Social Science & Medicine 73 (2011) 515–521

Contents lists available at ScienceDirect

Social Science & Medicine

journal homepage: www.elsevier.com/locate/socscimed

Theorising the 'human subject' in biomedical research: International clinical trials and bioethics discourses in contemporary Sri Lanka

Salla Sariola*, Bob Simpson

University of Durham, Durham, UK

ARTICLE INFO

Article history:
Available online 9 December 2010

Keywords:
Sri Lanka
'Human subjects' of research
Clinical trials
Bioethics
Autonomy
Paternalism
Global ethnography
Gender
Doctor-patient relationship

ABSTRACT

The global spread of clinical trials activity is accompanied by a parallel growth in research governance and human subject protection. In this paper we analyse how dominant ideas of the 'human subject' in clinical trials are played out in countries that are deemed to be scientifically under-developed. Specifically, we show how rhetorics of individualism, rationality and autonomy implicit in international ethical guidelines governing human subject research are operationalised and localised. We give insights into the ways in which new knowledge forms become embedded in practice. Using the recent upsurge in clinical trials in Sri Lanka as a case study, based on interviews with 23 doctors and researchers carried out during ethnographic fieldwork between 2008-2009, this article explores the tensions that arise for doctors involved with the promotion of bioethics and the attempts to bring local research governance up to international standards. The doctors and researchers intercept, interpret and critique the notions of human subject implicit in new forms of research governance. From their accounts we have identified two concerns. The first is a critique of dominant ideas of the 'human subject' that is informed by ideas of patiency rooted in paternalistic notions of the doctor-patient relationship. Second, 'human subjects' are seen as gendered, and located within family relationships. Both of these bring into question the research subjects' ability to give informed consent and compromise the ideal of an autonomous subject.

Introduction

That experimental research in the biomedical sciences travels is indisputable. In recent years, there has been an extraordinary rise in clinical trials with a significant shift in activity from Europe and North America to transitional countries such as Brazil, Russia, India and China and increasingly into developing world settings where there is a strong desire to build economic, technological and scientific capacity (Karlberg, 2008; Petryna, 2005 and 2009). At one end of the spectrum, there is a move to 'outsource' pharmaceutical company clinical trials. Amongst other things, this trend is driven by the possibility of cost-cutting within the drug development pipe-line, the regulatory requirement of having larger statistical sample sizes and by the quest for therapeutically naïve populations. At the other end of the spectrum are humanitarian efforts to address global health inequalities by intensifying research into diseases such as Malaria, Dengue, Leishmaniasis, and Tuberculosis, that, in market terms, are unprofitable but which, in human terms, are catastrophic for large numbers of people living in the developing world (COHRED, 1990). Somewhere in the middle are novel hybrids of public-private partnership in which corporate philanthropy and activism infuse responses to developing world health problems (Moran, Ropars, Guzman, Diaz, & Garrison, 2005).

What has been less obvious in the midst of this traffic are the ways in which research governance and the ethics of human subject research travel with experimentation. Here one engages with a complex genealogy of regulatory guidelines, codes of practice and declarations that aim to ensure that 'human subject' research is ethical. The genealogy of ethical guidelines can be traced back to 19th century (Vollmann & Winau, 1996), but became fully established only after the 'scientific' atrocities carried out in the concentration camps of the Third Reich (and which resulted in The Nüremberg Code and its subsequent amendment the Declaration of Helsinki). The genealogy has been extended as a result of other crises such as the Tuskegee trial carried out in the US between 1932-72 (which resulted in Belmont Report 1979). These statements, guidelines and entreaties aspire to universal systems and standards in the conduct of biomedical research wherever it is carried out. While variations exist in these documents, there is broad triangulation around notions of the 'human subject' with informed consent as the *sine qua non* of human experimental research. In order to participate in research, human subjects must know what is to be

* Corresponding author.
E-mail address: salla.sariola@durham.ac.uk (S. Sariola).

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doi:10.1016/j.socscimed.2010.11.024

done to them and why. More importantly, they should be free to consent to or refuse participation without coercion or fear of consequence.

These are powerful precepts, but are not without their critics. It has been argued that the philosophical underpinnings of bioethics reflect Anglo-American, rather than universal values (Christakis, 1992; Durante, 2009; Hedgecoe, 2004; Levine, 1991; Marshall, 1992; Turner, 2003). Indeed, the idea of a subject that is universal, autonomous and individualised, while transhistorical and acultural in its utility, is less convincing when carried into other settings. This notion of the subject, however, is fundamental to international policy documents on health and bioethics but at the same time one which, as we will see, stimulates counter-narratives concerning the biomedical subject. In this paper, we describe how doctors who are actively engaged in clinical trials and bioethics in Sri Lanka question the universality of these notions and theorise their own conceptual bridges between the 'subject' in medical research, international bioethical guidelines and the local medical system.

