do you take part in this?' puzzle is not simply a question for clinician-researchers to ponder; ethics committees to manage; and medical research activists to redefine. The availability of NHS patients as research subjects underpins a particular UK government vision to align and expand interests in the global life sciences industry and in the development of disease treatments. This vision aligns the dual values of economic advance and improved

*Email: mary.adams@kcl.ac.uk

national health and relies, in part, on the anticipated availability of NHS patients as research subjects.

The review was stimulated by first observations from an ongoing ethnographic study investigating views and practices of patient recruitment to clinical research in one clinical division of a large London teaching hospital. As the opening vignette illustrates, fieldwork suggests that the assumptions and declarations of altruism persist among staff despite evidence, not least from research participants themselves, that they enter this work for a variety of explicit motives. Indeed, a large body of literature illustrates that motivations for research participation may be other than altruistic, including economic reasons (Cooper and Waldby 2014), to gain access to unaffordable treatment (Fisher 2007) and to gain access to care perceived as enhanced (Fisher 2013). Nevertheless, the idea of altruism continues to have currency even as clinical research is increasingly understood as global bioeconomic activity with far reaching implications for those persuaded to undertake this clinical labour (Cooper and Waldby 2014). Tutton and Prainsack (2011) describe two distinctive forms of subjectivity articulated through web2.0 genetics database developments. They identify the 'enterprising self' promoted in a (US) biobank company where a consumer-centred model of research emphasises the values of choice, autonomy, self-awareness and self-responsibility for health. They contrast this to the UK BioBank, a publically funded charitable company that garners public involvement with invocations of 'public good'. These sorts of research subjectivities, the enterprising or altruistic, also track through studies of medical research participation. In this paper we begin to address why the notion of the altruistic patient is convincing to clinical researchers despite more than adequate evidence that patients engage in this work for varied and varying reasons.¹ In addition, this paper explores, through the author's initial conversations with research subjects, the capacity of this notion of the altruistic patient to elide not only various relationships of gift and return, but also the question of distribution of material, including commercial, benefit. We explore how this notion of altruism, particularly amongst NHS patients in non-commercial clinical research continues to be persuasive despite extensive anecdotal and social science evidence of a more complex, labile and nuanced view of research subjects' agency, including their expressions of motive.

Drawing on Strathern's (2005) perspective on new public sector organisations as forms of authority exercised by the anticipation of virtual social subjects, the authors focus on how ongoing health 'and biotechnology policy alliances – forged through the promise of research for 'health and wealth' for all – anticipate the entitlement to – and, increasingly, the availability of – the patient to clinical research. We examine how the patient in research is anticipated as a particular sort of altruistic subject – notably, one that offers individual labour, body and time without immediate calculus or expectation of direct return – and how this has taken shape in the contemporary ideological nexus that relocates the contemporary UK citizen/patient within the nostalgic of the 'NHS ethic', where a public institution provides its community with universal 'comprehensive health and rehabilitation services for prevention and cure of disease' (Beveridge 1942).

This paper examines, by an interpretive review of key literature, the particular circumstances whereby this nostalgia of the 'altruistic patient participating in the NHS community' carries resonance for some clinical research practitioners and communities. This review notes the enduring effects of the modern clinical science paradigm to deny the recognition of patient/research subject agency and the progressive gradual ethical regulation of this science that denies the promise of personal benefit for research subjects. Finally, the review traces the elaboration of this nostalgia in recent national policy drives

to expand this scientific activity as part of a globally competitive translational medicine industry.

Methods

This interpretive review follows the meta-narrative approach of Greenhalgh et al. (2005) that is a deliberate selection of key studies from across different research traditions or paradigms and which sought to outline the ‘unfolding story-lines’ of each of these traditions. These ‘story-lines’ involve consideration of the historical foundations, the theoretical scope, epistemology and unfolding debates as the contexts that shape different understandings of the same subject. The wider meta-study review tradition in which Greenhalgh et al.’s study is located also ‘involves scrutiny of the philosophical and theoretical assumptions of the included research papers; this includes looking at the wider context in which new theory is generated’ (Barnett-Page and Tomas 2009, 6).

