TEHDAS
Towards
European
Health
Data
Space

COUNTRY VISIT
Slovenia

Country visit – Slovenia

Objectives of the country visits

The objective of the TEHDAS country visits is to provide an overview of the status of national health data management in different European countries. This mapping exercise takes place in the form of country visits in which national stakeholders working with health data or exchanging health data are interviewed.

The Joint Action Towards the European Health Data Space (TEHDAS) supports EU member states and the European Commission in developing and promoting concepts for the secondary use of health data to benefit public health and health research and innovation in Europe.

When did it take place?

The visit to Slovenia took place face to face in Ljubljana between **20 and 23 September 2022.**

Who was involved?

9 stakeholder organisations were interviewed: Health Insurance Institute (ZZZS), Information Commissioner, Institute of Oncology Ljubljana, Ministry of Health, National Institute of Public Health (NIJZ), Primorska University, Statistical Office of the Republic of Slovenia (SURS), University of Ljubljana, University of Maribor.

Any questions?

Contact us at TEHDAS.sciensano@sciensano.be
Information about all country visits is available on tehdas.eu/country-visits.

Slovenia in brief

Slovenia was an early adopter of e-health, and has a well-developed health information system with a strong technical infrastructure. Almost all health data is digitalised, with wide implementation of EHRs connected to central services, for instance for EHR exchange. Health data management in Slovenia is highly centralised and the health information system is register-oriented. The Slovenian healthcare system is financed through statutory health insurance. The single compulsory public health insurance, the Health Insurance Institute of Slovenia (ZZZS), provides almost universal coverage for necessary services. Whilst several personal identifiers are used in health, the personal identification number is used for linkage of data across data sources. Some challenges were noted by stakeholders in terms of the legal framework surrounding the secondary use of health data.

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Data collections/sources

- The National Institute of Public Health (NIJZ) is responsible for population health registers, health service databases, and many surveys. Registries are defined in the Healthcare Databases Act and surveys are defined in Annual Programme of Statistical Surveys.
- The Slovenian Cancer Registry is maintained by the Institute of Oncology Ljubljana. It is the fourth population based cancer registry worldwide. Reporting is mandatory.
- The 'eHealth' system for digital health has been in place since 2015. Healthcare providers (HCPs) can choose EHR systems as long as they comply with central specifications. There are 35 EHR software providers. Seven participate to the eHealth infrastructure, covering 90% of the market.
- The Central Registry of Patient Data (CRPD) is a transient data repository of EHRs, with the main aim of facilitating national EHR exchange. HCPs' information systems are connected via APIs.
- The Health Insurance Institute of Slovenia (ZZZS) has data on health service reimbursements, cash benefits, medicines and medical devices. It has a register on insured persons, employers and HCPs.
- The Statistical Office of Slovenia (SURS) has some health-related data collections: National Health Accounts, EU-SILC (collaboration with NIJZ within EU-SILC on the following domains: Health status and disability; Health care; Health determinants); database on vital statistics.

Data quality

- Most health data in Slovenia is digitalised and some is structured.
- Data comes into NIJZ via the e-transfer portal ePrenosi, with automated data checks in the software. Errors are automatically fed back to HCPs for correction.
- eHealth has some automated quality control mechanisms but these are limited as the data is processed in real time. Stakeholders reported a need for a specific quality department.
- The Cancer Registry has strict coding rules. Trained nurses review information, perform coding and input data in a structured manner. Quality checks are applied at several points.
- ZZZS has rules for data input and checks are performed at the source.

Data infrastructure

- Data storage is centralised. Registries are stored at NIJZ with few exceptions (e.g., Cancer Registry).
- EHRs are centrally stored in the CRPD but archived information is at individual HCPs. The CRPD is a transient repository. It currently has capacity for storage of 5-10 years of electronic health data.
- eHealth data is kept in the territory of Slovenia using a national cloud with sufficient capacity.
- There is currently no national metadata catalogue. Registries are strictly defined in the Annex of the Healthcare Databases Act, including specific variables collected. NIJZ also has an online catalogue, with information on each database. It currently does not use international standards. Work is planned to implement international standards in the NIJZ catalogue.
- For data access, there is no national centralised procedure. Users apply to individual data holders.
- There is usually no difference made between national and international researchers.
- Generally, access is provided to anonymised data, or pseudonymised data when required.
- There is one secure processing environment (SPE) at SURS. NIJZ has a contract to use it. Data is sometimes sent directly to researchers after data protection committee approval, or they get access to the data in secure room.
- Generally, fees are only requested if the data holders performs the analysis and provides aggregated data or when microdata are prepared for research purposes. Fees are not charged to use the SPE.
- Linking individual level data is possible but it needs to be allowed in the law.
- The national Open Data Portal of Slovenia contains data from the public sector. Different institutes also have their own open data portals (e.g., NIJZ, Cancer Registry, SURS – SiStat Database).
- On data interoperability, NIJZ is responsible for classifications. Internationally recognised standards used include ICD-10 Australian Modification, ATC codes for medications, and ACHI for medical procedures. SNOMED CT is used in specific cases but not widely implemented. For data exchange, the CRPD uses openEHR. In the future HL7 FHIR will also be implemented.

