



EDITORIAL

Research in pediatrics: A long bureaucratic obstacle course



Investigar en pediatría: una larga carrera de obstáculos burocráticos

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Any research in the field of health must guarantee both the safety of the patients and the confidentiality of their personal data. The two documents that establish the ethical principles that any study must adhere to are the Declaration of Helsinki, published by the World Medical Association,¹ and the Good Clinical Practice Guideline of the International Council for Harmonisation. They set the foundations on which each country then develops its own internal rules and laws to regulate biomedical research.

In Spain, 3 laws regulate research in human subjects: Law 14/2007,² which regulates research requiring invasive procedures, the use of biological samples and research on embryos, Royal Decree 1090/2015,³ which regulates clinical trials using medicines and, lastly, Royal Decree 957/2020⁴ which regulates observational studies using medicines. In addition, the enactment of Organic Law 3/2018⁵ on the protection of personal data has regulated the handling of

personal patient data in medical research. As would be expected, legislation has focused on research aspects and study designs that may merit particular ethical consideration due to their characteristics and risks. All other types of study are not currently subject to specific regulation.

As regard patient data protection in Spain, in recent years there have been several initiatives to create databases of anonymised patient data. Some are of a regional scope, and there have been attempts to create nationwide databases. These databases are very useful for conduction of population-based and epidemiological studies. Several months ago, the Spanish government announced the intention to create a health data lake to make large amounts of raw data available to researchers and administrators, although this project is still in its initial stages. A joint health data space is also being developed at the European level to enable sharing health data for research purposes. This initiative is also at a very preliminary stage and its implementation will pose significant challenges, as the interests and laws of the different member states differ widely. In the present era of digitalization and globalization, it seems reasonable that future developments will include the development of a structure of this nature with the largest scope

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possible. The anonymization of the data facilitates the task of researchers by simplifying the requests for approval from institutions and for consent from patients, thus significantly reducing the bureaucratic burden of any study in which the data can be obtained through these databases.

Any study involving human participants, no matter how simple, needs to be evaluated by a Research Ethics Committee (REC) before starting data collection. These committees ensure that studies comply with the minimum ethical and legal standards. The current issue of *Anales de Pediatría* features an entire article on the subject, written by Solís Sánchez et al.⁶ The important role of RECs in this regard is unquestionable, and their performance is commendable, in many instances, despite their limited resources and substantial workloads. In addition, the approval of a study by a REC offers a guarantee to scientific journals.

As noted above, all studies that use medicines are currently regulated by law, and their evaluation by RECs is pretty uniform. On the other hand, there is no specific regulation on observational studies that do not involve the use of medicines (which are, by far, the most frequent type and also the type with the lowest ethical risk). In most instances, the sole important requirement is to ensure the confidentiality of the patient,⁵ as the study only requires collection of data from health records. In addition, these studies are frequently conducted in more than one centre to obtain large and representative samples. The digitalization of health records has allowed sharing of data and information between centres, but this exchange must always take place with adequate safeguarding of confidentiality, and RECs play a key role in ensuring that this is the case.

In many instances, this legal lacuna leads centres from which information is going to be obtained for an observational study without medicines to demand approval by their specific REC, even if it has already been approved by another REC. This results in a cascade of reports from different RECs for a single study, sometimes in disagreement, which in turn results in successive changes to informed consent forms, patient information sheets or the data to be collected. Each change in the research proposal must be notified to the REC that provided initial approval so that it can approve the introduced changes, thus entering a vicious cycle of reports by multiple RECs on a single study. Therefore, it is not uncommon for an observational study without medicines (which poses little to no risk to the patient) to face many more bureaucratic hurdles than studies with higher ethical risk in which the law determines that the ruling of a REC is a binding single opinion.^{3,4} Needless to say, this results in an increased cost of the study, heterogeneity in data collection and delays in the initiation of the project of, at best, a few weeks and, in the worst case scenario, months. Furthermore, the lack of legislation results in each administration, territorial authority or centre imposing different requirements, official authorizations or contracts for the project to take off. There have even been cases in which a REC at the autonomous community level has demanded that the investigators in a project conducted at the primary care level obtain the approval of the administration of the hospital

serving the catchment area (totally unrelated to the project and the primary care system), which evinces a lack of awareness of the organizational structure of paediatric care in Spain. Thus, researchers may be dragged into an endless course of bureaucratic hurdles that are utterly discouraging and waste considerable time and energy.

Given the above, it would be beneficial to establish official regulations for this type of multicentre study, requiring approval by a single REC only, and making the decision binding, at least for centres within the Spanish territory. It would also be useful for RECs to establish standard requirements for these studies, as well as a template for the informed consent form and patient information sheets. On the other hand, given that the responsibility over patient data falls with authorities at the autonomous community level, another strategy that could be contemplated would be the development of a standardised document to authorise the use of adequately anonymised data to be attached to the approval by the single REC, which would be completed in each of the autonomous communities involved in the study.

Research provides the foundation for the advancement of knowledge. Administrations are responsible for ensuring that research in medicine in general and in paediatrics in particular can be conducted in adherence with adequate ethical principles, but with minimum bureaucratic barriers to investigators.

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