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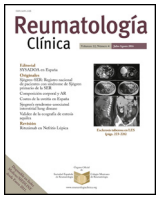

Review Article

The Patient Information Sheet (PIS) and Informed Consent (IC) for case reports and case series: Proposal for a standard model for presentations in congresses and other scientific publications☆

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ABSTRACT

A standard model of the Patient Information Sheet (PIS) and Informed Consent (IC) would facilitate compliance with the guaranteed rights of the patient when their health data is used in any form for purposes other than medical assistance, like the release of case reports and case series. This model would be suitable for the presentation of case reports in a congress in any form (verbal communication, poster or presentation), for its publication in a journal that does not require the completion of its own model, or even for teaching practice.

A standard model of the PIS and IC would facilitate the application of the current regulations and good clinical practices in clinical research: it would guarantee the compliance of the professionals' duty of protection of the patient's privacy against the use of their health data for purposes other than medical assistance.

Hoja de información al paciente y consentimiento informado de casos clínicos y series de casos: propuesta de un modelo estandarizado para comunicaciones en congresos y otras publicaciones científicas

Palabras clave:
DeCS: Derechos del paciente
Consentimiento informado
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RESUMEN

Un modelo estandarizado de Hoja de información al paciente (HIP) y Consentimiento informado (CI) facilitaría el cumplimiento de garantizar el derecho de los pacientes cuando se utilicen sus datos de salud en cualquier soporte con fines distintos al asistencial, como es la divulgación de casos clínicos y series de casos. Este modelo sería adecuado, para la presentación de casos clínicos en un Congreso en cualquier formato (comunicación oral, póster o ponencia), para su publicación en una revista que no exija la cumplimentación de un modelo propio o incluso para una actividad docente.

Un modelo estandarizado de HIP y CI facilita la aplicación de la normativa actual y de las Normas de Buena Práctica en Investigación Clínica: garantiza el cumplimiento del deber de los profesionales de proteger la intimidad de los pacientes ante el uso de sus datos de salud para fines distintos a la práctica asistencial.

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Introduction

Case reports and case series are descriptive observational studies. Although there is no agreement on the number of patients to be included in the definitions of both types, it is generally accepted that case reports describe selected observed characteristics of a single patient, while case series describe a group of patients with a certain condition in common.[1,2] Nevertheless, the scientific literature does not clearly differentiate between these definitions. For example, in PubMed both types of study are included under the single descriptor (or MeSH term) of "case reports", regardless of the number of patients observed (one or more than one).[3] One clearly established characteristic is that both types of study have no control group.

According to Oxford University, evidence-based principles of medicine place case series lower down in terms of level of scientific evidence than randomised clinical trials, systematic reviews or cohort studies. Case reports were excluded from its 2011 update.[4]

However, case reports have always been used in teaching[5] and they reflect contemporary medical and surgical practice. They show the decision-making process simply and didactically in patients with a specific and usually singular set of symptoms.[6] Case reports and case series often document the emergence of new diseases or adverse reactions to medication. In spite of their major limitations (as the lack of a control groups makes it impossible to evaluate a cause–effect relationship or to test a research hypothesis[1,7]), case reports and case series are a useful means of epidemiological vigilance and formulating causal relationships.[2,3,8,9] Case series are sometimes the only possible design (for example, to complete data on the long-term safety aspects of drugs).[10]

Evidence-based medicine uses randomised and controlled clinical trials (as well as meta-analysis and systematic reviews of them).[10] However, case reports and case series still form a part of medical knowledge, as is shown by the fact that more than 1,700,000 case reports and case series have now been registered in PubMed since the first publication of a case series in 1936.[11] This massive number of publications (a million more are recorded in PubMed than is the case for clinical trials) would have to be added to the majority of communications in scientific conferences that are not published in journals. These are known as "grey literature", and they often have this type of descriptive study design.

