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A New Challenge to Research Ethics: Patients-Led Research (PLR) and the Role of Internet Based Social Networks

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Abstract. A characteristic feature of the development of health-related social networks is the emergence of internet-based virtual communities, composed of patients. These communities go beyond the mere interchange of information concerning their conditions, intervening in the planning and execution of clinical research, including randomised controlled trials, in collaboration with health professionals. That was the case, in 2009, when patients suffering amyotrophic lateral sclerosis, a rare and severe disease, conducted a clinical trial in USA, organising themselves through an online platform. This initiative launched a new model for the planning and conduction of clinical research: “Participants-Led Research” (PLR). The distinctive particularities of this new research paradigm represent a challenge to the traditional standards used for judging the ethical soundness of clinical investigation. That is the case, for example, of informed consent. This article aims at identifying the ethical, legal, and social issues (ELSI) posed by PLR and the relevant concepts that may help in solving them. The following issues, in particular, are analysed, that may give place to a new social contract for the ethical assessment of clinical research: consent for participating in research and personal integrity; data protection and confidentiality; benefits sharing and intellectual property

Keywords. Community-Based Participatory Research, Ethics Research, Social Networks, Data

Introduction

The development of health related social networks (health devoted websites and social networks, discussion forums, blogs, and patient’s information and support websites, etc.) helped the creation of a novel kind of patient communities: Online Patient Networks, whose members interact among themselves through a number of different Internet based social networks. Some of these networks gather together patients suffering the same disease, usually severe and chronic.

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The members of these communities take advantage of these networks to interchange disease related real-world experiences, current treatments and, in particular, available drugs, their adverse effects, recent scientific research results and ongoing randomised trials, concerning their conditions.

There is a number of examples, in the United States of America, of such communities going beyond the mere interchange of relevant information, involving themselves in either observational or experimental clinical research, together with health professionals, sharing information in a peer to peer manner, in order to generate relevant new data for their conditions. A well-known example of this sort of cooperation is the online platform PatientsLikeMe, which organised, in 2009, the lithium study for amyotrophic lateral sclerosis (ALS), a severe and rare neurological condition, launching a new paradigm for planning and conducting clinical research [1-2].

Since 2012, a number of papers have coined the expression “crowdsourced health research studies” (CHRS) to designate this new health research model, pointing out to one of its original features, that of mobilising multiple sources of information to help health research, taking advantage of the dynamic group interactions existing in virtual communities and the communication tools currently available in internet. Melanie Swan distinguishes two different types of CHRS: one of them organised by clinical researchers (research organised CHRS), and the other led by patients themselves (participants-organised CHRS) [3]. The lithium study for ALS is an example of the latter.

Other authors have proposed the expression “apomediated research” to refer to this sort of investigations, pointing out to the fact that this type of research finds its way through the direct exchange of information and data among the members of the virtual communities, avoiding the traditional collection of data, mediated by specialised health professionals: physicians, pharmacists and clinical researchers [4]. Günther Eysenbach had used the voice “apomediation” in his framework describing Medicine 2.0 [5].

Recently, stakeholders of this new model of investigation have proposed the term “participants-led research” (PLR) to describe it, emphasising its participative nature, identified as one of its original and characteristic features [6]. As a matter of fact, all these expressions describe this novel research model, highlighting different distinctive aspects of its innovative structure.

Although recent, this new model of research has already motivated some publications (au lieu de “a significant number of”). One of them evaluates the potential value of this innovative approach, comparing it with the traditional one. Using this plan, the ethical, legal, and social issues (ELS) are examined. It has been, thus, proposed, that a new ethical and legal regulatory framework is needed to address the particularities of CHRS, different from that currently in use to examine standard research, nonetheless serving the same purposes [7].

After defining PLR, a recent contribution examines the potential benefits and risks associated to the growing of this research strategy. The authors recognise that the scientific value and social utility of PLR requires a new social contract, giving a thorough account of its relevant features [6].

Indeed, the PLR has so many particularities embedded in its structure, that they challenge the pertinence of the ethical principles themselves, which support the current ethical evaluation system. This is the case, for example, of informed consent, a key component of ethically sound research, whose importance could be put to question, as part of a research model in which those planning and conducting the investigation, act

as research subjects themselves [8]. This may result, for example, in a challenge to Research Ethical Committees (RECs) role, when evaluating these peculiar informed consents, aimed at protecting research participants from themselves.

In this context, this report aims at reflecting on some ELS issues concerning PLR. In particular, the protection of personal integrity, the confidentiality of data, and the new paradigm for data sharing and intellectual property in PLR generated information.

1. Methods

Our prospective analysis is based on a comprehensive research of published reports, indexed in relevant databases, addressing research led by patients' communities, through digital networks. In order to narrow our search, increasing the specificity of its results, we aimed at collecting only those reports addressing participants-organised CHRS, adopting the classification proposed by Swan [3]. We also considered those reports examining "research-organised" CHRS, in which professional researchers lead the initiative, to provide a comprehensive background to our analysis.

