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"Geographical randomization" and "Social exploitation" in clinical research: World trials in Santiago, Chile

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ABSTRACT

In the discussion of global clinical trials, two ideas are frequently advanced. Firstly, it is sometimes articulated that companies can displace clinical protocols between countries quite easily (what I propose to call "geographical randomization"). The second idea conveys that global trials lead to the exploitation of poor regions and poor people ("social exploitation"). By analyzing the context of Santiago, the capital city of Chile, I argue that, although these ideas are not myths, they cannot capture the whole complexity of global trials. On the one hand, geographical factors restrain the mobility of the clinical trials industry. On the other, studies tend to be concentrated in wealthier areas with more affluent people.

1. Introduction

1.1. The globalization of clinical trials

Since the 1990s, the pharmaceutical industry has undergone three important changes. Firstly, as old research pathways have become less capable of spawning new medicines, manufacturers started searching for innovative research strategies (Gassmann and Reepmeyer, 2005). Secondly, huge companies have been created as a result of mergers involving multinational firms (Magalhães et al., 2003). Finally, there has been a significant growth in the number of world clinical trials.

The latter are studies with human beings, conducted in two or more countries, aiming to assess the efficacy and safety of new therapeutic compounds. They often assume the form of *randomized* trials, that is, studies in which research subjects are distributed *at random* in two different arms: those who take the experimental drug, and those who are given an active medicine or a placebo.

Different authors highlight different factors leading to the global diffusion of randomized trials, such as the regulatory looseness of countries that are new to clinical research (Angell, 2005; Shah, 2006); the need for including ethnically diverse populations in trials (Marschner, 2010); the access to research subjects who seldom take medicines and whose bodies, therefore, provide more valuable results (Petryna, 2005); the regulatory shifts of countries where clinical research used to be concentrated, insofar as they are now mandating the inclusion of new national settings into clinical protocols (Epstein, 2007) and the diminution of costs enabled by the conduct of trials in poorer countries (Dainesi and Elkis, 2007; Shah, 2006; Fisher, 2009).

Although these reasons are sometimes mingled to explain the globalization of trials, they can be quite discordant. For instance, claiming that clinical researchers are looking for ethnic diversity implies the neglect of the economic argument that researchers are simply looking for low-costly locations.[1] However, the field of world clinical trials is informed by diverse rationalities and discourses that can be marshaled at different moments. Not surprisingly, Petryna (2005) has identified an "ethical variability" in this domain.

The globalization of trials is matched by the constitution of an international regulatory framework on clinical research (Abraham and Reed, 2001; Rozovsky and Adams, 2003) thus confirming the current relevance of rules and standards (Timmermans and Epstein, 2010), which often anticipate and prepare the arrival of global activities (Bicudo, 2006).

Clinical trials may be either directly conducted by pharmaceutical companies or taken over by Contract Research Organizations (CROs), which are companies specializing in the design,

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[1] I am grateful to an anonymous reviewer who made this important point.

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conduct, and monitoring of research protocols and whose services have made it easier to globalize clinical activities (Piachaud, 2002; Shuchman, 2007; Petryna, 2009; Fisher, 2009).

1.2. "Social exploitation" and "geographical randomization"

Many analysts have been striving to interpret the globalization of trials by using human sciences' theories and insights. From anthropology to economics, a broad range of ideas are employed to depict trials not only as a technical and statistical issue but also as a social, political, and cultural phenomenon. In spite of the differences between these explanations, two ideas seem to be embedded in several analysts' thoughts.

Firstly, there is the idea that world trials provoke the exploitation of poor regions, as well as "the world's poorest patients" (Shah, 2006), an interpretation that has produced a historical association between trials and vulnerable populations' enrollment. As Epstein (2007) demonstrated, socially disadvantaged people (prisoners, mentally ill, developmentally disabled children) were often recruited in the first clinical enterprises conducted in the United States during the 1970s. The roots of this association (trials and vulnerable people) have grown bigger through the decades, and nowadays many analysts would agree with Fisher's (2009, pp. 32) statement: "The poor and uninsured have become the groups whose disenfranchised bodies are used in the name of medical progress and pharmaceutical profit."

The second widespread idea is that multinational companies can rapidly transfer trials from country to country as soon as the economic scenario makes this relocation beneficial. I am proposing to name this idea "geographical randomization," for if one sustains it too fiercely, one will eventually believe that trials can be developed anywhere and clinical settings can be selected at random. The idea has its source in the trials industry itself, which, as Petryna (2009, pp. 173) points out, is eager to claim that "[…] companies can abandon sites and move investments elsewhere. They use this mobility to create competition between investigative sites and, if necessary, to isolate more demanding sites, while decreasing the cost of a trial."