We began with keyword searches of medical and social science databases and selected publications on the grounds of their representation of key research or disciplinary traditions or critical debates that address the subject of ‘patient altruism in research’. We included searches of electronic databases, free internet searches and hand-searched publications in the lower boundary of 2004, when UK health and bio-science research and development policy highlighted the potential of the translational medicine agenda (see below). We identified and mined three different disciplines that conceptualised the subject in different ways. These disciplinary areas were the critical social science studies of biomedical knowledge that emerged from the 1950s; the US, and particularly UK, sociologies of the ethical regulation of clinical science, particularly since the 1990s; and the post-2000s bioscience research and development policy, particularly in relation to NHS patients. These three bodies of key literature were then each synthesised by concurrent and reflexive reading that included examination of the findings, methods and theory of each key study. This reading led, iteratively, to a synthesis that is a ‘construction of constructions’ (Paterson et al 2001 in Barnett-Page and Thomas 2009). An interpretive review that seeks to identify the similarities and discrepancies between different accounts of the phenomenon across literatures is always explicitly subjective and exploratory.

Imagining the patient as research subject (1): the rationale of the clinical trial

Historically, as Berg (1995) notes, clinical research poses particular challenges in its concerted effort to become science. In its aim to represent health care realities, the boundaries separating the scientific experiment from the external world is especially porous (Latour and Woolgar 1979; cf. Rapley et al. 2006). From the 1950s, the ascent of the randomised controlled trial (RCT) and the ‘gold standard’, double blind RCT is notable (amongst other things) for its attempt to remove the messiness of interpretation altogether. The RCT sought to purify the efficacy of treatment, separating it from the background noise of placebo effects, biased observers and chance, and so establish mechanical objectivity (Lowy 2000; Lambert 2006; Lock and Nguyen 2010, 180).

While RCTs were always an ‘incomplete revolution’ for clinicians, they did present a distinctive particular biopolitical view both of the patient as research subject and of subject populations. The rationale of the RCT was that a few were subject to the uncertainties or risks of experiment to enable the calculation of knowledge for wider effective intervention. As Lock and Nguyen (2010, 186) also note, this methodology assumes that no direct link is claimed between the production of health in research subjects and the wellbeing of

the economy as a whole. Human research subjects 'are simply intermediaries who assist in the production of biomedical knowledge that will eventually, it is hoped, be profitable, have global application and cure disease'. This perspective echoes Goodman et al.'s (2003, 11) identification of a wider paradigmatic shift in twentieth-century medical science towards the 'post-Hippocratic body' where '[t]he assumption is that medical science is there to provide healing remedies for the sick individual . . . in fact its role in the modern era . . . has been to safeguard the collective national health'.

Dehue's (2010) history of clinical trial work also finds that additional assumptions about the patient as research subject underpin RCT design. These assumptions are founded on the interconnected maxims of western individualism, including a view of the problem to be solved as isolated within individuals and a view of efficacy established statistically and impersonally.

The residual question of what to do with the unwelcome interferences of patients and researchers as agents in RCT work was/is sometimes hammered out in the bioethical concepts of therapeutic misconception and of informed consent (Miller and Brody 2003; Kimmelman 2007). In the past two decades the idea of therapeutic misconception has expanded to sometimes describe a general failure to understand that 'the defining purpose of clinical research is to produce generalizable knowledge' (Henderson et al. 2007, 4). In these reified bioethical discussions the question of research subjects' (and clinicians') 'understanding' or 'levels of knowledge' has been a central concern. 'Knowledge vacuums' (Appelbaum et al. 1987) and 'defective reasoning' (Edwards et al. 1998) were considered to underlie not only patients' ignorance of the role of chance in treatment allocations but also patients' anticipation that they would benefit from research involvement.