Our work is thus part of a growing body of ethnographic and qualitative research into international medical research in developing countries. It throws light on the tensions that occur when clinical trials are carried out in settings which are culturally and economically very different from those of Europe and North America. These studies have looked at issues such as consent (in Kenya Gikonyo, Bejon, Marsh, & Molyneux, 2008; Molyneux, Wassenaar, Peshu, & Marsh, 2005a, and in The Gambia Leach et al., 1999), trust (in Kenya Gikonyo et al., 2008; Molyneux, Peshu, & Marsh, 2005b); ethics committees/internal review boards (in Dominican Republic McIntosh et al., 2008; Mexico Valdez-Martinez, Turnbull, Garduno-Espinosa, & Porter, 2006); social value of the research and dissemination of findings into policy change (in Kenya Lairumbo, 2008); formation of communities of trial participants (in The Gambia Geissler, Kelly, Pool, & Imoukhuede, 2008) and their engagement in research (in Kenya see Marsh, Kamuya, Rowa, Gikonyo, & Molyneux, 2008). The specific contribution that our own research makes is to bring a South Asian perspective to a body of literature that has mostly originated in Africa and South America. Furthermore, we are responding to Molyneux and Geissler's observation that the views of doctors and researchers are key to understanding the way that new forms of knowledge become embedded in developing world contexts, yet this remains a field that is currently under-researched (Molyneux & Geissler, 2008).

Methods and context

The research reported on here is part of a larger project which studies the imbrication of science and bioethics in biomedical research collaborations across Asia. This project is a collaboration between nine researchers in Anthropology departments in the Universities of Cambridge, Durham and Sussex working across eight different countries in Asia on the topic of science collaborations and bioethics. The specific focus of the research by the authors is contemporary Sri Lanka, where the development of research capacity in biomedicine is at an early stage. It is also a country that has been in a state of civil war for almost 30 years. During the ending of the conflict and the defeat of the Tamil separatist movement (LTTE) in early 2009, further political uncertainties have followed along with a strong tide of Buddhist nationalist sentiments and and an antagonism towards America and Europe following criticism of the way in which the war was brought to an end. Against this backdrop, Salla Sariola conducted ethnographic research on clinical trials and the expanding field of knowledge, practice and governmentality which is gathered under the heading 'bioethics'. The twenty three interviews that are reported in this article were held between February–April 2008 and October 2008–August 2009. The interviews were either tape-recorded and transcribed, or noted by hand during the interview. The doctors and researchers who were interviewed as part of the research were explained the purposes of the research and verbal consent was obtained. The research was approved by ethics committees at the Universities of Cambridge (Anthropology); Durham (Anthropology); Colombo (Faculty of Medicine) and Ruhuna (Faculty of Medicine).

Crucially, the ethnographic entry into the notion of subjectivity was not directly via clinical trials participants. Our broad focus was on collaboration strategies in international biomedical research and ethics. In this paper we report on multiple interviews with doctors and researchers who, in their roles as professionals, experts and intellectuals, perform a crucial brokerage role in the reception of new forms of knowledge. These doctors and researchers are the ones who bring clinical trials activity and related bioethics discourses to the island. They do not simply pass on such knowledge but, in the manner of para-ethnographers and theorists of the human conditions that they encounter, they also endorse, interpret, critique and question this knowledge according to the rationalities and pragmatics of their time and place (Boyer, 2008; Holmes & Marcus, 2005). A question we will answer is just how the notion of 'human subject' is received, negotiated and construed in the traffic of ideas, knowledge and practices that accompany clinical trials? Furthermore, how do existing competences, assumptions and understandings of doctor-patient relationships feature in the work of embedding these new forms of knowledge and practice into existing ones?

All doctors who were included in this analysis were Sinhala Buddhists. They were comprised of senior doctors as well as university staff involved in bioethics training, organising workshops and/or developing local bioethical guidelines. Some were also members of research ethics committees in Medical Faculties of the Universities of Colombo (the capital city) and Ruhuna (in the South). The interview group was also made up of junior doctors who were involved in the running of clinical trials. These were mostly younger staff waiting for their doctor training internships to start, who were working as research assistants on trials. Within the interview group some were clearly bioethics 'activists' who were very well-versed whereas the junior doctors had limited formal training in ethics. Despite these differences, there were common concerns in their accounts regarding the ethics of human subject research, which we will elaborate on later in the paper. The trials that doctors were involved with were of two kinds. One was a randomised, placebo-controlled, double-blind, multi-centred, phase 2 trial funded by an international pharmaceutical company that was testing a new drug for a chronic disease. This trial was aimed at gaining US Food and Drug Administration (FDA) approval, for a product that would most likely find its way into Western rather than Sri Lankan markets. The other trial was again a randomised placebo-controlled, double-blind, phase 2 trial that was predominantly funded by an international health research charity. This trial addressed a local health concern, aimed to improve patient management, and to lead to a better understanding of the condition.

The data was coded using the NVIVO7 qualitative data analysis programme and for this article we have included the relevant references to 'human subject' used in interviews as doctors' attempted to accommodate the governance of clinical trials in Sri Lanka. Within these references we identified two recurrent themes. The first concerns how subjects are seen as family-centred in Sri Lanka, that is, not autonomous or self-governing, but rather heteronomous and likely to seek the influence of others in their decision-making. The second modality concerns medical paternalism in doctor–patient relations in Sri Lanka. As we will see, what is discernible in these responses is something of an occidentalist discourse in which a conception of 'Western' individualism is contrasted with Asian socio-centricity (Buruma & Margalit, 2005; Carrier, 1995); both are overly-determined and essentialised when deployed in the rhetorical