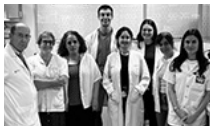

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A real-world snapshot of type 1 diabetes in Spain:

the power of the national patient registry

In public health, information is the most valuable resource for decision-making. Patient registries are systems for collecting clinical and sociodemographic data that enable accurate epidemiological surveillance. Without them, knowledge of a disease is limited to the experience of individual centers; with them, that experience is transformed into scientific evidence nationwide.

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A unified registry therefore becomes a strategic tool that makes it possible, first, to identify clear trends by determining whether the incidence of new cases is increasing and in which specific age groups. At the same time, it facilitates the assessment of real-world outcomes by analyzing the effectiveness of treatments and technologies used in patients' daily lives. Finally, this comprehensive perspective is essential for optimizing available resources. On the one hand, it helps both clinicians improve patients' day-to-day care and health care managers plan investments efficiently and accurately. On the other, it provides researchers with essential support for advancing scientific knowledge. Ultimately, this joint effort translates into higher-quality care and a direct improvement in patients' quality of life.

INTRODUCTION: THE NEED FOR A NATIONAL SNAPSHOT WHY DO WE NEED A REGISTRY?

Type 1 diabetes mellitus (T1DM) is not merely a metabolic disorder; it is a chronic autoimmune disease that requires complex, continuous management. It accounts for 5% to 10% of all diabetes cases worldwide, and its incidence—the number of new cases each year—is increasing in most developed countries.

Until very recently, asking how many people developed T1DM each year in Spain produced an incomplete and fragmented answer. Despite its health care and socioeconomic impact, epidemiological knowledge of T1DM in Spain depended on local or regional studies, most of which focused on the pediatric population and used differing methodologies. The "complete picture" was missing, and this lack of unified data prevented the development of public health plans that genuinely addressed the country's actual needs. However, this is about to change with the launch of the **Registro Nacional de Diabetes Mellitus Tipo 1 (RNDM1)** ***(Figure 1)***.

The RNDM1 was not created in isolation but under the coordination of the 3 most relevant scientific organizations in this field: the Fundación Sociedad Española de Diabetes (SED), the Fundación Sociedad Española de Endocrinología y Nutrición »