Beyond the confines of debates about clinical research methodology there has, of course, been extensive debate on the role of 'science', including clinical science, in society. New visions of 'knowledge utility' as well as of public accountability have shaped new perspectives not only on science (Nowotny et al. 2001) but also on that something that is 'the social' as both consumer and moral arbiter of expertise (Strathern 2005). However, within clinical science these shifts towards accommodating public accountability, as well as patients' experiences, have been uneven and varied. Those areas of clinical research where participant recruitment is more challenging (Faulkner 2010; Kelly 2010), or where established hierarchies of expertise in the clinical relationship have been explicitly challenged (as in some aspects of maternity care) appear to have explicitly incorporated the views and values of research participants into their projects of knowledge production. However, at least in the long established field of hospital-based clinical research with patient populations – the value of the gold-standard RCT work (defined by the elimination of bias by randomisation, blinding and the use of placebos) – there is limited recognition of the agency of research subjects.

Imagining the research subject (2): the ethical regulation of clinical research

The consolidation of ethical governance of clinical research over the past two decades has been powerful in fostering the norm of the altruistic patient. Simpson (2012), following Rose (1999), notes that the growth of ethical review is not simply about research protocols: it articulates a widely proliferating notion of governance built on the principles of neoliberalism and of protection of the individual in the face of biological risk and excess. From this perspective, informed consent encapsulates the notion of an empowered and personally responsible citizen, with wider ethical questions of risk and uncertainty

diffused into questions of personal choice and individual subjectivity (cf. Corrigan 2003). Goodman et al. (2003) note that this perspective skews the debate about human experimentation in two directions: away from questions of practice and towards formal ethical procedures and towards a focus on the doctor–patient relationship as well as the patient volunteer rather than towards wider relationships between researchers, doctors, the state and society.²

Several other factors redraw this image into discussions about bioethical regulation and value. As Jasanoff (2005) argues, bioethical debates unfold in relation to a longer history of ethical debate: the Hippocratic and Nuremberg ethical traditions’ emphasis on freely given and uncoerced consent remains central to the way that the ideals of patient recruitment to research operate. This emphasis resonates with prior English common law principles that deny personal property entitlements in the body. In this sense, benevolence is the only formal ethical position for patients’ participation in medical science.

A series of alternative views of research participation have emerged in the bioethical and social science literatures, particularly of the informed patient-citizen choosing to contribute as disinterested research subject. These views challenge the modern categorical distinctions of the individual and the social as well as of the private and the public (cf. Geissler 2011). For the most part these alternative perspectives implicate wider exercises in identity and community, most often focused around disease conditions (Epstein 1995; Lowy 2000; Gibbon 2008; Callon and Rabeharisoa 2003) or around claims for an alternative politics of common responsibility and obligation to ‘benefit sharing’ (Swan 2012; Tutton and Prainsack 2011; Hayden 2007). Such collectivities might articulate, at particular times, ‘research-driven sociality’ (Lock and Nguyen 2010, 201), crystallising around demands for research participation as citizen entitlement. The anticipation of such a collective of ‘shared good’ is a notable development in translational medical research and development policy in the UK in recent years, particularly in relation to the policy elaboration of an ‘NHS community’.

Imagining the research subject (3): translational research and research policy

A more recent development relevant to the author’s question is the rise of translational research, an effort to rethink clinical research and its practices, often understood as ‘the “bench-to-bedside” enterprise of harnessing knowledge from basic sciences to produce new drugs, devices, and treatment options for patients’ (Woolf 2008, 211). The idea of translational research captures and elaborates the wider social and bio-ethical debates that anticipate the availability of NHS patients for clinical research. UK policy documents often frame the National Health Service as the natural, collective and enduring structure for the development of ‘benefit sharing’ by research participation.