Little attention has been paid to patients' right to privacy in scientific publications of case reports and case series, including communications in Conferences or scientific journals. Based on anecdotal clinical observations rather than a prior hypothesis, works of this type are not designed using research project methodology and they are therefore not subject to approval by a Research Ethics Committee (REC). Thus when these studies are presented in Conferences or published in scientific journals, the researchers and even the editorial committees of journals generally ignore ethical-legal aspects. This is a striking fact, as given the small number of patients included in cases reports and series, together with the fact that they describe infrequent, exceptional or unexpected situations, it is far easier to identify the patients involved than it is for those in other types of study with larger samples.[5]

Legal basis

In the field of healthcare the right to privacy is divided into two differentiated rights[12]: (1) the right to **privacy** and (2) the **right to data protection**.

The right to privacy: *privacy* is a fundamental right that is one of the list of rights covered by the Spanish Constitution (SC) of 1978 (art. 18.1) and it derives from the right to respect for private and family life recognised in the 1948 Universal Declaration of Human Rights. The consideration that privacy is a "human right" gives it a special meaning, a value that is special or extra in comparison with other rights. The right to privacy includes the **right to confidentiality** and is comparable with "professional secrecy" ("confidentiality" is a better expression than "medical professional secrecy", as it is conceptually broader). It is understood to be an obligation that binds professionals when working in an area that includes personal privacy. On the other hand, professional secrecy stems from the self-regulation imposed by the profession (professional ethics), while confidentiality is a right held by patients. From a bioethical viewpoint based on classical principles, the respect for privacy, as well as being based on respect for the **principle of independence**, is also a part of the obligation of healthcare professionals not to do harm.[12,13]

The right to data protection: the protection of individuals in connection with how their personal data are managed is a fundamental right in law: all individuals have the right to *protection of their personal data* (art. 18.4 CE).[14–16]

At a European level, in May 2016 the European Data Protection Regulation[17] (EDPR) was published. This covers the protection of individuals respecting the management of their personal data and the free circulation of such data, replacing the Directive that had been in force.[18] This European Regulation, which became applicable in Spain on 25 May 2018, unifies and modernises European regulations on data protection, offering citizens better control of their personal data.

The following laws stand out among the applicable national laws governing the use of health data in observational research: the Spanish data protection law (LOPD),[19] the Royal Decree that expresses this[20] and the Law of Patient Autonomy (LBAP).[21] Until 25 May 2018, Spain and the other member states were able to adopt or initiate the preparation of specific regulations that may have been necessary to permit or facilitate the application of the EDPR. After 25 May 2018 the EDPR is obligatory in all of its elements, and it is directly applicable in each member state.

According to the EDPR, health and, as a novelty, biometric data,[1] are considered to be "*special categories of personal data*", and use of them is expressly prohibited unless this is necessary for care purposes or if some circumstance of general interest is present, or if the **individual involved expressly consents to the same** (article 9.2).

The EDPR introduces the "*pseudonymisation*"[2] of personal data as a means of reducing the risks to the patients involved and helping researchers to fulfil their obligations, without aiming to exclude any other data protection measure. Nevertheless, pseudonymisation (or coding or reversibly disassociating data, which are the same thing), and which in certain types of research studies and/or specific circumstances, and always after a previous finding in favour by a REC, allows us to use patient health data without their consent, is not applicable to the publication of a case report, as in this the researcher is fully aware of the identity of the patient.

Patient consent is one of the fundamental bases for working with personal data, and in our case with health data. The EDPR requires consent to be generally free, informed, specific and clear. For consent to be considered clear, the EDPR requires that the parties involved make a declaration or a positive action that expresses their agreement. Consent cannot be deduced from patient silence or inactivity.

[1] Personal data obtained from a specific technical process relating to the physical, physiological or behavioural characteristics of an individual that permit or confirm the unique identification of the said person, such as facial images or fingerprint data.

[2] Processing personal data in such a way that it cannot be attributed to an interested party without using additional information, on condition that the said additional information is supplied separately and is subject to technical and organisational measures with the aim of guaranteeing that personal data are not attributed to an identified or identifiable individual.