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Fast, cheap, and out of control? Speculations and ethical concerns in the conduct of outsourced clinical trials in India

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ABSTRACT

The globalization of biopharmaceutical clinical trials and their offshore outsourcing, from the West to low and middle-income countries, has come under increasing scrutiny from academic scholars, practitioners, regulatory agencies and the media. This article reports the results of a study conducted in Bangalore and Hyderabad between 2007 and 2009, to elicit the perspectives of stakeholders, concerning media representations of their work and the ethical issues that emanate from their engagement in the clinical trials enterprise. In acknowledging the inherently problematic nature of the outsourcing of clinical trials to low income countries, I argue that the practice of not prioritizing research on diseases that are most prevalent among communities, from which subjects are recruited, demands a coordinated and sustained critique. I propose that the critical discourse on the outsourcing of clinical trials should not only emphasize the perils of this practice, but also address some broader issues of equity and distributive justice that determine people's access to basic health care in low income countries. Close attention to the specific context of clinical trials in an increasingly neoliberal medical and health environment in emerging economies such as India can provide critical insights into the on-the-ground complexities and challenges of outsourced global clinical trials.

Introduction

The global pharmaceutical industry, which is increasingly offshoring and outsourcing biopharmaceutical clinical trials to emerging economies like Brazil, China and India, has been at the center of intense ethics and policy debates regarding its role in using trial subjects from the Third World to further consolidate its pharmaceutical research and marketing agenda (Glickman et al., 2009; Petryna, 2005, 2009; Prasad, 2009; Sariola & Simpson, 2011; Shuchman, 2007; Sunder Rajan, 2005, 2006, 2007). Proponents of outsourcing have pointed to several advantages it offers: substantial savings in operational costs while recruiting a large number of patients in a timely manner, speedy completion and approval, and more extensive validation of the trial drugs among genetically diverse and so-called treatment naïve populations. They also contend that clinical trials constitute a "social good" and not a "social evil" (Martin, 2006) that will ultimately bring unprecedented health benefits to the global community (Bhatt, 2004; Bobba & Khan 2003; Maiti & Raghavendra, 2007).

Critics, however, have contested these claims, arguing that the growth of clinical trials, particularly in developing countries, has resulted in exploitative and unethical practices such as "subject coercion, the lack of voluntary and informed participation, and inadequately informed consent" (Petryna, 2009: 124). Some have also documented case studies to show that these trials have resulted in deaths among trial subjects (Shah, 2006; Srinivasan, 2009a, 2009b). They have argued that it is mostly poor, disenfranchised and vulnerable people who are lured by pre-trial payments into participating in trials that ultimately contribute little or nothing to their health, let alone the health of the community from where they are recruited (Nundy & Gulhati, 2005; Sunder Rajan, 2007). Critics have argued that by conducting clinical trials in developing countries and among economically disenfranchised "ready-to-recruit" and "ready-to-consent" populations, and by offering these groups limited and problematic access to health care in exchange for their bodies as testing sites for new products (Fisher, 2009), pharmaceutical companies and Contract Research Organizations (CROs) abuse and exploit disadvantaged populations for the benefit of privileged groups (Abadie, 2010; Elliott & Abadie, 2008; Shuchman, 2007). Critics have emphasized the need to address the exploitative nature of global clinical trials, and the treatment of human subjects in Third World countries as "guinea pigs" or a "*sacrificial* population" (Srinivasan, 2004; Sunder Rajan, 2006). In the Indian context, for example, Nundy and Gulhati (2005) have described the outsourcing of clinical trials as a form of "new

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colonialism" in which poor and non-literate people are systematically exploited.

Amid the debates surrounding the advantages and disadvantages of the globalization of clinical trials, intense speculation has developed in the media and scholarly literature regarding the number of active clinical trials and investigative sites globally, and the actual number of international human subjects involved in these trials. This is especially true of the clinical trials offshored/outsourced by European and US-based multinational pharmaceutical companies (MPCs) to some of the large emerging economies. The emergent literature from science and technology studies and medical anthropology is only beginning to shed some light on the on-the-ground reality of clinical trials, especially in countries where they are being outsourced (Cooper, 2008; Petryna, 2009; Sunder Rajan, 2005, 2006, 2007).

Based on empirical research conducted in two cities in India, this article examines stakeholders' (sponsors, CRO executives, investigators and ethics committee members)[1] perspectives on the enactment of clinical trials in a new legal environment that has facilitated the offshore outsourcing of multicenter, multinational clinical trials from the West to India. While much of the existing social science literature on clinical trials has critiqued stakeholders' active utilization of speculative neoliberal capitalism to promote the outsourcing of drug trials, stakeholders' voices have been largely omitted in the critique. There is a need to bring the stakeholders' voices to the fore to better appreciate multiple perspectives on the outsourcing of clinical trials from the West to the Third World. As such, I juxtapose the media hype, speculation, and also the perils of clinical trials, with the perspectives discursively articulated in interviews by Indian stakeholders closely involved in the clinical trials enterprise. In acknowledging the inherently problematic nature of outsourcing of clinical trials to developing countries, I argue that the practice of not prioritizing research on diseases that are most prevalent among communities from which subjects are recruited, especially when these diseases cause high morbidity and mortality (Benatar, 2007), demands a coordinated and sustained critique. I also argue that standard of care, adequate compensation, health equity and distributive justice are key issues that are at stake in the outsourcing of clinical trials to an emerging economy like India. I propose that the current narrow debate on the effects of outsourcing of clinical trials to developing countries needs to be broadened to address not only the potential dangers and exploitative practices, but also engage some fundamental concerns regarding growing health inequalities, issues of global justice, the social determinants of health, and human development (London, 2005).