This idea carries a technical hallmark because it helps to apply to contemporary trials the rationale of old productive activities, namely: "In all cases […], the ultimate basis of producer preference for locations is the rate of earnings (wages, profits, or interest) obtainable at different places." (Hoover, 1948, pp. 6) With this approach, one will eventually believe that the trials industry (pharma companies and CROs) simply follows the directions indicated by the "invisible hand" of the market.

The main purpose of this paper is to discuss these two ideas. Such a discussion is important because with the expansion of international trials, the comprehension of current social relations, and the formulation of sound public policies depend on the capacity to answer to questions such as: How mobile in fact are global actors? How valuable are national and local contexts from their viewpoint? Does exploitation affect individuals or must it also be read in space? Is the presence of large poor populations in countries that are new to clinical research the only source of concern in the globalization of trials?

I argue that due to geographic phenomena, the "hypermobility" (Petryna, 2009, pp. 96) of global trials is much more a threat that is used by the trials industry than a fact. On the other hand, the paper will claim that although world trials do imply the enrollment of poor, vulnerable populations and regions, inequalities in terms of research infrastructures frequently determine a more intensive participation of more affluent areas and people.

The paper focuses on clinical activities undertaken in Santiago, the capital city of Chile. The study was carried out within two Brazilian research centers: the Laboratory of Political Geography and Environmental-Territorial Planning (Laboplan), a research unit of the Department of Geography, University of São Paulo; and the Center for Studies on Contemporary Culture (Cedec). This article presents some outcomes of a research project conducted in 2008, during which information on clinical trials in Latin America was gleaned. The project finished with a small scale piece of fieldwork conducted in December 2008, which consisted of interviewing five professionals working in institutions engaged in clinical trials in Santiago.[2]

To explore the aforementioned questions, the paper moves on to outlining the situation of world trials in Chile and Santiago. Subsequently, after having analyzed the access that global trialists have to research subjects and infrastructures, the paper discusses the ideas of "social exploitation" and "geographical randomization."

2. Data and analysis: world clinical trials in Chile and Santiago

2.1. World trials in Chile

Latin America is experiencing an exponential growth in the hosting of international trials (Medpace, 2010), having displayed the world's most intense expansion during the late 1990s (DataEdge, 2001). In Brazil, Argentina, Mexico, and Chile, these trends are stronger due to the modernization of their regulatory frameworks, the size of their population, and the quality of their research infrastructures.

According to Pinard (in Daher, 2005, pp. 100), the Chilean economy corresponds to only a fourth of the Argentinean and a tenth of the Brazilian economy. However, the country holds important factors including: dynamic economic sectors, actors realizing important investments in other Latin American countries (Daher, 2005), a large inflow of foreign investments (Pérez, 2005) along with an emerging business elite, especially in Santiago (Jones, 1998). Chile has also been positively evaluated by key global actors. For instance, in the 2006 World Economic Forum, when compared to other Latin American countries, Chile was given the top competitiveness rate, and was deemed the "best place to do business." (CORFO, 2010)

Since the late 1990s, clinical trials have thrived in Chile. From 2002 to 2007, over 500 clinical trials were conducted in the country, involving over 350,000 patients. Additionally over 30 CROs operate in the country in which infectious diseases, oncology, bronchiopulmonary and cardiology are the main therapeutic classes under study (CORFO, 2010). In my fieldwork in Santiago, it became clear that pharma companies and CROs from the United States and Europe are the main actors responsible for this expansion.

Chile holds characteristics that are important in global trials, such as a stable political environment and a quick legal and ethical review of research applications.[3] Thus, Chile figures in the short list of Latin American clinical sets, within which Brazil, Mexico, and Argentina are the principal locations. Even though Chile is not the main Latin American target for the trials industry, its study is relevant for two reasons. On the one hand, the attempts that have been made by Chilean institutions to attract

[2] Further to this project, I started in 2009 a Ph.D. research on the globalization of clinical trials and the role played by ethics committees, focusing on the situations of South Africa and Brazil. This research is being conducted at the Department of Political Economy, King's College London, UK, with the supervision of Alex Faulkner and Brian Salter. With a travel grant from the European Science Foundation, I am also conducting a study on the recruitment of participants for world trials in Spain, France, the UK, and Brazil.

[3] In 2010, the regulatory approval of clinical protocols took from 3.5 to 4.5 months in Chile, a performance comparable to that of Mexico (from 3 to 4 months) and faster than that of Argentina (from 4.5 to 5) and Brazil (from 6 to 7.5) (Medpace, 2010).