

Project title: "We Get Patients": Understanding the Culture of Patient Recruitment Organizations

Author: Elita Poplavska

Department: Social and administrative pharmacy program, Pharmaceutical care and health systems department, College of Pharmacy, University of Minnesota

Project summary:

Patient recruitment companies are small, private businesses that specialize in recruiting patients for clinical trials on behalf of pharmaceutical and medical device industries. The emergence of these companies around the 1990's is part of a broader tendency within the pharmaceutical industry to focus on outsourcing clinical trial research. The organizational complexity of clinical trials has led to the emergence of a new sector devoted to the management and administration of clinical trials. The shift of clinical research to the private sector has raised new questions and ethical concerns about relationships that emerge between the industry, regulating bodies, researchers and human participants. This thesis investigates and describes one aspect of the private clinical trial industry—patient recruitment for clinical research studies and issues that emerge from these activities.

The results are based on a year-long ethnographic study including participant observations, document analysis and interviews with stakeholders of recruitment industry. The central argument I develop is that rationales for recruitment tactics are intimately entwined with the market value that these companies see in patient recruitment, and with the market risk that attends this process. This worldview impacts every aspect of the patient recruitment business—starting from the structure of patient recruitment, to the development of marketing campaigns, communication with the public, and all the way through to the relations with clinicians. As a result, in the current organization of private

industry patient recruitment new ethical questions emerge that are not addressed by the current guidelines mostly focused on patients and clinicians interactions.

Results

Presentations:

Completed:

Poplavska, E. (2013) "Recruiting 'high quality' patients" at joint conference of *European Association of Social Anthropologists Medical Anthropology Network and American Anthropology Association Society for Medical Anthropology* held in Tarragona, Spain, June 2013.

Poplavska, E. (2013) "'We are not a clinic, they are not patients': Professional patient recruitment for clinical trials" at *3rd Global conference: The Patient* held in Lisbon, Portugal, May 2013.

Planned:

Poplavska, E. (2013) "'Only sites can enroll': the professional patient recruitment services" at conference of *Society for Social Studies of Science* in San Diego, USA, October 2013.

More presentations will be planned in 2014.

Publications

Planned:

Currently I am working on three papers which I plan to submit for publication in peer-reviewed journals. Working titles and the purpose of each article are provided below.

1. “We know more than we tell”: informed consent in professional patient recruitment.
The purpose of this paper is to present and discuss how patient recruitment companies structure, design and control the flow of information when communicating available clinical trials to patient populations. I also analyze implications of this communication process for the valid informed consent process.
2. Recruiting “high quality” patients.
The purpose of this paper is to analyze subjective assessment of potential research participants based on their social and economic characteristics for phase II and III clinical studies. I discuss ethical implications of the structure of the recruitment process which is designed to select individuals with these specific characteristics.
3. Clinicians’ experience with professional patient recruitment services.
The purpose of this paper is to analyze study coordinators’ experiences with professional patient recruitment services in the context of current organization of the research industry and to provide suggestions for improvement of these collaborations.

Future project plans

Dissertation defense: April, 2013

The funding was used to conduct full time fieldwork in one of the patient recruitment companies, transcribe interviews and attend one pharmaceutical industry conference dedicated to the issues of patient recruitment for clinical trials.

After obtaining my PhD, I plan to continue to research different aspects of patient involvement in clinical research studies.