HEALTH DATA TALK SERIES:

Belgium's New Vision for Register Policy

Recently, the National Institute for Health and Disability Insurance (RIZIV/INAMI) and the Federal Public Service Health (FOD Volksgezondheid/SPF Santé Publique) presented a new vision for the **future register policy** in Belgium. We spoke with **Ulla Cahay (RIZIV/INAMI)** why this shift is needed and what it means for the future re-use of health data.

What are registers and why do they matter?

"Registers are essentially **electronic databases that store structured healthcare data**," Ulla explains. "They are built from data directly collected from and manipulated and validated by healthcare providers and healthcare institutions. Once captured, these data are anonymized and/or pseudonymized for further use.

These registers serve multiple purposes, they can support targeted policy measures and decisions, enable integrated and personalized care, support a wide range of research based on real world evidence, serve as a basis for long-term surveillance and monitoring, and/or help different public institutions in their operations."

Concrete examples include the General Practitioner Barometer that collects data on antibiotic prescriptions, allowing national benchmarking and providing general practitioners with feedback on their prescribing behavior compared to the national average. Another example are the surveillance registers that monitor infectious diseases to support national infection control.

Why a new approach now?

"There are both practical and strategic reasons," Ulla explains. "On the one hand, we see national and international developments moving towards more advanced and automated approaches of capturing, storing, and re-using data between data holders and data users. Several initiatives from the field already point in this direction. Also the Belgian Integrated Health Record (BIHR), for example, is part of this evolution."

She adds that new legislation also played a key role. "The recent establishment of the Health Data Agency (HDA) in Belgium and the implementation of the European Health Data Space (EHDS) have been important drivers."

But the shortcomings of the current system itself were equally decisive. "We heard the challenges with the current register systems from different parties: there is a heavy administrative burden for healthcare providers regarding the data capture, there is lack of interoperability between different systems, but there is also limited access for re-use and analysis of the data," says Ulla. "The current system simply isn't user-friendly."

From static to dynamic registers

The key shift in the new policy is that we are moving away from static, centralized registers toward a **much more flexible system** for data capture, storage, and use," Ulla explains. "It's built on the principles of **federated data sharing and processing**, with at the core decentralized data management and the creation of a virtually integrated patient record."

She stresses the difference this will make in practice. "In the future, we won't talk about static registers anymore. Instead, we'll have **dynamic data collections**, drawn temporarily and securely from multiple (original) data sources. We aim to streamline data capture by following principles such as *"only once"*, while also focusing on standardization and interoperability. This will allow data to be collected in a more up-to-date and automated manner."

"It will make the data more readily available for analysis to authorized users, while at the same time reducing the burden on healthcare providers," Ulla emphasizes. She adds that the approach also safeguards the autonomy of data holders: "They will retain greater control over who can access data and for what purpose."

Who is involved?

"The initiative is jointly led by RIZIV/INAMI, Federal Public Service Health, and the Health Data Agency (HDA)," Ulla explains. "But it's not just about these central institutions. A broad range of stakeholders is involved."

She outlines the different groups: "On the one hand, you have the data holders (such as hospitals, laboratories, health care providers, government institutions, or emerging data networks). On the other hand, there are the data users, such as scientific associations and public authorities."

Governance and access management will also be shared responsibilities. "Trusted Third Parties and Health Data Access Bodies will play an important role in ensuring that the system runs securely and transparently," she adds.

Secondary use and Data protection

One of the key benefits of the new register policy is its facilitation to enable **secondary use of healthcare data** for research or policy-making purposes. Ulla explains "A public metadata catalog, developed and provided by the HDA, will provide a consolidated overview of available datasets in the registers. This way, all data users can easily see what exists and request access to data through the correct procedures. But access will be tightly controlled. The access to permanent registers are governed by law, while temporary data requests will follow EHDS procedures as deployed by the HDA," says Ulla. Statistical anonymous data can be transfered after request, while pseudonymized data requires a formal data permit.

Ulla emphasizes that all data use will take place in a highly secure setting. "Everything will be processed by the authorized user only within a **Secure Processing Environment (SPE)**, which prevents the extraction of sensitive data. On top of that, encryption and risk analyses, , are applied to minimize any chance of re-identification. A Small Cell Risk Analysis for example identifies unique data combinations ("small cells") that could reveal individuals' identities. To reduce this risk, data is altered, for example, by grouping sensitive variables like age or location into broader categories."

Looking ahead

The new policy vision was presented in spring 2025, and feedback has already been gathered from a wide group of stakeholders. The next milestone is the publication of a **Q&A document** addressing some of the frequently asked questions, such as the difference between permanent and temporary registers, questions about opt-out and informed consent, how stakeholders will be involved and what will happen with the existing registers. We will also publish a document about the different roles and responsibilities within the new register policy and who will take on these different rolls. This document will also be explained during a new information session that will take place later this year. The integration of healthdata.be into HDA will also be discussed during this session.

On the broader impact, Ulla is optimistic: "A federated system will allow Belgium to evolve toward dynamic data collection, sourced directly from data holders. Instead of centralizing everything in one database or register, data will be grouped (temporarily) for specific purposes. This ensures that data holders (hospitals, general practitioners, etc.) retain control over their data, while transparency is guaranteed on how data is (re)used.

The new federated model for registers will be based on **automated data exchange, decentralized storage, and proactive data sharing**," Ulla summarizes. Ulla concludes with the positive broader impact on the healthcare system: "By implementing this approach, and by agreeing on common semantic and technical standards, we will be able to strengthen the (re)use of healthcare data from registers for policy making, integrated and personalized care, research, etc. Ultimately, this will directly support the quality and efficiency of our healthcare system."

Interview with Ulla Cahay by the Health Data Talk Series Group

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