



Care in Clinical Trials involving Youth. Exploring Vulnerability through Empirical Philosophy in a Clinical Trials Unit.

Background

Should children be included in biomedical research? What ethical standards and criteria should be followed? Research ethics is the subfield of bioethics that examines these kinds of questions. Previous studies suggest that children belong to a vulnerable category of research subjects, therefore an extra effort should be made to avoid harm and to protect them. Researchers and healthcare professionals should assess their competency to provide informed assent, as well as the degree and the ways of involvement of parents or legal representatives in the decision-making process. The debate is made even more complex by the fact that, besides differences in socioeconomic conditions and experiences of life, children belong to a broad and heterogeneous category which includes all people between 0 and 18 years old. Several differentiations are therefore attempted to address medical and sociocultural considerations needed for different age ranges.

The research ethics debate has generated international interest after World War II and the Nuremberg Doctors' Trials, which brought to the world's attention the experiences of Nazi doctors and scientists with war prisoners. During the 20th century, several bioethics guidelines and regulations have followed, establishing what today are considered ethical standards of biomedical research by most Western countries. It was established, for instance, that research involving human subjects should be evaluated by local ethics committees that provide an extra examination, among other things, of the risk/benefits ratio, the way the study is presented and explained to possible participants, and the methods employed. Since the turn of the 21st century, however, the field of bioethics has grown an increasing interest in the study of professionals and patients' experiences, opinions and beliefs about medical practices. This new way of studying ethical issues has been named "the empirical turn" of bioethics and it is rarely employed in biomedical research ethics studies.

CareInTrials aims to explore the ethical issues concerning the participation of adolescents in clinical trials by examining ethical regulations and guidelines, as well as interactions in the hospital and stakeholders' narratives related to clinical trials. This research has been restricted to adolescence, as it constitutes the transitional period in which people gradually start making decisions for themselves and being socially recognized as subjects with legal rights.





Aims and Objectives

CareInTrials pursues three main objectives:

1. to analyze how international guidelines and regulations have framed, over almost a century, the meanings of autonomy and vulnerability in biomedical research with minors;
2. to observe social interactions within the daily practice of clinical trials involving adolescents;
3. to explore how adolescents, their accompanying adults and healthcare professionals make sense of adolescents' participation in clinical trials.

Theoretical Framework and Methodology

This is an empirical philosophy study, which makes use of qualitative methods to provide a philosophical reading of adolescents' participation in clinical trials.

To address the aforementioned objectives, on the one hand, it provides a document analysis of international ethical guidelines and regulations on research ethics from 1947 until today. On the other hand, it conducts ethnographic observations and semi-structured interviews with adolescents, accompanying adults and healthcare professionals (i.e. nurses and researchers) involved in selected clinical trials conducted in the University Hospital La Paz.

The analysis draws upon contemporary philosophy (especially philosophy of medicine and bioethics), interdisciplinary understandings of childhood, the lived embodied experiences, and the situated existential dimension in medicine. Particular importance will be placed in the dimension of care in the relationships studied.

The empirical part of this research is conducted at the University Hospital La Paz in Madrid (Spain) and the principal investigator makes regular research stays at the "Science, Philosophy and History" (SPHERE) Research Unit (CNRS - University of Paris-Cité), to contribute to and promote scientific exchanges.

Where are we at?

- We have conducted the document analysis and we are in the final phase of writing a first article on this topic;
- We received approval from the Research Ethics Committee of La Paz University Hospital (CEIm, with approval number: PI-4809) to conduct the fieldwork;
- We have conducted a cumulative 2 months full-time observations;





- We have conducted 22 interviews (of which 9 with minors aged from 12 to 16 years old, 6 accompanying adults and 7 healthcare professionals) in four different trial settings and disciplines: 1) the development of an anti - COVID-19 vaccine, 2) studies on dermatological diseases such as atopic dermatitis and psoriasis, 2) studies on hemophilia and 3) on the PIK3CA-related overgrowth spectrum.

The fieldwork will end in July 2022, when the last interview is scheduled. 14 interviews are already transcribed and the analysis has started of both the transcribed interviews and the ethnographic fieldwork notes.





Dissemination Activity

Oral presentations of parts of this study were made at the following national and international seminars and conferences:

- 3 seminars given to researchers of the Research and Clinical Trials Unit of La Paz University Hospital;
- An oral presentation of the project was given to researchers and healthcare professionals at 3 different units of La Paz University Hospital;
- Seminar on empirical philosophy organized by the University of Paris-Cité, France (June 2021);
- 14th World Conference on Bioethics, Medical Ethics and Health Law, Porto, Portugal (March 2022);
- International workshop “Pediatric cancers and genomics: a major change?” University of Lyon, France (foreseen in June 2022);
- The International Symposium on Critical Policy Studies, organized by the University of Karlstad, Sweden; the University of Adelaide and the University of Sydney, Australia ; The Graduate Institute, Geneva, Switzerland (foreseen in August 2022).

Other forms of dissemination:

- Mention of the project in Dr. Murano personal website of [SPHERE](#) Research Unit and on LinkedIn; Twitter account [@CareInTrials](#).

Expected Impact

Combining empirical and theoretical approaches, *CareInTrials* proposes a critical analysis of the ethics of biomedical research with adolescents. It contributes to the debate on how and to what extent ethical guidelines and regulations should be shaped by the experiences and opinions of different stakeholders. It also explores the care dimension of clinical trials and offers an interdisciplinary account of adolescent participation in biomedical research.





The research team:

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