Clinical trials in India: new directions

The conduct of pharmaceutical clinical trials in India is not new. What is new, however, is that in the last decade, the focus has shifted toward global competition and global, multicentric clinical trials (Bhatt, 2004; Sunder Rajan, 2005). The Indian government has introduced crucial legal measures to facilitate the process of making India a global player in biotechnology and clinical trials. One of the most concrete changes is the inclusion of Schedule Y in the Drugs and Cosmetics Act (1945) in 2005, which allows MPCs to conduct Phase 2, Phase 3, or Phase 4 trials without any "phase lag." Prior to the new law's introduction, if a phase 3 study had been completed elsewhere, only a phase 2 study was permitted in India. Thus, the Indian nation-state has been a key player in creating a legal environment to facilitate the acquisition of clinical trials that MPCs in the West would like to outsource, and making Indian bodies necessary for testing (Prasad, 2009; Srinivasan, 2009b). As in many other emerging economies, speculations in the media regarding the nature and magnitude of clinical trials in India abound. These speculations frustrate attempts to draw specific conclusions about the industry's size, the diseases and experimental therapies trialed in the country, and to determine how the Indian terrain compares with that of other 'nontraditional' economies where multi-sited trials are increasingly being conducted (see Cooper, 2008 for a comparative situation in China). In 2006, for example, less than 1% of the commercially sponsored global clinical trials were being conducted in India. In 2007, there were only 757 sites in India with a trial density of 0.7, as compared to 36,281 sites in the US, with a trial density of 120.3 (Thiers, Sinskey, & Berndt, 2008).

There are many reasons why India's clinical trials enterprise is marked by hype, speculation and uncertainty. First, India has recently emerged as one of the fastest growing economies in the world. Therefore, while MPCs and CROs are keen to tap into the growing economy for profit maximization, Indian stakeholders (physicians, corporate hospitals, pharmaceutical companies and for-profit institutional review boards) are equally keen to partake in the profits. Second, as a signatory to the World Trade Organization (WTO) in 1995, India opened up its economy to foreign investors on an unprecedented scale; it made efforts to adhere to the 'product patent regime' by 2005. This has allowed MPCs to conduct global trials in India, while also being guaranteed patent protection under the Trade-Related Intellectual Property Rights (TRIPS) agreement. Third, while India has successfully established itself as one of the leaders in the global IT industry, it is keen on becoming a global player in the biotech industry before the initiative is lost to other countries, particularly China, its rival, "where the government is playing an active role in encouraging foreign companies to conduct clinical trials" (Cooper, 2008: 84). Finally, neither international nor Indian stakeholders are certain about the true scope of the country's clinical trials industry.

Buoyed by initial optimism, the Indian government put its resources behind the industry by describing it as a "sunrise industry" deserving of aggressive support through a "tax holiday" (exemption from service tax on drug testing) based on the expectation that it will attract huge foreign investment funds, leading to jobs in the biopharma industry and national prestige (Bhatt, 2004; Prasad, 2009). "This is very much in keeping with a post-1990s ideology of economic liberalization that has been prominent in Indian elite and policy circles whose idea of India is as India Inc" (Sunder Rajan, 2006: 68). At the time, proponents claimed that "the Indian clinical research industry could attract US $1.5 billion of revenue from U.S. and European sponsors by 2010, creating a demand for more than 10,000 investigators, trained in good clinical practice (GCP) and supported by nearly 50,000 clinical research professionals" (Sahoo & Sawant 2007: 51). The Indian pharmaceutical industry, members of the Indian clinical trials industry, CROs, Confederation of Indian Industry, corporate hospitals and research investigators, in particular, are eager to become part of the lucrative multi-billion dollar global pharmaceutical industry. They have repeatedly called attention to the so-called "spillover" benefits of clinical trials through related business opportunities that could make India a major hub for global biotechnology research.

Scholars contend that MPCs and CROs are keen to conduct clinical trials in settings like India because they are able to complete the trials speedily and cheaply, mainly due to the lower salaries of physicians, nurses, study coordinators, payments to trial participants and insurance premiums (Glickman et al., 2009). Simultaneously, critics have pointed out that the clinical trials outsourced to India are going ethically awry because of inadequate regulatory

[1] Other stakeholders such as patients, family members, nurses, and community leaders were not included in the study.