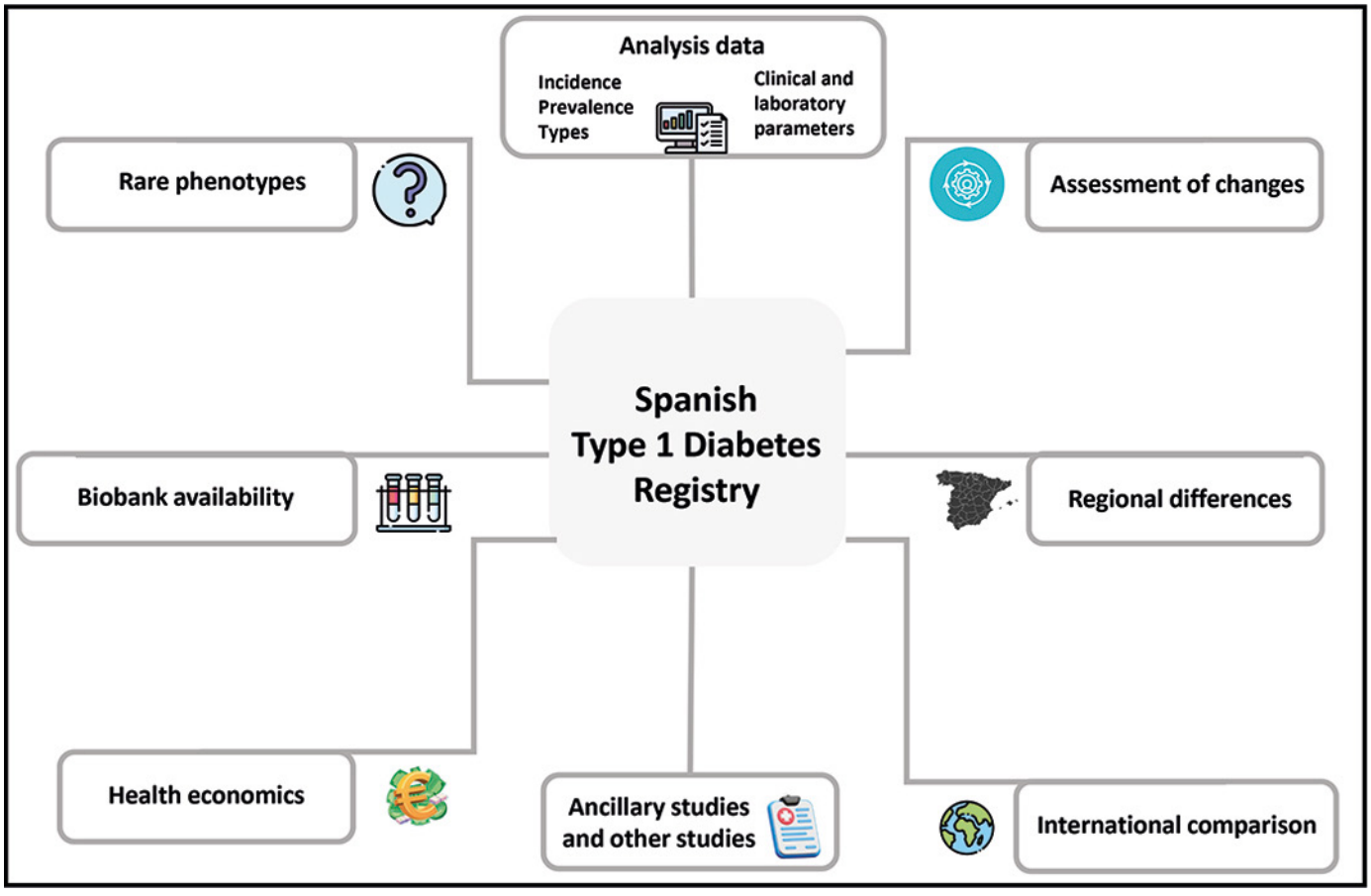

FIGURE 1.- Practical value of a national type 1 diabetes registry.