Since the 1940s, UK health policy initiatives have occasionally evoked the rhetoric of social solidarity sustained by personal donations to the social good of public healthcare (Tutton 2002; Busby 2006). The revival of this vision for the NHS gathered pace through the 2000s driven by national interests in the expansion of the ‘UK bioscience economy (focusing on healthcare)’ (www.ukcrc.org/aboutus, accessed 12 June 2013). The Department of Science and Innovation and the Department of Health jointly commissioned strategic research by the Bioscience, Innovation and Growth Team (BIGT) that identified the NHS as a ‘unique institution, globally providing a gateway to the largest pool of patients in the world and caring for those patients from cradle to grave’ (Bioscience 2015 Report (2003,9): cf. Kelly 2010). It promised that, with sufficient infrastructural support for clinical researchers (including the work of patient recruitment, see BIGT Report 2003, 18)

industrial research prospects and national health benefit could be jointly enhanced (BIGT Report 2003, 9). This vision was echoed by the Research for Patient Benefit Working Party that stressed the ‘twin benefits of improving national health and increasing national wealth’ through translational research (Department of Health (2007,1). This vision was echoed in the formation of the UK Clinical Research Collaboration (2004–2012) that comprised research funding bodies, academics, the NHS, regulatory bodies, bio scientists and patients (www.ukcrc.org/aboutus, accessed 12 June 2013) and that anticipated future health and wealth advantages from bioscience research as a matter of smooth ‘bench to bedside’ flows of benefit conversions secured through the medium of the large-scale NHS structures. As Waldby and Mitchell (2006) note, Titmuss’s thesis – that promoted a nationalised, welfarist model resting on the values of civic duty to give for collective benefit – continues to inform popular and well as institutionalised bioethical views on the intrinsic value of gratuitous donation.

The popularisation of the rationale of the intrinsic good of patient availability for research is evident in contemporary recruitment campaigns. For example, in 2013, INVOLVE – an organ of the UK’s National Institute of Health Research (NIHR) – charged with promoting citizen engagement in health and social care research, conducted a ‘Research is for Everyone’ campaign that spread the egalitarian message through hospital trusts and community health trusts during a dedicated national ‘clinical trials day’ (www.invo.org.uk, accessed 10 June 2013). Such campaigns reiterate a configuration of the NHS as the sturdy bridge through which the gift and benefit of patient participation in clinical research will continue to flow (cf. Kelly 2010).

However, the egalitarian message in the encouragement to participate in NHS trials gives a novel twist to the notion of altruism, with such participation recast as entitlement. The NIHR through its policies, website and campaigns promotes patient and public availability for clinical research with a discourse that elides concepts of voluntarism with those of consumer entitlement. For example, a 2012 mystery shopping exercise commissioned by the NIHR found that ‘91% of hospital sites visited did not have any information on clinical research activity in their reception area on notice boards, on electronic screens or leaflets displays’ (NIHR Clinical Research Network 2013). The findings were reported in the broadsheet press as evidence that patients were being ‘thwarted’ in their efforts to enter drugs trials (*The Observer*, Saturday 5 January 2013). This led to increased activity to encourage patients to seek out opportunities to take part in trials, such as the ‘OK to ask’ campaign that calls on ‘patients and carers to ask their doctors about NHS research they can take part in’. The rationale behind the campaign is explained thus:

Much of the life-saving clinical research carried out in the NHS could not happen without hundreds of thousands of patients and carers stepping forward every year to take part. Those who volunteer in this way report a range of benefits and are pleased to be potentially helping others like them with the same condition. NIHR’s national ‘OK to ask’ campaign . . . is about encouraging many more people to ask their doctor about being in research as part of their care and treatment and highlighting that they have a right to information about ‘relevant and appropriate’ research under the NHS Constitution. (www.nihr.ac.uk/newsroom/news).

Most notable here is the elision of citizen involvement in health research from that of ‘engagement’, which assumes engagement in a wider politics of knowledge production (Callard, Rose, and Wykes 2012), to that of ‘recruitment’, which assumes a position of uncritical availability (see www.invo.org.uk). This recent shift reflects the new organisational and clinical research priority of ‘body hunting’ (cf. Epstein 2008).