Data governance

- There is currently no specific legal framework for the secondary use of health data.
- The Slovenian constitution states that all personal data processing must be provided for in the law.
- The main legislation governing health data use is the Healthcare Databases Act. It defines all registries, as well as specific eligible users and purposes for each database. Data linkage is only allowed if explicitly stipulated per database.
- The other main laws relevant to the use of health data in Slovenia include: GDPR, Personal Data Protection Act, National Statistics Act, Health Care and Health Insurance Act, Act on Patients' Rights, Act on Communicable Diseases.
- Stakeholders noted that the main challenges for secondary use of health data are legal. For instance, the lack of systematic data linkage prevents research focusing on wider health determinants.
- There is a strong strategic focus on the eHealth infrastructure, with significant digitalisation of the health sector. The new eHealth strategy, "Slovenia – eHealth for a healthier society", has been developed with support from the European Commission's Structural Reform and Support Programme.
- There is a plan to move the management of the eHealth infrastructure from NIJZ to the Ministry of Health, possibly establishing a separate body for IT services for the eHealth infrastructure.
- On citizen engagement, citizens have access to their data through the zVEM patient portal and mobile app. Patients can opt out from specific institutions using their patient summary, or consent to a specific doctor to access their records through the patient portal.
- The Information Commissioner is the national agency with the primary role of monitoring whether personal data is lawfully handled and protected, in compliance with the GDPR. There is a strong focus on data privacy in the Slovenian population, giving the Information Commissioner a central role in policymaking.

Resources (human, technical, financial)

- Human resource needs identified by different stakeholders:
  - Cybersecurity experts
  - Data analysts
  - Semantic experts
  - Additional human resources to deal with increased requests with the EHDS
- Financial resources:
  - The technical infrastructure is generally well-developed and well-resourced but stakeholders note that additional financial resources would be needed to further develop it (e.g., creation of new SPEs)

Capacity building

- Examples of training opportunities identified:
  - Training on data protection
  - Training for young doctors with short courses on eHealth and health information
  - Data analytics training
  - School of Public Health by the NIJZ
  - SURS annual conference with researchers where they present outputs and receive feedback
- Examples of training needs identified:
  - Training to healthcare providers on how to input data in a structured manner

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Best practices

- Several best practices were identified during the country visit in Slovenia.
- The best municipality awards reward the municipality that has most improved indicators and invested in health, providing incentives to improve their data collection for the registries.
- The Slovenian Cancer Registry has specially educated nurses who register cancer cases in a structured manner and follow international cancer registry courses. The nurses are educated for one year before they can work independently. The Cancer Registry reported that every cancer case is reviewed manually by professional coders, allowing careful determination of all rare cancer entities, which could otherwise slip through processing massive information.
- The architecture of Slovenian eHealth infrastructure enables it to harness the full potential of digital records in a timely manner. For instance, data inputted once is transferred to different relevant databases (e.g., vaccination data).

European Health Data Space (EHDS)

- In general, Slovenian stakeholders recognise the potential benefits of the EHDS.
- However, stakeholders note that more clarity is needed on certain aspects. For instance:
  - It is important to ensure the comparability and quality of data
  - The option for patients to remove or restrict access to certain parts of their EHR may have implications on data integrity, consistency and usability for secondary use
  - The exemption of micro-enterprises as data holders may incur data gaps, especially in a country where a large proportion of healthcare is provided by micro-enterprises

- The technical infrastructure is well-developed in Slovenia to support implementation of the EHDS, but will require enlargement. Slovenia is not yet part of MyHealth@EU due to lack of staff to set up the national contact point for primary use at NIJZ. Operation is planned for 2023.
- NIJZ is currently the competent authority for the direct grants supporting the establishment of a Health Data Access Body (HDAB) for the EHDS. It is being decided if NIJZ or a new institution would become the HDAB and/or national contact point (NCP) for secondary use.
- There are some legal challenges that need to be addressed at national level. Stakeholders note that a final agreed legislative text on the EHDS is required before legislative changes are made at national level.

- Needs for the EHDS:
  - Guidance on how to implement the EHDS, with a clear roadmap of what to do when
  - Assistance to understand differences in reporting between Member States despite harmonised methodologies
  - Strengthening of human resources and financial support for implementation
  - Need for a clearer legislative text and clear definition of responsibilities and terminologies

- Expectations of the EHDS:
  - Understanding that Member States are not at the same starting point
  - The European Commission should consider and clarify the short-, mid- and long-term goals for EHDS implementation
  - Harmonisation of guidelines from the EU (e.g., set of standards to be used)
  - Ensuring quality assurance (e.g., ensuring quality of data inputted by patients into Personal Health Records, training for proper coding at the source)
  - Take stock of good work and European cooperation already done in other areas, such as cancer registries

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