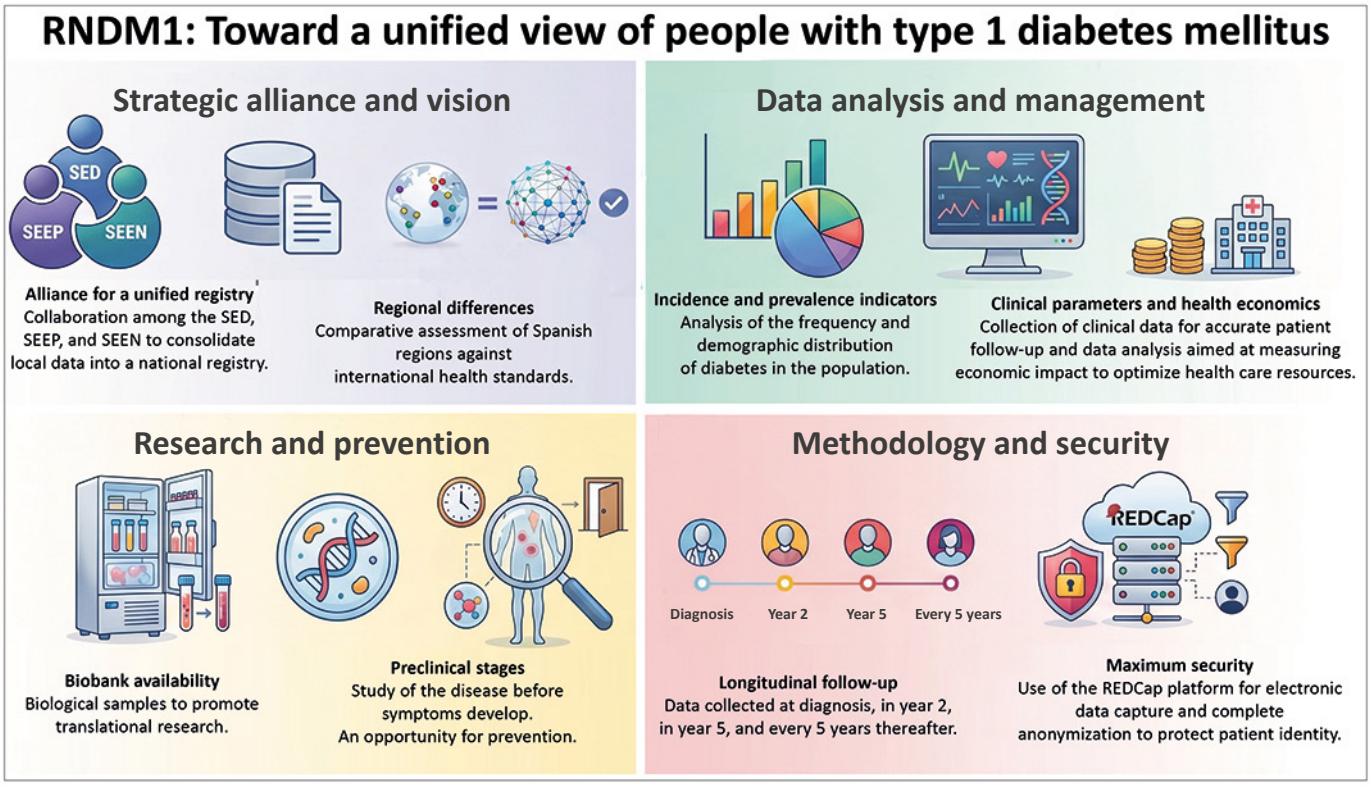

FIGURE 2.- Structure and fundamental pillars of the national type 1 diabetes registry.

» (SEEN), and the Fundación Sociedad Española de Endocrinología Pediátrica (SEEP), together with the essential involvement of patients themselves. The main objective of the initiative is to establish a unified clinical and sociodemographic profile.

In addition, the project includes a biobank for collecting biological samples alongside clinical data. This will promote translational research, the scientific discipline that serves as a direct bridge for transferring laboratory discoveries to the patient's bedside. The registry therefore becomes an essential driver of progress toward increasingly personalized medicine. Ultimately, a robust registry is the most powerful tool for transforming an individual patient's experience into a benefit for society as a whole.

METHODOLOGY: RIGOR IN DATA CAPTURE

For a registry to be scientifically useful, its design must be robust. This project has therefore been structured as an observational study—that is, one that examines the natural course of patients without intervening in their treatment—a prospective study, because it collects information from the present onward over time, and a multicenter study, meaning that hospitals and health centers throughout Spain participate. Its key characteristics are as follows:

- **Study population:** the registry focuses on incident cases, that is, individuals recently diagnosed with T1DM according to the criteria of the American Diabetes Association (ADA).

- **Longitudinal follow-up:** unlike a one-time survey, this system follows patients over time. Data are collected at diagnosis, or clinical onset, and updated periodically at key milestones: during the second year, the 5th year, and every 5 years thereafter.

- **Inclusion during early stages:** one of the most innovative aspects is the inclusion of patients in preclinical or presymptomatic stages. This makes it possible to study the disease even before symptoms become fully apparent, opening a window of opportunity for prevention.

Managing data from thousands of patients requires a state-of-the-art technological infrastructure. The registry therefore uses the REDCap (Research Electronic Data Capture) platform. This tool provides an intuitive interface for entering electronic data and complies with the highest security standards. To ensure maximum reliability, the system includes intelligent filters that immediately detect human error and prevent biologically impossible data from being entered. In addition, the platform transparently records who adds information and when it is entered. To comply with data-protection legislation, the system completely separates each patient's name from their medical record, ensuring that their identity remains anonymous at all times ***(Figure 2)***. »

» A STRATEGIC GEOGRAPHIC ROLLOUT

A project of this magnitude is being implemented in stages to ensure the proper integration of all Spanish hospitals: an initial phase involving autonomous communities such as Andalusia, Asturias, Cantabria, La Rioja, Navarre, and the Basque Country; a second phase involving the incorporation of the rest of Spain; and a third phase reserved for the major population centers of Madrid and Catalonia, as well as the island regions. The project has now reached this 3rd phase, marking the decisive step toward complete registry coverage.

This rollout ensures that the registry is genuinely representative of the geographic and sociodemographic diversity of the Spanish population and will also make it possible to compare health outcomes across different regions. Indeed, owing to the active progress made by centers throughout the country, the system already includes more than 1,200 registered patients. D

CONCLUSIONS

The RNDM1, promoted by the SED, SEEN, and SEEP, represents an unprecedented qualitative leap in the management of T1DM in Spain. By centralizing information from across the country under a single set of criteria, the health care system can move beyond assumptions and, for the first time, establish an accurate picture of the disease. This tool will not only make it possible to optimize public resources and assess the real-world impact of treatments but will also be crucial for matching suitable patients with new clinical trials, thereby accelerating research and the development of more effective therapies.

For the more than 2,500 patients diagnosed with this condition each year, and for their families, this project offers a clear promise: medicine based on real-world data, far more agile research, and, ultimately, a better quality of life.

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