Clin Investig Arterioscler. 2017;29(6):254–255

Sociedad Española de Arteriosclerosis

CLÍNICA E INVESTIGACIÓN EN ARTERIOSCLEROSIS

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EDITORIAL

Is a national registry of dyslipidaemia necessary?☆

¿Es necesario un registro nacional de dislipemias?

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Received 7 September 2017; accepted 9 October 2017

The progress achieved in cardiovascular disease prevention over the last two decades is largely attributable to the implementation of evidence-based medicine. This consists of the judicious use of the best observations, tests, results and rationale derived from clinical research for decision-making in individualised patient care, understanding by evidence that which is proven or verified. It therefore involves applying the most effective medical interventions to maximise patient quality and quantity of life.

The clinical trial is the best method for evaluating any diagnostic performance or new therapy. In particular, the randomised clinical trial is really the most solid scientific evidence available as regards the efficacy of a medical intervention carried out under ideal conditions, often different from the usual clinical setting. In clinical trials, certain populations are disregarded or underrepresented relatively often in accordance with established inclusion/exclusion criteria. Therefore, the generalisation of results is not always correct. Their impact on healthcare activity is usually slow, and their execution requires considerable financial, human and organisational resources, especially when they are multicentre in nature.[1] There may be selective publication bias due to the fact that those with positive or significant results are more likely to be published. This means that some systematic reviews and meta-analyses are skewed, and could lead to clinicians making erroneous decisions.[2,3] As a result of publication bias, in clinical trials sponsored by both biopharmaceutical companies and non-profit institutions,[4] at the end of 2013, the European Parliament stipulated that pharmaceutical companies and academic researchers should make public the results of clinical trials in a freely accessible database.[5]

In those situations in which there are no clinical trials or these are inconclusive, information from other alternative research designs[6] should be used, such as meta-analyses/systematic reviews/meta-regression analyses or observational studies, in particular registries.

To the question raised in the title, the answer is beyond doubt: registries are necessary and useful. They provide information on the actual situation, without the patient selection bias of interventional studies or clinical trials, help to determine resource needs, highlight the correct or incorrect use of resources and report treatment outcomes. This information is useful – perhaps even essential – to establish an appropriate health organisation, improve medical care and assess the impact of new treatment methods; and it is of interest not only for clinicians and patients, but also for the health authorities, pharmaceutical industry and even, occasionally, for insurance companies. For these reasons, registries of patients with specific diseases are becoming increasingly common, despite the cost, and especially the effort, that their set up and implementation requires. The clinical registries sponsored by scientific societies arise from the need to optimise our healthcare activity, and to determine aspects that can be improved, mainly related to the

DOI of original article: http://dx.doi.org/10.1016/j.arteri.2017.10.001

☆ Please cite this article as: Pedro-Botet J. ¿Es necesario un registro nacional de dislipemias?. Clin Invest Arterioscler. 2017;29:254–255.

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different diagnostic and therapeutic procedures used in routine clinical practice.

This edition of clínica e Investigación en arteriosclerosis presents the current situation of the National Dyslipidaemia Registry of the Spanish Society of Atherosclerosis (SEA). The Registry is an online retrospective and prospective database, created in 2013, where the various accredited Spanish lipid units can enter data on patients with lipid metabolism disorders. This anonymised multicentre registry enjoys well-deserved prestige and, up to June 2017, included clinical, analytical, genetic and follow-up data from 4449 patients. It thus gives us an insight into the epidemiological reality of lipid metabolism disorders in Spain, deepens our understanding of their main clinical and demographic characteristics, and identifies variations in therapeutic behaviour between different hospitals, care settings and levels, and autonomous regions of Spain, as well as changes over time of therapeutic strategies, adherence to clinical practice guidelines and outcomes with regard to short- and long-term morbidity and mortality. In order to meet the operational objectives proposed for the current year, I consider the incentive plan for patient inclusion to be a huge success; achievement of these objectives will undoubtedly raise the registry to the position of worldwide reference, and will help to standardise the clinical management of dyslipidaemia patients.

Funding of the registry is not only adequate, but is assured, since it is owned by the SEA,[7] whose solvency is beyond doubt. Data collection has been professionalised to some extent, and the payment of staff who carry it out is guaranteed, as is the administrative, computer and statistical support necessary. It has a quality control system and two annual meetings are planned with representatives from the different Spanish lipid units.

Finally, we should just remember that the survival of a disease registry depends on the tenacity of the researchers who have developed it, and that its usefulness becomes evident through the relevant scientific publications. Fortunately, the current coordinating team has these and other characteristics that ensure the stability and continuity of the national dyslipidaemia registry.

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