Discussion

This interpretive review indicates the inherent difficulties of realising the collectivist notion of ‘shared patient benefit’ – by giving research participation for the advance of new treatments – particularly in the NHS. This imagery relies on the elision between what Blume (2006, 252) calls the rhetoric of evidence and the expectations of medicine. The imagery of shared and ever-increasing health knowledge sustained by the research contribution taps the modern progressive ‘myth of infinite benefit’ (Sarewitz 1996). As Rajan (2007) notes, the distinctive quality of bio-capital is its capacity to over-determine therapeutic value as well as to carry collective moral value. Indeed, Rajan suggests that bio-capital operates through the ‘discursive act’ of future visions, promises and speculation that also includes the identification of new ‘patients-in-waiting’ (Rajan 2006, 41, 175). In addition, however, the rhetoric of evidence in clinical and healthcare science can as often run counter to expectations of future care provisioning. At least since the 1990s, evidence incorporates questions of efficiency as well as safety and the ‘cost/benefit’ rubric involves calculations of collective cost against individual benefit (see, for example, Lowy 2000).

As significant, the very nature and conditions of modern biotechnology, with its complex interconnections with global capital, raises doubts about any straightforward simple ‘bench to bedside’ or ‘circulating benefit’ models of translational medicine (Waldby and Mitchell 2006). Birch and Tyfield (2012) highlight the changing nature of key facets of bio-capital, whereby profits accrue not from therapeutic products but from speculative ‘asset-based enterprises’ founded, for example, on the ownership of databases that might be necessary for not-yet-discovered innovations requiring trial populations in the future. In such situations the futuristic and speculative nature of health/wealth benefits is likely to drive the commercial value of clinical research subjects in and of themselves.

What is notable in the recent Department of Health sponsored drive to increase patient, as well as public, recruitment to research is the claim that individuals who choose to give their labour, time, bodies or bodily products are entitled to *not* be ignored. Thus, the government-sponsored body that publishes the national league tables on clinical research activity in the NHS explains its objectives as supporting ‘research opportunities for patients’ (www.invo.org.uk, accessed 10 June 2013). More recently, ‘being offered a chance to take part in a clinical trial’ is promoted as an entitlement (rather than as a gift), and is indicated particularly for those ‘that have a health problem affecting their daily life’ (Davis in *NIHR Life-Science Industry Report Bulletin June 2012*).

As indicated above, the notion of a patient’s entitlement to science also circulates in policy that anticipates patient availability to clinical science. At least since the early 2000s, the slippages between the bioethically distinct activities of clinical research and clinical care have been significant for some patients who are subjects of clinical science as well as for clinical researchers (for example, Will 2012; Hallowell et al. 2009). The indication of some possibility of therapeutic benefit to those who are research subjects is sometimes indicated in clinical research and development policy. For example, the BIGT Report (2004) also identified the clinical benefits for some *individuals* as research participants. This was for patients with ‘rare or expensive-to-treat’ conditions to gain access to ‘emerging innovations’ by participation in clinical trials (Bioscience 2015 Report (2003)). More recently, the indirect identification of the ‘desperately sick’ as a distinct category of research participant has entered Department of Health policy as research funders and health trusts seek to delineate their financial obligations to NHS patients receiving experimental or unapproved treatments at the close of a research study (Department

of Health 2012). The ‘desperate patient’, entitled to science, now also figures in this policy effort for ‘increasing research and innovation in health and social care’ (Department of Health 2012, 1). However it is notable that this figure is not the community activist seeking epistemological gains for a wider disease community. Rather, this policy anticipates the ‘desperate patient’ as the individual positioned to risk his labour, time and body for his own therapeutic benefit.