2. Results and Discussion

We identified three major new issues related to PLR and the emergence of patient's virtual community's involvement in research.

PLR shifts the equilibrium of power, from professional researchers to research subjects, differentiating this innovative model from traditional research. In PLR, patients not only participate in organising and conducting the investigation, but also on the recollection and analysis of the data resulting from the research, *vis-à-vis* those professionals participating in the investigation. As a result of this involvement, the centre of gravity of research is displaced from the professional interests to those belonging to the patients' community, thanks to their active involvement through digital networking. This collaboration permits a previously inexistent mix of lay expertise (coming from those patients acting as research subjects themselves) and professional expertise (coming from those physicians and pharmacists that collaborate with the execution of the study and the analysis of the data).

This entirely new situation, blurring the border between the patient as passive participant and its new role as protagonist of the research, actively participating in planning and conducting the investigation, generates a number of previously unsuspected issues, concerning the notion of personal protection. In fact, this notion has to be understood not only as protection against research related risks, but also as protection and confidentiality of personal health information, in a setting in which patients are both actors and participants in clinical research.

In PLR, patients provide their personal data, voluntarily sharing them with other patients, in order to get useful information for the diagnosis and treatment of their condition. When sharing the data, they resign their right to the confidentiality of this information, overcoming this traditional principle of human subject's research, as a demonstration of "self-empowerment" of patients themselves. A novel challenge to the role of RECs is to discern if they are entitled to protect patients from themselves, concerning their data protection, as they were originally meant to be protected from third parties, engaged in human subject's research.

This dilemma might be considered as a result of the progressive differentiation between the personal and public spheres, originating in the eighteenth century enlightened western society, empowering the individual with, nowadays, universally recognised rights. These rights, aimed at protecting the individuals from the intrusion of the state and the dominant class in their private sphere and decisions, were not meant to protect individuals from their own decisions, or to compel them to behave in a certain manner to avoid being harmed. The role of RECs in the protection of human subjects is consistent with this enlightened approach, and the recognition of their rights is enshrined in a number of covenants and declarations. PLR, as a new paradigm of patients' empowerment in research, challenges this traditional approach, questioning the meaning, for example, of data protection in this new setting and the role of RECs in overseeing the fulfilment of this right.

Is it conceivable that human subjects might resign the right to protection of their data, when participating in PLR? It is widely accepted that some rights are unwaivable, for example the right to not be enslaved, but some authors pose that this is not the case with every human right: "...one cannot waive one's rights to autonomy and liberty, [but] one probably can, in certain circumstances, waive one's human right to privacy" [9]. It is debatable if this is the case with data collected in PLR, but it is beyond doubt that this is a major issue that has to be addressed, when discussing the appropriateness of current RECs regulation. Some authors have pointed out, even, the need of a new social contract for fulfilling the functions of these committees [6].

The second major issue we identified, as a result of the blurring border between the patient and the researcher, is related with the purpose and the quality of the data obtained from PLR. This new kind of research, concerning the knowledge and therapeutics of certain diseases, represent a valuable source of information in certain areas, which not always is easily obtained from traditional research, as it is the case of pharmacovigilance, for example. This new way of collecting and assembling data, however, compels the scientific community to check the quality of the information that is gathered by PLR, and the need for empowering this new sort of citizens' generated science with the required tools for ensuring the quality and reproducibility of the data. A major challenge to PLR, thus, is represented by the need of professionalizing the role of patient-researcher, when feeding the results of clinical research with self-reported data, to match the current standards of traditional investigations proceedings, and avoiding the potential multiplication of error occasioned by a multi-source of data collection. This massive involvement of patient-researchers, at the same time, represents a precious opportunity to improve the statistical power of clinical research, and the common difficulties in finding and enrolling patients. Vayena et al. [6] consider this issue, concerning the quality of data generated by PLR, as a key part to be considered in the new social contract that needs to be agreed by the scientific and lay communities, when taking charge of these new developments.

A third issue, singled out in our search, and not previously identified by those who have systematically addressed this subject, is posed by the need of discussing new strategies regarding intellectual property, and the sharing of benefits originating in this new kind of research, led by patients, and with the occasional collaboration of academic and for-profit sectors. This discussion is particularly relevant for those chronic and rare conditions, in which the collaboration of patients' organizations is crucial for the success of clinical research [10].

In summary, PLR represents, at the same time, an innovative manner for organising clinical research, a precious opportunity for improving pharmacovigilance

[11], for increasing the enrolment of patients, particularly in uncommon conditions, and –most notably- a challenge to the framework used by RECs for the standard ethical assessment of investigation on human subjects.

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