The author’s initial and exploratory conversations with patients involved in research suggest that the notion of the altruistic patient frequently circulates in everyday talk about clinical research recruitment and participation but that ‘giving something back’ glosses a complexity of perspectives and uncertainties over the conditions and directions of gift and return in clinical research work. For example, Sue, a former long-term patient with a history of late miscarriage spoke of why she travelled long distances with her new baby to work, voluntarily, as a patient advisor to a preterm delivery research team. She explained: ‘It’s really to do something to make sense of it all . . . to save a life rather than lose one . . . a sort of turning things around . . . so I’m doing it for me in the end.’

Then, again, Jerry, a patient advisor and cancer patient who had participated in several high-risk drugs trials understood his position differently. He explained:

Well they’ll tell you that there are no guarantees, that it’s fifty-fifty, but you do know with the symptoms you get [when you are on active treatment], and I knew that I was getting it . . . that makes it a good deal all round . . . and I wouldn’t have done it without knowing that . . . no, I wouldn’t have done it at all without getting the treatment I can tell you . . . no, if it hadn’t been for me getting that chance . . . well, I wouldn’t be standing here . . . so it’s worth you doing . . . it’s a good deal really . . . everybody benefits.

These examples of cursory discussions with patients in research indicate that an experience of availability to science is not only epistemological but also about assumptions of being and relationships (Rose 2007; Prainsack and Buyx (2012). From his studies of medical research participation in non-western settings, Geissler (2011) argues from the development of a ‘situated ethics’ of biomedical research work that involves analysis of how ‘the social’ facilitates and underwrites research participation both in the values that it transfers and as sources of sociality that shape these values. Such an analysis is also indicated for understanding the implications of the extension of clinical research within the NHS, particularly in the context of urgent commercial valuations of patient signatories to extend this work, and the uncertainties over the distribution of commercial returns for the public good.

Conclusion

This interpretive review outlines some conditions for the salience of the image of the patient as the altruistic research subject. These are, first, the necessary disinterest of clinical research subjects in personal clinical benefit; second, the bioethical imperative of the patient as un-coerced subject; and, third, the recent policy articulation of the highly abstracted ‘take and give’ of collective treatment development. This review finds that, particularly in post-2000s UK bioscience policy, the NHS assumes salience as a source of ‘national wealth and health’ operating both as a source of research subjects and as a recipient of clinical innovation. This promise relies on both an uncomplicated ‘bench to bedside’ or ‘circulating good’ view of translational medicine and on the presence of patients

as clinical research subjects – as either altruistically available to clinical science or, less often, as entitled to this science.

Goodman et al.'s (2003) collection of detailed case studies of 'useful [human] bodies' in US and UK twentieth-century medical science finds that such activities always implicate wider regimes of citizenship, particularly as forms of belonging through embodied value. Goodman et al. find that therapeutic and non-therapeutic scientific experimentation inevitably involved the state 'as actor, legitimator and provider' as shifting ideas of human 'usefulness' to science emerged as 'the point of contact between human experimentation, knowledge and the state' (Goodman et al. 2003, 1–2). However, as Strathern (2005, 465) observes, the exercise of state authority in contemporary public-sector organisations involves a particular sort of citizen-subject that is always anticipated by policy makers and that means a 'successive replacement of actual consumers . . . by abstracted models that come to stand in their stead'. This review illuminates the author's ongoing ethnographic research, which focuses on the day-to-day practices of recruitment, in which are played out the felt disjunctures and ongoing negotiations between these abstracted models of patients as research subjects and the lived experiences and subjectivities of clinical research work for patients and research staff alike.

Acknowledgements

This research is supported by the National Institute of Health Research Biomedical Research Centre at Guys and St. Thomas' NHS Foundation Trust and King's College London.

Notes

1. Not surprisingly, an influential systematic review commissioned to increase public and patient recruitment to clinical research found it difficult to identify a singular set of motives (McDonald et al. 2006).
2. However, it should be noted from the author's ethnography that for both clinical researchers and many patient advisors working with research teams, the ethical governance of NHS clinical research has significance primarily as a difficult bureaucratic hurdle to be surmounted before research work begins.

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